Registration No. 333-232261

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

FORM S-1/A

(Amendment No. 1)

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

GT BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

DELAWARE
(State or other jurisdiction of incorporation or organization)

2834
(Primary Standard Industrial Classification Code)

94-1620407
(I.R.S. Employer Identification Number)

310 N. Westlake Blvd, Suite 206
Westlake Village, CA 91362
(800) 304-9888
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

The Corporation Trust Company
Corporation Trust Center
1209 Orange Street
Wilmington, Delaware 19801
Telephone: (302) 658-7581
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies of Communications to:
Gary R. Henrie, Esq.
P.O. Box 107
315 Kimball's Garden Circle
Nauvoo, IL 62354
Tel: (309) 313-5092
Email: grhlaw@hotmail.com

Approximate date of commencement of proposed sale to public:
From time to time after the effective date of this registration statement.

If any securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

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. [ ]

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities To Be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Share	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common stock, par value $.001 per share	40,216,064 shares(1)	$0.28(2)	$11,260,498	$1,364.77

(1) The 40,216,064 common shares are being registered for resale by Selling Stockholders.
(2) The closing price of the common shares on June 17, 2019.

The Registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and the selling stockholders are not soliciting offers to buy these securities in any state where such offers are not permitted.

Subject to completion,

July _____, 2019

PROSPECTUS

40,216,064 Shares

GT BIOPHARMA, INC.

Common Stock

We are registering the resale of 40,216,064 shares of common stock of GT Biopharma, Inc., a Delaware corporation (the "Company"), by the Selling Stockholders who may acquire such shares upon the conversion of notes or upon the conversion of Series J-1 Preferred Stock (the "Conversion Shares"). The Selling Stockholders will receive all of the proceeds from the sale of the Conversion Shares. We will pay all expenses incident to the registration of the shares under the Securities Act of 1933, as amended.

At the present time our common stock is listed on the OTCQB under the symbol GTBP. The Selling Stockholders will sell the shares at prevailing market prices or at privately negotiated prices.

Investing in our common stock involves risks, which are described in the "Risk Factors" section beginning on page 10 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is July _____, 2019.

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You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with any information or represent anything not contained in this prospectus, and, if given or made, any such other information or representation should not be relied upon as having been authorized by us. The selling stockholders are not offering to sell, or seeking offers to buy, our common stock in any jurisdiction where the offer or sale is not permitted. You should not assume that the information provided in this prospectus is accurate as of any date other than the date on the front cover of this prospectus.

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the Securities and Exchange Commission utilizing a "shelf" registration process. Under this shelf registration process, the selling stockholders may offer from time to time up to an aggregate of 40,216,064 shares of common stock in one or more offerings. The registration statement of which this prospectus is a part is being filed in accordance with the registration rights agreement, dated as of May 22, 2019, by and among GT Biopharma, Inc. and the selling stockholders party thereto and in some cases pursuant to the preferences and designations of the Series J-1 Preferred Stock. Pursuant to the registration rights agreement, we have agreed to indemnify and hold harmless, to the extent permitted by law, each of the selling stockholders party to the registration rights agreement and each of such selling stockholder's directors, officers, partners, members, employees, agents, representatives of and each other person, if any, who controls such selling stockholder within the meaning of the Securities Act of 1933, as amended (the "Securities Act"), from and against certain losses, claims, damages and liabilities, including certain liabilities under the Securities Act.

You should rely only on the information contained in this prospectus and any free writing prospectus prepared by or on behalf of us that we have referred you to. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. No person has been authorized to giveany information or make any representations in connection with this offering other than those contained or incorporated by reference in this prospectus, any accompanying prospectus supplement and any related issuer free writing prospectus in connection with the offering described herein and therein. Neither this prospectus nor any prospectus supplement nor any related issuer free writing prospectus shall constitute an offer to sell or a solicitation of an offer to buy offered securities in any jurisdictionin which it is unlawful for such person to make such an offering or solicitation. This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits.

No action is being taken in any jurisdiction outside the United States to permit a public offering of common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restriction as to this offering and the distribution of this prospectus applicable to those jurisdictions.

Unless otherwise indicated, information contained in this prospectus concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors." These and other factors could cause our future performance to differ materially from our assumptions and estimates. See "Cautionary Note Regarding Forward-Looking Statements."

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, or will be filed as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading "Where You Can Find Additional Information."

All references to the number of shares issued or outstanding in this prospectus, and all per share and other similar data, reflect a 1for 300 reverse stock split that we effected on August 21, 2017.

All product and company names are trademarks of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Throughout this prospectus, the terms "we," "us," "our," and "our company" refer to GT Biopharma, Inc., a Delaware corporation and its related subsidiaries.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state or jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED JUNE 19, 2019

PRELIMINARY PROSPECTUS

PROSPECTUS SUMMARY

This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference in this prospectus. Because this is only a summary, it does not contain all of the information that may be important to you or that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially "Risk Factors" set forth in this prospectus, the other information incorporated by reference in this prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering. This prospectus contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may vary materially from those discussed in the forward-looking statements as a result of various factors, including, without limitation, those set forth in "Risk Factors" as well as other matters described in this prospectus.

Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE), Tetra-specific Killer Engager (TetraKE) and bi-specific 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 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 whichprovides 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 second TriKE product candidate, GTB-C3550, is a next-generation version of GTB-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 GTB-1615 which 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. GTB-1615 is designed to enable a patient's NK cells to kill not only the heterogeneous population of cancer cells found in many solid tumors but also kill the cancer stem cells that are typically responsible for recurrences. We intend to initiate human clinical testing for certain of our solid tumor product candidates in 2020.
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 2019. We believe ourTriKEs 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, GTB-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 GTB-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.

