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, 2019

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, 2019 was approximately $7.2 million. As of March 23, 2019, there were 70,602,433 shares of the registrant's common stock, $0.001 par value, issued 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™), Tetra-specific Killer Engager (TetraKE™) and bi-specific ligand-directed single-chain fusion protein technology platforms. Our TriKE and TetraKE platforms 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. TriKEs and TetraKEs are made up of recombinant fusion proteins, 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 and TetraKE platforms with the intent to bring to market immuno-oncology products that can treat a range of hematologic malignancies, sarcoma and solid tumors. The platforms are scalable, and we are putting processes in place to be able to produce IND-ready moieties in a timely manner after a specific TriKE or TetraKE 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 TriKEs and TetraKEs may have the ability, if approved for marketing, to be used on a stand-alone basis, 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 and TetraKE platforms 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).

We also believe our bi-specific, ligand-directed single-chain fusion proteins are examples of the next generation of antibody-drug conjugates (ADCs). We believe GTB-1550 has certain properties that could result in competitive advantages over recently FDA-approved ADC products targeting leukemias and lymphomas and/or have utility in other niche populations. In a Phase 1 trial, of nine patients that achieved adequate blood levels, in two heavily pretreated patients a continuous partial remission (PR) and complete remission (CR) were observed. One of these patients, who had failed multiple previous treatment regimens, has been in remission since early 2015.

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 and TetraKE platforms and are generating additional intellectual property around specific moieties.

Immuno-Oncology Platform

Tri-specific Killer Engagers (TriKEs) and Tetra-specific Killer Engagers (TetraKEs)

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 unmet medical need for targeted immuno-oncology therapies that can have the potential to be dosed in a patient-friendly outpatient setting, can be used on a stand-alone basis, augment the current monoclonal antibody therapeutics or be used in conjunction with more traditional cancer therapy. We believe our TriKE and TetraKE 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

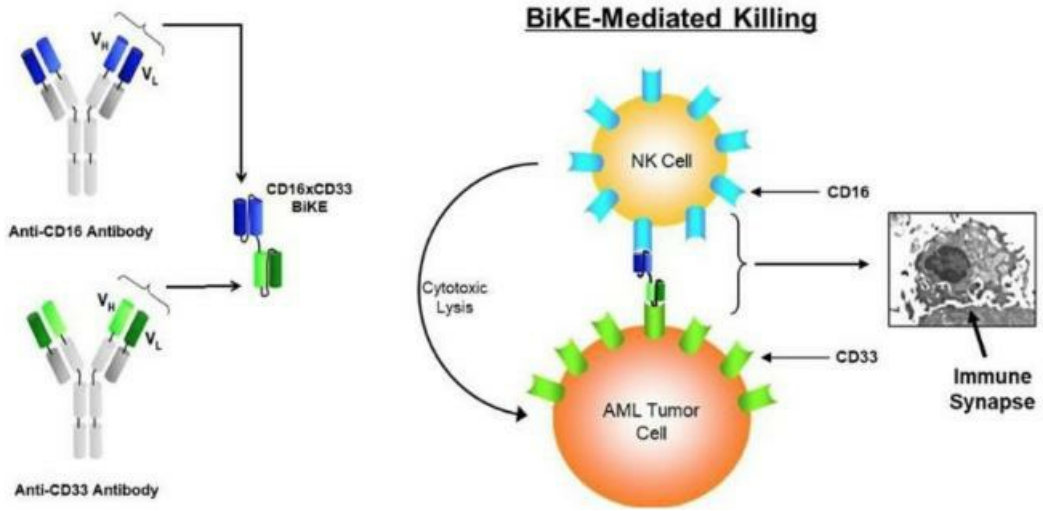
GTB-3550 is the Company's first TriKE™ product candidate which is a single-chain, tri-specific recombinant fusion protein construct composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. The GTB-3550 Phase I/II clinical trial 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.

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, TriKEs and TetraKEs are small single-chain fusion proteins that bind the CD16 receptor of NK cells directly producing a potent and lasting response, as demonstrated by preclinical studies. An additional benefit they may have is 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, TriKEs and TetraKEs are 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

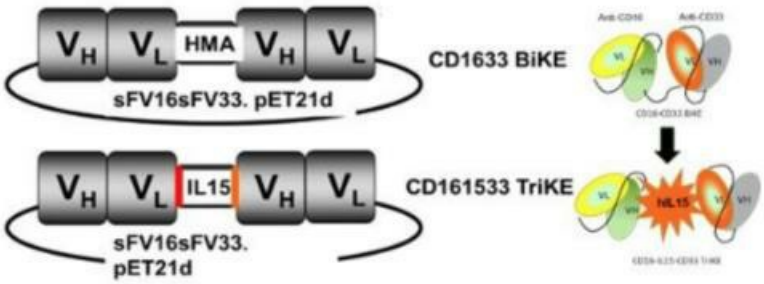
In conjunction with our research agreement with the Masonic Cancer Center at the University of Minnesota, the exploration of targeting NK cells to a variety of tumors initially focused on novel bi-specific killer engagers, or BiKEs, composed of the variable portions of antibodies targeting the CD16 activating 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.

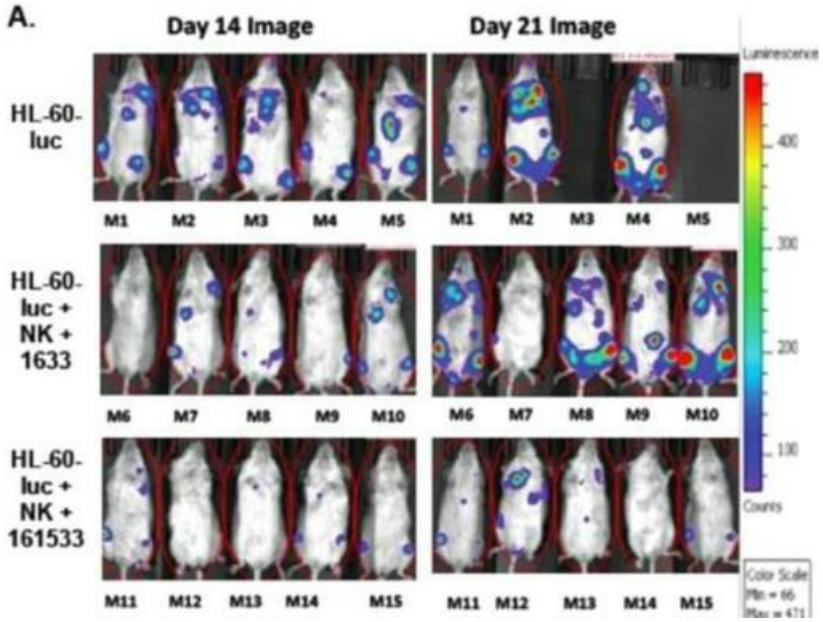
When compared to the CD16 x CD33 BiKE, the CD16 x IL-15 x CD33 TriKE is also capable of potently restoring killing capacity of post- transplant NK cells against CD33-expressing HL-60 Targets and primary AML blasts. These results demonstrated the ability to functionally incorporate an IL-5 cytokine into 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 BiKEs (1633) and TriKEs (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.

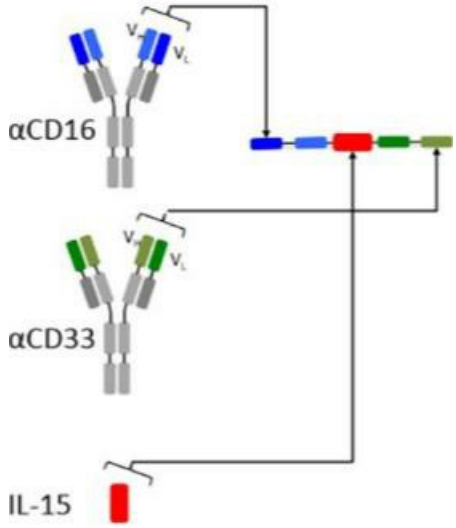
Figure A below shows the results (tumor burden and mortality) when dosing NK cells alone (top panel), the BiKE version (lacking IL-15) of GTB-3550 (middle panel; called 1633), and the TriKE, GTB-3550 (bottom panel; then called 161533) in the above described human tumor model, HL-60-luc. In the NK-cell-only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



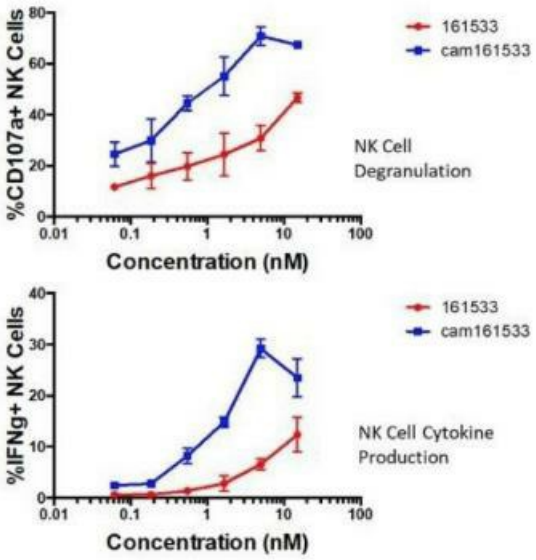
Based on these results, and others, the IND for GTB-3550 was filed in June 2017 by the University of Minnesota. FDA requested that additional preclinical toxicology be conducted prior to initiating clinical trials. The FDA also requested some additional information and clarifications on the manufacturing (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 January 2020.

