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, 2017

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.)

1825 K Street NW, Suite 510
Washington, DC 20006
(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, 2017 was approximately $2.5 million. As of February 28, 2018, there were 50,117,978 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 Antibody Drug Conjugate (ADC) technology platforms. Our TriKE and TetraKE platforms generate proprietary moieties designed to harness and enhance the cancer killing abilities of a patient's own natural killer, or NK, cells. Once bound to a NK cell, our moieties are designed to enhance the NK cell and precisely direct it to one or more specifically-targeted proteins (tumor antigens) expressed on a specific type of cancer, ultimately resulting in the cancer 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. They are designed to be dosed in a common outpatient setting similar to modern antibody therapeutics and are expected to have reasonably low cost of goods. Our ADC platform generates product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of ADCs.

Our most advanced bi-specific ADC, which targets CD19+ and/or CD22+ hematological malignancies, is in a Phase 2 NHL/ALL trial, and we plan to begin a Phase 1 trial in CD33+ hematologic malignancies for our most advanced TriKE product candidate in the second half of 2018. We are initially targeting certain hematologic malignancies as we believe our product candidates may have certain advantages over existing and other in-development products. We are also developing TetraKE product candidates designed to target the larger solid tumor market and expect to begin human clinical trials in 2019.

We also are focused on developing a portfolio of three central nervous system, or CNS, product candidates that are covered by issued or filed composition of matter patents and consist of innovative reformulations and/or repurposing of existing therapies. We expect to take advantage of our CNS portfolio by generating proof-of-concept data and/or achieving other milestones and ultimately entering into strategic transactions, which may include transactions with commercialization-oriented pharmaceutical companies.

Our TriKE product candidates 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 that precisely targets a specific tumor antigen. We utilize the NK stimulating cytokine human IL-15 as a crosslinker between the two scFvs which provides a self-sustaining signal that leads to the proliferation and activation of NK cells thus enhancing their ability to kill cancer cells mediated by antibody-dependent cell-mediated cytotoxicity (ADCC) via the highly potent CD16 activating receptor on our moieties. Our lead TriKE, OXS-3550, targeting CD33+ malignancies is expected to begin clinical testing in the second half of 2018. Our second TriKE product candidate, OXS-C3550, is a next-generation version of OXS-3550 containing a modified CD16 component.

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 target two specific tumor antigens expressed on specific types of cancer cells. An example of a TetraKE product candidate is OXS-1615which targets 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. OXS-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 are typically responsible for recurrences. We intend to initiate human clinical testing for certain of our solid tumor product candidates in 2019.

Our TriKEs and TetraKEs act by binding to a patient's NK cell and a specific tumor antigen enabling an immune synapse between the now IL-15-enhanced NK cell and the targeted cancer cell. The formation of this immune synapse induces NK cell activation leading to the death of the cancer cell. The self-sustaining signal caused by our IL-15 cross-linker enables prolonged and enhanced proliferation and activation of NK cells similar to the increased proliferation of T-cells caused by 41BB-L or CD28 intracellular domains in CAR-T therapy but without the need to enhance the patient's NK cells ex vivo.

We are using our TriKE and TetraKE platforms with the intent to bring to market multiple immuno-oncology products that can treat a wide 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 approximately 90-120 days after a specific TriKE or TetraKE 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 in the second half of 2018. 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, be used in conjunction with more traditional cancer therapy and potentially overcome certain limitations of current chimeric antigen receptor, or CAR-T, therapy.

We also believe our bi-specific, ligand-directed single-chain fusion proteins represents the next generation of ADCs. Our lead bi-specific ADC, OXS-1550, which targets CD19+ and/or CD22+ hematological malignancies is currently in a Phase 2 trial being conducted at the University of Minnesota Masonic Cancer Center in patients with relapsed/refractory B-cell leukemias or lymphomas. We believe OXS-1550 has certain properties that could result in competitive advantages over recently approved ADC products targeting leukemias and lymphomas. In a Phase 1 trial, of nine patients that achieved adequate blood levels, we saw a durable complete response, or CR, in two heavily pretreated patients. One patient, who had failed multiple previous treatment regimens, has been cancer free 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.

We also are focused on developing a portfolio of central nervous system, or CNS, product candidates that are covered by formulation patents and issued or filed composition of matter patents and consist of innovative reformulations and/or repurposing of existing therapies. We believe our CNS product candidates represent potentially near-to-market opportunities that may have broader potential applicability beyond their initial indication. Certain members of our management team have a track-record of developing CNS products and product candidates with similar strategies including at Chase Pharmaceuticals and Prestwick Pharmaceuticals. We have designed our CNS clinical programs with the intent to efficiently advance each program to an FDA New Drug Application in a certain initial indication and expand applicable markets potentially after approval. Our three product candidates are initially targeting a rare autoimmune disease Myasthenia Gravis, a rare neuropathic pain indication, trigeminal neuralgia, and a vestibular disorder, motion sickness.

Immuno-Oncology Platform

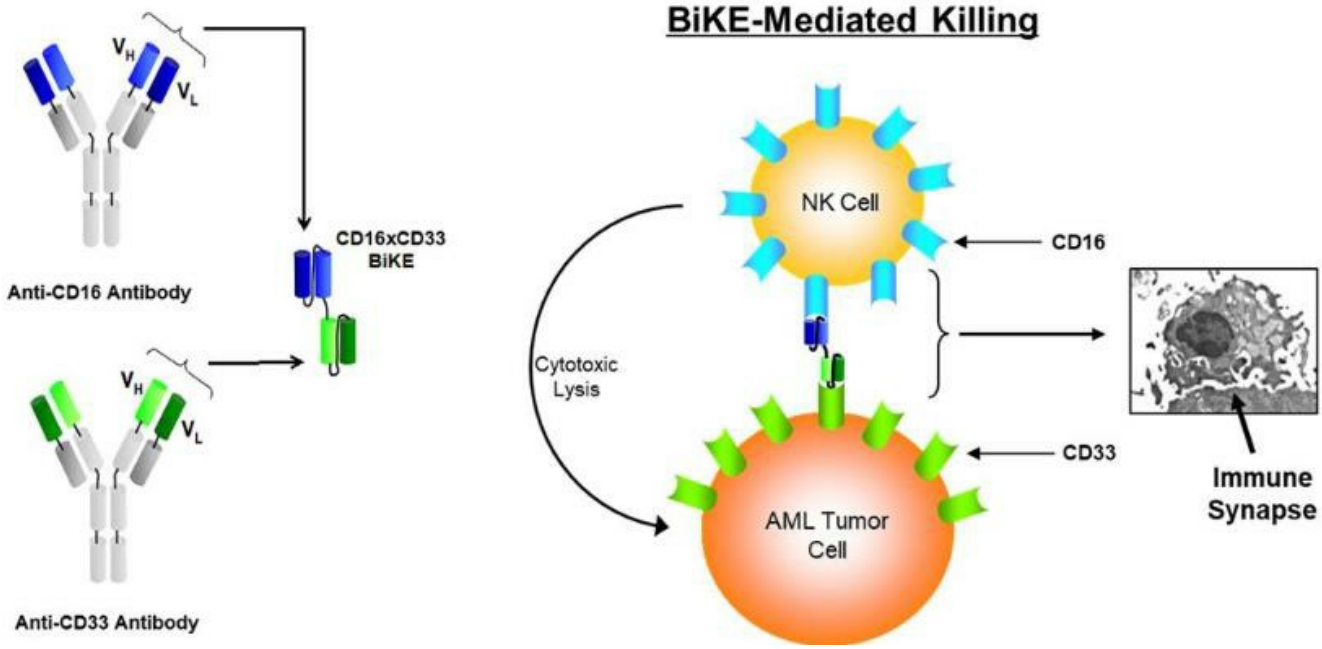
Tri-specific Killer Engagers (TriKEs) and Tetra-specific Killer Engagers (TetraKEs)

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. We believe there is an unmet need for targeted immuno-oncology therapies that 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 and/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.

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

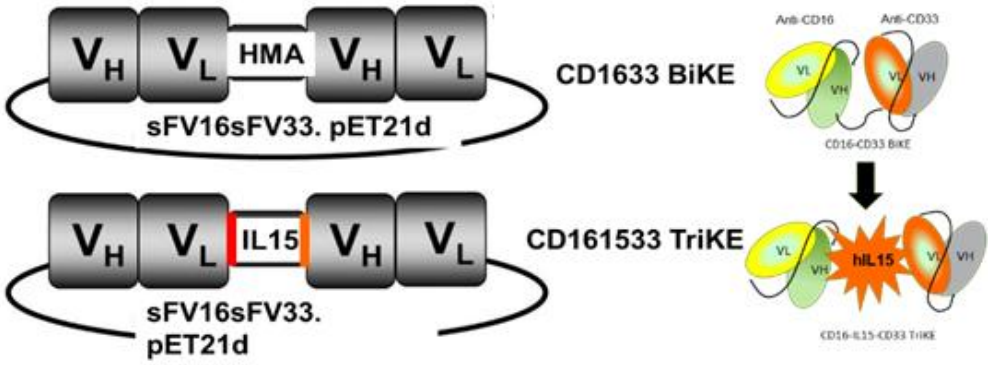
In conjunction with our research agreement with the Masonic Cancer Center at the University of Minnesota, the exploration of targeting NK cells to a variety of tumors initially focused on novel bi-specific killer engagers, or BiKEs, composed of the variable portions of antibodies targeting the CD16 activating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

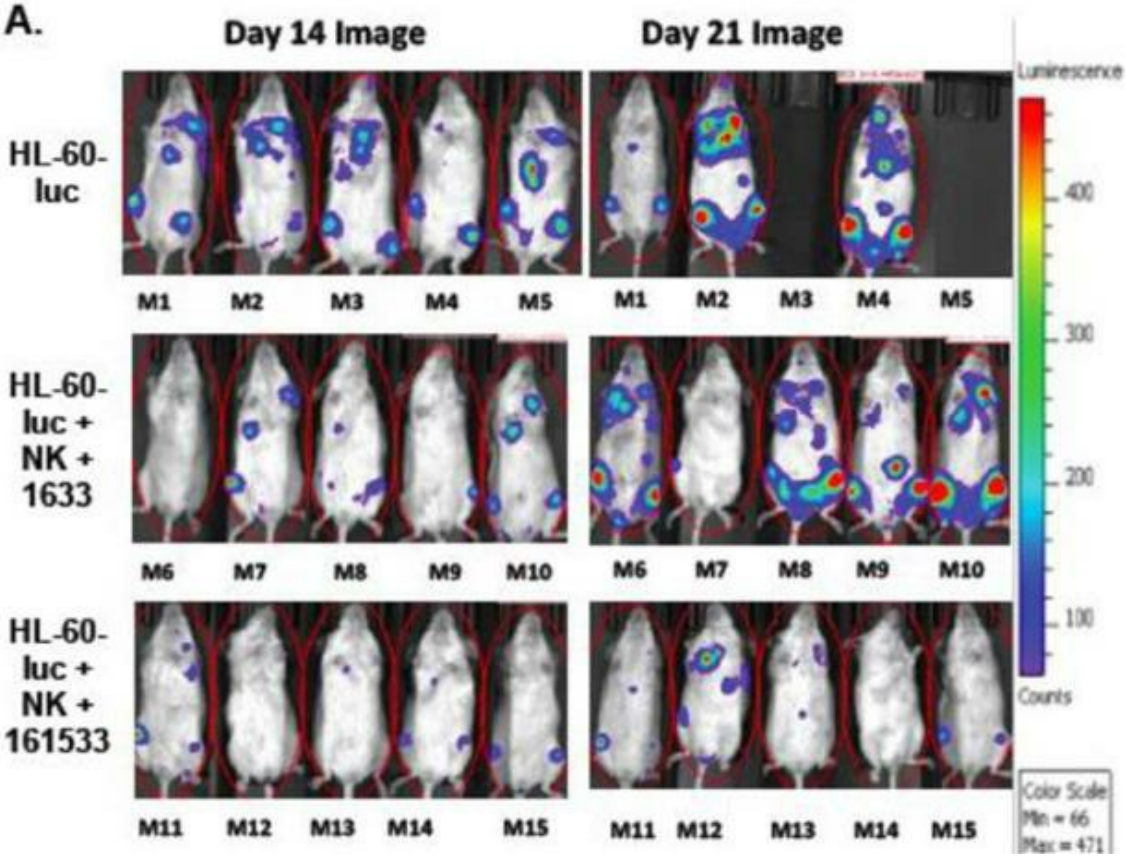
When compared to the CD16 x CD33 BiKE, the CD16 x IL-15 x CD33 TriKE is also capable of potently restoring killing capacity of post-transplant NK cells against CD33-expressing HL-60 Targets and primary AML blasts. These results demonstrated the ability to functionally incorporate an IL-5 cytokine into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

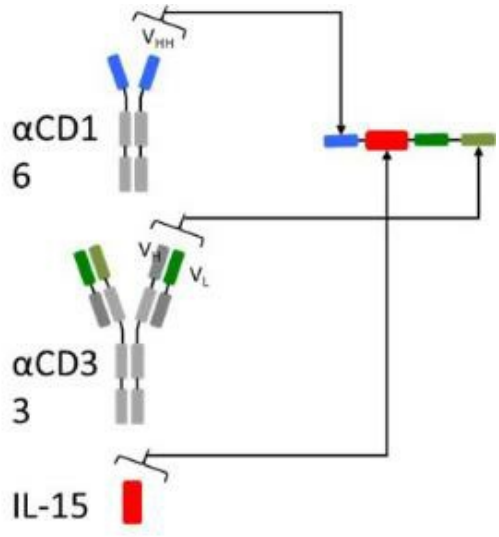
Figure A below shows the results (tumor burden and mortality) when dosing NK cells alone (top panel), the BiKE version (lacking IL-15) of OXS-3550 (middle panel; called 1633), and the TriKE, OXS-3550 (bottom panel; then called 161533) in the above described human tumor model, HL-60-luc. In the NK-cell-only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



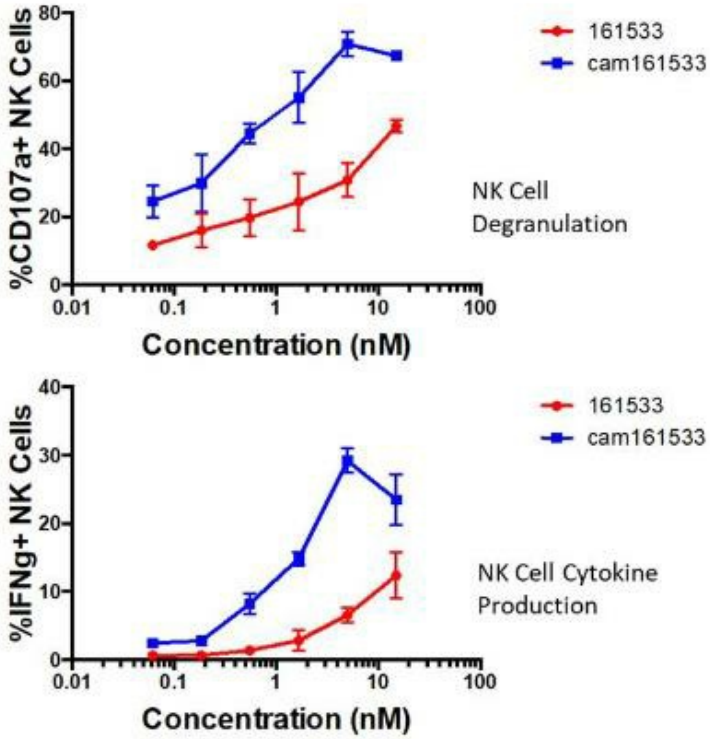
Based on these results, and others, the IND for OXS-3550 was filed in June 2017 by the University of Minnesota. FDA requested that additional nonclinical toxicology be conducted prior to initiating clinical trials. The FDA also requested some additional information and clarifications on the manufacturing (CMC) and clinical packages. We plan to incorporate the requested additional toxicology studies, information and clarifications in the IND that was transferred to us from the University of Minnesota in October 2017. We expect to begin a Phase 1 clinical trial for OXS-3550 in the second half of 2018.

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 (OXS-C3550) compared to the original TriKE (OXS-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. We intend to initiate human clinical testing for certain of our solid tumor product candidates in 2019.