Also, in connection with the acquisition of Georgetown Translational Pharmaceuticals on September 1, 2017, we acquired a portfolio of in-process research and development central nervous system assets consisting of innovative reformulations and/or repurposing of existing therapies. These CNS assets address disease states such as chronic neuropathic pain, myasthenia gravis and motion sickness. We are currently pursuing out-licensing opportunities related to these assets.

Immuno-Oncology Product Candidates

GTB-1550

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

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

The initial Phase 1 study enrolled 25 patients with mature or precursor B-cell lymphoid malignancies expressing the CD19 receptor or CD22 receptor or both receptors. All 25 patients received at least a single course of therapy. The treatment at the higher doses produced objective tumor responses with one patient in continuous partial remission and the second in complete remission. A Phase 2 trial of GTB-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 GTB-1550.

We began enrolling patients in Phase 2 trial of GTB-1550 during the first quarter of 2017 and the first patient began dosing in April 2017.

GTB-3550

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

The GTB-3550 IND will focus on AML, 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 believe GTB-3550 could serve as a relatively safe, cost-effective, and easy-to-use therapy for resistant/relapsing AML and could also be combined with chemotherapy as frontline therapy thus targeting the larger market.

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

GTB-C3550

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

GTB-1615

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

Central Nervous System

Our CNS portfolio consists of in-process R&D ("IPR&D") assets acquired in connection with the acquisition of Georgetown Translational Pharmaceuticals ("GTP") on September 1, 2017, consisting of innovative reformulations and/or repurposing of existing therapies. These CNS assets address disease states such as chronic neuropathic pain (product candidate PainBrake, utilizing AccuBreak technology), myasthenia gravis (product candidate GTP-004) and motion sickness (product candidate GTP-011).

In the 3rd quarter of 2018, the Company experienced changes in key senior management, led by the appointment of a CEO with extensive experience in oncology drug development. These changes resulted in the prioritization of immuno-oncology development candidates relative to the CNS development candidates acquired from Georgetown Translational Pharmaceuticals. In conjunction with these strategic changes, limited internal resources have delayed the development of the CNS IPR&D assets. The limited resources, changes in senior leadership, and favorable market conditions for immuno-oncology development candidates have resulted in the Company choosing to focus on development of its immuno-oncology portfolio. We are assessing our options to realize value from the CNS IPR&D assets.

Summary Risk Factors

Investing in our common stock involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties discussed under the section titled "Risk Factors" beginning on page 10, as well as any amendments thereto reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus in their entirety, together with other information in this prospectus, the documents incorporated by reference and any free writing prospectus that we may authorize for use in connection with a specific offering.

Our Offices

Our principal executive offices are located at 310 N. Westlake Blvd, Suite 206, Westlake Village, CA 91362, and our telephone number is (800) 304¬9888.

Our Website

Our website is located at www.gtbiopharma.com. Information contained on or accessible through our website is not, and should not be considered, part of, or incorporated by reference into, this prospectus.

THE OFFERING

Securities offered by the selling stockholders: Up to 40,216,064 shares of common stock

Offering Price: Fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices.

Use of proceeds: We will not receive any proceeds from the sale of common stock by the selling stockholders.

OTC Markets symbol
GTBP

Unless otherwise indicated, all information contained in this prospectus gives effect to a 1-for-300 reverse stock split that we effected on August 21, 2017.

Risk factors:

The purchase of our common stock involves a high degree of risk. You should carefully review and consider "Risk Factors" beginning on page 10.

We will pay all expenses incident to the registration of the shares under the Securities Act.

Summary Financial Information

The tables and information below are derived from the Company's unaudited consolidated financial statements as of March 31, 2019, and for the three months ended March 31, 2019 and 2018 and also as of December 31, 2018.

Balance Sheet Summary (in thousands)	**March 31, 2019**	**December 31, 2018**
Cash and cash equivalents	$ 51	$ 60
Total assets	25,539	25,399
Total current liabilities	15,523	14,029
Total equity	10,016	11,370

Statement of Operations Summary (in thousands except per share data)	**March 31, 2019**	**March 31, 2018**
Revenue	$ -	$ -
Selling, general and administrative expenses	3,222	3,687
Research and development	834	3,473
Loss from operations	(4,056)	(7,160
Net loss	$ (4,510)	$ (10,091
Net loss per share – basic and diluted	$ (0.09)	$ (0.20

The tables and information below are derived from the Company's audited consolidated financial statements for the years ended December 31, 2018 and 2017.

Balance Sheet Summary (in thousands)	December 31, 2018	December 31, 2017
Cash and cash equivalents	$ 60	$ 576
Total assets	25,399	254,368
Total current liabilities	14,029	2,679
Total equity	11,370	251,689

Statement of Operations Summary (in thousands except per share data)	December 31, 2018	December 31, 2017
Revenue	$ -	$ -
Selling, general and administrative expenses	12,487	134,502
Research and development	9,067	1,068
Loss from operations	(250,069)	(135,570
Net loss	$ (259,186)	$ (144,172
Net loss per share – basic and diluted	$ (5.16)	$ (8.60

RISK FACTORS

Investment in our securities involves risks. Prior to making a decision about investing in our securities, you should consider carefully the risk factors, together with all of the other information contained or incorporated by reference in this prospectus and any prospectus supplement, including any additional specific risks described in the section entitled "Risk Factors" contained in any supplements to this prospectus, as updated by annual, quarterly and other reports and documents we file with the SEC after the date of this prospectus and that are incorporated by reference herein or in the applicable prospectus supplement. Each of these risk factors could have a material adverse effect on our business, results of operations, financial position or cash flows, which may result in the loss of all or part of your investment.