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, TriKEs and TetraKEs are small single-chain fusion proteins that bind the CD16 receptor of NK cells directly producing a potentially more potent and lasting response as demonstrated by preclinical studies. An additional benefit that they may have is an attractive biodistribution, because of their smaller size, which we expect to be important in the treatment of solid tumors. In addition to these potential advantages, TriKEs and TetraKEs are 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 2020.

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

We are using our TriKE and TetraKE platforms 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 expression system of the TriKEs and TetraKE 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 companies. We are currently evaluating over a dozen moieties and intend to announce additional clinical product candidates.

We believe our TriKEs and TetraKEs 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.

Bi-specific Antibody-Drug Conjugates Ligand-Directed Single-Chain Fusion Therapeutic Protein Program

Antibody–drug conjugates (ADCs) are a class of potent biopharmaceutical drugs designed as a targeted therapy for the treatment of cancer. ADCs combine the antitumor potency of highly cytotoxic small-molecule drugs with the high selectivity, pharmacokinetic profile of mAbs. These attributes allow sensitive discrimination between healthy and diseased tissue. We believe our bi-specific, ligand-directed single-chain fusion protein represents an example of the next generation of ADCs.

We are currently utilizing a single chain bispecific recombinant fusion protein consisting of an anti-CD22 sFv, an anti-CD19 sFv, and DT390 (the catalytic and translocation domains of diphtheria toxin). It is a cytotoxic molecule produced by recombinant DNA techniques composed of a fusion gene consisting of sequences for DT390 and also sequences encoding two separate and distinct sFvs, one recognizing CD22 and one recognizing CD19. The anti-CD22 sFv comes from the monoclonal antibody RFB4 and this sFv is currently in clinical trials involving another anti-CD22 immunotoxin called BL22. The anti-CD19 sFv is from the monoclonal antibody HD37 that has previously been used clinically. Published preclinical studies have shown that the presence of both sFvs on the same single chain molecule results in a bispecific fusion toxin that has superior activity and anti-cancer effects compared to the monospecific fusion toxins. Between the VL and VH regions of the sFvs, we have introduced aggregation reducing sequences (ARL) which has produced a product which has demonstrated better activity against scid mouse systemic models of B cell malignancy. The action of DT2219 occurs as a result of binding to the CD22 and/or CD19 receptors, subsequent internalization, and enzymatic inhibition of protein synthesis leading to cell death.

We believe that our single-chain bi-specific recombinant fusion proteins utilizing novel linkers and innovative warheads represent an important advance over currently marketed ADCs. Utilizing our bi-specific ADC platform we have the ability to generate novel ADCs with unique targets, linkers and warheads. This platform provides us with the ability to rapidly construct novel ADCs with the potential to treat a wide range of cancers, including hematologic and solid tumors.

GTB-1550 is a novel, multi-target bispecific cytotoxic therapeutic agent consisting of diphtheria toxin and bispecific single-chain variable fragments (scFV) of antibodies targeting human CD19 and CD22. By simultaneously targeting cancer cells that express either CD19 or CD22 or both, GTB-1550 is capable of killing a broader variety of hematological malignancies than either a traditional a CD19 antibody drug conjugate or a CD19 CAR-T immunotherapy which are only able to target and attack CD19 expressing hematological malignancies. Simultaneously targeting multiple cancer targets such as CD19 and CD22 using a single therapeutic agent potentially makes GT Biopharma's multi-target bispecific drug conjugate therapy the next generation of advanced cancer therapies.

To date, GTB-1550 has completed one dose escalation Phase I-II expansion clinical trial, and one fixed dose Phase I-II expansion clinical trial which collectively enrolled a combined 43 patients.

Top-line Consolidated Results:

- Two patients exhibited a Complete Remission (CR) with one patient currently disease-free at 50 months post treatment.
- Five patients exhibited Stable Disease (SD) with the longest response lasting 12 months post treatment.
- Two patients with transformed lymphoma showed transient tumor shrinkage, however, therapy was discontinued due to dose-limiting toxicities after the 1st cycle.
- Greater than 50% of evaluable patients receiving 60 mg/kg dose had positive clinical response defined as stable disease, partial remission, or complete remission.

Immuno-Oncology Product Candidates

Our most advanced bi-specific ADC, GTB-1550, which targets CD19+ and/or CD22+ hematological malignancies, is in the Phase 2 component of a Phase 1/2 Non-Hodgins Lymphoma (NHL)/Acute Lymphocytic Leukemia (ALL) trial which is an open-label, investigator-led study. 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).
Our TetraKE product candidates are single-chain fusion proteins composed of human single-domain anti-CD16 antibody, wild-type IL-15 and the variable regions of the heavy and light chains of two antibodies that are designed to target two specific tumor antigens expressed on specific types of cancer cells.An example of a TetraKE product candidate is GTB-1615 which is designed to target EpCAM and CD133 positive solid tumors. EpCAM is found on many solid tumor cells of epithelial origin and CD133 is a marker for cancer stem cells. GTB-1615 is designed to enable a patient's NK cells to kill not only the heterogeneous population of cancer cells found in many solid tumors but also kill the cancer stem cells that can be responsible for recurrences.

GTB-1550

GTB-1550 is a bispecific scFv recombinant fusion protein-drug conjugate composed of the variable regions of the heavy and light chains of anti-CD19 and anti-CD22 antibodies and a modified form of diphtheria toxin (DT390) as its cytotoxic drug payload. CD19 is a membrane glycoprotein present on the surface of all stages of B-lymphocyte development and is also expressed on most B-cell mature lymphoma cells and leukemia cells. CD22 is a glycoprotein expressed on B-lineage lymphoid precursors, including precursor acute lymphoblastic leukemia, and often is co-expressed with CD19 on mature B-cell malignancies such as lymphoma.

GTB-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When GTB-1550 binds to cancer cells, the cancer cells internalize GTB-1550, and are killed due to the action of drug's cytotoxic diphtheria toxin payload. GTB-1550 has completed a Phase 1 human clinical trial in patients with relapsed/refractory B-cell lymphoma or leukemia.

The initial Phase 1 study enrolled 25 patients with mature or precursor B-cell lymphoid malignancies expressing the CD19 receptor or CD22 receptor or both receptors. All 25 patients received at least a single course of therapy. The treatment at the higher doses produced objective tumor responses with one patient in continuous partial remission and the second in complete remission. A Phase 1/2 trial of GTB-1550 in 18 patients was recently completed in patients with ALL/NHL. The FDA-approved clinical trial was conducted at the University of Minnesota's Masonic Cancer Center. The data is currently being analyzed. We expect to submit data from this Phase 1/2 study for presentation/publication.

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.

The GTB-3550 IND will focus on AML. These patients typically receive frontline therapy, usually chemotherapy, including cytarabine and an anthracycline, a therapy that has not changed in over 40 years. About half will have relapses and require alternative therapies. In addition, MDS incidence rates have dramatically increased in the population of the United States from 3.3 per 100,000 individuals from 2001-2004 to 70 per 100,000 annually, MDS is especially prevalent in elderly patients that have a median age of 76 years at diagnosis. The survival of patients with MDS is poor due to decreased eligibility, as a result of advanced age, for allogeneic hematopoietic cell transplantation (Allo-HSCT), the only curative MDS treatment (Cogle CR. Incidence and Burden of the Myelodysplastic Syndromes. *Curr Hematol Malig Rep.* 2015; 10(3):272-281). We believe GTB-3550 could serve as a relatively safe, cost-effective, and easy-to-use therapy for resistant/relapsing AML and could also be combined with chemotherapy as frontline therapy thus targeting the larger market.

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 January 2020.

GTB-C3550

GTB-C3550 is a next-generation, follow-on, to our lead TriKE, GTB-3550. GTB-C3550 contains a modified CD16 moiety which has improved binding characteristics and enhanced tumor cell killing based on functional assays and animal models of AML. Using our platform technology, we substituted the anti-CD16 scFv arm in GTB-3550 with a novel humanized single-domain anti-CD16 antibody to create this second-generation molecule which may have improved functionality. Single-domain antibodies, such as GTB-C3550, typically have several advantages, including better stability and solubility, more resistance to pH changes, can better recognize hidden antigenic sites, lack of a VL portion thus preventing VH/VL mispairing and are suitable for construction of larger molecules. GTB-C3550 induced a potent increase in NK cell degranulation, measured by CD107a expression against HL-60 AML tumor targets when compared to our first- generation TriKE (70.75±3.65% vs. 30.75±5.05%). IFN production was similarly enhanced (29.2±1.8% vs. 6.55±1.07%). GTB-C3550 also exhibited a robust increase in NK cell proliferation (57.65±6.05% vs. 20.75±2.55%). GTB-3550 studies will help inform the development of GTB-C3550 which we expect will de-risk the GTB-C3550 program as data will be generated to make an informed decision on which, or both, will be brought into later phase studies.

GTB-1615

GTB-1615 is an example of our first-generation TetraKEs designed for the treatment of solid tumors. It is a single-chain fusion protein composed of CD16-IL15-EpCAM-CD133. EpCAM is found on many solid tumor cells of epithelial origin and CD133 is a marker for cancer stem cells. This TetraKE is designed to target not only the heterogeneous population of cancer cells found in solid tumors but also the cancer stem cells that are typically responsible for recurrences. Depending on the availability of drug supply, we hope to initiate human clinical testing for certain of our solid tumor product candidates in 2020.

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:

Expedite clinical development, regulatory approval and commercialization of our bi-specific ADC, GTB-1550, in specific indications with a high unmet-medical need such as patients who are resistant or refractory to conventional treatment and also assess fast-to- market strategies in potential orphan indications

Based upon promising clinical results from the initial GTB-1550 Phase 1 study, we began enrolling patients in a Phase 2 trial during the first quarter of 2017 for our most advanced oncology product candidate, GTB-1550, for the treatment of patients with relapsed/refractory B- cell leukemias or lymphomas. In the Phase 1 study, of the nine patients who received GTB-1550 at the higher doses, two had durable complete responses in heavily pretreated patients. One of these patients, who had failed multiple previous treatment regimens, has been cancer free since the beginning of 2015.