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 in the second half of 2018.

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 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.

OXS-1550, our bi-specific ADC, is 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.

Immuno-Oncology Product Candidates

OXS-1550

OXS-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.

OXS-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When OXS-1550 binds to cancer cells, the cancer cells internalize OXS-1550, and are killed due to the action of drug's cytotoxic diphtheria toxin payload. OXS-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 2 trial of OXS-1550 is underway in patients with ALL/NHL. The FDA-approved clinical trial is being conducted at the University of Minnesota's Masonic Cancer Center. There are currently 18 patients enrolled in this clinical trial. Patients in this trial are given an approved increased dosage and schedule of OXS-1550.

We began enrolling patients in Phase 2 trial of OXS-1550 during the first quarter of 2017 and the first patient began dosing in April 2017. We expect data from this Phase 2 trial to be available in the second half 2018.

OXS-3550

OXS-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 OXS-3550 IND will focus on AML, the most common form of adult leukemia with 21,000 new cases expected in 2018 alone (American Cancer Society). 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 expect OXS-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 OXS-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 toxicology studies, information and clarifications will be incorporated by our company in the IND that was transferred to us from the University of Minnesota in October 2017. We expect to begin a Phase 1 clinical trial in the second half of 2018.

OXS-C3550

OXS-C3550 is a next-generation, follow-on, to our lead TriKE, OXS-3550. OXS-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 OXS-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 OXS-C3550, typically have several advantages, including better stability and solubility, more resistance to pH changes, can better recognize hidden antigenic sites, lack of a V_L portion thus preventing V_H/V_L mispairing and are suitable for construction of larger molecules. OXS-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%). OXS-C3550 also exhibited a robust increase in NK cell proliferation (57.65±6.05% vs. 20.75±2.55%).

OXS-3550 studies will help inform the development of OXS-C3550 which we expect will de-risk the OXS-C3550 program as data will be generated to make an informed decision on which, or both, will be brought into later phase studies.

OXS-1615

OXS-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. We intend to initiate human clinical testing for certain of our solid tumor product candidates in 2019.

Central Nervous System

Our CNS portfolio consists of innovative reformulations and/or repurposing of existing therapies and are covered by issued formulation or filed composition of matter patents (PCTs and provisionals). We believe our CNS product candidates address numerous unmet medical needs that can lead to improved efficacy and/or address tolerability and safety issues that tend to limit the usefulness of the original approved drug. Our CNS drug candidates address disease states such as chronic neuropathic pain (trigeminal neuralgia), myasthenia gravis and vestibular disorders.

In January 2018, we completed dosing in our Phase 1 clinical trial for GTP-004, our product candidate for the treatment for the symptoms of myasthenia gravis. Based on the data, and discussions with key opinion leaders, we expect to be in a position to initiate a Phase 2 clinical trial in patients in the second half of 2018. We also began a proof-of-concept clinical trial for GTP-011, a 72-hour patch for the prevention of motion sickness, in late February 2018. We anticipate that the new drug application, or NDA, will be a 505(b)2 NDA for each of these programs. PainBrake® is designed to enable accurate dose fractionation for the treatment of certain forms of neuropathic pain and we expect to complete the manufacturing tablets for a bioequivalence study in the second half of 2018 and to conduct a bioequivalence study subsequently.

CNS Product Candidates

GTP-004

GTP-004 is a fixed-dose combination tablet for the treatment of the muscle weakness associated with myasthenia gravis, or MG, a chronic autoimmune disease of the neuromuscular junction characterized by muscle weakness. MG affects an estimated approximately 36,000 to 60,000 people in the U.S. The basic abnormality in MG is a reduction in nicotinic acetylcholine receptors (AChRs) or neighboring proteins at the neuromuscular junctions (Drachman, 2016). In neonatal myasthenia, the fetus may acquire antibodies from a mother affected with MG. Generally, cases of neonatal MG are temporary and the child's symptoms usually disappear within 2-3 months after birth (Myasthenia Gravis Fact Sheet; National Institute of neurological Disorders and Stroke, 2016). Rarely, children may have congenital myasthenic syndrome (CMS) caused by defective gene mutations (Engel, 2012). In some cases, degeneration of the nerves that innervate muscles such as occurs with aging (Lexel, 1997) leads to a myasthenic syndrome. Recently (Makarious et al, 2017), have reported on a myasthenic syndrome associated with the use of checkpoint inhibitors.

Cholinesterase inhibitors, or ChEIs, that do not get into the brain (do not cross the blood-brain barrier), such as pyridostigmine and neostigmine are used to treat the muscular weakness associated with myasthenia gravis and other myasthenic syndromes). However, ChEIs also act at cholinergic synapses in the gut to cause GI side effects such as diarrhea, nausea and vomiting, which are dose-limiting (Engel 2012; Abicht et al, 2003 updated in 2014).

GTP-004 combines pyridostigmine with ondansetron, designed to attenuate the gastrointestinal, or GI, side effects of pyridostigmine alone. Mitigating the GI side effects of pyridostigmine with a drug that prevents diarrhea, nausea and vomiting should lead to greater patient comfort, safety, and compliance as well as to improved efficacy. Several provisional patent applications protecting the combination of neostigmine or pyridostigmine with a number of antiemetic drugs were filed by GTP in early 2017.

GTP-004 completed dosing in a Phase 1 clinical trial in January 2018. The objective of the Phase 1 clinical trial was to demonstrate that GI side effects of pyridostigmine are reduced with GTP-004. Healthy volunteers were enrolled in the Phase 1 study. Following enrollment, subjects received single increasing oral doses of pyridostigmine (ranging from 30 to 120mg) administered once daily in the morning. Once subjects experienced intolerable GI side effects and reached First Intolerable Dose -FID1- as defined by protocol criteria, upward dose escalation of pyridostigmine was discontinued and subjects were washed out for 2 to 7 days. Next, subjects that reached FID received daily increasing doses of pyridostigmine in combination with ondansetron.

Three subjects (2 males, one female; aged 34 to 43) reached intolerable gastrointestinal side effects with pyridostigmine alone. The dose-limiting gastro-intestinal adverse event occurred at 60 mg for 2 subjects, and 90 mg for the third subject. When these three subjects received GTP-004 (pyridostigmine with ondansetron), gastro-intestinal adverse events were abrogated, and all subjects tolerated doses as high as 120 mg, the maximum allowed dose allowed by the protocol.

Based on the data from the Phase 1 clinical trial, and discussions with key opinion leaders, we expect to be in a position to initiate a Phase 2 clinical trial in patients in the second half of 2018.

Provisional patent applications protecting the combination of Mestinon® or Prostigmine® with a number of antiemetic drugs were filed by GTP in early 2017.

PainBrake

PainBrake is a new patented formulation of carbamazepine (Tegretol®) that enables accurate dose fractionation for the treatment of neuropathic pain, a condition that results from a dysfunction of nerves involved in the perception of pain and that is typically chronic and particularly prevalent in elderly patients. An NIH-supported study published in 2009 estimated that almost 16 million Americans suffer from chronic neuropathic pain (Yawn et al., 2009) and this number is expected to increase due to the aging population. Current drugs provide a useful degree of pain relief in only about half the patients, very few patients achieve complete relief of pain (Nightingale, 2012). Peak dose-limiting side effects, mainly sedation, somnolence, dizziness and balance problems which are poorly tolerated by the elderly (Oomens et al., 2015) cause patients to be under-dosed, thereby contributing to inadequate pain relief. This is particularly true for carbamazepine, a drug that is considered to be the first line therapy for the treatment of certain forms of neuropathic pain (Zakrzewska, 2015).

To overcome dose-limiting side effects, PainBrake tablets employ an innovative bilayered, deeply scored design patented by AccuBreak. The top layer contains carbamazepine and is pre-divided by deep scoring during the manufacturing process to provide accuracy of dose adjustments by enabling easy tablet splitting into exact doses. The bottom layer provides mechanical stability and serves as the break region when splitting the tablet. We have in-licensed against milestones and royalties the worldwide rights to the use of the AccuBreak technology for the delivery of drugs that like carbamazepine are voltage-gated sodium channel blockers. The core patent for the AccuBreak technology expires in 2025.

PainBrake® is designed to enable accurate dose fractionation for the treatment of certain forms of neuropathic pain and we expect to complete the manufacturing tablets for a bioequivalence study in the second half of 2018 and to begin a bioequivalence study as a subsequent step.

GTP-011

We are developing GTP-011 as a 72-hour transdermal product for the prevention of motion sickness, a well-known syndrome that typically involves nausea and vomiting in otherwise healthy people and that occurs upon exposure to certain types of motion.

Currently, the scopolamine patch (Transderm Scop® from Novartis) is viewed as a first-line medication for prevention of motion sickness (Gil et al., 2012; Brainard and Gresham, 2014). However, side effects can be of particular concern and include sedation (Spinks et al., 2004), reduced memory for new information, impaired attention, and lowered feelings of alertness (Parrott, 1989). Mental confusion or delirium can occur after application of scopolamine patch (Seo et al., 2009). Elderly people as well as people with undetected incipient dementia or mild cognitive impairment, or MCI, may be particularly prone to develop mental confusion after applying the scopolamine patch (Seo et al., 2009).

GTP-011, like scopolamine, is a transdermal formulation that contains a muscarinic receptor antagonist. Unlike scopolamine, however, GTP-011's active ingredient has been reported not to affect memory and cognition and has a low incidence of sedation (Kay et al., 2012). GTP-011 may thus be a more favorable alternative, if approved for marketing, to the scopolamine patch for the treatment of motion sickness. Since GTP-011 is expected to be a new formulation of an approved drug, we anticipate that the NDA will be a 505(B)2 NDA. We began a proof-of-concept clinical trial for GTP-011 in late February 2018.

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 and to generate value from our CNS product candidates. Key elements of our strategy are to:

Expedite clinical development, regulatory approval and commercialization of our bi-specific ADC, OXS-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 OXS-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, OXS-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 OXS-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.

The approximately 34 patient, open label, two stage, FDA-approved Phase 2 trial is being conducted at the University of Minnesota's Masonic Cancer Center. The trial is a continuation of the dose and schedule finding component of the Phase 1 study using the dose limiting toxicity identified in the Phase 1 but with a higher number of cycles. The trial is designed to confirm the safety of OXS-1550 and make a preliminary determination of activity level by disease. There are currently 18 patients enrolled in the Phase 2 trial and we expect data from this Phase 2 trial to be available in the second half 2018.

We will also utilize our bi-specific ADC platform to generate novel ADCs with unique targets, linkers and warheads. We anticipate that this platform will give us the ability to rapidly construct novel ADCs with the potential to treat a wide range of cancers, including hematologic and solid tumors.

Rapidly advanced our Tri-specific Killer Engagers (TriKEs), OXS-3550 and OXS-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 OXS-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 expect to begin a Phase 1 clinical trial in the second half of 2018 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.

OXS-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 OXS-3550 and OXS-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.

OXS-C3550 is a next-generation, follow-on, to our lead TriKE, OXS-3550. OXS-3550 studies will help inform the development of OXS-C3550. We believe this will de-risk the OXS-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 are currently evaluating over a dozen moieties and intend to announce additional clinical product candidates in the second half of 2018. We intend to initiate human clinical testing for certain of our solid tumor product candidates in 2019.

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.

Continue our collaborative relationship with the Masonic Cancer Center at the University of Minnesota, under a program led by Dr. Jeffrey Miller and become the leading NK-oriented immune-oncology company

We believe that the TriKE and TetraKE constructs represent potentially groundbreaking innovations in immunotherapy. In July 2016 we entered into an exclusive license agreement with the University of Minnesota to develop and commercialize cancer therapies using TriKE and TetraKE technology developed by researchers at the university to target NK cells to cancer.

We believe TriKE and TetraKE therapeutics have the potential to significantly impact the standard of care for hematologic malignancies, sarcomas, as well as solid tumors. The direct engagement of the NK cell with the tumor cell via very specific receptors may increase the efficacy while decrease the toxicity seen with other forms of immunotherapies. If approved, we expect the TriKEs and TetraKEs will be able to be administered at cancer treatment facilities without the need for specialized centers or product-specific trained staff.

We also intend to selectively evaluate and potentially acquire or enter into licensing or other agreements for technologies and/or product candidates that we believe would complement our oncology product candidates and platform technologies.

Monetize our CNS programs through transactions with commercialization-oriented pharmaceutical companies and/or other transactions

Our CNS portfolio consists of innovative reformulations and/or repurposing of existing therapies and are covered by formulation patents or filed composition of matter patents (PCTs and provisional applications) and represent, what we believe to be, near-to-market product opportunities. Our CNS programs address numerous unmet medical needs that, if approved, we believe may lead to improved efficacy while addressing tolerability and safety issues that tend to limit the usefulness of the original approved drugs.

We expect to take advantage of our CNS portfolio by generating proof-of-concept data and/or achieving other milestones and ultimately entering into transactions with commercialization-oriented pharmaceutical companies, which could result in income, or enter into other transaction structures with the intent to generate value for our shareholders.

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). Bcell lymphomas may be either indolent (slow-growing) or aggressive (fast-growing). Most Bcell lymphomas are non-Hodgkin lymphomas. 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. It is the most common type of non- Hodgkin lymphoma among adults, with an annual incidence of 7–8 cases per 100,000 people per year.

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.

It is estimated that there will be approximately 6,000 new cases of ALL reported in the United States in 2018 (ACS Cancer Facts & Figures 2018). "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 and 5 years. ALL is the most common childhood cancer constituting about 23 to 30% of cancers before age 15. Although 80 to 90% of children will have a durable complete response with treatment it is the leading cause of cancer-related deaths among children.

Multiple Myeloma

Multiple myeloma is a type of cancer that forms in white blood cells and will affect an estimated 30,770 people in 2018 in the U.S. causing about 12,770 deaths. 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 3–5% per 100,000 populations. The median age at the time of diagnosis is 65–69 years. AML is an aggressive disease and is fatal without anti-leukemic treatment. AML is the most common form of adult leukemia with 20,000 new cases each year. 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.

Solid Tumors

In the United States, in 2018, it is estimated there will be approximately 1,735,350 new cases of cancer resulting in over 600,000 deaths. Greater than 80% of these cancers will be classified as solid tumors. The most prevalent new cases of solid tumors being breast, lung, prostate, colorectal and bladder. (American Cancer Society, Cancer Facts & Figures 2018)

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 American Cancer Society's estimates for soft tissue sarcomas in the United States for 2018 are (these statistics include both adults and children): about 13,040 new soft tissue sarcomas will be diagnosed (7,370 cases in males and 5,670 cases in females). 5,150 Americans (2,770 males and 2,380 females) are expected to die of soft tissue sarcomas. 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 2018)

CNS Markets

Chronic Neuropathic Pain

Neuropathic pain has many causes, including trigeminal neuralgia, diabetes, certain forms of chemotherapy, trauma, toxins, infection such as postherpetic infection, immune deficiencies, ischemic disorders, and multiple sclerosis. According to the latest market report published by Persistence Market Research (November 2016) titled “Global Market Study on Neuropathic Pain: Anticonvulsants Drug Class Segment Projected to Witness the Highest Growth Through 2024,” the global neuropathic pain market was valued at $5.2 billion in 2015 and was estimated to reach a market valuation of $5.4 billion by 2016. The market is projected to expand at a compound annual growth rate of 5.6% during an eight-year forecast period 2016–2024 and reach $8.3 billion by the end of 2024.

The chronic pain market continues to represent a major unmet medical need. Current drugs provide a useful degree of pain relief in only about half the patients (Nightingale, 2012). It is estimated that only one in four patients with neuropathic pain experiences over 50% pain relief, and 30% of patients have no or very little relief. Very few patients achieve complete pain relief. In most patients, pain relief is obtained at the price of burdensome side effects. For many drugs, inadequate pain relief is due to side effects that occur when drugs reach peak concentrations in the blood, these side effects are dose-dependent and dose-limiting and prevent the use of fully effective doses. As a consequence, patients are chronically under-dosed. This is particularly true for carbamazepine, a drug with which it may be possible to achieve nearly complete relief of pain in many patients who suffer from forms of neuropathic pain that respond to carbamazepine.