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 testingprior 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 March 31, 2019, we had an accumulated deficit of approximately $533.3 million. We have not generated any significant revenue to date and are not profitable, and have incurred losses in each year since our inception. We do not expect to generate any product sales or royalty revenues for at least four years. We expect to incur significant additional operating losses for the foreseeable future as we expand research and development and clinical trial efforts.

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

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

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

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

We may not be successful in generating and/or maintaining operating cash flow, and the timing of our capital expenditures and other expenditures may not result in cash sufficient to sustain our operations through the next 12 months. If financing is not sufficient and additional financing is not available or available only on terms that are detrimental to our long-term survival, it could have a material adverse effect on our ability to continue to function. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for capital needs in 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 defendingour 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 full-time 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 fromgovernmental investigations or other actions or lawsuits stemming from a failure by our employees to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Before we can submit an application for regulatory approval in the United States, we must conduct a pivotal, Phase 3 trial. We will also need to agree on a protocol with the FDA for a clinical trial before commencing the trial. Phase 3 clinical trials frequently produce unsatisfactory results even though prior clinical trials were successful. Therefore, even if the results of our Phase 2 trials are successful, the results of the additional trials that we conduct may or may not be successful. Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials. The FDA or other foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. Any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or other regulatory agencies may require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or other regulatory agencies.

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

We 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 tothe 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 claimfor 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 thatour 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 beable 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.

Pre-clinical 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 maintainsuch 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 defendourselves 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 trialswe 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 requireus 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 manufactureour 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 thedevelopment 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.

USE OF PROCEEDS

The selling stockholders will receive all net proceeds from the sale of the shares of common stock registered by this prospectus and offered by any accompanying prospectus supplement. We will not receive any proceeds from the sale of common stock by the selling stockholders.

We, and not the selling stockholders, will pay the costs, expenses and fees in connection with the registration of the shares covered by this prospectus.

MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

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

Trading in our common stock has fluctuated greatly during the past fifteen months. 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.

Fiscal Year 2019	**High ($)**	**Low ($)**
First Quarter	0.96	0.30
Fiscal Year 2018		
Fourth Quarter	2.16	0.62
Third Quarter	2.75	1.42
Second Quarter	2.52	1.25
First Quarter	5.06	1.60
Fiscal Year 2017		
Fourth Quarter	6.99	4.25
Third Quarter	29.55	4.66
Second Quarter	9.90	3.36
First Quarter	69.00	3.81

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 June 15, 2019, there were 23 stockholders of record, which total does not include stockholders who hold their shares in "street name." The transfer agent for our common stock is ComputerShare, whose address is 8742 Lucent Blvd., Suite 225, Highland Ranch, CO 80129.

Dividends

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

Equity Compensation Plan Information

The information included under the heading "Equity Compensation Plan Information" in "Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters." is hereby incorporated by reference into this paragraph.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus are forward-looking statements about what may happen in the future. Forward-looking statements include statements regarding our current beliefs, goals, and expectations about matters such as our expected financial position and operating results, our business strategy, and our financing plans. The forward-looking statements in this prospectus are not based on historical facts, but rather reflect the current expectations of our management concerning future results and events. The forward-looking statements generally can be identified by the use of terms such as “believe,” “expect,” “anticipate,” “intend,” “plan,” “foresee,” “likely” or other similar words or phrases. Similarly, statements that describe our objectives, plans or goals are or may be forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be different from any future results, performance and achievements expressed or implied by these statements. We cannot guarantee that our forward-looking statements will turn out to be correct or that our beliefs and goals will not change. Our actual results could be very different from and worse than our expectations for various reasons. You should review carefully all information, including the discussion of risk factors herein and “Item 7: Management’s Discussion and Analysis of Financial Condition and Results of Operations” of the Form 10-K for the year ended December 31, 2018. Any forward-looking statements in this prospectus are made only as of the date hereof and, except as may be required by law, we do not have any obligation to publicly update any forward-looking statements contained in this prospectus to reflect subsequent events or circumstances.

Throughout this prospectus, the terms “GTBP,” “we,” “us,” “our,” “the company” and “our company” refer to GT Biopharma, Inc., a Delaware corporation formerly known as Oxis International, Inc., DDI Pharmaceuticals, Inc. and Diagnostic Data, Inc, together with our subsidiaries.

Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE), Tetra-specific Killer Engager (TetraKE) and bi-specific Antibody Drug Conjugate (ADC) technology platforms. 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.

We also have a CNS portfolio consists of innovative reformulations and/or repurposing of existing therapies. We believe 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.

Recent Developments

Financing

On May 22, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement with ten purchasers (individually, a "Purchaser," and collectively, the "Purchasers") pursuant to which the Company has issued to the Purchasers Convertible Debentures in an aggregate principal amount of $1,300,000 (the "Debentures"), which Debentures are convertible into the Company's common stock (the "Common Stock") at a price of $0.35 per share. The Company and each Purchaser also entered into a Registration Rights Agreement.

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

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

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

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

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

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

On May 22, 2019, the Company consummated an additional financing in the same format and structure as the February 4, 2019, financing. The notes issued in the May 22, 2019, financing totaled $1,300,000 in the aggregate.

Results of Operations

Comparison of the Three Months Ended March 31, 2019 and 2018

Research and Development Expenses

During the three months ended March 31, 2019 and 2018, we incurred $.8 million and $3.5 million of research and development expenses. Research and development costs decreased due primarily to the reductions employees, consultants and preclinical expenses. We anticipate our direct clinical costs to increase in second half of 2019 upon the initiation of a phase one clinical trial of our most advanced TriKe product candidate, OXS-3550.

Selling, general and administrative expenses

During the three months ended March 31, 2019 and 2018, we incurred $3.2 million and $3.7 million of selling, general and administrative expenses. The decrease in selling, general and administrative expenses is primarily attributable the reduction of salaries.