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

Our TriKE and TetraKE 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 the fourth quater of 2019 in 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 contains a humanized single-domain anti-CD16 moiety which demonstrated improved binding characteristics and enhanced tumor cell killing based on functional assays and animal models of AML.

We have designed GTB-3550 and GTB-C3550, if approved for marketing, to serve as a relatively safe, cost-effective, and easy-to-use therapies for resistant/relapsing AML or MDS which could also be combined with chemotherapy as frontline therapy thus targeting a broad AML/MDS market.

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 and TetraKE 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 and TetraKE platforms 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 TriKEs and TetraKE 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 TriKEs and TetraKEs 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.

Multiple Myeloma

Multiple myeloma is a type of cancer that forms in white blood cells. Multiple myeloma causes cancer cells to accumulate in the bone marrow, where they crowd out healthy blood cells. Multiple myeloma is also characterized by destructive lytic bone lesions (rounded, punched-out areas of bone), diffuse osteoporosis, bone pain, and the production of abnormal proteins which accumulate in the urine. Anemia is also present in most multiple myeloma patients at the time of diagnosis and during follow-up. Anemia in multiple myeloma is multifactorial and is secondary to bone marrow replacement by malignant plasma cells, chronic inflammation, relative erythropoietin deficiency, and vitamin deficiency. Plasma cell leukemia, a condition in which plasma cells comprise greater than 20% of peripheral leukocytes, is typically a terminal stage of multiple myeloma and is associated with short survival.

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.

Daniel A. Vallera, Ph.D. License Agreement

We are party to an exclusive worldwide license agreement with Daniel A. Vallera, Ph.D. and his co-inventor Jeffrey Lion, or jointly, Dr. Vallera, to further develop and commercialize DT2219ARL (GTB-1550), a novel therapy for the treatment of various human cancers. Under the terms of the agreement, we receive exclusive rights to conduct research and to develop, make, use, sell, and import DT2219ARL 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 DT2219ARL, 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, Dr. Vallera will receive an upfront license fee, royalty fees ranging from 3% for net sales and 25% of net sublicensing revenues, and certain milestone payments totaling $1,500,000.

Employees

As of December 31, 2019, we had two 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.

As of December 31, 2019, we had an accumulated deficit of $567,332,000. 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 2020 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 2020 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 postmarketing 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 qui tam (whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. In addition, the Affordable Care Act amended the federal civil False Claims Act to provide that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and/or exclusion from the Medicare program. In addition, a majority of states have adopted similar state whistleblower and false-claims provision. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws. Any future investigations of our business or executives, or enforcement action or prosecution, could cause us to incur substantial costs, and result in significant liabilities or penalties, as well as damage to our reputation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our therapeutic immuno-oncology 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 2 clinical trial for GTB-1550 and phase 1 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 listed for trading on the OTCQB 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.

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.

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 do not currently have and may never obtain research coverage by securities and industry 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 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. The Company and Plaintiffs are in the process of negotiating a settlement that would fully resolve Plaintiffs' asserted claims, but no formal agreement has been finalized.

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.

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.

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. Since August 2017, our common stock has been quoted on the OTCQB under the "GTBP" trading symbol.

Trading in our common stock has fluctuated greatly during the past year. Accordingly, the prices for our common stock quoted on the OTCQB or Pink OTC Markets Inc. may not necessarily be reliable indicators of the value of our common stock. The following table sets forth the high and low bid prices for shares of our common stock for the quarters noted, as reported on the OTCQB and the Pink OTC Markets Inc. The following price information reflects inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

YEAR	PERIOD	HIGH	LOW
Fiscal Year 2018	First Quarter	5.06	1.60
	Second Quarter	2.52	1.25
	Third Quarter	2.75	1.42
	Fourth Quarter	2.16	0.62
Fiscal Year 2019	First Quarter	0.84	0.32
	Second Quarter	0.57	0.21
	Third Quarter	0.26	0.14
	Fourth Quarter	0.24	0.08

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

Stockholders

As of December 31, 2019, there were 23 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

In accordance with a consulting agreement dated November 25, 2019, the Company issued 2,000,000 shares of unregistered, Rule 144 restricted Common Stock.

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™), Tetra-specific Killer Engager (TetraKE™) and bi-specific ligand-directed single-chain fusion protein technology platforms. Our TriKE and TetraKE platforms 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. TriKEs and TetraKEs are made up of recombinant fusion proteins, 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 $567,332,000 through December 31, 2019. On a consolidated basis, the Company had cash and cash equivalents of $28,000 at December 31, 2019. 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.

Corporate Developments

Employment Contracts

On February 14, 2018, the Company entered into the First Amendment to the Employment Agreement with Dr. Clarence-Smith, amending the Employment Agreement, dated September 1, 2017, between the Company and Dr. Clarence-Smith. Under the First Amendment, Dr. Clarence-Smith's title was revised to reflect her new position and included an annual salary of $500,000, paid in equal monthly installments. All other terms of her original Employment Agreement remain unchanged. In October 2018, Dr. Clarence-Smith resigned from her position with the Company. In connection with this resignation, the Company entered into a separation agreement which superseded the Employment Agreement.

On October 18, 2018, the Company entered into a Consultant Agreement with Anthony Cataldo. The term of the Consultant Agreement shall remain in effect until September 30, 2019. This Agreement supersedes the Consultant Agreement dated February 14, 2018 and will pay Mr. Cataldo $25,000 per month during the term of the Agreement.

On October 19, 2018, the Company entered into an Executive Employment Agreement with Dr. Raymond 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.

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 the we will collaborate exclusively in the clinical development of a novel 161533 TriKE fusion protein for cancer therapies using our TriKE technology.

License Agreements

Pursuant to a patent license agreement with the ID4, dated December 31, 2014, we received a non-exclusive, worldwide license to certain intellectual property, including intellectual property related to treating a p62-mediated disease (e.g., multiple myeloma).

On February 25, 2015, we licensed exclusive rights to three antibody-drug conjugates, or ADCs, that MCIT will prepare for further evaluation by GTBP as prospective therapeutics for the treatment of triple-negative breast cancer, and multiple myeloma and associated osteolytic bone disease. Under the terms of the agreement, MCIT will develop three ADC product candidates which contain GTBP's lead drug candidates OXS-2175 and OXS-4235.

We executed an exclusive worldwide license agreement with Daniel A. Vallera, Ph.D. and his associate (jointly "Dr. Vallera"), to further develop and commercialize DT2219ARL (GTB-1550), a novel therapy for the treatment of various human cancers. Under the terms of the agreement, we receive exclusive rights to conduct research and to develop, make, use, sell, and import DT2219ARL worldwide for the treatment of any disease, state or condition in humans. GTBP 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 DT2219ARL, including without limitation the FDA and the European Agency for the Evaluation of Medicinal Products in the European Union. Under the agreement, Dr. Vallera will receive an upfront license fee, royalty fees, and certain milestone payments.

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

On January 22, 2018, the Company entered into a Securities Purchase Agreement ("SPA") with fourteen accredited investors (individually, a "Buyer" and collectively, the "Buyers") pursuant to which the Company agreed to issue to the Buyers senior convertible notes in an aggregate principal amount of $7,760,510 (the "Notes"), which Notes shall be convertible into the Company's common stock, par value $0.001 per share (the "Common Stock") at a price of $4.58 per share, and five-year warrants to purchase the Company's Common Stock representing the right to acquire an aggregate of approximately 1,694,440 shares of Common Stock (the "Warrants").

Pursuant to the terms of SPA the Notes were subject to an original issue discount of 10% resulting in proceeds to the Company of $7,055,000 from the transaction.

Upon the purchase of the Notes, the Buyers received Warrants to purchase 1,694,440 shares of Common Stock. Such Warrants are exercisable for (5) years from the date the shares underlying the Warrants are freely saleable. The initial Exercise Price is $4.58. According to the terms of the warrant agreement, the Warrants are subject to certain adjustments depending upon the price and structure of a subsequent financing, including a qualified financing with gross proceeds of at least $20 million, as defined in the agreements.

The issuance of the Notes and Warrants were made in reliance on the exemption provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act") for the offer and sale of securities not involving a public offering, and Regulation D promulgated under the Securities Act.

Contemporaneously with the execution and delivery of the SPA, the Company and the Buyers executed and delivered a Registration Rights Agreement (the "Registration Rights Agreement") pursuant to which the Company has agreed to provide certain registration rights with respect to the Registrable Securities under the 1933 Act and the rules and regulations promulgated thereunder, and applicable state securities laws.

Senior Convertible Debentures

On August 2, 2018, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement with the purchasers identified on the signature pages thereto (individually, a "Purchaser," and collectively, the "Purchasers") pursuant to which the Company issued to the Purchasers one year 10% Senior Convertible Debentures in an aggregate principal amount of $5,140,000 (the "Debentures"), which Debentures shall be convertible into the Company's common stock, par value $0.001 per share (the "Common Stock"), at a price of $2 per share. The Company used a portion of these proceeds to repay $4.4 million of the notes issued on January 22, 2018. Additionally, the remaining $3.3 million of the notes issued on January 22, 2018 were converted into the Debentures at the same terms discussed above.

On September 7, 2018, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement with the purchasers identified on the signature pages thereto (individually, a "Purchaser," and collectively, the "Purchasers") pursuant to which the Company has issued to the Purchasers one year 10% Senior Convertible Debentures in an aggregate principal amount of $2,050,000 (the "Debentures"), which Debentures shall be convertible into the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial price of $2 per share.