Current treatments for neuropathic pain treat the symptom (pain) and include narcotic analgesics, voltage-gated sodium channel blockers, voltage-gated calcium channel blockers, glutamate NMDA NR2B antagonists (ketamine), drugs that increase monoamine transmission, and cannabinoids. However, these therapies have safety and tolerability issues including, for some, tolerance, abuse and addiction liability. Many have dose-limiting side effects that prevent patients from receiving fully effective doses of medication, further limiting efficacy. Some of the key players operating in the global neuropathic pain market are Depomed Inc. (NASDAQ:DEPO), Pfizer Inc. (NYSE:PFE), Johnson & Johnson (NYSE:JNJ), Bristol-Myers Squibb (NYSE:BMY), Eli Lilly and Company (NYSE:LLY), GlaxoSmithKline PLC (NYSE:GSK), Sanofi S.A. (NYSE:SNY), Biogen Idec Inc. (NASDAQ:BIIB), and Baxter Healthcare Corporation (NYSE:BAX), among others.

Myasthenia Gravis

MG is a rare, chronic autoimmune disease of the neuromuscular junction caused by antibodies that attack components of the postsynaptic membrane, impair neuromuscular transmission, and lead to varying degrees of weakness and fatigue of skeletal muscle. Recently, anti-cancer treatments with check-point inhibitors have been associated in some patients with rapidly progressive severe myasthenia gravis. The prevalence of MG in the United States is estimated at 14 to 20 per 100,000 population, approximately 36,000 to 60,000 cases in the US (Howard, 2015). Rarely, children may show signs of congenital myasthenia or congenital myasthenic syndrome (CMS). These are not autoimmune disorders, but are caused by defective genes that produce abnormal proteins instead of those that normally are involved in cholinergic transmission: acetylcholinesterase (the enzyme that breaks down acetylcholine), acetylcholine receptors, and other proteins present along the muscle membrane (Engel, 2012).In some rare cases, a myasthenic syndrome is due to bi-allelic variants in the gene encoding the vesicular acetylcholine transporter (VAChT) located in the presynaptic terminal (O'Grady et al, 2016). In other cases, degeneration of the nerves that innervate muscles such as occurs with aging (Lexel, 1997) leads to a myasthenic syndrome.

Only two drugs are currently approved for the muscular symptoms of myasthenia gravis, namely Mestinon® and Prostigmine®. Both have the same mechanism of action, and both are associated with gastrointestinal side effects, which are an important source of discomfort for the patient, may be the source of non-compliance, or may result in the need to decrease the dose of ChEI to mitigate these side effects when these become dose-limiting. In many patients the side effects are dose limiting and prevent the administration of the fully effective dose. Attempts at overcoming these side effects using dose fractionation or a slow release formulation (Mestinon TimeSpan) have been disappointing.

Motion Sickness

The current transdermal market leader for the prevention of motion sickness is the 72-hour scopolamine patch (Gil et al., 2012) commercialized by Sandoz. However, this medication can cause a number of worrisome side effects., especially in the elderly, such as confusion and memory impairment. The scopolamine patch is not approved for children.

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

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.

The following is a list of the patent applications that we licensed from the University of Minnesota:

Appl. No.	Title	Country	Status
U.S. Patent Application Number 62/237,835	Therapeutic compounds and its uses	US	Expired
PCT Patent Application Number PCT/US2016/055722	Therapeutic compounds and methods	US	Pending

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 (OXS1550), 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.

The following is a list of the patent applications and patents that we licensed from Dr. Vallera under our license agreements:

Pat./Pub. No.	Title	Country	Status
U.S. Patent Application Number 61/160,530	Methods and compositions for bi-specific targeting of cd19/cd22	US	Expired
U.S. Patent Number 9,371,386	Methods and compositions for bi-specific targeting of cd19/cd22	US	Issued
U.S. Patent Application Number 15/187,579	Methods and compositions for bi-specific targeting of cd19/cd22	US	Pending

ID4 License Agreement

Pursuant to a patent license agreement with ID4, dated December 31, 2014, or the ID4 License Agreement, we received an exclusive, worldwide license to certain intellectual property, including intellectual property related to treating a p62mediated disease (e.g., multiple myeloma). The terms of this license require us to pay ID4 royalties equal to 3% of net sales of products and 25% royalty of net sublicensing revenues. The license will expire upon expiration of the last patent contained in the licensed patent rights, unless terminated earlier. We may terminate the licensing agreement with ID4 by providing ID4 with a 30 days written notice.

We will owe the following cash amounts to ID4 Pharma upon the attainment of the following milestones:

(i) Filing of an investigational new drug application with a competent regulatory authority anywhere in the world $50,000.
(ii) Initiation of Phase I Human Clinical Trial: $50,000.
(iii) Initiation of Phase II Human Clinical Trial: $100,000.
(iv) Initiation of pivotal Phase III Human Clinical Trial: $250,000. and
(v) Receipt of the first marketing approval: $250,000

The following is a list of the patent applications and patent that we licensed from ID4 under the ID4 license agreement:

Pat./Appl. No.	Title	Country	Status
U.S. Patent Number 9,580,382	P62zz chemical inhibitor	US	Issued
U.S. Patent Application Number 61/521,287	P62zz chemical inhibitor	US	Expired
PCT Patent Application Number PCT/US2012/049911	P62zz chemical inhibitor	PCT	Expired
U.S. Patent Application Number 14/727,710	P62zz chemical inhibitor	US	Pending
Chinese Patent Application 201280048718	P62zz chemical inhibitor	US	Pending

Patents for AccuBreak Tablets

We have in-licensed the rights to use the AccuBreak patents with drugs that, like carbamazepine, are voltage-gated sodium channel blockers in North America. The license field includes voltage gated sodium channels inhibitors and blockers for the treatment of epilepsy, neuropathic pain, and bipolar disorder.

Under the agreement, AccuBreak received an upfront license fee of $35,000, royalty fees ranging from 2.5% to 5%, minimum annual royalty payments, and 20% of net sublicensing revenues.

We will owe the following cash amounts to AccuBreak upon the attainment of the following milestones:

- $50,000 six months after the first approval of the first indication by the FDA;
- $50,000 nine months after the first approval of the first indication by the FDA;
- $100,000 12 months after the first approval of the first indication by the FDA;
- $25,000 upon achievement of $25,000,000 of cumulative net sales in the world;
- $50,000 upon achievement of $50,000,000 of cumulative net sales in the world; and
- $100,000 upon achievement of $75,000,000 of cumulative net sales in the world.

Four formulation patents protect the AccuBreak Technology:

Pat. No.	Title	Country	Status
U.S. Patent Number 7,838,031	Method for administering a partial dose using a segmented pharmaceutical tablet	US	Issued
U.S. Patent Number 7,879,352	Scored pharmaceutical tablets comprising a plurality of segments	US	Issued
U.S. Patent Number 8,158,148	Pharmaceutical tablets comprising two or more unitary segments	US	Issued
U.S. Patent Number 8,231,902 (ABT-054)	Segmented pharmaceutical dosage forms	US	Issued

The core patent expires in 2025.

Patent Applications for GTP-004

Four patent applications filed by GTP in 2017 with the U.S. PTO protect the combination of pyridostigmine or neostigmine + an antiemetic for the treatment of myasthenia gravis. We plan to file extensions under the Patent Cooperation Treaty, or PCT, in 2018. All patents list below are owned by the Company.

Pat. No.	Title	Country	Status
U.S. Patent Application Number 62/443,904	Use and composition for treating Myasthenia Gravis	US	Expired
U.S. Patent Application Number 62/449,699	Neostigmine combination for treating Myasthenia Gravis	US	Expired
U.S. Patent Application Number 62/536,595	Method and composition for treating Myasthenia Gravis	US	Pending
U.S. Patent Application Number 62/536,580	Neostigmine pharmaceutical combination for treating Myasthenia Gravis	US	Pending
PCT Application Number PCT/US/18/12754	Use and composition for treating Myasthenia Gravis	PCT	Claims priority from US 62/443,904
Taiwan Application Number 107100813		TW	Awaiting FC Report
PCT Application Number PCT/US18/014700	Neostigmine pharmaceutical combination for treating Myasthenia Gravis	PCT	Claims priority from US 62/449,699
Taiwan Application Number 101702591		TW	Awaiting FC Report

Patent Application for GTP-011

One patent application filed by GTP in 2017 with the U.S. PTO protects a 72-hour patch of oxybutynin for the treatment of motion sickness. We plan to file a PCT extension in 2018. All patents list below are owned by the Company.

Appl. No.	Title	Country	Status
U.S. Patent Application Number 62/440,575	Use and composition for preventing and treating motion sickness	US	Expired
US Patent Application Number 62/595,667	Use, method, and device for the prevention and treatment of motion sickness	US	Pending*
PCT Application Number PCT/US/17/68944	Use and composition for preventing and treating motion sickness	PCT	Claims priority from US 62/440,575
Taiwan Application Number 107100079		TW	Awaiting FC Report

***** This application is pending, but was used as priority document of the PCT '944, including its subject matter

Research and Development

Expenditures for research and development activities related to continuing operations were $1,068,000 and $975,000 million for the years ended December 31, 2017 and 2016, respectively.

Our currently projected expenditures for 2018 include approximately $10 million to $12 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.

Competition

The biotechnology and pharmaceutical industries are subject to rapid technological change. Competition from domestic and foreign biotechnology companies, large pharmaceutical companies and other institutions is intense and expected to increase. A number of companies are pursuing the development of pharmaceuticals in our targeted areas. 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, at the end of 2015 there were 135 drugs in development for the treatment of lymphomas (blood cell cancers including multiple myeloma).

Many compounds are in development for the treatment of neuropathic pain. Current treatments for neuropathic include narcotic analgesics, voltage-gated sodium channel blockers, voltage-gated calcium channel blockers, glutamate NMDA NR2B antagonists (ketamine), drugs that increase monoamine transmission, and cannabinoids. Some of the key players operating in the global neuropathic pain market are Depomed Inc. (NASDAQ:DEPO), Pfizer Inc. (NYSE:PFE), Johnson & Johnson (NYSE:JNJ), Bristol-Myers Squibb (NYSE:BMY), Eli Lilly and Company (NYSE:LLY), GlaxoSmithKline PLC (NYSE:GSK), Sanofi S.A. (NYSE:SNY), Biogen Idec Inc. (NASDAQ:BIIB), and Baxter Healthcare Corporation (NYSE:BAX), among others. In the field of myasthenia gravis, pharmaceutical research and development efforts focus on the discovery of a cure for the disease. A cure would make treatment with GTP-004 obsolete. In the field of motion sickness, research may be ongoing for better anti-motion sickness drugs.

Government Regulation

Government Regulation and Product Approval

Government authorities in the United States at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, (including manufacturing changes), quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, marketing, export and import of products such as those we are developing. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources.

U.S. Drug Development Process

In the United States, the FDA regulates drugs and biological products under the FDCA and the FDA's implementing regulations.

Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process, or after approval, may subject an applicant to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawal of an approval, a clinical hold, untitled or warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties. The process required by the FDA before a drug or biologic may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices regulations;
- submission to the FDA of an IND, which must become effective before human clinical studies may begin;
- approval by an independent IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical studies according to GCP regulations, to establish the safety and efficacy of the proposed drug or biologic for its intended use;
- preparation and submission to the FDA of an NDA or BLA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMP to assure that the facilities, methods, and controls are adequate to preserve the drug's or biologic’s identity, strength, quality, and purity; and
- FDA review and approval of the NDA or BLA.

The testing and approval process requires substantial time, effort and financial resources, and we cannot be certain that any approvals for our product candidates (or those of our collaborators or licensees) will be granted on a timely basis, if at all.

An IND sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data and any available clinical data or literature, to the FDA as part of the IND. The sponsor must also include a protocol detailing, among other things, the objectives of the initial clinical study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated if the initial clinical study lends itself to an efficacy evaluation. Some preclinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA raises concerns or questions related to a proposed clinical study and places the study on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical study can begin. Clinical holds also may be imposed by the FDA at any time before or during clinical studies due to safety concerns or non-compliance, and may be imposed on all product candidates within a certain pharmaceutical class. The FDA also can impose partial clinical holds, for example, prohibiting the initiation of clinical studies of a certain duration or for a certain dose.

All clinical studies must be conducted under the supervision of one or more qualified investigators in accordance with GCP regulations. These regulations include the requirement that all research subjects provide informed consent in writing before their participation in any clinical study. Further, an IRB must review and approve the plan for any clinical study before it commences at any institution, and the IRB must conduct continuing review and reapprove the study at least annually. An IRB considers, among other things, whether the risks to individuals participating in the clinical study are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the information regarding the clinical study and the consent form that must be provided to each clinical study subject or his or her legal representative and must monitor the clinical study until completed. Each new clinical protocol and any amendments to the protocol must be submitted for FDA review, and to the IRBs for approval. Protocols detail, among other things, the objectives of the clinical study, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Study sites are subject to inspection for compliance with GCP.

Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health (NIH), for public dissemination on their ClinicalTrials.gov website.

Human clinical studies are typically conducted in three sequential phases that may overlap or be combined:

- *Phase 1.* The product is initially introduced into a small number of healthy human subjects or patients and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion and, if possible, to gain early evidence on effectiveness. In the case of some products for severe or life-threatening diseases, especially when the product is suspected or known to be unavoidably toxic, the initial human testing may be conducted in patients.

- *Phase 2.* Involves clinical studies in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage and schedule.

- *Phase 3.* Clinical studies are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical study sites. These clinical studies are intended to establish the overall risk/benefit relationship of the product and provide an adequate basis for product labeling.

Progress reports detailing the results of the clinical studies must be submitted at least annually to the FDA and safety reports must be submitted to the FDA and the investigators for serious and unexpected suspected adverse events. Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within any specified period, if at all. The FDA or the sponsor may suspend or terminate a clinical study at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical study at its institution if the clinical study is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients.

U.S. Review and Approval Processes

Assuming successful completion of the required clinical testing, the results of product development, preclinical studies and clinical studies, along with descriptions of the manufacturing process, analytical tests conducted on the drug, proposed labeling and other relevant information, are submitted to the FDA as part of an NDA for a new drug or BLA for a new biological drug product, requesting approval to market the product.

The submission of an NDA or BLA is subject to the payment of a substantial application user fee although a waiver of such fee may be obtained under certain limited circumstances. For example, the agency will waive the application fee for an orphan product or for the first human drug application that a small business or its affiliate submits for review. The sponsor of an approved NDA or BLA is also subject to annual product and establishment user fees

In addition, under the Pediatric Research Equity Act of 2003, or PREA, an NDA or BLA application (or supplements to an application) for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration must contain data that are adequate to assess the safety and effectiveness of the drug or biologic for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the applicant has obtained a waiver or deferral.

In 2012, the FDASIA amended the FDCA to require that a sponsor who is planning to submit a marketing application for a drug that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan, or PSP, within sixty days of an End-of-Phase 2 meeting or as may be agreed between the sponsor and the FDA. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including study objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of data or full or partial waivers. The FDA and the sponsor must reach agreement on the PSP. A sponsor can submit amendments to an agreed-upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical studies, and/or other clinical development programs.

The FDA also may require submission of a REMS to mitigate any identified or suspected serious risks. The REMS could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools.

The FDA reviews all NDAs and BLAs submitted to ensure that they are sufficiently complete for substantive review before it accepts them for filing. The FDA may request additional information rather than accept an application for filing. In this event, the application must be re-submitted with the additional information. The re-submitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review to determine whether the product is safe and effective for its intended use.

The FDA may refer the NDA or BLA to an advisory committee for review, evaluation and recommendation as to whether the application should be approved and under what conditions. An advisory committee is a panel of experts, including clinicians and other scientific experts, who provide advice and recommendations when requested by the FDA. The FDA is not bound by the recommendation of an advisory committee, but it considers such recommendations when making decisions.

Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure clinical data supporting the submission were developed in compliance with GCP.

The approval process is lengthy and difficult and the FDA may refuse to approve an NDA or BLA if the applicable regulatory criteria are not satisfied, or may require additional clinical data or other data and information. Even if such data and information are submitted, the FDA may ultimately decide that the NDA or BLA does not satisfy the criteria for approval. Data obtained from clinical studies are not always conclusive and the FDA may interpret data differently than an applicant interprets the same data.