Interest Expense

Interest expense was $.5 million and $2.9 million for the three months ended March 31, 2019 and 2018 respectively. The decrease is primarily due to a decrease related to the amortization of the original issue discount and the value of warrants issued with the January 2018 financing.

Comparison of the Fiscal Years Ended December 31, 2018 and 2017

Research and Development Expenses

During the years ended December 31, 2018 and 2017, we incurred $9.1 million and $1.1 million of research and development expenses, respectively. 2018 research and development costs increased due primarily to the addition of new employees, increased regulatory and preclinical consultant costs to support the GTB-3550 IND, higher costs to advance the CNS portfolio and position the assets for licensing efforts, and higher preclinical and clinical expenses incurred at the University of Minnesota to continue development of our immune-oncology assets. 2018 expenses also include non-cash compensation of $6.8 million. We anticipate our direct clinical and preclinical costs to continue to increase throughout 2019, totaling approximately $12 to $15 million, as we initiate a Phase 1 clinical trial of our most advanced TriKe product candidate, GTB-3550 in the first half of 2019, and initiate IND-enabling activities for GTB-C3550, and GTB-1615.

Selling, general and administrative expenses

During the years ended December 31, 2018 and 2017, we incurred $12.5 million and $134.5 million of selling, general and administrative expenses, respectively. Selling, general and administrative expenses in 2017 were driven by stock compensation related to the acquisition of Georgetown Translational Pharmaceuticals on September 1, 2017. Stock compensation expenses totaled $2.3 million and $129.1 million for in 2018 and 2017, respectively. Additional selling, general, and administrative expenses in 2018 were due to increased spending on investor relations campaigns to broaden awareness of the Company, and increased legal costs primarily associated with financing efforts. We anticipate selling, general and administrative expenses, excluding stock compensation, to range between $1 and $2 million in the coming quarters.

Loss on impairment

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

Interest Expense

Interest expense was $9.1 million and $8.6 million for the years ended December 31, 2018 and 2017, respectively. The increase is due to an increase in non-cash amortization of debt issuance costs associated with convertible debentures and warrants issued in January 2018.

Liquidity and Capital Resources

The Company's current operations have focused on business planning, raising capital, establishing an intellectual property portfolio, hiring, and conducting preclinical studies and clinical trials. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future. During the three months ended March 31, 2019, the Company raised $1 million through a series of issuances of convertible debentures in February. Also, as noted above, the Company raised $1.3 million on May 22, 2019, through the issuance of convertible notes. We anticipate that cash utilized for selling, general, and administrative expenses will range between $1 and $2 million in the coming quarters, while research and development expenses will vary depending on clinical activities.

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

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of $533.4 million and cash of $51 thousand as of March 31, 2019. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales or revenue from out-licensing of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: public offerings of equity and/or debt securities, payments from potential strategic research and development, licensing and/or marketing arrangements with pharmaceutical companies. Management has also implemented cost saving efforts, including reduction in executive salaries and reduced travel. Management believes that these ongoing and planned financing endeavors, if successful, will provide adequate financial resources to continue as a going concern for at least the next six months from the date the financial statements are issued; however, there can be no assurance in this regard. If the Company is unable to secure adequate additional funding, its business, operating results, financial condition and cash flows may be materially and adversely affected.

Critical Accounting Policies

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

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 ASC 360, whenever events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. Estimates of future cash flows and timing of events for evaluating long-lived assets for impairment are based upon management's judgment. If any of our intangible or long-lived assets are considered to be impaired, the amount of impairment to be recognized is the excess of the carrying amount of the assets over its fair value.

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

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 June 15, 2019.

DESCRIPTION OF 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 an 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.

We are using our TriKE and TetraKE platforms with the intent to bring to market immuno-oncology products that can treat a range of hematologic malignancies, sarcoma and solid tumors. The platforms are scalable, and we are putting processes in place to be able to produce IND-ready moieties in a timely manner after a specific TriKE or TetraKE conceptual design. After conducting market and competitive research, specific moieties can then be advanced into the clinic on our own or through potential collaborations with larger companies. We are also evaluating, in conjunction with our Scientific Advisory Board, additional moieties designed to target different tumor antigens. We believe our TriKEs and TetraKEs may have the ability, if approved for marketing, to be used on a stand-alone basis, augment the current monoclonal antibody therapeutics, be used in conjunction with more traditional cancer therapy and potentially overcome certain limitations of current chimeric antigen receptor, or CAR-T, therapy.

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

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

Also, in connection with the acquisition of Georgetown Translational Pharmaceuticals on September 1, 2017, we acquired a portfolio of in-process research and development central nervous system ("CNS") assets consisting of innovative reformulations and/or repurposing of existing therapies. These CNS assets address disease states such as chronic neuropathic pain, myasthenia gravis and motion sickness. We are currently pursuing out-licensing opportunities related to these assets.