On September 24, 2018, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement with the purchasers identified on the signature pages thereto (individually, a "Purchaser," and collectively, the "Purchasers") pursuant to which the Company has issued to the Purchasers one year 10% Senior Convertible Debentures in an aggregate principal amount of $800,000 (the "Debentures"), which Debentures shall be convertible into the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial price of $2 per share.

The issuance of the Senior Convertible Debentures was made in reliance on the exemption provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the "Securities Act"), for the offer and sale of securities not involving a public offering and Regulation D promulgated under the Securities Act.

On February 4, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the 15 purchasers (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on February 4, 2019, Secured Convertible Notes in an aggregate principal amount of $1,352,224 (the "Notes"), consisting of gross proceeds of $1,052,224 and settlement of existing debt of $300,000, which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.60 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on August 2, 2019. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

Contemporaneously with the execution and delivery of the Purchase Agreement, on February 4, 2019, the Company and certain of its wholly-owned subsidiaries entered into a Security Agreement (the "Security Agreement") with Alpha Capital Anstalt, as collateral agent on behalf of the Purchasers, and with the Purchasers, pursuant to which the Purchasers have been granted a first-priority security interest in substantially all of the assets of the Company and such subsidiaries securing (i) an aggregate principal amount of $1,352,224 of Notes and (ii) an aggregate principal amount of $9,058,962 of the Company's 10% Senior Convertible Debentures issued on August 2, 2018, September 7, 2018 and September 24, 2018 held by such Purchasers.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 14 days after February 4, 2019, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement. The Form S-3 was filed by the Company on February 14, 2019 and became effective on March 11, 2019

On May 22, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the ten purchasers (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on May 22, 2019, Secured Convertible Notes in an aggregate principal amount of $1,300,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.35 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on November 22, 2019. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days after May 22, 2019, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement. The Form S-1 was filed by the Company on June 21, 2019 and became effective on July 12, 2019.

Between July 31 and August 28, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the eleven purchasers (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, Secured Convertible Notes in an aggregate principal amount of $975,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.20 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature between January 31 and February 28, 2020. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement. The Form S-1 was filed by the Company on September 13, 2019 and became effective in October 2, 2019.

On December 19, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the one purchaser (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on December 19, 2019, Secured Convertible Notes in an aggregate principal amount of $200,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.20 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on August 19, 2020. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days after December 19, 2019, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement.

On January 30, 2020 GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the one purchaser (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on January 30, 2020, Secured Convertible Notes in an aggregate principal amount of $200,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.20 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on September 30, 2020. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days after January 30, 2020, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement.

Results of Operations

Research and Development Expenses

During the years ended December 31, 2019 and 2018, we incurred $1.7 million and $9.1 million of research and development expenses, respectively. 2018 research and development costs were high due primarily to the addition of new employees, increased regulatory and preclinical consultant costs to support the GTB-3550 IND, higher costs to advance the CNS portfolio and position the assets for licensing efforts, and higher preclinical and clinical expenses incurred at the University of Minnesota to continue development of our immune-oncology assets. 2018 expenses also include non-cash compensation of $6.8 million. We anticipate our direct clinical and preclinical costs to continue to increase throughout 2020, totaling approximately $12 to $15 million, as we have initiated the Phase 1 clinical trial of our most advanced TriKe product candidate, GTB-3550 in January 2020, and initiate IND-enabling activities for GTB-C3550, and GTB-1615 later in 2020.

Selling, general and administrative expenses

During the years ended December 31, 2019 and 2018, we incurred $9.7 million and $12.5 million of selling, general and administrative expenses, respectively. Additional selling, general, and administrative expenses in 2018 were due to increased spending on investor relations campaigns to broaden awareness of the Company, and increased legal costs primarily associated with regulatory and financing efforts. We anticipate selling, general and administrative expenses, excluding stock compensation, to range between $1 and $2 million in the coming quarters.

Loss on impairment

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, 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 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.

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.

Interest Expense

Interest expense was $2.1 million and $9.1 million for the years ended December 31, 2019 and 2018, respectively. The decrease is due to an decrease in non-cash amortization of debt issuance costs associated with convertible debentures and warrants issued in January 2018.

Liquidity and Capital Resources

As of December 31, 2019, we had cash and cash equivalents of $28,000. 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, 2019, the Company raised $3.5 million through a series of issuances of convertible debentures.. 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. The Company is pursuing several alternatives to address this situation, including the raising of additional funding through equity or debt financings. In order to finance existing operations and pay current liabilities over the next twelve months, the Company will need to raise an additional $15 million of capital in 2020.

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 Consolidation

The consolidated financial statements contained in this report include the accounts of GT Biopharma, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated.

Long-Lived Assets

Our long-lived assets include property, plant and equipment, capitalized costs of filing patent applications and other indefinite lived intangible assets. We evaluate our long-lived assets for impairment, other than indefinite lived intangible assets, in accordance with ASC 360, whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Estimates of future cash flows and timing of events for evaluating long-lived assets for impairment are based upon management's judgment. If any of our intangible or long-lived assets are considered to be impaired, the amount of impairment to be recognized is the excess of the carrying amount of the assets over its fair value.

Applicable long-lived assets are amortized or depreciated over the shorter of their estimated useful lives, the estimated period that the assets will generate revenue, or the statutory or contractual term in the case of patents. Estimates of useful lives and periods of expected revenue generation are reviewed periodically for appropriateness and are based upon management's judgment.

The Company's long-lived assets currently consist of indefinite lived intangible assets associated with IPR&D ("In-Process Research & Development") projects and related capitalized patents acquired in the acquisition of Georgetown Translational Pharmaceuticals, Inc. Intangible assets associated with IPR&D projects are not amortized until approval by the Food and Drug Administration (FDA) is obtained in a major market subject to certain specified conditions and management judgment. The useful life of an amortizing asset generally is determined by identifying the period in which substantially all of the cash flows are expected to be generated.

The Company evaluates indefinite lived intangible assets for impairment at least annually and whenever impairment indicators are present in accordance with ASC 350. When necessary, the Company records an impairment loss for the amount by which the fair value is less than the carrying value of these assets. The fair value of intangible assets other than goodwill is typically determined using the "relief from royalty method", specifically the discounted cash flow method utilizing Level 3 fair value inputs. Some of the more significant estimates and assumptions inherent in this approach include: the amount and timing of the projected net cash flows, which includes the expected impact of competitive, legal and/or regulatory forces on the projections and the impact of technological risk associated with IPR&D assets, 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.

The Company performs impairment testing for all other long-lived assets whenever impairment indicators are present. When necessary, the Company calculates the undiscounted value of the projected cash flows associated with the asset, or asset group, and compares this estimated amount to the carrying amount. If the carrying amount is found to be greater, we record an impairment loss for the excess of book value over fair value.

Research and Development

Research and development costs are expensed as incurred and reported as research and development expense. Research and development costs totaled $1.7 million and $9.1 million for the years ended December 31, 2018 and 2017, respectively. Research and development costs for the year ended December 31, 2018 included non-cash compensation of $6.8 million.

Certain Expenses and Liabilities

On an ongoing basis, management evaluates its estimates related to certain expenses and accrued liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of liabilities that are not readily apparent from other sources. Actual results may differ materially from these estimates under different assumptions or conditions.

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, 2019.

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, 2019. 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, 2019, 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, 2019, 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, 2019. 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 small 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, 2019. 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

None.

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 February 28, 2019. 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
Steven Weldon	44	Chief Financial Officer, Principal Accounting Officer and 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.

Steven Weldon was appointed Chief Financial Officer and to our board of directors on March 20, 2019. Previously Mr. Weldon was appointed to the Board of Directors of the Company in September 2014 and as our Chief Financial Officer in November 2014 until October 2018.. Mr. Weldon has over 15 years of financial and accounting experience. Mr. Weldon's financial background includes experience in managerial, private accounting and planning. He has served on the board of several publicly traded companies as both, chief executive officer and chief financial officer. Mr. Weldon was appointed as chief financial officer and as a member of the board of directors of GB Sciences, Inc. (OTCMKTS:GBLX) in September 2005 and served in both positions until November 2014. Mr. Weldon also served as chief executive officer of GB Sciences from December 2009, through May 2011, and from April 2012, through March 2014. For several years, he taught accounting and tax courses to undergrad students at Florida Southern College. He received his bachelor of science degree and his Master's in Business Administration from Florida Southern College and is a licensed Certified Public Accountant in the State of Florida.

Due to the small number of directors, at the present time the duties of an Audit Committee, Nominating and Governance Committee, and Compensation Committee are performed by the board of directors as a whole. At such time as we have more directors on our board of directors, these committees will be reconstituted.

Code of Ethics

A copy of the company's code of ethics is attached to this annual report as exhibit 99.

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, Kathleen Clarence-Smith and Raymond Urbanski filed one Form 3 late and Raymond Urbanski, Anthony J. Cataldo and Steven Weldon each filed one 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, 2019 and 2018 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, 2019 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 (7)	2019	$ 225,000	$ -	$ 1,281,000	$ -	$ -	$ -	$ 75,000	$ 1,581,000
Chief Executive Officer	2018	$ 190,000	$ -	$ -	$ -	$ -	$ -	$ 404,151	$ 594,151
Steven Weldon (6)	2019	$ 230,000	$ -	$ 823,500	$ -	$ -	$ -	$ -	$ 1,053,500
Chief Financial Officer	2018	$ 230,000	$ -	$ -	$ -	$ -	$ -	$ -	$ 230,000
Raymond Urbanski, M.D., Ph.D. (4)	2019	$ 318,000	$ -	$ -	$ -	$ -	$ -		$ 318,000
Former Chief Executive Officer	2018	$ 321,154	$ -	$ 7,644,490	$ -	$ -	$ -	$ -	$ 7,965,644
Shawn Cross (5)	2018	$ 233,942	$ 20,000	$ -	$ -	$ -	$ -	$ -	$ 253,942
Former Chief Executive Officer									
Kathleen Clarence-Smith (8)	2018	$ 278,846	$ -	$ -	$ -	$ -	$ -	$ -	$ 278,846
Former Chief Executive Officer									

(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. Cross was appointed President and Chief Operating Officer on October 15, 2017 and Chairman and Chief Executive Officer on February 14, 2018. Mr. Cross resigned from the Company on July 2, 2018.