After the FDA's evaluation of an application, the FDA may issue an approval letter, or, in some cases, a complete response letter to indicate that the review cycle is complete and that the application is not ready for approval. A complete response letter generally contains a statement of specific conditions that must be met to secure final approval of the application and may require additional clinical or preclinical testing for the FDA to reconsider the application. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical studies. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the application, addressing all of the deficiencies identified in the letter, or withdraw the application or request an opportunity for a hearing.

Even with submission of additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. In addition, the FDA may require post-approval studies, including Phase 4 clinical studies, to further assess safety and effectiveness after approval and may require testing and surveillance programs to monitor the safety of approved products that have been commercialized. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

ANDAs and Section 505(b)(2) New Drug Applications

Most drug products obtain FDA marketing approval pursuant to an NDA or BLA (described above) for innovator products, or an ANDA for generic products. Relevant to ANDAs, the Hatch-Waxman amendments to the FDCA established a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are also referred to as listed drugs). Because the safety and efficacy of listed drugs have already been established by the brand company (sometimes referred to as the innovator), the FDA does not require a demonstration of safety and efficacy of generic products. However, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the API is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the listed drug. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling and stability data.

The third alternative is a special type of NDA, commonly referred to as a Section 505(b)(2) NDA, which enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. The applicant may rely upon the FDA's findings with respect to certain preclinical or clinical studies conducted for an approved product. The FDA may also require companies to perform additional studies or measurements to support the change from the approved product. The FDA may then approve the new product candidate for all or some of the label indications for which the referenced product has been approved, as well as for any new indication sought by the Section 505(b)(2) applicant.

In seeking approval for a drug through an NDA, including a 505(b)(2) NDA, applicants are required to list with the FDA certain patents of the applicant or that are held by third parties whose claims cover the applicant's product. Upon approval of an NDA, each of the patents listed in the application for the drug is then published in the Orange Book. Any subsequent applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book or a 505(b)(2) NDA referencing a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. This last certification is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA or 505(b)(2) application refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent.

If the reference NDA holder or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA or 505(b)(2) application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the branded reference drug has expired as described in further detail below. Thus approval of a Section 505(b)(2) NDA or ANDA can be stalled until all the listed patents claiming the referenced product have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, listed in the Orange Book for the referenced product has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA or Section 505(b)(2) applicant.

Post-Approval Requirements

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to extensive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping (including certain electronic record and signature requirements), periodic reporting, product sampling and distribution, advertising and promotion and reporting of certain adverse experiences, deviations, and other problems with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

The FDA strictly regulates labeling, advertising, promotion and other types of information on products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Further, manufacturers must continue to comply with cGMP requirements, which are extensive and require considerable time, resources and ongoing investment to ensure compliance. In addition, changes to the manufacturing process generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

Manufacturers and certain other entities involved in the manufacturing and distribution of approved products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. The cGMP requirements apply to all stages of the manufacturing process, including the production, processing, sterilization, packaging, labeling, storage and shipment of the product.

Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

The FDA may impose a number of post-approval requirements as a condition of approval of an application. For example, the FDA may require post-marketing testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

The FDA may withdraw a product approval if compliance with regulatory requirements is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, problems with manufacturing processes, or failure to comply with regulatory requirements, may result in restrictions on the product or even complete withdrawal of the product from the market.

Potential implications include required revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs/BLAs or supplements to approved NDAs/BLAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

In addition, the distribution of prescription drugs and biologics is subject to the Prescription Drug Marketing Act (PDMA), which regulates the distribution of the products and product samples at the federal level, and sets minimum standards for the registration and regulation of distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations, guidance, and policies are often revised or reinterpreted by the agency in ways that may significantly affect our business and our product candidates. It is impossible to predict whether further legislative or FDA regulation or policy changes will be enacted or implemented and what the impact of such changes, if any, may be.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States, sales of any products for which we may receive regulatory approval for commercial sale will depend in part on the availability of coverage and reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. The process for determining whether a payor will provide coverage for a drug may be separate from the process for setting the reimbursement rate that the payor will pay for the product. Some of the additional requirements and restrictions on coverage and reimbursement levels imposed by third-party payors influence the purchase of healthcare services and products. Third-party payors may limit coverage to specific drugs on an approved list, or formulary, which might not include all of the FDA-approved drugs for a particular indication, or place drugs at certain formulary levels that result in lower reimbursement levels and higher cost-sharing obligation imposed on patients. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Further, one payor's determination to provide coverage does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement may differ significantly from payor to payor.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain and maintain coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our drugs and product candidates from coverage and limit payments for pharmaceuticals.

In addition, we expect that the increased emphasis on managed care and cost containment measures in the United States by third-party payors and government authorities to continue and will place pressure on pharmaceutical pricing and coverage. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Employees

As of December 31, 2017, we had five 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.

Agreement and Plan of Merger

On September 1, 2017, we entered into an Agreement and Plan of Merger whereby we acquired 100% of the issued and outstanding capital stock of GTP. GTP is a biotechnology company focused on acquiring or discovering and patenting what it believes to be close-to-market improved treatments for CNS disease (neurology and pain) and shepherding the products through the FDA approval process potentially to NDA. GTP products currently include a treatment for neuropathic pain, the symptoms of myasthenia gravis, and motion sickness. In exchange for the ownership of GTP, we issued a total of 16,927,878 shares of our common stock to the three prior owners of GTP, which represented 33% of our issued and outstanding capital stock on a fully diluted basis at the time of closing.

Upon the consummation of the acquisition, Anthony J. Cataldo resigned as our chief executive officer and was simultaneously elected as executive chairman of the board of directors. Kathleen Clarence-Smith, M.D., Ph.D., the founder of GTP, was then elected as our chief executive officer and a member of the board of directors.

As conditions to the acquisition of GTP, (i) we raised $4,540,000 upon the sale of debentures which were subsequently converted into 3,575,109 shares of restricted common stock and 208,224 shares of Series J Preferred Stock to a total of nine persons or entities; (ii) canceled debt in the amount $17,295,352 upon the issuance of 13,712,516 shares of common stock and 700,278 shares of Series J Preferred Stock to a total of 26 persons or entities; (iii) issued 494,911 shares of common stock and 5,046 shares of Series J Preferred Stock upon the cashless exercise of warrants to a total of 22 persons or entities; and (iv) converted 25,000 shares of Series H Preferred Stock and 1,666,667 Series I Preferred Stock into 5,327,734 shares of common stock held by a total of three persons or entities. All stock issuances were exempt from the registration requirements of Section 5 of the Act of 1933, as amended, or the Act, pursuant to Section 4(a)(2) of the Act because the issuances did not involve any public offering.

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 and have only recently begun clinical trials for our CNS product candidates. 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, 2017, we had an accumulated deficit of $267,896,000. 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 2018 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.

We have identified material weaknesses in our internal control over financial reporting have not 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; and (ii) 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. We are continuing to adopt and implement written policies and procedures for accounting and financial reporting. We plan to hire additional qualified personnel to address inadequate segregation of duties, although the timing of such hires is largely dependent on our securing additional financing to cover such costs. 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 of, 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 five fulltime employees. The loss of the services of any of our key product or business development 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, 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 intend to pursue Section 505(b)(2) regulatory approval filings with the FDA for at least three of our product candidates. If the FDA concludes that certain of our product candidates fail to satisfy the requirements under Section 505(b)(2), or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for such product candidates may take significantly longer, cost substantially more and entail greater complications and risks than anticipated and, in either case, may not be successful. In addition, if under certain circumstances, exclusivity of competitors would delay approval of our product candidates, then we may pursue approval through the Section 505(b)(1) regulatory pathway, which may require us to conduct additional preclinical or clinical trials or obtain a right to reference the preclinical or clinical data of others.

We are currently developing three product candidates, GTP-004, GTP-011 and PainBrake for which we intend to seek FDA approval through the Section 505(b)(2) regulatory pathway, and may decide to seek FDA approval for other products through the Section 505(b)(2) regulatory pathway in the future. A Section 505(b)(2) NDA is a special type of NDA that enables the applicant to rely, in part, on the FDA's findings of safety and efficacy of an existing previously approved product, or published literature, in support of its application. Section 505(b)(2) NDAs often provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products. Such filings involve significant filing costs, including filing fees.

Reliance on existing safety findings could expedite the development program for our product candidates by decreasing the amount of preclinical or clinical data that we would need to generate in order to obtain FDA approval. If the FDA does not allow us to pursue the Section 505(b)(2) regulatory pathway as anticipated, or if the Section 505(b)(2) regulatory pathway fails to significantly decrease the amount of testing we must conduct, we may need to conduct additional preclinical or clinical trials, provide additional data and information and meet additional standards to obtain regulatory approval. In such case, the time and financial resources required to obtain FDA approval for product candidates for which we seek approval through the Section 505(b)(2) pathway in the future, and complications and risks associated with these product candidates, likely would increase substantially. Moreover, our inability to pursue the Section 505(b)(2) regulatory pathway could prevent us from introducing our product candidates into the market prior to our competitors, which could harm our competitive position and prospects. Even if the FDA allows us to pursue approval through the Section 505(b)(2), we cannot guarantee that it would ultimately lead to faster product development, and our product candidates may not receive the requisite approvals for commercialization.

Furthermore, Section 505(b)(2) NDAs are subject to special requirements designed to protect the patent rights of sponsors of previously approved drugs referenced in a Section 505(b)(2) NDA, and pursuing the Section 505(b)(2) pathway could lead to patent litigation and other significant delays if a current patent holder challenges our application for pre-market approval. In addition, a manufacturer of an approved referenced product to file a citizen petition with the FDA seeking to delay approval of, or impose additional approval requirements for, pending competing products. If successful, such petitions can significantly delay, or even prevent, the approval of the new product. However, even if the FDA ultimately denies such a petition, the FDA may substantially delay approval while it considers and responds to the petition.

Furthermore, award of three-year exclusivity by the FDA to a competitor with a Section 505(b)(2) NDA could delay approval of a product candidate of ours submitted pursuant to Section 505(b)(2) of the Food, Drug, and Cosmetic Act if the FDA were to determine that the products have overlapping conditions of approval, even if our Section 505(b)(2) NDA does not rely on the competing Section 505(b)(2) NDA. Alternatively, we may pursue approval through the Section 505(b)(1) regulatory pathway, which may require us to conduct additional preclinical or clinical trials or obtain a right to reference the preclinical or clinical data of others. These alternatives may increase the time and/or financial resources required to obtain approval.

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.

For some of our products, we currently lack sufficient 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 our 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, including 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.

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.

Our CNS portfolio compounds also face considerable competition. Many compounds are in development for the treatment of neuropathic pain. Current treatments for neuropathic include narcotic analgesics, voltage-gated sodium channel blockers, voltage-gated calcium channel blockers, glutamate NMDA NR2B antagonists (ketamine), drugs that increase monoamine transmission, and cannabinoids. Some of the key players operating in the global neuropathic pain market are Depomed Inc. (NASDAQ:DEPO), Pfizer Inc. (NYSE:PFE), Johnson & Johnson (NYSE:JNJ), Bristol-Myers Squibb (NYSE:BMY), Eli Lilly and Company (NYSE:LLY), GlaxoSmithKline PLC (NYSE:GSK), Sanofi S.A. (NYSE:SNY), Biogen Idec Inc. (NASDAQ:BIIB), and Baxter Healthcare Corporation (NYSE:BAX). In the field of myasthenia gravis, pharmaceutical R&D efforts focus on the discovery of a cure for the disease. A cure would make treatment with GTP-004 obsolete. In the field of motion sickness, research may be ongoing for better anti-motion sickness drugs.

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 do not currently have product liability insurance. 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 engaged to continue conduct our clinical trials including the University of Minnesota for our phase 2 clinical trial for OXS-1550. 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. 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.

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, if the price of our common stock returns to $5.00 per share or lower, 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 1825 K Street NW, Suite 510, Washington, D.C. 20006. We also maintained an office in Tampa, Florida. Our lease for the Tampa office expired in December 2017 and was not renewed. Our total monthly rent expense is approximately $9,000.

ITEM 3. LEGAL PROCEEDINGS

On June 23, 2016, we were served with a complaint filed in the Circuit Court of the 13th Judicial Circuit in and for Hillsborough County, Florida, Case No. 16-CA-004791, by Lippert/Heilshorn and Associates, Inc. Lippert/Heilshorn and Associates, Inc. is alleging it is owed compensation for consulting services provided to us and is seeking payment of $73,898. We have engaged legal counsel to answer the complaint.

On February 15, 2017, MultiCell Immunotherapeutics, or MultiCell, filed an arbitration proceeding against us with the American Health Lawyers Association, Claim #3821. MultiCell is seeking $207,783 plus interest and costs of arbitration pursuant to alleged contract rights against us under a research agreement between MultiCell and us. Following a hearing held September 1, 2017, the arbitrator awarded MultiCell the payment amount of $207,783 plus interest in the amount of $34,699. We have engaged legal counsel to advise us in connection with this matter.

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 is 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 2016	First Quarter	960.00	123.00
	Second Quarter	180.00	93.00
	Third Quarter	108.00	45.00
	Fourth Quarter	57.00	11.79
Fiscal Year 2017	First Quarter	69.07	3.81
	Second Quarter	9.91	3.36
	Third Quarter	29.58	4.66
	Fourth Quarter	7.55	4.25

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, 2017, there were 31 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 350 Indiana Street, Golden, CO 80401.

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

We did not issue any unregistered securities during the fourth quarter of the fiscal year covered by this report.

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 an immuno-oncology company also focused on developing a portfolio of three central nervous system, or CNS, product candidates. Our immuno-oncology portfolio is based off a proprietary technology platform consisting of single-chain bi-, tri- and tetra-specific scFv's, combined with proprietary antibody-drug linkers and drug payloads. Constructs include bispecific and trispecific scFv constructs, proprietary drug payloads, bispecific targeted antibody-drug conjugates, or ADCs, as well as tri- and tetra-specific antibody-directed cellular cytotoxicity, or ADCC. Our proprietary tri- and tetra-specific ADCC platform engages natural killer cells, or NK cells. NK cells are cytotoxic lymphocytes of the innate immune system capable of immune surveillance. NK cells mediate ADCC through the highly potent CD16 activating receptor. Upon activation, NK cells deliver a store of membrane penetrating apoptosis-inducing molecules. Unlike T cells, NK cells do not require antigen priming.

Our CNS portfolio consists of innovative reformulations and/or repurposing of existing therapies. These therapeutic agents address certain unmet medical needs that can lead to improved efficacy while addressing tolerability and safety issues that tended to limit the usefulness of the original approved drug. Our CNS drug candidates address disease states such as chronic neuropathic pain, myasthenia gravis and vestibular disorders.

As shown in the accompanying consolidated financial statements, the Company has incurred an accumulated deficit of $267,896,000 through December 31, 2017. On a consolidated basis, the Company had cash and cash equivalents of $576,000 at December 31, 2017. 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.

Recent Developments

Amendment to Certificate of Incorporation

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.

Agreement and Plan of Merger

On September 1, 2017, we entered into an Agreement and Plan of Merger whereby we acquired 100% of the issued and outstanding capital stock of GTP. GTP is a biotechnology company focused on acquiring or discovering and patenting what it believes to be close-to-market improved treatments for CNS disease (neurology and pain) and shepherding the products through the FDA approval process potentially to NDA. GTP products currently include a treatment for neuropathic pain, the symptoms of myasthenia gravis, and motion sickness. In exchange for the ownership of GTP, we issued a total of 16,927,878 shares of our common stock to the three prior owners of GTP, which represented 33% of our issued and outstanding capital stock on a fully diluted basis at the time of closing.

Upon the consummation of the acquisition, Anthony J. Cataldo resigned as our chief executive officer and was simultaneously elected as executive chairman of the board of directors. Kathleen Clarence-Smith, M.D., Ph.D., the founder of GTP, was then elected as our chief executive officer and a member of the board of directors.