Immuno-Oncology Platform

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

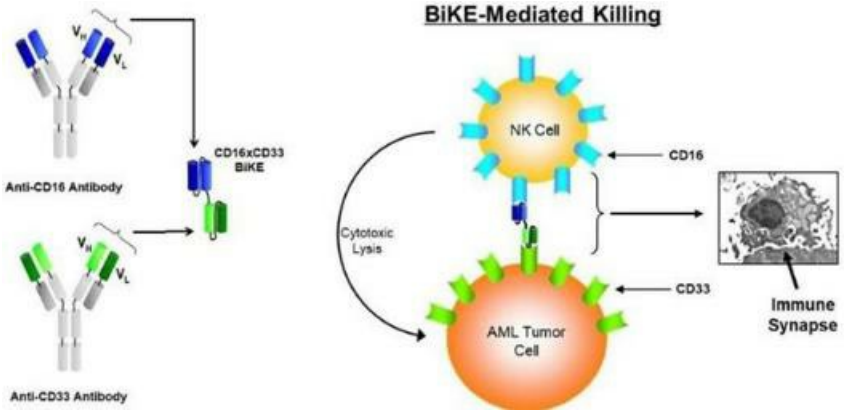
The generation of chimeric antigen receptor, or CAR, expressing T cells from monoclonal antibodies has represented an important step forward in cancer therapy. These therapies involve the genetic engineering of T cells to express either CARs, or T cell receptors, or TCRs, and are designed such that the 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

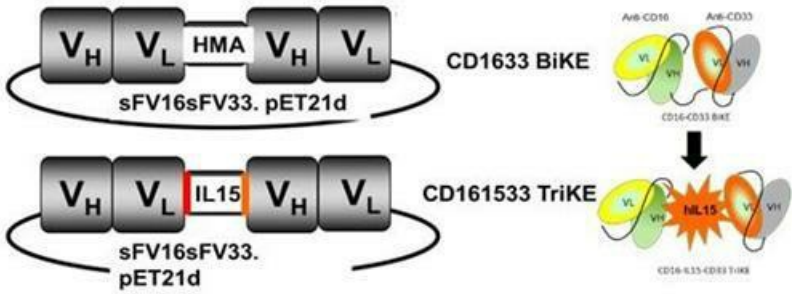
In conjunction with our research agreement with the Masonic Cancer Center at the University of Minnesota, the exploration of targeting NK cells to a variety of tumors initially focused on novel bi-specific killer engagers, or BiKEs, composed of the variable portions of antibodies targeting the CD16 activating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

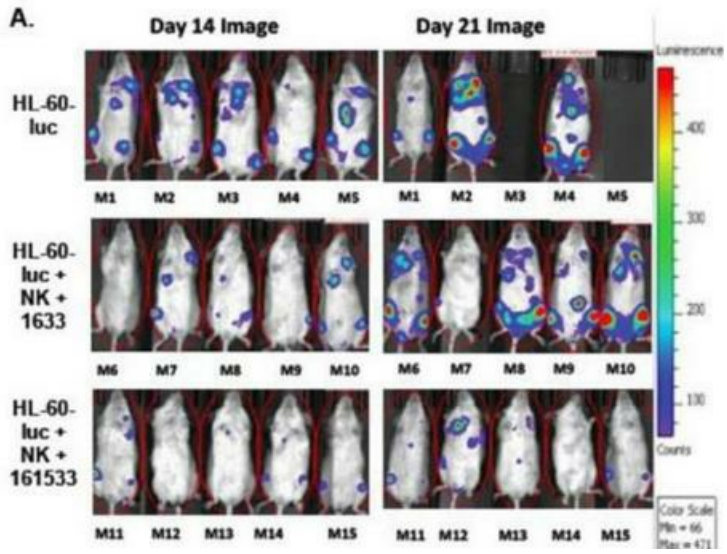
When compared to the CD16 x CD33 BiKE, the CD16 x IL-15 x CD33 TriKE is also capable of potently restoring killing capacity of post- transplant NK cells against CD33-expressing HL-60 Targets and primary AML blasts. These results demonstrated the ability to functionally incorporate an IL-5 cytokine into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

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



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

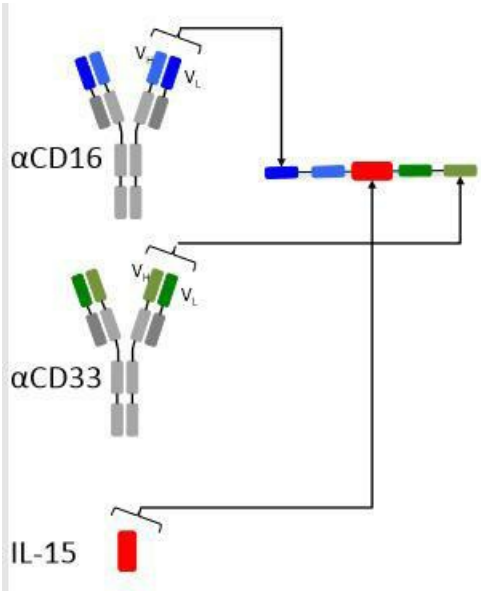
Figure A below shows the results (tumor burden and mortality) when dosing NK cells alone (top panel), the BiKE version (lacking IL-15) of GTB-3550 (middle panel; called 1633), and the TriKE, GTB-3550 (bottom panel; then called 161533) in the above described human tumor model, HL-60-luc. In the NK-cell-only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



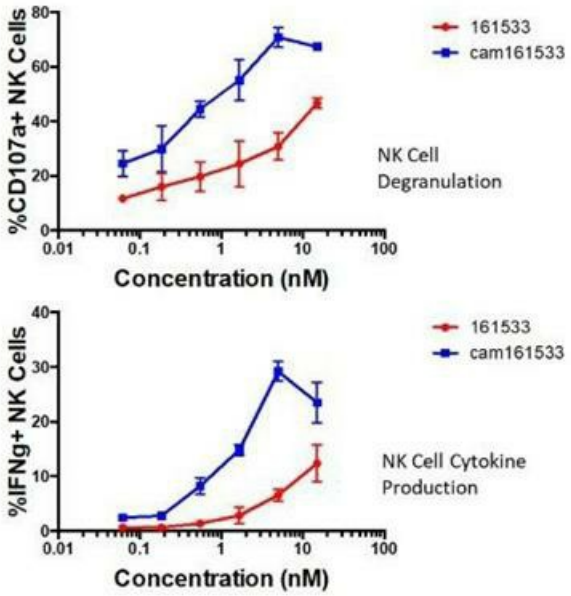
Based on these results, and others, the IND for GTB-3550 was filed in June 2017 by the University of Minnesota. FDA requested that additional preclinical toxicology be conducted prior to initiating clinical trials. The FDA also requested some additional information and clarifications on the manufacturing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

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

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



These single-domain antibodies are thought to have certain attractive features for antibody engineering, including physical stability, ability to bind deep grooves, and increased production yields, amongst others. Pre-clinical studies demonstrated increased activity (NK Cell Degranulation) and functionality (NC Cell Cytokine Production) of the single-domain CD16 TriKE (GTB-C3550) compared to the original TriKE (GTB-3550) (see figure below). These data were presented at the 2017 American Society of Hematology Conference.