(6) Mr. Weldon was appointed Chief Financial Officer on March 20, 2019. He was previously the Chief Financial Officer from November 3, 2014 until October 11, 2018.

(7) 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.

(8) Dr. Clarence-Smith was Chief Executive Officer from September 1, 2017 to February 14, 2018. Dr. Clarence-Smith served as our Vice-Chairwoman and President of the Neurology Division from February 14, 2018 until her resignation from the Company on October 9, 2018.

Employment Agreements

On October 18, 2018, the Company entered into a Consultant Agreement with Anthony Cataldo. The term of the Consultant Agreement shall remain in effect until September 30, 2019. This Agreement supersedes the Consultant Agreement dated February 14, 2018 and will pay Mr. Cataldo $25,000 per month during the term of the Agreement.

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, 2019, 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
Steven Weldon	-	-	-	$ -
Anthony Cataldo	-	-	-	$ -

Director Compensation

Beginning in January 2018, non-employee members of the Board of Directors are to receive $42,500 per year, plus $15,000 annually for Chairing a Committee and $5,000 annually as a member of a Committee. Also, upon shareholder approval of a Stock Option Plan, Directors will be granted 150,000 options that vest over a three-year period. Vesting will accelerate if the Company undergoes a change of control transaction for cash.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)	Stock Awards ($)	Total ($)
Dr. John Bonfiglio (1)	$ 15,325	$ -	$ -	$ 15,325
Dr. Peter Kiener (1)	$ 15,325	$ -	$ -	$ 15,325
Geoffrey Davis (1)	$ 15,325	$ -	$ -	$ 15,325

(1) Dr. Bonfiglio, Dr. Kiener and Mr. Davis resigned from the Board on March 20, 2019

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 March 24, 2020, (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 March 24, 2020, there were 70,602,433 shares of our common stock issued and outstanding. Shares of common stock subject to stock options and preferred stock that are currently exercisable or exercisable within 60 days of March 24, 2019 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.

Name and Address of Beneficial Owner	Number of Shares of Common Stock Beneficially Owned	Percent of Shares of Outstanding Common Stock
Security Ownership of Certain Beneficial Owners:		
Kathleen Clarence-Smith, M.D., Ph.D. (4)	7,521,051	10.65%
Mark Silverman (4)	7,226,108	10.23%
Bristol Investment Fund, Ltd. (1)	6,989,641	9.99%
Adam Kasower (2)	3,645,620	5.16%
Alpha Capital Anstalt (3)	6,736,475	9.54%
Security Ownership of Management and Directors:		
Anthony J. Cataldo (5)	10,734,320	15.20%
Steven Weldon (6)	6,769,707	9.59%
Executive officers and directors as a group — 2 people	17,504,027	24.79%

(1) As reported on Schedule 13G/A filed with the SEC on January 16, 2020. Paul Kessler, manager of Bristol Capital Advisors, LLC, the investment advisor to Bristol Investment Fund, Ltd., has voting and investment control over the securities held by Bristol Investment Fund, Ltd. Mr. Kessler disclaims beneficial ownership of these securities except to the extent of his pecuniary interest therein. The address of Bristol Capital Advisors, LLC is 662 N. Sepulveda Blvd., Suite 300, Los Angeles, California 90049.

(2) Includes 1,011,274 shares issuable upon conversion of principal on outstanding convertible debentures and 120,088 shares available through exercise of warrants

(3) As reported on Schedule 13G filed with the SEC on February 4, 2020 The address of Alpha Capital Anstalt is Lettstrasse 32, FL-9490 Vaduz, Furstentums, Liechtenstein

(4) Security interest in these shares has been granted to various holders of the Company's senior convertible notes to secure the Company's obligations under these notes in accordance with a Stock Pledge Agreement dated August 2, 2018.

(5) Security interest in 3,234,320 shares has been granted to various holders of the Company's senior convertible notes to secure the Company's obligations under these notes in accordance with a Stock Pledge Agreement dated August 2, 2018.

(6) Security interest in 2,269,707 shares has been granted to various holders of the Company's senior convertible notes to secure the Company's obligations under these notes in accordance with a Stock Pledge Agreement dated August 2, 2018.

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

None of our directors qualify as "independent directors" 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.

Transactions with Dr. Raymond Urbanski

On December 21, 2018, Dr. Raymond Urbanski, the former Chief Executive Officer and Chairman of the Board, provided a short-term loan of $100,000 to the Company to meet immediate capital needs. The loan matured on January 20, 2019 and carried an interest rate of 5%. The loan plus accrued interest has been repaid.

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 and 2018. 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 2019 and 2018 fiscal years.

	2019	2018
Audit Fees (1)	$ 70,500	$ 69,000
Audit-Related Fees (2)	$ -	$ -
Tax Fees (3)	$ 4,000	$ 4,000
All Other Fees	$ -	$ -
Total	$ 74,500	$ 73,000

(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 2019 and 2018 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.

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**
2.1	Agreement and Plan of Merger	10-Q	11/14/17	2.1	
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 Amended and Restated Certificate of Incorporation of GT Biopharma, Inc.	10-K	03/31/11	3.2	
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series H Convertible Preferred Stock of GT Biopharma, Inc., dated February 5, 2010	8-K	02/16/10	3.1	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series I Convertible Preferred Stock of GT Biopharma, Inc., dated March 18, 2011.	10-K	03/31/11	3.4	
3.5	Bylaws, as restated effective September 7, 1994 and as amended through April 29, 2003	10-QSB	08/13/03	3	
3.6	Certificate of Amendment to the Certificate of Incorporation of the Registrant, effective as of July 19, 2017.	8-K	3/15/18		
10.1	License Agreement with ID4 Pharma LLC	10-Q	08/11/17	10.1	
10.2	License Agreement with MultiCell Immunotherapeutics, Inc.	10-Q	08/11/17	10.2	
10.3	License Agreement with the University of Minnesota	10-Q	08/11/17	10.3	
10.4	License Agreement with Daniel A. Vallera, Ph.D.	10-Q	08/11/17	10.4	
10.9	Warrant Conversion Agreement	10-Q	11/14/17	10.6	
10.10	Preferred Conversion Agreement	10-Q	11/14/17	10.7	
10.11	Amended Note Conversion Agreement	10-Q	11/14/17	10.8	
10.12	Amended Warrant Conversion Agreement	10-Q	11/14/17	10.9	
10.13	Amended Preferred Conversion Agreement	10-Q	11/14/17	10.10	
10.15	Securities Purchase Agreement	8-K	01/13/17	10.1	
10.16	10% Senior Convertible Debenture	8-K	01/13/17	10.2	
10.17	Common Stock Purchase Warrant	8-K	01/13/17	10.3	
10.18	Securities Purchase Agreement by and among the Company and the Buyers, dated January 22, 2018.	8-K	1/23/18	10.1	
10.19	Form of Registration Rights Agreement by and among the Company and the Buyers, dated January 22, 2018.	8-K	1/23/18	10.2	
10.20	Form of Note.	8-K	1/23/18	10.3	
10.21	Form of Warrant.	8-K	1/23/18	10.4	
10.22	First Amendment to the Employment Agreement, dated as of February 14, 2018, between the Company and Dr. Clarence-Smith.	8-K	2/21/18	10.2	
10.23	Consultant Agreement, dated as of February 14, 2018, between the Company and Mr. Cataldo.	8-K	2/21/18	10.3	
10.24	Form of 10% Senior Convertible Debenture	8-K	08/03/18	4.1	
10.25	Security Purchase Agreement	8-K	08/03/18	10.1	
10.26	Form of 10% Senior Convertible Debenture	8-K	09/07/18	4.1	
10.27	Security Purchase Agreement	8-K	09/07/18	10.1	
10.28	Form of 10% Senior Convertible Debenture	8-K	09/24/18	4.1	
10.29	Security Purchase Agreement	8-K	09/24/18	10.1	
10.30	Separation Agreement between the Company and Dr. Clarence-Smith	8-K	10/12/18	10.1	
10.31	Resignation of Steven Weldon	8-K	10/16/18		
10.32	Stock Pledge Agreement	10-Q	08/14/18	10.10	
10.33	Executive Employment Agreement with Dr. Urbanski	10-Q	11/14/18	10.17	
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: March 27, 2020

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	Postion	Date
/s/ Anthony J. Cataldo Anthony J. Cataldo	Chief Executive Officer and Chairman of the Board	March 27, 2020
/s/ Steven Weldon Steven Weldon	Chief Financial Officer (Principal Accounting Officer) and Director	March 27, 2020

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2019 AND 2018

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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 sheets of GT Biopharma, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2019, 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 as of December 31, 2019 and 2018 and the consolidated results of its operations and its consolidated cash flows for each of the years in the two-year period 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 audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 audits we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 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 have served as the Company's auditor since 2008.