As conditions to the acquisition of GTP, (i) we raised $4,540,000 upon the sale of debentures which were subsequently converted into 3,575,109 shares of restricted common stock and 208,224 shares of Series J Preferred Stock to a total of nine persons or entities; (ii) canceled debt in the amount $17,295,352 upon the issuance of 13,712,516 shares of common stock and 700,278 shares of Series J Preferred Stock to a total of 26 persons or entities; (iii) issued 494,911 shares of common stock and 5,046 shares of Series J Preferred Stock upon the cashless exercise of warrants to a total of 22 persons or entities; and (iv) converted 25,000 shares of Series H Preferred Stock and 1,666,667 Series I Preferred Stock into 5,327,734 shares of common stock held by a total of three persons or entities. All stock issuances were exempt from the registration requirements of Section 5 of the Act of 1933, as amended, or the Act, pursuant to Section 4(a)(2) of the Act because the issuances did not involve any public offering.

Employment Contracts

In connection with the acquisition, we entered into employment contracts on September 1, 2017, with Mr. Cataldo as executive chairman, Dr. Clarence-Smith as chief executive officer, Dr. Raymond Urbanski as chief medical officer and Steven Weldon as chief financial officer. We entered into an employment contract on November 15, 2017, with Mr. Cross as president and chief operating officer.

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 has been revised to reflect her new position and she will be paid an annual salary of $500,000, paid in equal monthly installment. All other terms of her original Employment Agreement remain unchanged.

On February 14, 2018, the Company entered into a Consultant Agreement with Mr. Cataldo. The term of the Consultant Agreement lasts until August 31, 2020 and is terminable at will and is subject to automatic extension for successive one-year periods. Mr. Cataldo will be paid $41,666.67 per month during the term of the Consultant Agreement and will be entitled to participate in the Company's bonus plans.

On February 15, 2018, the Company entered into an Executive Employment Agreement with Mr. Cross, pursuant to which Mr. Cross will be employed as the Company's Chief Executive Officer. The term of the Executive Employment Agreement is three years and is terminable at will by either the Company or Mr. Cross and subject to automatic extensions for successive one year periods. Mr. Cross will be paid an annual salary of $500,000, paid in equal monthly installment. Mr. Cross is also entitled to participate in the Company's bonus plans. Under the Executive Employment Agreement, the Company has agreed that it will recommend to the Board that the Company grant Mr. Cross an option to purchase 2,000,000 shares of the Company's common stock at an exercise price equal to the fair market value of each share as determined by the Board as of the date of the grant. The stock option grant would vest according to the following schedule: (i) 34% of the shares on February 15, 2018, (ii) 33% of the shares on February 15, 2019, and (iii) 33% of the shares on February 15, 2020.

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 (OXS-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.

In September 2017, we in-licensed the rights to use the AccuBreak patents with drugs that, like carbamazepine, are voltage-gated sodium channel blockers in North America. The license field includes voltage gated sodium channels inhibitors and blockers for the treatment of epilepsy, neuropathic pain, and bipolar disorder.

Financing

In January 2016, the Company entered into a securities purchase agreement with one accredited investor to sell 10% convertible debentures, with and an exercise price of $1.25, with an initial principal balance of $150,000 and warrants to acquire up to 80,000 shares of the Company's common stock at an exercise price of $1.25 per share.

In May 2016, the Company entered into a securities purchase agreement with twenty accredited investors to sell 10% convertible debentures, with and an exercise price of $0.40, with an initial principal balance of $1,390,044 and warrants to acquire up to 3,475,111 shares of the Company's common stock at an exercise price of $0.45 per share.

In July 2016, the Company entered into a securities purchase agreement with one accredited investor to sell 10% convertible debentures, with and an exercise price of $0.40, with an initial principal balance of $112,135 and warrants to acquire up to 280,338 shares of the Company's common stock at an exercise price of $0.45 per share.

In August 2016, the Company entered into a securities purchase agreement with one accredited investor to sell 10% convertible debentures up $1,000,000, with and an exercise price of $0.40, with an initial principal balance of $250,000 and warrants to acquire up to 2,500,000 shares of the Company's common stock at an exercise price of $0.45 per share.

In January 2017, the Company entered into a securities purchase agreement with eight accredited investors to sell 10% convertible debentures with and an exercise price of the lesser of (i) $15.00 or (ii) the average of the three (3) lowest intra-day trading prices of the Common Stock during the 20 Trading Days immediately prior to the date on which the Notice of Conversion is delivered to the Company, with an initial principal balance of $633,593 and warrants to acquire up to 42,239 shares of the Company's common stock at an exercise price of $15.00 per share.

In March 2017, the Company entered into a securities purchase agreement with two accredited investors to sell 10% convertible debentures with and an exercise price of the lesser of (i) $15.00 or (ii) the average of the three (3) lowest intra-day trading prices of the Common Stock during the 20 Trading Days immediately prior to the date on which the Notice of Conversion is delivered to the Company, with an initial principal balance of $232,313 and warrants to acquire up to 15,487 shares of the Company's common stock at an exercise price of $15.00 per share.

In April 2017, the Company entered into a securities purchase agreement with two accredited investors to sell 10% convertible debentures with and an exercise price of the lesser of (i) $15.00 or (ii) the average of the three (3) lowest intra-day trading prices of the Common Stock during the 20 Trading Days immediately prior to the date on which the Notice of Conversion is delivered to the Company, with an initial principal balance of $70,000 and warrants to acquire up to 4,666 shares of the Company's common stock at an exercise price of $15.00 per share.

In May 2017, the Company entered into a securities purchase agreement with two accredited investors to sell 10% convertible debentures with and an exercise price of the lesser of (i) $15.00 or (ii) the average of the three (3) lowest intra-day trading prices of the Common Stock during the 20 Trading Days immediately prior to the date on which the Notice of Conversion is delivered to the Company, with an initial principal balance of $125,000 and warrants to acquire up to 8,333 shares of the Company's common stock at an exercise price of $15.00 per share.

In July 2017, we entered into a securities purchase agreement with three accredited investors to sell 10% convertible debentures with and an exercise price of the lesser of (i) $15.00 or (ii) the average of the three lowest intra-day trading prices of the common stock during the 20 trading days immediately prior to the date on which the notice of conversion is delivered to us, with an initial principal balance of $650,000 and warrants to acquire up to 43,333 shares of our common stock at an exercise price of $15.00 per share.

In August 2017, we entered into a securities purchase agreement with three accredited investors to sell 10% convertible debentures with an exercise price of the lesser of (i) $15.00 or (ii) the average of the three lowest intra-day trading prices of the common stock during the 20 trading days immediately prior to the date on which the notice of conversion is delivered to us, with an initial principal balance of $3,890,000 and warrants to acquire up to 259,333 shares of our common stock at an exercise price of $15.00 per share.

On January 22, 2018, the Company entered into a Securities Purchase Agreement with the investors listed on the Schedule of Buyers attached thereto (individually, a “Buyer” and collectively, the “Buyers”) pursuant to which the Company has 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”), 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”).

The issuance of the Notes and Warrants is being 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 (as defined thereto) under the 1933 Act and the rules and regulations promulgated thereunder, and applicable state securities laws. All descriptions of the SPA, the Registration Rights Agreement, the Notes and the Warrants contained herein are qualified in their entirety by reference to the exhibits filed herewith.

Results of Operations

Research and Development Expenses

During the year ended December 31, 2017 and 2016, we incurred $1,068,000 and $975,000 of research and development expenses.

Selling, general and administrative expenses

During the year ended December 31, 2017 and 2016, we incurred $134,502,000 and $8,399,000 of selling, general and administrative expenses. The increase in selling, general and administrative expenses is primarily attributable to an increase of non-cash stock compensation.

Change in value of warrant and derivative liabilities

During the year ended December 31, 2017, we recorded a gain as a result of a decrease in the fair market value of outstanding warrants and beneficial conversion features of $925,000, compared to a gain of $25,697,000 during the year ended December 31, 2016. We recorded a decrease as a result of the conversion to common or preferred stock of all outstanding debt and equity securities accounted for as derivative liabilities.

Interest Expense

Interest expense was $8,602,000 and $6,555,000 for the year ended December 31, 2017 and 2016 respectively. The decrease is primarily due to an increase in the non-cash amortization of the debt issuance costs associated with the convertible debentures and demand notes payable and expenses related the issuance of additional shares

Liquidity and Capital Resources

As of December 31, 2017, we had cash and cash equivalents of $576,000. This cash and cash equivalents is in part the result of the proceeds from borrowings in 2017. On the same day we had total current assets of $576,000, and a working capital deficit of $2,103,000. Based upon the cash position, it is necessary to raise additional capital by the end of the next quarter in order to continue to fund current operations. 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 approximately $8-10 million of capital.

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.

Revenue Recognition

License Revenue

License arrangements may consist of non-refundable upfront license fees and various performance or sales milestones and future product royalty payments. Some of these arrangements are multiple element arrangements. Non-refundable, up-front fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue when the license term commences and the licensed data, technology and/or compound is delivered. We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of our performance under the other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement.

Long-Lived Assets

Our long-lived assets include property, plant and equipment, capitalized costs of filing patent applications and goodwill and other assets. We evaluate our long-lived assets for impairment in accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" 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. Goodwill and other assets are not amortized.

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.

Derivative Financial Instruments

During the normal course of business, from time to time, we issue warrants as part of a debt or equity financing. We do not enter into any derivative contracts for speculative purposes. We recognize all derivatives as assets or liabilities measured at fair value with changes in fair value of derivatives reflected as current period income or loss unless the derivatives qualify for hedge accounting and are accounted for as such. During fiscal 2017 and 2016, we issued warrants to purchase -0- and 5,101,500 shares of common stock, respectively, in connection with equity transactions. In accordance with ASC Topic 815-40, "Derivatives and Hedging — Contracts in Entity's Own Stock" ("ASC 815-40"), the value of these warrants is required to be recorded as a liability, as the holders have an option to put the warrants back to us in certain events, as defined.

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, 2017.

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 elsewhere in this annual report and incorporated herein by reference.

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 financial 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, 2017. Based on that evaluation we have concluded that our disclosure controls and procedures were not effective as of December 31, 2017.

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 financial 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, 2017, 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, 2017. The most significant issues identified were: 1) lack of segregation of duties due to very small staff and significant reliance on outside consultants, and 2) risks of executive override also due to lack of established policies, and small employee staff. Based on the material weaknesses identified above, management has concluded that internal control over financial reporting was not effective as of December 31, 2017.

As the company's operations increase, the company intends to hire additional employees in its accounting department. This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting.

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 20, 2018. 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
Shawn Cross	50	Chief Executive Officer and Chairman of the Board
Steven Weldon	42	Chief Financial Officer and Director
Raymond Urbanski, M.D., Ph.D.	58	Chief Medical Officer
Kathleen Clarence-Smith, M.D., Ph.D.	71	Vice-Chairwoman of the Board and President of Neurology Division
Anthony J. Cataldo	66	Director
Geoffrey Davis	70	Director

Shawn Cross has been our President and Chief Operating Officer since November 2017 and our Chief Executive Officer and Chairman of the Board since February 15, 2018. Mr. Cross was a Managing Director, and senior calling officer focused on the biopharmaceutical industry, in Healthcare Investment Banking at Deutsche Bank Securities Inc. (NYSE:DB) from November 2015 to October 2017. He was a Managing Director in the Wells Fargo Securities, LLC (NYSE:WF) Healthcare Group from December 2010 to November 2015. Mr. Cross began his 20-year investment banking career at Alex. Brown & Sons Inc. and has lived and worked in the major financial centers of London, New York City and San Francisco. He received his bachelor of science degree from the University of California, Los Angeles and his Master's in Business Administration from Columbia Business School with honors and a concentration in Finance.

Steven Weldon was appointed to our board of directors in September 2014 and as our Chief Financial Officer in November 2014. 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.

Raymond Urbanski, M.D., Ph.D., has been our Chief Medical Officer since September 2017. Before joining us, he was the Chief Medical Officer for MannKind Corporation (NASDAQ:MNKD) from August 2015 to September 2017. He was the Chief Medical Officer for Mylan Inc. (NASDAQ:MYL) from August 2012 to September 2014. Dr. Urbanski spent eight years with Pfizer Inc. (NYSE:PFE), or Pfizer, and held several positions with Pfizer, including Vice President and Chief Medical Officer of the Established Products Business Unit, Senior Medical Director of Oncology Clinical R&D, Senior Medical Director of Breast Cancer Products and Medical Director of Diversified Products. He brings extensive experience in developing and overseeing clinical studies, including Phase 3b and Phase 4 studies (including line extensions) for sunitinib (Sutent), exemestane (Aromasin), irinotecan (Camptosar), epirubicin (Ellence), axitinib, IGF1R inhibitor, and tremilimumab. In addition to his role with Pfizer, Dr. Urbanski has also served as chief medical officer of Metabolex Inc. from October 2011 to June 2012, and senior director of U.S. Medical Affairs for Aventis (NYSE:SNY).

Anthony J. Cataldo served as our Executive Chairman since September 1, 2017 to February 14, 2018. He was appointed to the board of directors on July 31, 2014 and he served as Chief Executive Officer from November 19, 2014 to September 1, 2017. Most recently, from February 2011 to November 2013, Mr. Cataldo served as Chairman and Chief Executive Officer of Iovance Biotherapeutics, Inc. (NASDAQ: IOVA). Mr. Cataldo also served as chairman of the board of directors of Brand Partners Group, Inc., a provider of integrated products and services dedicated to providing financial services and traditional retail clients with turnkey environmental solutions, from October 2003 through August 2006. Mr. Cataldo also served as nonexecutive cochairman of the board of MultiCell Technologies, Inc., a supplier of functional, nontumorigenic immortalized human hepatocytes from February 2005 through July 2006. Mr. Cataldo has also served as executive chairman of Calypte Biomedical Corporation (OTCMKTS:CBMC), a publicly traded biotechnology company, involved in the development and sale of urine-based HIV1 screening tests from May 2001 through November 2004.

Kathleen Clarence-Smith, M.D., Ph.D., co-founded Georgetown Translational Pharmaceuticals, Inc. ("GTP") in 2015. Prior to founding GTP, Dr. Clarence-Smith co-founded Chase Pharmaceuticals Corporation in Washington D.C. and served as Chief Medical Officer and member of the Chase Pharmaceuticals board from founding to 2014. Chase Pharmaceuticals was acquired by Allergan, PLC (NYSE: AGN) in 2016. Dr. Clarence-Smith also held executive management positions with Sanofi (NYSE:SNY), Roche Holding AG (VTX:ROG), Otsuka Pharmaceutical, and Prestwick Scientific Capital. She is co-founder and a managing member of KM Pharmaceutical Consulting in Washington, D.C. She is currently serving as a member of the boards of Riverside Pharmaceuticals Corporation, Westhaven Therapeutics Corporation and Chase Therapeutics Corporation. Dr. Clarence-Smith has been an observer of the board of the American Society for Experimental Neurotherapeutics, or ASENT, since 1996 and has been a member of the American Academy of Neurology since 1990.

Geoffrey Davis, is the founding partner of Barker Davis LLC, a law firm specializing in advising companies in the life sciences industry, and has been the managing partner since its inception in January 2015. Prior to Barker Davis, Mr. Davis was partner at Ropes & Gray LLC from September 1987 to December 2014. During his more than 25 years as a partner at Ropes & Gray, Mr. Davis played a significant role in establishing the firm's internationally recognized Life Sciences group. His work includes numerous corporate partnering and licensing transactions for major pharmaceutical and medical device companies, as well as for public and private biotechnology companies and major medical centers. He has also worked extensively on public and private financings for biomedical companies of all sizes, ranging from newly organized companies to established industry leaders, on behalf of both companies and their investment bankers. He received his bachelor of arts degree from Yale University and his Juris Doctor degree from Harvard Law School.