Targeting Solid Tumors and Other Potentially Attractive Characteristics

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

Examples of our earlier stage solid tumor targeting product candidates are focused on EpCAM, Her2, Mesothelin (mesothelioma and lung adenocarcinoma), and CD133 alone and in combination. We believe certain of these constructs have the potential to target prostate, breast, colon, ovarian, liver, and head and neck cancers. Depending on the availability of drug supply, we hope to initiate human clinical testing for certain of our solid tumor product candidates in 2020.

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

We are using our TriKE and TetraKE platforms with the intent to bring to market multiple immuno-oncology products that can treat a range of hematologic malignancies, sarcomas and solid tumors. The platforms are scalable and we are currently working with several third parties investigating the optimal expression system of the TriKEs and TetraKE constructs which we expect to be part of a process in which we are able to produce IND-ready moieties in approximately 90-120 days after the construct conceptual design.

After conducting market and competitive research, specific moieties can then be rapidly advanced into the clinic on our own or through potential collaborations with larger companies. We are currently evaluating over a dozen moieties and intend to announce additional clinical product candidates in the second half of 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.

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.

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

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

Immuno-Oncology Product Candidates

Our most advanced bi-specific ADC, GTB-1550, which targets CD19+ and/or CD22+ hematological malignancies, is in the Phase 2 component of a Phase 1/2 Non-Hodgins Lymphoma (NHL)/Acute Lymphocytic Leukemia (ALL) trial which is an open-label, investigator-led study. We are initially targeting certain hematologic malignancies as we believe our product candidates may have certain advantages over existing and other in-development products.

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

Our TetraKE product candidates are single-chain fusion proteins composed of human single-domain anti-CD16 antibody, wild-type IL-15 and the variable regions of the heavy and light chains of two antibodies that are designed to target two specific tumor antigens expressed on specific types of cancer cells. An example of a TetraKE product candidate is GTB-1615 which is designed to target EpCAM and CD133 positive solid tumors. EpCAM is found on many solid tumor cells of epithelial origin and CD133 is a marker for cancer stem cells. GTB-1615 is designed to enable a patient's NK cells to kill not only the heterogeneous population of cancer cells found in many solid tumors but also kill the cancer stem cells that can be responsible for recurrences.

GTB-1550

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

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

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

GTB-3550

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

The GTB-3550 IND will focus on AML, 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 believe GTB-3550 could serve as a relatively safe, cost-effective, and easy-to-use therapy for resistant/relapsing AML and could also be combined with chemotherapy as frontline therapy thus targeting the larger market.

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

GTB-C3550

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

GTB-1615

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

Central Nervous System

Our CNS portfolio consists of in-process R&D ("IPR&D") assets acquired in connection with the acquisition of Georgetown Translational Pharmaceuticals ("GTP") on September 1, 2017, consisting of innovative reformulations and/or repurposing of existing therapies. These CNS assets address disease states such as chronic neuropathic pain (product candidate PainBrake, utilizing AccuBreak technology), myasthenia gravis (product candidate GTP-004) and motion sickness (product candidate GTP-011).

In the 3rd quarter of 2018, the Company experienced changes in key senior management, led by the appointment of a CEO with extensive experience in oncology drug development. These changes resulted in the prioritization of immuno-oncology development candidates relative to the CNS development candidates acquired from Georgetown Translational Pharmaceuticals. In conjunction with these strategic changes, limited internal resources have delayed the development of the CNS IPR&D assets. The limited resources, changes in senior leadership, and favorable market conditions for immuno-oncology development candidates have resulted in the Company choosing to focus on development of its immuno-oncology portfolio. We are assessing our options to realize value from the CNS IPR&D assets.

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, GTB-1550, in specific indications with a high unmet-medical need such as patients who are resistant or refractory to conventional treatment and also assess fast-to- market strategies in potential orphan indications

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

A Phase 1/2 trial of GTB-1550 in 18 patients was recently completed in patients with ALL/NHL. The FDA-approved clinical trial was conducted at the University of Minnesota's Masonic Cancer Center. The data is currently being analyzed. We expect to submit data from this Phase 1/2 study for presentation/publication.

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), GTB-3550 and GTB-C3550

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

GTB-C3550 contains a humanized single-domain anti-CD16 moiety which demonstrated improved binding characteristics and enhanced tumor cell killing based on functional assays and animal models of AML.

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

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

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

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

We are currently evaluating over a dozen moieties and intend to announce additional clinical product candidates in the second half of 2019. Depending on the availability of drug supply, we hope to initiate human clinical testing for certain of our solid tumor product candidates in 2020.

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 IPR&D assets acquired in connection with the acquisition of GTP on September 1, 2017, consisting of innovative reformulations and/or repurposing of existing therapies. These CNS assets address disease states such as chronic neuropathic pain, myasthenia gravis and motion sickness.