White Plains, New York
March 27, 2020

GT Biopharma, Inc. and Subsidiaries
Consolidated Balance Sheets
(in thousands, except par value and share data)

	December 31, 2019	December 31, 2018
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 28	$ 60
Prepaid expenses	246	30
Total Current Assets	274	90
Intangible assets	-	25,262
Operating lease right-to use asset	110	-
Deposits	12	12
Fixed assets, net	-	35
Total Other Assets	122	25,309
TOTAL ASSETS	$ 396	$ 25,399
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,940	$ 1,762
Accrued expenses	2,379	1,023
Accrued interest	2,029	432
Line of credit	31	31
Note Payable to Related Party	-	100
Deferred Rent	-	8
Operating lease liability	120	
Convertible debentures	13,207	10,673
Total Current Liabilities	19,706	14,029
Total liabilities	19,706	14,029
Commitments and Contingencies		
Stockholders' (deficit) Equity:		
Convertible preferred stock - $0.001 par value; 15,000,000 shares authorized:		
Series C - 96,230 and 96,230 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	1	1
Series J – 2,353,548 and 1,163,548 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	2	1
Common stock - $0.001 par value; 750,000,000 shares authorized; and 69,784,699 and 50,650,478 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	70	51
Additional paid-in capital	548,118	540,171
Accumulated deficit	(567,332)	(528,685)
Noncontrolling interest	(169)	(169)
Total Stockholders' (deficit) Equity	(19,310)	11,370
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 396	$ 25,399

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

GT Biopharma, Inc. and Subsidiaries
Consolidated Statements of Operations
(in thousands except per share data)

	December 31	
	2019	**2018**
Operating expenses:		
Research and development	$ 1,667	$ 9,067
Selling, general and administrative expenses	9,790	12,487
Loss on impairment	4,599	228,515
Total operating expenses	16,056	250,069
Loss from operations	(16,056)	(250,069)
Other income (expense):		
Loss on disposal of assets	(20,463)	-
Interest expense	(2,128)	(9,117)
Total other income (expense)	(22,591)	(9,117)
Loss before provision for income taxes	(38,647)	(259,186)
Provision for income tax	-	-
Net loss	$ (38,647)	$ (259,186)
Net loss per common share – basic and diluted	$ (0.67)	$ (5.16)
Weighted average common shares outstanding – basic and diluted	57,527	50,240

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

GT Biopharma, Inc. and Subsidiaries
Consolidated Statement of Stockholders' Equity
For the Years Ended December 31, 2019 and 2018

	Preferred Shares		Common Shares		Paid-in	Accumulated
	Shares	Amount	Shares	Amount	Capital	Deficit
Balance at December 31, 2018	**1,260**	**$ 2**	**50,118**	**$ 50**	**$ 521,305**	**$ (269,499)**
Issuance of warrants					8,304	
Issuance of common stock for convertible notes			162	0	325	
Beneficial conversion feature on convertible notes					544	
Issuance of common stock for compensation			370	1	9,693	
Net loss						(259,186)
Balance at December 31, 2018	**1,260**	**$ 2**	**50,650**	**$ 51**	**$ 540,171**	**$ (528,685)**
Issuance of preferred stock	1,190	1			1,139	
Issuance of common stock for convertible notes			3,484	3	1,357	
Beneficial conversion feature on convertible notes					158	
Issuance of common stock for compensation			15,650	16	5,293	
Net loss						(38,647)
Balance at December 31, 2019	**2,450**	**$ 3**	**69,784**	**$ 70**	**$ 548,118**	**$ (567,332)**

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

GT Biopharma, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands)

	Twelve Months Ended December 31,	
	2019	**2018**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (38,647)	$ (259,186)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	4	7
Loss on impairment of long-lived assets	4,599	228,515
Loss on the disposal of assets	20,494	-
Stock compensation expense for options and warrants issued to employees and non-employees	5,308	9,696
Amortization of debt discounts	505	8,663
Non-cash interest expense	1,140	441
Amortization of loan costs	-	1,076
Changes in operating assets and liabilities:		
Prepaid Expenses	(216)	(30)
Other assets	-	(3)
Other liabilities	-	8
Accounts payable and accrued liabilities	3,154	136
Net cash used in operating activities	(3,659)	(10,677)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of fixed assets		(36)
Disposal of fixed assets	200	-
Net cash used by investing activities	200	(36)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable	3,527	15,145
Loan costs	-	(533)
Repayment of note payable	(100)	(4,415)
Net cash provided by financing activities	3,427	10,197
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(32)	(516)
CASH AND CASH EQUIVALENTS - Beginning of period	60	576
CASH AND CASH EQUIVALENTS - End of period	$ 28	$ 60
Supplemental cash flow disclosures:		
Issuance of common stock upon conversion of convertible notes	$ 1,360	$ 325
Issuance of common stock for interest expense	$ 21	$ -

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

1. The Company

Business

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. In July 2017, the Company changed its name to GT Biopharma, Inc.

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™), Tetra-specific Killer Engager (TetraKE™) and bi-specific ligand-directed single-chain fusion protein technology platforms. Our TriKE and TetraKE platforms 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. TriKEs and TetraKEs are made up of recombinant fusion proteins, can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization.

Basis of Consolidation

The accompanying consolidated financial statements include the accounts of GT Biopharma, Inc. and its subsidiaries. All intercompany balances and transactions have been eliminated. The Company's financial statements are prepared using the accrual method of accounting.

Going Concern

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.

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 negative cash flows from operations since its inception and has an accumulated deficit of $567 million and cash of $28 thousand as of December 30, 2019. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales 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, 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.

Use of Estimates

The financial statements and notes are representations of the Company's management, which is responsible for their integrity and objectivity. These accounting policies conform to accounting principles generally accepted in the United States of America and have been consistently applied in the preparation of the financial statements. The preparation of financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses and disclosures of contingent assets and liabilities at the date of the financial statements. Actual results could differ from those estimates.

Segment Information

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision-maker in making decisions regarding resource allocation and assessing performance. To date, the Company has viewed its operations and manages its business as one segment operating in the United States of America.

2. Summary of Significant Accounting Policies

Advertising and promotional fees

Advertising expenses consist primarily of costs incurred in the design, development, and printing of Company literature and marketing materials. The Company expenses all advertising expenditures as incurred. There were no advertising expenses for the years ended December 31, 2019 and 2018, respectively.

Cash and Cash Equivalents

The Company considers all highly liquid investments with original maturities of three months or less to be cash equivalents.

Concentrations of Credit Risk

The Company's cash and cash equivalents, marketable securities and accounts receivable are monitored for exposure to concentrations of credit risk. The Company maintains substantially all of its cash balances in a limited number of financial institutions. The balances are each insured by the Federal Deposit Insurance Corporation up to $250,000. The Company had no balances in excess of this limit at December 31, 2019.

Stock Based Compensation to Employees

The Company accounts for its stock-based compensation for employees in accordance with Accounting Standards Codification ("ASC") 718. The Company recognizes in the statement of operations the grant-date fair value of stock options and other equity-based compensation issued to employees and non-employees over the related vesting period.

The Company granted no stock options during the years ended December 31, 2019 and 2018, respectively.

Long-Lived Assets

Our long-lived assets include property, plant and equipment, capitalized costs of filing patent applications and other indefinite lived intangible assets. We evaluate our long-lived assets for impairment, other than indefinite lived intangible assets, in accordance with ASC 360, whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Estimates of future cash flows and timing of events for evaluating long-lived assets for impairment are based upon management's judgment. If any of our intangible or long-lived assets are considered to be impaired, the amount of impairment to be recognized is the excess of the carrying amount of the assets over its fair value.

Applicable long-lived assets are amortized or depreciated over the shorter of their estimated useful lives, the estimated period that the assets will generate revenue, or the statutory or contractual term in the case of patents. Estimates of useful lives and periods of expected revenue generation are reviewed periodically for appropriateness and are based upon management's judgment.

Impairment of Long-Lived Assets

The Company's long-lived assets currently consist of indefinite lived intangible assets associated with IPR&D ("In-Process Research & Development") projects and related capitalized patents acquired in the acquisition of Georgetown Translational Pharmaceuticals, Inc. as described in Note 3 below. Intangible assets associated with IPR&D projects are not amortized until approval by the Food and Drug Administration (FDA) is obtained in a major market subject to certain specified conditions and management judgment. The useful life of an amortizing asset generally is determined by identifying the period in which substantially all of the cash flows are expected to be generated.

The Company evaluates indefinite lived intangible assets for impairment at least annually and whenever impairment indicators are present in accordance with ASC 350. When necessary, the Company records an impairment loss for the amount by which the fair value is less than the carrying value of these assets. The fair value of intangible assets other than goodwill is typically determined using the "relief from royalty method", specifically the discounted cash flow method utilizing Level 3 fair value inputs. Some of the more significant estimates and assumptions inherent in this approach include: the amount and timing of the projected net cash flows, which includes the expected impact of competitive, legal and/or regulatory forces on the projections and the impact of technological risk associated with IPR&D assets, 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.

The Company performs impairment testing for all other long-lived assets whenever impairment indicators are present. When necessary, the Company calculates the undiscounted value of the projected cash flows associated with the asset, or asset group, and compares this estimated amount to the carrying amount. If the carrying amount is found to be greater, we record an impairment loss for the excess of book value over fair value.

Income Taxes

The Company accounts for income taxes using the asset and liability approach, whereby deferred income tax assets and liabilities are recognized for the estimated future tax effects, based on current enacted tax laws, of temporary differences between financial and tax reporting for current and prior periods. Deferred tax assets are reduced, if necessary, by a valuation allowance if the corresponding future tax benefits may not be realized.

Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period, plus the potential dilutive effect of common shares issuable upon exercise or conversion of outstanding stock options and warrants during the period.