Committees of the Board of Directors

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 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, 2017 and 2016 of all persons who served as our principal executive officers and as our principal financial officer during the fiscal year ended December 31, 2017. No other executive officers received total annual compensation during the fiscal year ended December 31, 2017 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 ($)	Total ($)
Shawn Cross(3) Chief Operating Officer	2017	$ 104,165	$ —	$ —	$ —	$ —	$ —	$ —	$ 104,165
Steven Weldon, Chief Financial Officer (Principal Financial Officer)[4]	2017	$ 245,333	$ —	$8,472,797	$ —	$ —	$ —	$ —	$8,718,130
	2016	$ 168,000	$ —	$ 752,852	$ —	$ —	$ —	$ —	$ 920,852
	2015	$ 168,000	$ —	$ 197,845	$ —	$ —	$ —	$ —	$ 365,845
Raymond Urbanski, M.D., Ph.D. Chief Medical Officer	2017	$ 133,333	$ —	$8,366,120	$ —	$ —	$ —	$ —	$8,499,453
Anthony J. Cataldo, Former Chief Executive Officer[5]	2017	$ 310,667	$ 90,000	$7,275,253	$ —	$ —	$ —	$ —	$7,594,920
	2016	$ 216,000	$ —	$4,417,026	$ 20,707	$ —	$ —	$ —	$4,653,733
	2015	$ 216,000	$ 134,000	$ —	$ 102,535	$ —	$ —	$ —	$ 452,535
Kathleen Clarence-Smith, M.D., Ph.D.(6) Former Chief Executive Officer	2017	166,667	$ —	$ —	$ —	$ —	$ —	$ —	166,667

(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) Mr. Cross was appointed President and Chief Operating Officer on October 15, 2017 and Chairman and Chief Executive Officer on February 14, 2018.

(4) Mr. Weldon was appointed Chief Financial Officer on November 3, 2014.

(5) Dr. Urbanski was appointed Chief Medical Officer on September 1, 2017.

(6) Mr. Cataldo 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.

(7) Dr. Clarence-Smith was Chief Executive Officer on September 1, 2017 to February 14, 2018. Dr. Clarence-Smith currently serves as our Vice-Chairwoman and President of the Neurology Division.

Employment Agreements

We entered into employment contracts with our executive officers on September 1, 2017, with Mr. Cataldo as executive chairman, Dr. Clarence-Smith as chief executive officer, Dr. Urbanski as chief medical officer and Mr. Weldon as chief financial officer.

Mr. Cataldo's contract is for three years. Under the terms of his contract, he received an up-front restricted stock award of 5,129,600 common shares and will be paid an annual salary of $500,000. Dr. Clarence-Smith's contract is for three years. Under the terms of her contract, she will receive an annual salary of $500,000 and an up-front restricted stock award in an amount to be determined by our board. Dr. Urbanski's contract is for three years. Under the terms of his contract, he received a restricted stock award of 1,528,898 common shares that vest over two years and will be paid an annual salary of $400,000. Mr. Weldon's contract is for three years pursuant to which he received an up-front restricted stock award of 2,564,830 common shares and will be paid an annual salary of $400,000. All four executives are entitled to participate in any performance business plan established by us.

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 has been revised to reflect her new position and she will be paid an annual salary of $500,000, paid in equal monthly installment. All other terms of her original Employment Agreement remain unchanged.

On February 14, 2018, the Company entered into a Consultant Agreement with Mr. Cataldo. The term of the Consultant Agreement lasts until August 31, 2020 and is terminable at will and is subject to automatic extension for successive one-year periods. Mr. Cataldo will be paid $41,666.67 per month during the term of the Consultant Agreement and will be entitled to participate in the Company's bonus plans.

In November 16, 2017, Shawn Cross was appointed the President and Chief Operating Officer of the GT Biopharma, Inc. by the Board of Directors. The Company has entered into an Employment agreement with Mr. Cross. Mr. Cross's contract is for three years and under the terms of his contract, he will receive restricted stock awards of 150,000 common shares on January 1, 2018, 1,000,000 common shares on January 1, 2019 and 1,850,000 common shares on January 1, 2020 and will be paid an annual salary of $500,000. He is also entitled to participate in any performance business plan established by the Company.

On February 15, 2018, the Company entered into an Executive Employment Agreement with Mr. Cross, pursuant to which Mr. Cross will be employed as the Company's Chief Executive Officer. The term of the Executive Employment Agreement is three years and is terminable at will by either the Company or Mr. Cross and subject to automatic extensions for successive one year periods. Mr. Cross will be paid an annual salary of $500,000, paid in equal monthly installment. Mr. Cross is also entitled to participate in the Company's bonus plans. Under the Executive Employment Agreement, the Company has agreed that it will recommend to the Board that the Company grant Mr. Cross an option to purchase 2,000,000 shares of the Company's common stock at an exercise price equal to the fair market value of each share as determined by the Board as of the date of the grant. The stock option grant would vest according to the following schedule: (i) 34% of the shares on February 15, 2018, (ii) 33% of the shares on February 15, 2019, and (iii) 33% of the shares on February 15, 2020.

If any of our executive officers' employment with us is terminated involuntarily, or any executive resigns with good reason as a result of a change in control, the executive will receive (i) all compensation and benefits earned through the date of termination of employment; (ii) a lump-sum payment equal to the greater of (a) the bonus paid or payable to the executive for the year immediately prior to the year in which the change in control occurred and (b) the target bonus under the performance bonus plan in effect immediately prior to the year in which the change in control occurs; (iii) a lump-sum payment equivalent to the remaining base salary (as it was in effect immediately prior to the change in control) due to the executive from the date of involuntary termination to the end of the term of the employment agreement or one half of the executive's base salary then in effect, whichever is the greater; and (iv) reimbursement for the cost of medical, life, disability insurance coverage at a level equivalent to that provided by us for a period expiring upon the earlier of (a) one year or (b) the time the executive begins alternative employment where said insurance coverage is available and offered to the executive.

Stock Option Grants

The following table sets forth information as of December 31, 2017, 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
Anthony Cataldo	358	-	-	$ 750.00	07/01/19
Anthony Cataldo	358	-	-	$ 1,500.00	07/01/19
Anthony Cataldo	358	-	-	$ 2,250.00	07/01/19
Steven Weldon	-	-	-	-	
Kathleen Clarence-Smith, M.D., Ph.D.	-	-	-	-	
Raymond Urbanski, M.D., Ph.D.	-	-	-	-	
Shawn Cross	-	-	-	-	

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, Directors are 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. There was not compensation paid to non-employee directors during fiscal 2017.

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 February 20, 2018, (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 February 20, 2018, there were 50,117,978 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 February 20, 2018 are deemed to be outstanding for 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 1825 K Street NW, Suite 510, Washington, D.C. 20006.

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:		
Mark Silverman	8,172,079	16.31%
Bristol Investment Fund, Ltd. (1)	4,060,185	9.62%
Theorem Group, LLC (2)	3,540,130	7.06%
William Heavener	2,584,568	5.16%
Canyons Trust	2,560,822	5.11%
Adam Kasower	2,514,258	5.02%
Security Ownership of Management:		
Kathleen Clarence-Smith, M.D., Ph.D.	8,505,633	16.97%
Anthony J. Cataldo	5,143,036	10.26%
Steven Weldon	2,566,835	5.12%
Raymond Urbanski, M.D., Ph.D.	1,528,898	3.05%
Shawn Cross	-	0.00%
Executive officers and directors as a group — 6 persons	17,744,402	35.41%

(1) As reported on Schedule 13G/A filed with the SEC on February 7, 2018. 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) As reported on Schedule 13G filed with the SEC on November 14, 2017. The address of Theorem Group LLC is 315 Beverly Drive, Suite 502, Beverly Hills, CA 90212

Equity Compensation Plan Information

The following is a summary of our equity compensation plans at December 31, 2017:

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 Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders (1)	1,246	$ 1,428.00	-
Equity compensation plans not approved by security holders	-	-	-
Total	1,246	$ 1,428.00	-

(1) As of December 31, 2017, we had options issued and outstanding to purchase 1,246 shares of common stock under our 2014 Stock Incentive Plan.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE

Director Independence

One of our four 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.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Seligson & Giannattasio, LLP was our independent registered public accounting firm for the fiscal years ending December 31, 2016 and 2017. The Audit Committee appointed Seligson & Giannattasio, LLP as our independent registered public accounting firm for the fiscal year ending December 31, 2017. 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 2016 and 2017 fiscal years.

	2017	2016
Audit Fees (1)	$ 56,000	$ 56,000
Audit-Related Fees (2)	-	-
Tax Fees (3)	4,000	4,000
All Other Fees	-	-
Total	$ 60,000	$ 60,000

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(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 2017 and 2016 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	
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	
10.5	Employment Agreement with Anthony Cataldo	10-Q	11/14/17	10.1	
10.6	Employment Agreement with Dr. Kathleen Clarence-Smith	10-Q	11/14/17	10.3	
10.7	Employment Agreement with Steven Weldon	10-Q	11/14/17	10.4	
10.8	Employment Agreement with Dr. Raymond Urbanski	10-Q	11/14/17	10.5	
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	
10.14	Agreement, effective as of November 16, 2017, between the Company and Mr. Cross	8-K	11/16/17	10.1	
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	Executive Employment Agreement, dated as of February 15, 2018, between the Company and Cross	8-K	02/21/18	10.1	
10.19	First Amendment to the Employment Agreement, dated as of February 14, 2018, between the Company and Dr. Clarence-Smith	8-K	02/21/18	10.2	
10.20	Consulting Agreement, dated as of February 14, 2018, between the Company and Mr. Cataldo	8-K	02/21/18	10.3	
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.

Dated: March 1, 2018

GT Biopharma, Inc.

By: /s/ Shawn Cross
Shawn Cross
Chief Executive Officer and Chairman of the Board

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

Name	Position	Date
/s/ Shawn Cross Shawn Cross	Chief Executive Officer and Chairman of the Board	March 1, 2018
/s/ Steven Weldon Steven Weldon	Chief Financial Officer (Principal Financial Officer), and Director	March 1, 2018
/s/ Dr. Kathleen Clarence-Smith Dr. Kathleen Clarence-Smith	Vice Chairwoman and Director	March 1, 2018
/s/Anthony J. Cataldo Anthony J. Cataldo	Director	March 1, 2018
/s/ Geoffrey Davis Geoffrey Davis	Director	March 1, 2018

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONSOLIDATED FINANCIAL STATEMENTS
YEARS ENDED DECEMBER 31, 2017 AND 2016

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the board of directors of

GT Biopharma, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of GT Biopharma, Inc. (the "Company") and subsidiaries as of December 31, 2017 and 2016, the related consolidated statements of operations, stockholders' deficit and cash flows for each of the two years in the period ended December 31, 2017, and the related notes (collectively referred to as the "financial statements". In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company and subsidiaries as of December 31, 2017 and 2016 and the consolidated results of its operations and its consolidated cash flows for each of the two years in the period ended December 31, 2017, 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 1, 2018

GT Biopharma, Inc. and Subsidiaries
December 31, 2017 and 2016
Consolidated Balance Sheets

	December 31, 2017	December 31, 2016
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 576,000	$ 19,000
Prepaid expenses	-	2,000
Total Current Assets	576,000	21,000
Intangible assets	253,777,000	-
Deposits	9,000	-
Fixed assets, net	6,000	4,000
Total Other Assets	253,792,000	4,000
TOTAL ASSETS	$254,368,000	$ 25,000
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current Liabilities:		
Accounts payable	$ 2,546,000	$ 2,100,000
Accrued interest	-	3,800,000
Accrued expenses	102,000	219,000
Line of credit	31,000	31,000
Warrant liability	-	417,000
Settlement note payable	-	691,000
Demand notes payable, net of discount of $-0- and $-0-	-	452,000
Convertible debentures, net of discount of $-0- and $794,000 current portion	-	10,350,000
Senior secured convertible debentures	-	889,000
Total Current Liabilities	2,679,000	18,949,000
Long term liabilities:		
Convertible debentures, net of discount of $-0- and $2,536,000	-	-
Total long term liabilities	-	0
Total liabilities	2,679,000	18,949,000
Stockholders' Deficit:		
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, 2017 and December 31, 2016, respectively	1,000	1,000
Series H – 25,000 shares issued and outstanding at December 31, 2016	-	-
Series I – 1,666,667 shares issued and outstanding December 31, 2016	-	2,000
Series J – 1,163,548 shares issued and outstanding at December 31, 2017	1,000	-
Common stock - $0.001 par value; 750,000,000 shares authorized; and 50,117,977 and 104,218 shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	50,000	0
Additional paid-in capital	519,702,000	105,891,000
Accumulated deficit	(267,896,000)	(124,649,000)
Noncontrolling interest	(169,000)	(169,000)
Total Stockholders' Deficit	251,689,000	(18,924,000)
TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT	$254,368,000	$ 25,000

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

GT Biopharma, Inc. and Subsidiaries
December 31, 2017 and 2016
Statements of Operations

	December 31,	
	2017	**2016**
Revenue:		
Product revenues	$ -	$ -
License revenues	-	-
TOTAL REVENUE	-	-
Cost of Product Revenue	-	-
Gross profit	-	-
Operating Expenses:		
Research and development	1,068,000	975,000
Selling, general and administrative	134,502,000	8,399,000
Total operating expenses	135,570,000	9,374,000
Loss from Operations	(135,570,000)	(9,374,000)
Other income (expense)		
Change in value of warrant and derivative liabilities	925,000	25,697,000
Interest expense/income	(8,602,000)	(6,555,000)
Total Other Income (Expense)	(7,677,000)	19,142,000
Income (loss) before minority interest and provision for income taxes	(143,247,000)	9,768,000
Less: Net loss attributable to the noncontrolling interests	-	-
Income (loss) before provision for income taxes	(143,247,000)	9,768,000
Provision for income taxes	-	-
Net income (loss)	(143,247,000)	9,768,000
Weighted average shares outstanding		
Basic	16,769,431	81,460
Diluted	16,769,431	81,460
Net income (loss) per share		
Basic	$ (8.54)	$ 119.91
Diluted	$ (8.54)	$ 119.91

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

GT Biopharma, Inc. and Subsidiaries
Consolidated Statement of Stockholders' Deficit
For the Years Ended December 31, 2017 and 2016

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated
	Shares	Amount	Shares	Amount	Capital	Deficit
Balance at December 31, 2015	1,787,897	$ 3,000	8,000	$ -0	$84,014,000	$(134,417,000)
Issuance of stock options					42,000	
common stock for convertible notes and interest			18,012	-	2,489,000	
Issuance of common stock for warrants			52,091	-	9,043,000	
Issuance of common stock for compensation			26,115	-	10,303,000	
Net income						9,768,000
Balance at December 31, 2016	1,787,897	$ 3,000	**104,218**	**$ -**	**$105,891,000**	**$(124,649,000)**
Issuance of common stock for acquisition			16,927,878	17,000	253,901,000	
Issuance of common and preferred stock for convertible notes and interest	908,502	1,000	17,677,904	18,000	24,329,000	
Issuance of common and preferred stock for warrants	5,046		496,855	-	5,819,000	
Issuance of common stock for preferred stock	(2,041,667)	(2,000)	5,677,734	6,000	(4,000)	
Issuance of common and preferred stock for compensation	600,000		9,233,388	9,000	129,766,000	(143,247,000)
Net loss						
Balance at December 31, 2017	**1,259,778**	**$ 2,000**	**50,117,977**	**$ 50,000**	**$519,702,000**	**$(267,896,000)**

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

GT Biopharma, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Years Ended December 31, 2017 and 2016

	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$(143,247,000)	$ 9,768,000
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation	2,000	1,000
Amortization of intangible assets	-	-
Stock compensation expense for options and warrants issued to employees and non-employees	130,124,000	6,591,000
Note Allonges	100,000	65,000
Amortization of debt discounts	4,914,000	2,897,000
Non-cash interest expense	2,197,000	1,632,000
Change in value of warrant and derivative liabilities	(925,000)	(25,697,000)
Note settlement	-	-
Changes in operating assets and liabilities:		
Inventory	-	-
Other assets	(7,000)	-
Accounts payable and accrued liabilities	1,412,000	2,813,000
Net cash used in operating activities	(5,430,000)	(1,930,000)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of fixed assets	(4,000)	-
Net cash used by investing activities	(4,000)	-
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable	5,991,000	1,902,000
Repayment of note payable	-	-
Net cash provided by financing activities	5,991,000	1,902,000
Minority interest	-	-
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	557,000	(28,000)
CASH AND CASH EQUIVALENTS - Beginning of period	19,000	47,000
CASH AND CASH EQUIVALENTS - End of period	$ 576,000	$ 19,000
Supplemental disclosures:		
Issuance of common stock for interest expense	$ 5,179,000	$ 528,000
Issuance of common stock for debt	$ 19,166,000	$ 1,944,000

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

1. The Company and Summary of Significant Accounting Policies

We are an immuno-oncology company with a close-to-market central nervous system, or CNS, portfolio of products. Our immuno-oncology portfolio is based off a robust technology platform consisting of single-chain bi-, tri- and tetra-specific scFv's, combined with proprietary antibody-drug linkers and drug payloads. Constructs include bispecific and trispecific scFv constructs, , proprietary drug payloads, bispecific targeted antibody-drug conjugates, or ADCs, as well as tri- and tetra-specific antibody-directed cellular cytotoxicity, or ADCC. Our proprietary tri- and tetra-specific ADCC platform engages natural killer cells, or NK cells. NK cells are cytotoxic lymphocytes of the innate immune system capable of immune surveillance. NK cells mediate ADCC through the highly potent CD16 activating receptor. Upon activation, NK cells deliver a store of membrane penetrating apoptosis-inducing molecules. Unlike T cells, NK cells do not require antigen priming.