In the 3rd quarter of 2018, the Company experienced changes in key senior management, led by the appointment of a CEO with extensive experience in oncology drug development. These changes resulted in the prioritization of immuno-oncology development candidates relative to the CNS development candidates acquired from Georgetown Translational Pharmaceuticals. In conjunction with these strategic changes, limited internal resources have delayed the development of the CNS IPR&D assets. The limited resources, changes in senior leadership, and favorable market conditions for immuno-oncology development candidates have resulted in the Company choosing to focus on development of its immuno-oncology portfolio.

We expect to monetize our CNS portfolio through licensing deals 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). B-cell lymphomas may be either indolent (slow- growing) or aggressive (fast-growing). Non- Hodgkin lymphoma has an incidence rate of 19.4 per 100,000 per year and B-cell lymphomas make up most (about 85%) of NHL in the United States. There are many different types of B-cell non- Hodgkin lymphomas. These include Burkitt lymphoma, chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL), diffuse large B-cell lymphoma, follicular lymphoma, and mantle cell lymphoma.

Acute Lymphoblastic Leukemia

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

It is estimated that there will be 5,930 new cases of ALL reported in the United States in 2019 (ACS Cancer Facts & Figures 2019). "Acute" is defined by the World Health Organization standards, in which greater than 20% of the cells in the bone marrow are blasts. Chronic lymphocytic leukemia is defined as having less than 20% blasts in the bone marrow. Acute lymphoblastic leukemia is seen in both children and adults; the highest incidence is seen between ages 2 to 3 years (>90 cases per 1 million per year). ALL is the most common cancer diagnosed in children and represents approximately 25% of cancer diagnoses among children younger than 15 years. Among children with ALL, approximately 98% attain remission, and approximately 85% of patients aged 1 to 18 years with newly diagnosed ALL treated on current regimens are expected to be long-term event-free survivors, with over 90% surviving at 5 years.

Multiple Myeloma

Multiple myeloma is a type of cancer that forms in white blood cells and will affect an estimated 32,110 people in 2019 in the U.S. causing about 12,960 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 4.3% per 100,000 populations. The median age at the time of diagnosis is 68 years. AML is an aggressive disease and is fatal without anti-leukemic treatment. AML is the most common form of adult leukemia with an estimated 21,450 new cases in 2019 in the U.S. These patients will require frontline therapy, usually chemotherapy including cytarabine and an anthracycline, a therapy that has not changed in over 40 years. Myelodysplastic syndromes (MDS) are a heterogeneous group of myeloid neoplasms characterized by dysplastic features of erythroid/myeloid/megakaryocytic lineages, progressive bone marrow failure, a varying percentage of blast cells, and enhanced risk to evolve into acute myeloid leukemia. It is estimated that over 10,000 new cases of MDS are diagnosed each year and there are minimal treatment options; other estimates have put this number higher. In addition, the incidence of MDS is rising for unknown reasons.

Solid Tumors

In the United States, in 2019, it is estimated there will be approximately 1,762,450 new cases of cancer resulting in 606,880 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 2019)

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 2019 are (these statistics include both adults and children): about 12,750 new soft tissue sarcomas will be diagnosed (7,240 cases in males and 5,510 cases in females). 5,270 Americans (2,840 males and 2,430 females) are expected to die of soft tissue sarcomas. The most common types of sarcoma in adults are undifferentiatedpleomorphic sarcoma (previously called malignant fibrous histiocytoma), liposarcoma, and leiomyosarcoma. Certain types occur more often in certain areas of the body than others. For example, leiomyosarcomas are the most common abdominal sarcoma, while liposarcomas and undifferentiated pleomorphic sarcoma are most common in legs. But pathologists (doctors who specialize in diagnosing cancers by how they look under the microscope), may not always agree on the exact type of sarcoma. Sarcomas of uncertain type are very common. (American Cancer Society, Cancer Facts & Figures 2019)

Manufacturing

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

Patents and Trademarks

Immuno-oncology platform

University of Minnesota License Agreement

We (through our wholly owned subsidiary Oxis Biotech, Inc.) are party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, to further develop and commercialize cancer therapies using TriKE technology developed by researchers at the university to target NK cells to cancer. Under the terms of the agreement, we receive exclusive rights to conduct research and to develop, make, use, sell, and import TriKE technology worldwide for the treatment of any disease, state or condition in humans. We shall be responsible for obtaining all permits, licenses, authorizations, registrations and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as the TriKE technology, including without limitation the FDA in the United States and the European Agency for the Evaluation of Medicinal Products in the European Union. Under the agreement, the University of Minnesota will receive an upfront license fee, royalty fees ranging from 4% to 6%, minimum annual royalty payments of $250,000 beginning in 2022, $2,000,000 in 2025, and $5,000,000 in 2027 and certain milestone payments totaling $3,100,000.

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 componds 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 (GTB-1550), a novel therapy for the treatment of various human cancers. Under the terms of the agreement, we receive exclusive rightsto 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 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

Central Nervous System

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

Employees

As of December 31, 2018, we had three employees. Many of our activities are outsourced to consultants who provide services to us on a project basis. As business activities require and capital resources permit, we will hire additional employees to fulfill our company's needs.

Form and Year of Organization

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

Legal Proceedings

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

MANAGEMENT

The following table sets forth the name, age and position held by each of our executive officers and directors as of June 15, 2019. Directors are elected for a period of one year and thereafter serve until the next annual meeting at which their successors are duly elected by the stockholders.

Name	Age	Position
Anthony J. Cataldo	67	Chief Executive Officer and Chairman of the Board
Steven Weldon	43	Chief Financial Officer, Principal Accounting Officer and Director

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

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

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

Code of Ethics

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors, and persons who own more than 10% of a registered class of the company's equity securities, to file reports of ownership and changes in ownership with the Securities and Exchange Commission ("SEC"). Executive officers, directors and greater than 10% stockholders are required by SEC regulations to furnish the company with copies of all Section 16(a) forms they file. All of our executive officers and directors filed the required reports; however, Kathleen Clarence-Smith and Raymond Urbanski filed one Form 3 late and Raymond Urbanski, Anthony J. Cataldo and Steven Weldon each filed one Form 4 late.