During 2019, there were three repricings related to the conversion price of the convertible debt and the exercise price of the warrants. The Company prepared the calculations of the change in value pursuant to ASU 2017-11, and determined there was no deemed dividend to include in the calculation of earnings per share.

The computation of basic and diluted net loss per share for the years ended December 31, 2019 and 2018 excludes the common stock equivalents of the following potentially dilutive securities because their inclusion would be anti-dilutive:

	December 31,	
	2019	2018
Exercise of common stock warrants	9,065,265	1,813,053
Conversion of preferred stock into common stock	11,768,295	1,163,659
Conversion of convertible debentures into common stock	66,136,870	5,704,543
Exercise of common stock options	40	1,113
	86,970,470	8,682,368

Patents

Acquired patents are capitalized at their acquisition cost or fair value. The legal costs, patent registration fees and models and drawings required for filing patent applications are capitalized if they relate to commercially viable technologies. Commercially viable technologies are those technologies that are projected to generate future positive cash flows in the near term. Legal costs associated with patent applications that are not determined to be commercially viable are expensed as incurred. All research and development costs incurred in developing the patentable idea are expensed as incurred. Legal fees from the costs incurred in successful defense to the extent of an evident increase in the value of the patents are capitalized.

Capitalized costs for pending patents are amortized on a straight-line basis over the remaining twenty-year legal life of each patent after the costs have been incurred. Once each patent is issued, capitalized costs are amortized on a straight-line basis over the shorter of the patent's remaining statutory life, estimated economic life or ten years.

Fixed Assets

Fixed assets are stated at cost. Depreciation is computed on a straight-line basis over the estimated useful lives of the assets, which are 3 to 10 years for machinery and equipment and the shorter of the lease term or estimated economic life for leasehold improvements.

Fair Value

The carrying amounts reported in the balance sheets for current liabilities qualify as financial instruments and are a reasonable estimate of fair value because of the short period of time between the origination of such instruments and their expected realization and their current market rate of interest. The three levels are defined as follows:

- Level 1 inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets. The Company's Level 1 assets include cash equivalents, primarily institutional money market funds, whose carrying value represents fair value because of their short-term maturities of the investments held by these funds.

- Level 2 inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument. The Company's Level 2 liabilities consist of liabilities arising from the issuance of convertible securities and in accordance with ASC 815-40: These liabilities are remeasured each reporting period if required by ASC 815-40. Fair value is determined using the Black-Scholes valuation model based on observable market inputs, such as share price data and a discount rate consistent with that of a government-issued security of a similar maturity. There were no such liabilities at December 31, 2019 .

- Level 3 inputs to the valuation methodology are unobservable and significant to the fair value measurement. The Company does not have any assets or liabilities measured using Level 3 inputs.

Research and Development

Research and development costs are expensed as incurred and reported as research and development expense. Research and development costs totaled $1.7 million and $9.1 million for the years ended December 31, 2019 and 2018, respectively. Research and development costs for the year ended December 31, 2018 included non-cash compensation of $6.8 million.

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standard Update ("ASU") No. 2016-02, "Leases." This ASU requires all lessees to be recognized on the balance sheet as right to use assets and lease liabilities for the rights and obligations created by lease arrangements with terms greater than 12 months. The Company adopted the ASU as of January 1, 2019. The effect of the adoption of the ASU was to increase the other assets and liabilities by approximately $174,000.

3. Intangibles

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.

4. Debt

Convertible Notes

On January 22, 2018, the Company entered into a Securities Purchase Agreement (“SPA”) with fourteen accredited investors (individually, a “Buyer” and collectively, the “Buyers”) pursuant to which the Company agreed to issue to the Buyers senior convertible notes in an aggregate principal amount of $7,760,510 (the “Notes”), which Notes shall be convertible into the Company’s common stock, par value $0.001 per share (the “Common Stock”) at a price of $4.58 per share, and five-year warrants to purchase the Company’s Common Stock representing the right to acquire an aggregate of approximately 1,694,440 shares of Common Stock (the “Warrants”).

Pursuant to the terms of SPA the Notes were subject to an original issue discount of 10% resulting in proceeds to the Company of $7,055,000 from the transaction.

Upon the purchase of the Notes, the Buyers received Warrants to purchase 1,694,440 shares of Common Stock. Such Warrants are exercisable for (5) years from the date the shares underlying the Warrants are freely saleable. The initial Exercise Price is $4.58. According to the terms of the warrant agreement, the Warrants are subject to certain adjustments depending upon the price and structure of a subsequent financing, including a qualified financing with gross proceeds of at least $20 million, as defined in the agreements.

The issuance of the Notes and Warrants were made in reliance on the exemption provided by Section 4(a)(2) of the Securities Act of 1933, as amended (the “Securities Act”) for the offer and sale of securities not involving a public offering, and Regulation D promulgated under the Securities Act.

Contemporaneously with the execution and delivery of the SPA, the Company and the Buyers executed and delivered a Registration Rights Agreement (the “Registration Rights Agreement”) pursuant to which the Company has agreed to provide certain registration rights with respect to the Registrable Securities under the 1933 Act and the rules and regulations promulgated thereunder, and applicable state securities laws.

Senior Convertible Debentures

On August 2, 2018, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement with the purchasers identified on the signature pages thereto (individually, a "Purchaser," and collectively, the "Purchasers") pursuant to which the Company issued to the Purchasers one year 10% Senior Convertible Debentures in an aggregate principal amount of $5,140,000 (the "Debentures"), which Debentures shall be convertible into the Company's common stock, par value $0.001 per share (the "Common Stock"), at a price of $2 per share. The Company used a portion of these proceeds to repay $4.4 million of the notes issued on January 22, 2018. Additionally, the remaining $3.3 million of the notes issued on January 22, 2018 were converted into the Debentures at the same terms discussed above.

On September 7, 2018, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement with the purchasers identified on the signature pages thereto (individually, a "Purchaser," and collectively, the "Purchasers") pursuant to which the Company has issued to the Purchasers one year 10% Senior Convertible Debentures in an aggregate principal amount of $2,050,000 (the "Debentures"), which Debentures shall be convertible into the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial price of $2 per share.

On September 24, 2018, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement with the purchasers identified on the signature pages thereto (individually, a "Purchaser," and collectively, the "Purchasers") pursuant to which the Company has issued to the Purchasers one year 10% Senior Convertible Debentures in an aggregate principal amount of $800,000 (the "Debentures"), which Debentures shall be convertible into the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial price of $2 per share.

On February 4, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the 15 purchasers (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on February 4, 2019, Secured Convertible Notes in an aggregate principal amount of $1,352,224 (the "Notes"), consisting of gross proceeds of $1,052,224 and settlement of existing debt of $300,000, which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.60 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on August 2, 2019. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

Contemporaneously with the execution and delivery of the Purchase Agreement, on February 4, 2019, the Company and certain of its wholly-owned subsidiaries entered into a Security Agreement (the "Security Agreement") with Alpha Capital Anstalt, as collateral agent on behalf of the Purchasers, and with the Purchasers, pursuant to which the Purchasers have been granted a first-priority security interest in substantially all of the assets of the Company and such subsidiaries securing (i) an aggregate principal amount of $1,352,224 of Notes and (ii) an aggregate principal amount of $9,058,962 of the Company's 10% Senior Convertible Debentures issued on August 2, 2018, September 7, 2018 and September 24, 2018 held by such Purchasers.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 14 days after February 4, 2019, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement. The Form S-3 was filed by the Company on February 14, 2019 and became effective on March 11, 2019.

On May 22, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the ten purchasers (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on May 22, 2019, Secured Convertible Notes in an aggregate principal amount of $1,300,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.35 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on November 22, 2019. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days after May 22, 2019, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement. The Form S-1 was filed by the Company on June 21, 2019 and became effective on July 12, 2019.

Between July 31 and August 28, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the eleven purchasers (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, Secured Convertible Notes in an aggregate principal amount of $975,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.20 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature between January 31 and February 28, 2020. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement. The Form S-1 was filed by the Company on September 13, 2019 and became effective in October 2, 2019.

On December 19, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the one purchaser (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on December 19, 2019, Secured Convertible Notes in an aggregate principal amount of $200,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.20 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on August 19, 2020. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days after December 19, 2019, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement.

Financing Agreement

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 percent per annum. There is $31,000 due on this credit line at December 31, 2019 .

5. Accrued Expenses

Accrued Expenses are comprised of the following:

	2019	2018
Rent	52,000	-
License Fee	50,000	-
Research & Development	1,675,000	585,000
Professional Fees	95,000	162,000
Consulting and Advisory Services	161,000	161,000
Board of Directors Service Costs	101,000	94,000
Payroll and Benefits	245,000	21,000
Accrued Expenses	**2,379,000**	**1,023,000**

6. Related Party Transactions

On December 21, 2018, Dr. Raymond Urbanski, Chief Executive Officer and Chairman of the Board, provided a short-term loan of $100,000 to meet immediate capital needs. The loan matured on January 20, 2019 and carries an interest rate of 5%. The loan was repaid in January, 2019.

7. Stockholders' Equity

Common Stock

For the year ended December 31, 2018, the Company issued 162,500 shares of common stock upon conversion of $325,000 of senior convertible notes.

For the year ended December 31, 2018, the Company issued a total of 245,000 shares of Rule 144 restricted common stock in full settlement of outstanding legal matters, and 125,000 shares of Rule 144 restricted common stock in connection with consulting services.

For the year ended December 31, 2019, the Company issued a total 3,484,222 shares of common stock upon conversion of $1,361,034 in principal and interest on senior convertible notes.