Our CNS portfolio consists of innovative reformulations and/or repurposing of existing therapies. These new therapeutic agents address numerous unmet medical needs that can lead to improved efficacy while addressing tolerability and safety issues that tended to limit the usefulness of the original approved drug. These CNS drug candidates address disease states such as chronic neuropathic pain, myasthenia gravis and vestibular disorders.

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.

Going Concern

As shown in the accompanying consolidated financial statements, the Company has incurred an accumulated deficit of $267,896,000 through December 31, 2017. On a consolidated basis, the Company had cash and cash equivalents of $576,000 at December 31, 2017. The Company's plan is to raise additional capital until such time that the Company generates sufficient revenues to cover its cash flow needs and/or it achieves profitability. However, the Company cannot assure that it will accomplish this task and there are many factors that may prevent the Company from reaching its goal of profitability.

The current rate of cash usage raises substantial doubt about the Company's ability to continue as a going concern, absent any sources of significant cash flows. In an effort to mitigate this near-term concern the Company intends to seek additional equity or debt financing to obtain sufficient funds to sustain operations. However, the Company cannot provide assurance that it will successfully obtain equity or debt or other financing, if any, sufficient to finance its goals or that the Company will generate future product related revenues. The Company's financial statements 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 that the Company cannot continue in existence.

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, 2017 and 2016, respectively.

Basis of Consolidation and Comprehensive Income

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.

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 $316,000 of balances in excess of this limit at December 31, 2017.

Fair Value of Financial Instruments

The carrying amounts of cash and cash equivalents, restricted cash, accounts receivable, inventory, accounts payable and accrued expenses approximate fair value because of the short-term nature of these instruments. The fair value of debt is based upon current interest rates for debt instruments with comparable maturities and characteristics and approximates the carrying amount.

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.

Impairment of Long Lived Assets

The Company's long-lived assets currently consist of capitalized patents. The Company evaluates its long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. If any of the Company's long-lived assets are considered to be impaired, the amount of impairment to be recognized is equal to the excess of the carrying amount of the assets over the fair value of the assets.

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. The weighted average number of potentially dilutive common shares excluded from the calculation of net income (loss) per share totaled in 1,164,795 in 2017 and 126,145 in 2016.

Goodwill and Other Intangible Assets

Certain intangible assets were acquired as part of a business combination (see note 3) and have been capitalized at their acquisition date fair value of $253,777,000, based on the share value of the Company's stock issued for the acquisition of the assets. Acquired definite life intangible assets are amortized using the straight-line method over their respective estimated useful lives. The Company evaluates the potential impairment of intangible assets if events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable or that the useful lives of these assets are no longer appropriate. Goodwill is not amortized but is evaluated for impairment within the Company's single reporting unit on an annual basis, during the fourth quarter, or more frequently if an event occurs or circumstances change that would more-likely-than-not reduce the fair value of the Company's reporting unit below its carrying amount.

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 cost 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 receivables and current liabilities each 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: a warrant liability for detachable warrants, as well as an accrued derivative liability for the beneficial conversion feature. These liabilities are remeasured each reporting period. Fair value is determined using the Binomial 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 not such liabilities at December 31, 2017.

- Level 3 inputs to the valuation methodology are unobservable and significant to the fair value measurement.

Research and Development

Research and development costs are expensed as incurred and reported as research and development expense. Research and development costs totaling $1,068,000 and $975,000 for the years ended December 31, 2017 and 2016, respectively.

Revenue Recognition

License Revenue

License arrangements may consist of non-refundable upfront license fees, exclusive licensed rights to patented or patent pending technology, and various performance or sales milestones and future product royalty payments. Some of these arrangements are multiple element arrangements.

Non-refundable, up-front fees that are not contingent on any future performance by us, and require no consequential continuing involvement on our part, are recognized as revenue when the license term commences and the licensed data, technology and/or compound is delivered. We defer recognition of non-refundable upfront fees if we have continuing performance obligations without which the technology, right, product or service conveyed in conjunction with the non-refundable fee has no utility to the licensee that is separate and independent of our performance under the other elements of the arrangement. In addition, if we have continuing involvement through research and development services that are required because our know-how and expertise related to the technology is proprietary to us, or can only be performed by us, then such up-front fees are deferred and recognized over the period of continuing involvement.

Payments related to substantive, performance-based milestones in a research and development arrangement are recognized as revenue upon the achievement of the milestones as specified in the underlying agreements when they represent the culmination of the earnings process.

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.

Recently Issued Standards

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 amendments in this ASU are effective for fiscal years beginning after December 15, 2018 and for interim periods therein. The Company is in the process of assessing the impact the adoption this ASU will have on its consolidated financial position, results of operations and cash flows. At a minimum, total assets and total liabilities will increase in the period the ASU is adopted. Early adoption of this ASU is permitted. At December 31, 2017, the Company’s undiscounted future minimum payments outstanding for lease obligations (including those currently included as capital lease obligations) were approximately $297,000.

In May 2014, the FASB issued ASU No. 2014-09, “Revenue from Contracts with Customers: Topic 606.” This ASU replaces nearly all existing U.S. GAAP guidance on revenue recognition. The standard prescribes a five-step model for recognizing revenue, the application of which will require significant judgment. The amendments in this ASU are effective for fiscal years beginning after December 15, 2017, and for interim periods therein. The provisions of this ASU may be applied retroactively or on a modified retrospective (cumulative effect) basis. The Company will adopt the standard using the modified retrospective approach in its fiscal year beginning January 1, 2018. Adoption of this ASU will not have a significant impact on the Company’s consolidated financial position, results of operations and cash flows.

2. Debt

Senior secured convertible debentures

On October 25, 2006, the Company entered into a securities purchase agreement ("2006 Purchase Agreement") with four accredited investors (the "2006 Purchasers"). In conjunction with the signing of the 2006 Purchase Agreement, the Company issued secured convertible debentures ("2006 Debentures") and Series A, B, C, D, and E common stock warrants ("2006 Warrants") to the 2006 Purchasers, and the parties also entered into a security agreement (the "2006 Security Agreement") pursuant to which the Company agreed to grant the 2006 Purchasers, pari passu, a security interest in substantially all of the Company's assets.

Pursuant to the terms of the 2006 Purchase Agreement, the Company issued the 2006 Debentures in an aggregate principal amount of $1,694,250 to the 2006 Purchasers. The 2006 Debentures are subject to an original issue discount of 20.318% resulting in proceeds to the Company of $1,350,000 from the transaction. The 2006 Debentures were due on October 25, 2008. The 2006 Debentures are convertible, at the option of the 2006 Purchasers, at any time prior to payment in full, into shares of common stock of the Company. As a result of the full ratchet anti-dilution provision the current conversion price is the lesser of $0.40 or 60% of the average of the lowest three trading prices occurring at any time during the 20 trading days preceding conversion (the "2006 Conversion Price"). Beginning on the first of the month beginning February 1, 2007, the Company was required to amortize the 2006 Debentures in equal installments on a monthly basis resulting in a complete repayment by the maturity date (the "Monthly Redemption Amounts"). The Monthly Redemption Amounts could have been paid in cash or in shares, subject to certain restrictions. If the Company chose to make any Monthly Redemption Amount payment in shares of common stock, the price per share would have been the lesser of the Conversion Price then in effect and 85% of the weighted average price for the 10-trading days prior to the due date of the Monthly Redemption Amount. The Company did not make any of the required monthly redemption payments.

Pursuant to the provisions of the 2006 Debentures, such non-payment was an event of default and penalty interest has accrued on the unpaid redemption balance at an interest rate equal to the lower of 18% per annum and the maximum rate permitted by applicable law. In addition, each of the 2006 Purchasers has the right to accelerate the cash repayment of at least 130% of the outstanding principal amount of the 2006 Debenture (plus accrued but unpaid liquidated damages and interest) and to sell substantially all of the Company's assets pursuant to the provisions of the 2006 Security Agreement to satisfy any such unpaid balance.

The Company and Bristol entered into a Forbearance Agreement on December 3, 2015, pursuant to which Bristol agreed to refrain and forbear from exercising certain rights and remedies with respect the 2006 Debentures for three months. In exchange for the Forbearance Agreement, the Company issued an allonge in the amount of $350,000 increasing the principal amount if the 2006 Debentures.

During the year ended December 31, 2017 the Company converted the remaining balance of $889,000 of the 2006 Debentures into common stock of the Company.

Convertible debentures

From October 2009 to September 2016, the Company has entered into multiple convertible debenture arrangements with several accredited investors ("Convertible Debentures"). Interest on the Convertible Debentures ranges for 0% to 18% with a default rate of 18%. The Convertible Debentures are either two year or six month notes.

The conversion price of the Convertible Debentures is subject to full ratchet anti-dilution adjustment in the event that the Company thereafter issues common stock or common stock equivalents at a price per share less than the conversion price or the exercise price, respectively, and to other normal and customary anti-dilution adjustment upon certain other events. As a result of the full ratchet anti-dilution provision the current conversion price is $0.40 per share and the default conversion price is 65% of the average of the lowest three trading prices occurring at any time during the 20 trading days preceding conversion .

The holders of the Convertible Debentures have contractually agreed to restrict their ability to convert their Convertible Debentures and receive shares of our common stock such that the number of shares of the Company common stock held by holders and its affiliates after such conversion or exercise does not exceed 4.9% or 9.9% of the Company's then issued and outstanding shares of common stock. On August 31, 2017, the Company converted all Convertible Debentures into common and Series J preferred stock of the Company.

Convertible Debentures held by the Company are as follows:

Note Agreement	Balance at December 31, 2017	Balance at December 31, 2016
2009 Debentures	$ -	$ 305,000
June 2011 Debentures	-	64,000
November 2011 Debentures	-	125,000
March 2012 Debentures	-	140,000
May 2012 Debentures	-	225,000
December 2012 Debentures	-	425,000
November 2013 Debentures	-	172,000
July 2014 Debentures	-	3,140,000
October 2014 Debentures	-	1,250,000
March 2015 Debentures	-	2,175,000
July 2015 Debentures	-	500,000
October 2015 Debentures	-	330,000
November 2015 Debentures	-	190,000
December 2015 Debentures	-	200,000
January 2016 Debentures	-	150,000
May 2016 Debentures	-	1,503,000
September 2016 Debentures	-	250,000
January 2017 Debentures	-	-
March 2017 Debentures	-	-
April 2017 Debentures	-	-
July 2017 Debentures	-	-
August 2017 Debentures	-	
Total convertible debentures	$ -	$ 11,144,000
Less: discount	-	(794,000)
Total convertible debentures, net of discount	$ -	$ 10,350,000
Total short term convertible debentures, net of discount	$ -	$ 10,350,000

Settlement Note Payable

On August 8, 2012, a Settlement Agreement and Mutual General Release ("Agreement") was made by and between OXIS and Bristol Investment Fund, Ltd., in order to settle certain claims regarding certain convertible debentures held by Bristol.

Pursuant to the Agreement, OXIS shall pay Bristol (half of which payment would redound to Theorem Capital LLC ("Theorem")) a total of $1,119,778 as payment in full for the losses suffered and all costs incurred by Bristol in connection with the Transaction. Payment of such $1,119,778 shall be made as follows: OXIS shall issue restricted common stock to each of Bristol and Theorem, in an amount such that each Bristol and Theorem shall hold no more than 9.99% of the outstanding shares of OXIS (including any shares that each may hold as of the date of issuance). The shares so issued represent $417,475.65 of the $1,119,778 payment (111,327 shares at $3.75 per share, of which 36,675 will be retained by Bristol and 74,652 will be issued to Theorem). The remaining balance of the payment shall be made in the form of two convertible promissory notes in the respective amounts of $422,357.75 for Bristol and $279,944.60 for Theorem (collectively, the "Notes") with a maturity of December 1, 2017 having an 8% annual interest rate, with interest only accruing until January 1, 2013, and then level payments of $3,750 each beginning January 1, 2013 until paid in full on December 1, 2017. In the event a default in the monthly payments on the Notes has occurred and is continuing each holder of the Notes shall be permitted to convert the unpaid principal and interest of the Notes into shares of OXIS at $0.40 cents per share. In the absence of such continuing default no conversion of the Notes will be permitted. OXIS will have the right to repay the Notes in full at any time without penalty. On August 31,2017 the Company converted the remaining balance of $691,000 of the Settlement Note Payable into common stock of the Company.

Demand Notes

On February 7, 2011 the Company entered into a convertible demand promissory note with Bristol pursuant to which Bristol purchased an aggregate principal amount of $31,375 of convertible demand promissory notes for an aggregate purchase price of $25,000 (the "February 2011 Bristol Note"). The February 2011 Bristol Note is convertible into shares of common stock of the Company at a price equal to the lesser of (i) $15.00 or (ii) the average of the three (3) lowest intra-day trading prices of the Common Stock during the 20 Trading Days immediately prior to the date on which the Notice of Conversion is delivered to the Company. During the quarter ended March 31, 2017 the Company converted the entire balance of $31,375 into common stock of the Company.

On March 4, 2011 the Company entered into a convertible demand promissory note with Bristol pursuant to which Bristol purchased an aggregate principal amount of $31,375 of convertible demand promissory notes for an aggregate purchase price of $25,000 (the "March 2011 Bristol Note"). The March 2011 Bristol Note is convertible at the option of the holder at any time into shares of common stock, at a price equal to the lesser of (i) $15.00 or (ii) the average of the three (3) lowest intra-day trading prices of the Common Stock during the 20 Trading Days immediately prior to the date on which the Notice of Conversion is delivered to the Company. During the quarter ended March 31, 2017 the Company converted the entire balance of $31,375 into common stock of the Company.

On October 26, 2011 the Company entered into a convertible demand promissory note with Theorem pursuant to which Theorem purchased an aggregate principal amount of $200,000 of convertible demand promissory notes for an aggregate purchase price of $157,217 (the "October 2011 Theorem Note"). The October 2011 Theorem Note is convertible into shares of common stock of the Company, at a price equal to the lesser of (i) $15.00 or (ii) the average of the three (3) lowest intra-day trading prices of the Common Stock during the 20 Trading Days immediately prior to the date on which the Notice of Conversion is delivered to the Company. During the quarter ended March 31, 2017 the Company converted the entire balance of $200,000 into common stock of the Company.

In December, 2013, the Company entered into a convertible demand promissory note with an initial principal balance of $189,662 convertible at a price equal to the lesser of (i) $15.00 or (ii) the average of the three (3) lowest intra-day trading prices of the Common Stock during the 20 Trading Days immediately prior to the date on which the Notice of Conversion is delivered to the Company. On August 31,2017, the Company converted the remaining balance of $189,662 of this Demand Note Payable into common stock of the Company.

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, 2017.

3. Stockholders' Equity

Stock Split

In July 2017, the Company approved a one for three hundred reverse stock split. The Company has reported the effect of the split retroactively for all periods presented.

Common Shares

In July 2017, the Company amended its articles of incorporation to change the number of authorized common shares to 750,000,000 shares of $.001 par value stock.

Common Stock

During the year ended December 31, 2016, the Company issued an aggregate of 41,934 shares of common stock to a total of 34 persons or entities in exchange of the cancellation of warrants on a cashless basis.

During the year ended December 31, 2016, the Company also issued an aggregate of 6,741 shares of common stock to a total of 17 persons as payment for consulting services provided to the Company. The average valuation of these shares was $600.00 per share.

During the year ended December 31, 2016, the Company also issued an aggregate of 15,375 shares of common stock to two executive officers of the Company in fulfilment of contractual rights held by the officers pursuant to their employment agreements.

During the year ended December 31, 2016, the Company also issued an aggregate of 19,857 shares of common stock to a total of 18 persons as payment for the conversion of certain note and the related accrued interest. The conversion price of these shares was $120.00 per share.

In August 2016, the Company issued 3,717 shares of common stock to H.C. Wainwright and Co., LLC as payment for investment banking services provided to the Company.

In October 2016, the Company issued an aggregate of 1,982 shares of common stock to one noteholder as payment for the conversion of a certain note. The conversion price of these shares was $25.23 per share based on 60% of the average of the lowest three trading prices occurring at any time during the 20 trading days preceding conversion.

In November 2016, the Company issued an aggregate of 3,250 shares of common stock to one noteholder as payment for the conversion of a certain note. The conversion price of these shares was $15.39 per share based on 60% of the average of the lowest three trading prices occurring at any time during the 20 trading days preceding conversion.

In December 2016, the Company issued an aggregate of 3,414 shares of common stock to one noteholder as payment for the conversion of a certain note. The conversion price of these shares was $14.65 per share based on 60% of the average of the lowest three trading prices occurring at any time during the 20 trading days preceding conversion.

All shares issued during 2016 were exempt from the registration requirements of Section 5 of the Securities Act of 1933 (the “Act”) pursuant to Section 4(2) of the Act since the shares were issued to persons or entities closely associated with the Company and there was no public offering of the shares.

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). GTP is a biotechnology company focused on acquiring or discovering and patenting late-stage, de-risked, and close-to-market improved treatments for CNS disease (Neurology and Pain) and shepherding the products through the FDA approval process to the NDA. In exchange for the ownership of GTP, the Company issued a total of 16,927,878 shares of its common stock to the three prior owners of GTP which represents 33% of the issued and outstanding capital stock of the Company.

During the six months ended June 30, 2017 the Registrant has issued a total of 390,279 shares of common stock to a total of eleven entities or individuals in exchange for the cancellation of debt in the total amount of $2,025,000 and interest in the total amount of $486,000.

In August 2017, the Company has issued a total of 17,287,625 shares of common stock in exchange for the cancellation of debt in the total amount of $17,141,000 and interest in the total amount of $4,693,000.

In August 2017, the Company issued 496,855 shares of common stock upon the exercise of warrants on a cashless basis.

In August 2017, the Company converted 25,000 Series H and 1,666,667 Series I shares of preferred stock into 5,327,734 shares of common stock.

In December 2017, the Company converted 350,000 Series J shares of preferred stock into 350,000 shares of common stock.

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, 2017.

On December 4, 2008, the Company entered into and closed an Agreement (the “Bristol Agreement”) with Bristol Investment Fund, Ltd. pursuant to which Bristol agreed to cancel the debt payable by the Company to Bristol in the amount of approximately $20,000 in consideration of the Company issuing Bristol 25,000 shares of Series G Convertible Preferred Stock, which such shares carry a stated value equal to $1.00 per share (the “Series G Stock”).

The Series G Stock is convertible, at any time at the option of the holder, into common shares of the Company based on a conversion price equal to the lesser of $2.50 or 60% of the average of the three lowest trading prices occurring
at any time during the 20 trading days preceding the conversion. The Series G Stock, as amended, shall have voting rights on an as converted basis multiplied by 100.

In the event of any liquidation or winding up of the Company, the holders of Series G Stock will be entitled to receive, in preference to holders of common stock, an amount equal to the stated value plus interest of 15% per year.

The Series G Stock restricts the ability of the holder to convert the Series G Stock and receive shares of the Company’s common stock such that the number of shares of the Company common stock held by Bristol and its affiliates after such conversion does not exceed 4.9% of the Company’s then issued and outstanding shares of common stock.

The Series G Stock was previously referred to in an 8-K filed by the Company on December 10, 2008 in error as the "Series E Stock". Further, the Series G Stock initially incorrectly provided that it voted on an as converted basis multiplied by 10. This incorrectly reflected the intent of the Company and the holder.

On October 13, 2009 the Company was informed by Theorem Group, LLC that it had purchased all of the outstanding Series G Preferred Stock and Theorem gave notice to the Company that it intended to exercise its ability to vote on all shareholder matters utilizing the super voting privileges provided by the Series G Stock.

Effective February 10, 2010, the Company issued 25,000 shares of its new Series H Convertible Preferred Stock (the "Series H Preferred") to Theorem Group, LLC, a California limited liability company (the "Stockholder"), in exchange for the 25,000 shares of Series G Stock then owned by the Stockholder. The foregoing exchange was effected pursuant to that certain Exchange Agreement, dated February 10, 2010, between the Company and the Stockholder (the "Exchange Agreement").

The Certificate of Designation of the Series H Preferred is based on, and substantially similar to the form and substance of the Certificate of Designation of the Series G Preferred. Some of the corrections, changes and differences between the Certificate of Designation of the Series G Preferred and the Certificate of Designation of the Series H Preferred include the following:

- As previously disclosed, the holder of the Series H Preferred is entitled to vote with the common stock, and is entitled to a number of votes equal to (i) the number of shares of common stock it can convert into (without any restrictions or limitations on such conversion), (ii) multiplied by 100.
- The holder of the Series H Preferred cannot convert such preferred stock into shares of common stock if the holder and its affiliates after such conversion would own more than 9.9% of the Company's then issued and outstanding shares of common stock.
- The Series G Preferred contained a limitation that the holder of the Series G Preferred could not convert such preferred shares into more than 19.999% of the issued and outstanding shares of common stock without the approval of the stockholders if the rules of the principal market on which the common stock is traded would prohibit such a conversion. Since the rules of the Company's principal market did not require such a limitation, that provision has been deleted.

In August 2017, the Company converted 25,000 Series H stock into 5,119,401 shares of common stock.

On November 8, 2010, the Company sold 1,666,667 shares of the Company's Series I Preferred Stock, $.001 par value, at a price of $0.15 per share ($250,000).

The holder of the Series I Preferred Stock will be entitled to receive, out of funds legally available, dividends in cash at the annual rate of 8.0% of the Preference Amount ($0.15), when, as, and if declared by the Board. No dividends or other distributions shall be made with respect to any shares of junior stock until dividends in the same amount per share on the Series I Preferred Stock shall have been declared and paid or set apart during that fiscal year. Dividends on the Series I Preferred Stock shall not be cumulative and no right shall accrue to the Series I Preferred Stock by reason of the fact that the Company may fail to declare or pay dividends on the Series I Preferred Stock in the amount of the Dividend Rate per share or in any amount in any previous fiscal year of the Company, whether or not the earnings of the Company in that previous fiscal year were sufficient to pay such dividends in whole or in part.

Each share of Series I Preferred Stock shall entitle the holder thereof to such number of votes per share as shall equal the number of shares of Common Stock (rounded to the nearest whole number) into which such share of Series I Preferred Stock is then convertible.

Upon any liquidation of the Company, subject to the rights of any series of Preferred Stock that may from time to time come into existence, before any distribution or payment shall be made to the holders of any Junior Stock, the holders of the shares of Series I Preferred Stock then outstanding shall be entitled to receive and be paid out of the assets of the Company legally available for distribution to its stockholders liquidating distributions in cash or property at its fair market value as determined by the Board in the amount of $0.15 per share (as adjusted for any stock dividends, combinations or splits with respect to such shares).

Shares of Series I Preferred Stock may, at the option of the holder thereof, be converted at any time or from time to time into fully paid and non-assessable shares of Common Stock. The number of shares of Common Stock which a holder of shares of Series I Preferred Stock shall be entitled to receive upon conversion of such shares shall be the product obtained by multiplying the Conversion Rate by the number of shares of Series I Preferred Stock being converted. Initially, the Series I Preferred Stock is convertible into 6,667 shares of common stock.

In the event that the per-share Market Price of the Common Stock over a period of 20 consecutive trading days is equal to at least 130% of the initial conversion price (130% of $0.15), all outstanding shares of Series I Preferred Stock shall be converted automatically into the number of shares of Common Stock into which such shares of Series I Preferred Stock are then convertible without any further action by the holders of such shares and whether or not the certificates representing such shares of Series I Preferred Stock are surrendered to the Company or its transfer agent.

In August 2017, the Company converted 1,666,667 Series I shares of preferred stock into 208,333 shares of common stock.

On September 1, 2017, the Company authorized 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 September 1, 2017 the Company issued a total of 700,278 shares of Series J Preferred Stock in exchange for the cancellation of debt in the total amount of $840,000.

On September 1, 2017 the Company issued 5,046 shares of Series J Preferred Stock upon the exercise of warrants on a cashless basis.

On September 1, 2017 the Company also issued 600,000 shares of Series J Preferred Stock to one entity as payment for $720,000 of consulting services provided to the Company.

In December 2017, the Company converted 350,000 Series J shares of preferred stock into 350,000 shares of common stock.

Common Stock Warrants

Warrant transactions for the years ended December 31, 2016 and 2015 are as follows:

	Number of Warrants	Weighted Average Exercise Price
Outstanding, December 31, 2015:	41,752	$ 375.00
Granted	17,005	135.00
Forfeited	(1,173)	375.00
Exercised	(42,034)	375.00
Outstanding at December 31, 2016:	15,550	$ 135.00
Granted	486,351	15.00
Forfeited		
Exercised	(501,901)	15.00
Outstanding at December 31, 2016	-	$ -
Exercisable warrants:		
December 31, 2017	-	$ -
December 31, 2016	41,752	$ 375.00

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, 2017, 445 shares of common stock were available for grant and options to purchase 888 shares of common stock are outstanding under the 2014 Plan.

In addition, the Company has reserved 7 shares of its common stock for issuance outside of its stock incentive plans. At December 31, 2017, options to purchase 7 shares of common stock are outstanding outside of its stock incentive plans.

The following table summarizes stock option transactions for the years ended December 31, 2017 and 2016:

	Number of Options	Weighted Average Exercise Price
Outstanding, December 31, 2015	1,249	$ 1,464.00
Granted	-	-
Exercised	-	-
Expired	(3)	16,881.00
Outstanding, December 31, 2016	1,246	$ 1,428.00
Granted	-	-
Exercised	-	-
Expired	-	-
Outstanding, December 31, 2017	1,246	$ 1,428.00
Exercisable Options:		
December 31, 2016	1,246	$ 1,428.00
December 31, 2017	1,246	$ 1,428.00

The weighted-average fair value of options granted was $1,780,000 for 2017 and 2016.

The following table summarizes information about all outstanding and exercisable stock options at December 31, 2017:

	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	1,246	1.38	$ 1,428.73	1,246	$ 1428.73

4. 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:

	December 31,	
	2017	2016
Deferred tax assets:		
Federal net operating loss carryforward	$ 15,949,000	$ 19,819,000
Other	-	1,634,000
Patent amortization	(6,000)	(11,000)
Deferred tax assets before valuation	15,943,000	21,422,000
Valuation allowance	(15,943,000)	(21,422,000)
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 decreased by $5,499,000 during the year ended December 31, 2017, which includes a decrease due to a change in rates resulting from the Tax Cuts and Jobs Act totaling $6,908,000.

Tax Carryforward

At December 31, 2017, the Company had net operating loss carryforwards of approximately $53,165,000 to reduce United States federal taxable income in future years. These carryforwards expire from 2018 through 2037.

The Company is no longer subject to U.S. and state tax examinations for years ending before the fiscal year ended December 31, 2013. 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, 2017 and 2016.

6. Commitments and Contingencies

Leases

On September 1, 2017, the Company has 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. These executory costs are not included in the table below. 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, 2017 (in thousands):

Year ending December 31:	
2018	108,000
2019	108,000
2020	81,000
Total minimum lease payments	$ 297,000

Rent expense for the year ended December 31, 2017 and 2016 was $9,000 and $-0-, respectively.

Employment Agreements

In connection with the acquisition, we entered into employment contracts on September 1, 2017, with Mr. Cataldo as executive chairman, Dr. Clarence-Smith as chief executive officer, Dr. Raymond Urbanski as chief medical officer and Steven Weldon as chief financial officer. We entered into an employment contract on November 15, 2017, with Mr. Cross as president and chief operating officer.

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 has been revised to reflect her new position and she will be paid an annual salary of $500,000, paid in equal monthly installment. All other terms of her original Employment Agreement remain unchanged.

On February 14, 2018, the Company entered into a Consultant Agreement with Mr. Cataldo. The term of the Consultant Agreement lasts until August 31, 2020 and is terminable at will and is subject to automatic extension for successive one-year periods. Mr. Cataldo will be paid $41,666.67 per month during the term of the Consultant Agreement and will be entitled to participate in the Company's bonus plans.

On February 15, 2018, the Company entered into an Executive Employment Agreement with Mr. Cross, pursuant to which Mr. Cross will be employed as the Company's Chief Executive Officer. The term of the Executive Employment Agreement is three years and is terminable at will by either the Company or Mr. Cross and subject to automatic extensions for successive one year periods. Mr. Cross will be paid an annual salary of $500,000, paid in equal monthly installment. Mr. Cross is also entitled to participate in the Company's bonus plans. Under the Executive Employment Agreement, the Company has agreed that it will recommend to the Board that the Company grant Mr. Cross an option to purchase 2,000,000 shares of the Company's common stock at an exercise price equal to the fair market value of each share as determined by the Board as of the date of the grant. The stock option grant would vest according to the following schedule: (i) 34% of the shares on February 15, 2018, (ii) 33% of the shares on February 15, 2019, and (iii) 33% of the shares on February 15, 2020.

If any of our executive officers' employment with us is terminated involuntarily, or any executive resigns with good reason as a result of a change in control, the executive will receive (i) all compensation and benefits earned through the date of termination of employment; (ii) a lump-sum payment equal to the greater of (a) the bonus paid or payable to the executive for the year immediately prior to the year in which the change in control occurred and (b) the target bonus under the performance bonus plan in effect immediately prior to the year in which the change in control occurs; (iii) a lump-sum payment equivalent to the remaining base salary (as it was in effect immediately prior to the change in control) due to the executive from the date of involuntary termination to the end of the term of the employment agreement or one half of the executive's base salary then in effect, whichever is the greater; and (iv) reimbursement for the cost of medical, life, disability insurance coverage at a level equivalent to that provided by us for a period expiring upon the earlier of (a) one year or (b) the time the executive begins alternative employment where said insurance coverage is available and offered to the executive.

5. Change in Prior Year Financials

The financial statements for the year ended December 31, 2016 have been restated to correct an error in the reporting of the change in valuation of the warrant and derivative liabilities. The effect of the change is to increase the net income for 2016 by $11,265,000.

6. Subsequent Events

On January 22, 2018, the Company entered into a Securities Purchase Agreement with the investors listed on the Schedule of Buyers attached thereto (individually, a "Buyer" and collectively, the "Buyers") pursuant to which the Company has 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"), 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").

The issuance of the Notes and Warrants is being 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 (as defined thereto) under the 1933 Act and the rules and regulations promulgated thereunder, and applicable state securities laws. All descriptions of the SPA, the Registration Rights Agreement, the Notes and the Warrants contained herein are qualified in their entirety by reference to the exhibits filed herewith.

Exhibit 31.1

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

I, Shawn Cross, certify that:

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

2. 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;

3. 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;

4. 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:

    a) 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;

    b) 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;

    c) 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

    d) 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

5. 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):

    a) 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

    b) 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 1, 2018

By: /s/ Shawn Cross
Name: Shawn Cross
Title: Chief Executive Officer and Chairman of the Board (Principal Executive Officer)

Exhibit 31.2

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

I, Steven Weldon, certify that:

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

2. 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;

3. 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;

4. 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:

    a) 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;

    b) 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;

    c) 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

    d) 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

5. 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):

    a) 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

    b) 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 1, 2018

By: /s/ Steven Weldon
Name: Steven Weldon
Title: Chief Financial Officer and Director (Principal Financial Officer)

Exhibit 32.1

CERTIFICATION TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, I, Shawn Cross, 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, 2017 (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 1, 2018

By: /s/ Shawn Cross
Name: Shawn Cross
Title: Chief Executive Officer and Chairman of the Board (Principal Executive Officer)

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, 2017 (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 1, 2018

By: /s/ Steven Weldon
Name: Steven Weldon
Title: Chief Financial Officer and Director
(Principal Financial Officer)