For the year ended December 31, 2019, the Company issued CEO AnthonyCataldo a total of 7,000,000 and the Company's CFO Steven Weldon a total of 4,500,000 shares of Rule 144 restricted common stock as compensation, and 4,150,000 shares of Rule 144 restricted common stock in connection with consulting services.

Preferred Stock

The 96,230 shares of Series C preferred stock are convertible into 111 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 .20 or more than .2889 common shares for each Series C preferred share. 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 .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. No dividends to Series C preferred stockholders were issued or unpaid through December 31, 2019 .

On September 1, 2017, the Company designated 2,000,000 shares of Series J Preferred Stock. Shares of Series J Preferred Stock will have the same voting rights as shares of common stock with each share of Series J Preferred Stock entitled to one vote at a meeting of the shareholders of the Corporation. Shares of Series J 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 J Preferred Stock will participate, on an as-if-converted-to-common stock basis, in any dividends to the holders of common stock. Each share of the Series J Preferred Stock is convertible into one share of our common stock at any time at the option of the holder.

On the same day, the Board issued 1,513, 548 of those shares in exchange for the cancellation of debt. 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. Legal research determined that despite the fact the Company had issued shares of Series J Preferred Stock, those shares had, in fact, never existed.

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 Series J-1 Preferred Stock. On April 19, 2019, the Company issued 2,353,548 of those shares. The issuance was in lieu of the 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 an expense in general and administrative costs in the year ended December 31, 2019 totaling $1,140,000.

The Shares are convertible into shares of common stock of the Registrant at the rate of $0.60 per share. The issuance was exempt from the registration requirements of Section 5 of the Securities Act of 1933 pursuant to Section 4(2) of the same Act since the issuance of the Shares did not involve any public offering.

Common Stock Warrants

Warrant transactions for the years ended December 31, 2019 and 2018 are as follows:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding, December 31, 2018	-	-
Granted	1,813,053	0.20
Exercised	-	-
Expired	-	-
Outstanding, December 31, 2019	1,813,053	-
Granted	-	-
Exercised	-	
Expired	-	
Outstanding, December 31, 2019	1,813,053	0.20
Exercisable Warrants:		
December 31, 2019	1,813,053	0.20
December 31, 2018	1,813,053	0.20

Stock Options

The Company reserved 1,333 shares of its common stock at December 31, 2014 for issuance under the 2014 Stock Incentive Plan (the "2014 Plan"). The 2014 Plan, approval by stockholders in May 2015, permits the Company to grant stock options to acquire shares of the Company's common stock, award stock bonuses of the Company's common stock, and grant stock appreciation rights. At December 31, 2019 , 87 shares of common stock were available for grant and options to purchase 40 shares of common stock are outstanding under the 2014 Plan.

The following table summarizes stock option transactions for the years ended December 31, 2019 and 2018:

	Number of Options	Weighted-Average Exercise Price
Outstanding, December 31, 2017	1,246	1,320.00
Granted	-	-
Exercised	-	-
Expired	(133)	1,020.00
Outstanding, December 31, 2018	1,113	1,320.00
Granted	-	-
Exercised	-	-
Expired	(1,073)	1,500.00
Outstanding, December 31, 2019	40	877.50
Exercisable Options:		
December 31, 2019	40	877.50
December 31, 2018	1,113	1,320.00

The following table summarizes information about all outstanding and exercisable stock options at December 31, 2019 :

	Outstanding Options			Exercisable Options	
Range of Exercise Prices	Number of Options	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Number of Options	Weighted-Average Exercise Price
$750.00 to$2,225.00	40	0.89	$ 877.50	40	$ 877.50

8. Income Taxes

Deferred Taxes

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

	December 31,	
	2019	2018
Deferred tax assets:		
Federal net operating loss carryforward	36,803,000	25,306,000
Intellectual property	58,504,000	61,787,000
Accrued expense	1,262,000	129,000
Patent amortization	4,000	5,000
Deferred tax asseets before valuation	96,573,000	87,227,000
Valuation allowance	(96,573,000)	(87,227,000)
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. The valuation allowance increased by approximately $9,346,000 during the year ended December 31, 2019 .

Tax Carryforward

At December 31, 2019 , the Company had net operating loss carryforwards of approximately $122,676,000 to reduce United States federal taxable income in future years. These carryforwards expire from 2020 through 2039.

The Company is no longer subject to U.S. and state tax examinations for years ending before the fiscal year ended December 31, 2015. Management does not believe there will be any material changes in our unrecognized tax positions over the next twelve months.

The Company's policy is to recognize interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. There was no accrued interest or penalties associated with any unrecognized tax benefits, nor was any interest expense recognized during the years ended December 31, 2019 and 2018.

9. Commitments and Contingencies

Leases

On September 1, 2017, the Company entered into a three-year lease agreement for its office in Washington, D.C. In addition to minimum rent, certain leases require payment of real estate taxes, insurance, common area maintenance charges and other executory costs. The Company recognizes rent expense under such arrangements on a straight-line basis over the effective term of each lease. This lease was terminated as of June 30, 2018.

On October 1, 2018, the Company entered into a three-year lease agreement for its office in Westlake Village, CA. In addition to minimum rent, certain leases require payment of real estate taxes, insurance, common area maintenance charges and other executory costs. The Company recognizes rent expense under such arrangements on a straight-line basis over the effective term of each lease.

The following table summarizes the Company’s future minimum lease commitments as of December 31, 2019 (in thousands):

Year ending December 31:	
2020	71,000
2021	61,000
Total minimum lease payments	132,000

Rent expense for the years ended December 31, 2019 and 2018 was $69,000 and $9,000, respectively.

Employment Agreements

On February 14, 2018, the Company entered into the First Amendment to the Employment Agreement with Dr. Clarence-Smith, amending the Employment Agreement, dated September 1, 2017, between the Company and Dr. Clarence-Smith. Under the First Amendment, Dr. Clarence-Smith’s title was revised to reflect her new position and included an annual salary of $500,000, paid in equal monthly installments. All other terms of her original Employment Agreement remain unchanged. In October 2018, Dr. Clarence-Smith resigned from her position with the Company. In connection with this resignation, the Company entered into a separation agreement which superseded the Employment Agreement.

On October 18, 2018, the Company entered into a Consultant Agreement with Anthony Cataldo. The term of the Consultant Agreement shall remain in effect until September 30, 2019. This Agreement supersedes the Consultant Agreement dated February 14, 2018 and will pay Mr. Cataldo $25,000 per month during the term of the Agreement.

On October 19, 2018, the Company entered into an Executive Employment Agreement with Dr. Raymond 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.

10. Subsequent Events

Financing

On January 30, 2020 GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the one purchaser (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on January 30, 2020, Secured Convertible Notes in an aggregate principal amount of $200,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.20 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on September 30, 2020. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days after January 30, 2020, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement.

On March 24, 2020 GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement (the "Purchase Agreement") with the one purchaser (individually, a "Purchaser," and collectively, the "Purchasers"), pursuant to which the Company issued to the Purchasers, on January 30, 2020, Secured Convertible Notes in an aggregate principal amount of $200,000 (the "Notes"), which Notes shall be convertible at any time after issuance into shares (the "Conversion Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), at an initial conversion price of $0.20 per share (the "Conversion Price").

The Notes accrue interest at the rate of 10% per annum and mature on September 30, 2020. Interest on the Notes is payable in cash or, at a Purchaser's option, in shares of Common Stock at the Conversion Price. Upon the occurrence of an event of default, interest accrues at 18% per annum. The Notes contain customary default provisions, including provisions for potential acceleration, and covenants, including negative covenants regarding additional indebtedness and dividends. The Conversion Price is subject to adjustment due to certain events, including stock dividends and stock splits, and is subject to reduction in certain circumstances if the Company issues Common Stock or Common Stock equivalents at an effective price per share that is lower than the Conversion Price then in effect. The Company may only prepay the Notes with the prior written consent of the respective Purchasers thereof.

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not effect any Variable Rate Transaction (as defined in the Purchase Agreement) and that, for as long as a Purchaser holds any Notes or Conversion Shares, the Company shall amend the terms and conditions of the Purchase Agreement and the transactions contemplated thereby with respect to such Purchaser to give such Purchaser the benefit of any terms or conditions under which the Company agrees to issue or sell any Common Stock or Common Stock equivalents that are more favorable to an investor than the terms and conditions granted to such Purchaser under the Purchase Agreement and the transactions contemplated thereby.

In addition, the Company entered into a registration rights agreement (the "Registration Rights Agreement") with the Purchasers, pursuant to which the Company has agreed to file, within 30 days after March 24, 2020, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement.

Common Stock

In the first quarter of 2020, the Company issued 814,733 shares of common stock upon conversion of $162,947 in principal and interest on senior convertible notes.

Exhibit 31.1

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT.

I, Anthony Caraldo, certify that:

a. I have reviewed this report on Form 10-K of GT Biopharma, Inc.;

b. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

c. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

d. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

i) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

ii) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

iii) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

iv) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

e. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2020

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

Exhibit 31.2

CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT.

I, Steven Weldon, certify that:

a. I have reviewed this report on Form 10-K of GT Biopharma, Inc.;

b. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

c. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

d. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f) for the registrant and have:

   i) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   ii) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   iii) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   iv) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

e. I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   i) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 27, 2020

By: /s/ Steven Weldon
Name: Steven Weldon
Title: CFO, Principal Accounting Officer and Director

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 Caraldo, 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, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 27, 2020

By: /s/ Anthony Caraldo
Name: Anthony Caraldo
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, Steven Weldon, Chief Financial 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, 2019 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(ii) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

Date: March 27, 2020

By: /s/ Steven Weldon
Name: Steven Weldon
Title: CFO, Principal Accounting Officer and Director