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, 2018 and 2017 of all persons who served as our principal executive officers and as our principal financial officer during the fiscal year ended December 31, 2018. No other executive officers received total annual compensation during the fiscal year ended December 31, 2018 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 ($) (1)	All Other Compensation ($) (2)	Total ($)
Anthony J. Cataldo	2018	-	-	-	404,151	404,151
CEO (6)	2017	310,667	90,000	77,275,253	-	77,675,920
Steven Weldon	2018	230,000	-	-	-	230,000
CFO (5)	2017	245,333	-	38,472,797	-	38,718,130
Raymond Urbanski, M.D.	2018	321,154	-	7,644,490	-	7,965,644
Former CEO (3)	2017	133,333	-	7,644,490	-	7,777,823
Shawn Cross	2018	233,942	20,000	-	-	253,942
Former CEO (4)	2017	104,165	-	-	-	104,165
Kathleen Clarence-Smith	2018	278,846	-	-	-	278,846
Former CEO (7)	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) The amount in this column represents compensation earned under Consultant Agreements with the Company.

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

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

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

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

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

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

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

Stock Option Grants

The following table sets forth information as of December 31, 2018, concerning unexercised options, unvested stock and equity incentive plan awards for the executive officers named in the Summary Compensation Table.

Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Steven Weldon	-	-	-	$ -	
Anthony Cataldo	358	-	-	$ 750	2019-7-1
Anthony Cataldo	358	-	-	$ 1,500	2019-7-1
Anthony Cataldo	358	-	-	$ 2,250	2019-7-1

Director Compensation

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

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)	Stock Awards ($)	Total ($)
Dr. John Bonfiglio (1)	$ -	$ -	$ -	$ -
Dr. Peter Kiener (1)	$ 8,173	$ -	$ -	$ 8,173
Geoffrey Davis (1)	$ 26,250	$ -	$ -	$ 26,250
Anthony Cataldo	$ -	$ -	$ -	$ -
Federica O'Brien (2)	$ 8,173	$ -	$ -	$ 8,173

(1) Dr. Bonfiglio, Dr. Kiener and Mr. Davis resigned from the Board on March 20, 2019
(2) Ms. O'Brien resigned from the Board on July 2, 2018

VOTING SECURITIES AND PRINCIPAL HOLDERS

The following table sets forth certain information regarding beneficial ownership of our common stock as of June 16, 2019, (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 ofJune 16, 2019, there were 51,374,417 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 June 16, 2019 are deemed to be outstanding for purposes of computing the percentage ownership of that person but are not treated as outstanding for computing the percentage ownership of any other person. Unless indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable. Except as otherwise indicated, the address of each stockholder is c/o GT Biopharma, Inc. at 310 N. Westlake Blvd., Suite 206, Westlake Village, CA 91362.

Name and Address of Beneficial Owner	Number of Shares of Common Stock Benefically Owned	Percent of Shares of Outstanding Common Stock
Security Ownership of Certain Beneficial Owners:		
Kathleen Clarence-Smith, M.D., Ph.D. (7)	7,521,051	14.66%
Mark Silverman (7)	7,226,108	14.09%
William Heavener (1)	4,674,749	9.11%
Bristol Investment Fund, Ltd. (2)	4,534,795	8.84%
Adam Kasower (3)	3,645,620	7.11%
Theorem Group, LLC (4)	3,540,130	6.90%
Alpha Capital Anstalt (5)	2,966,667	5.78%
The Rosalinde and Arthur Gilbert Foundation (6)	2,739,267	5.34%
Security Ownership of Management and Directors:		
Anthony J. Cataldo (7)	3,734,320	7.28%
Steven Weldon (7)	2,269,707	4.43%
Executive officers and directors as a group — 2 people	6,004,027	11.71%

(1) As reported on Schedule 13G/A filed with the SEC on February 5, 2019. The address of William Heavener is 3300 University Blvd, Suite 218, Winter Park, FL 32792

(2) As reported on Schedule 13G/A filed with the SEC on February 12, 2019. 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.

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

(4) 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

(5) As reported on Schedule 13G filed with the SEC on February 13, 2019. The address of Alpha Capital Anstalt is Lettstrasse 32, FL-9490 Vaduz, Furstentums, Liechtenstein

(6) Includes 2,655,205 shares issuable upon conversion of principal on outstanding convertible debentures and 84,062 shares available through exercise of warrants

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

Equity Compensation Plan Information

The following is a summary of our equity compensation plans at December 31, 2018:

Plan Category	Number of Securities To be Issued Upon Exercise of Outstanding Options, Warrants, and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants, and Rights (b)	Number of Securities Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a)) (c)
Equity compensation plans approved by security holders (1)	1,113	$ 1,320	-
Equity compensation plans not approved by security holders	-	$ -	-
Total	1,113	$ 1,320	-

(1) As of December 31, 2018, we had options issued and outstanding to purchase 1,113 shares of common stock under our 2014 Stock Incentive Plan.

SELLING STOCKHOLDERS

This prospectus relates in part to our registering the resale of 40,216,064 shares of common stock of the Company by Selling Stockholders who may acquire such shares upon the conversion of notes and Series J-1 Preferred Stock. There can be no assurance that the Selling Stockholders will sell any or all of their common stock offered by this prospectus. We do not know if, when, or in what amounts, the selling stockholders may offer the common stock for sale.

Selling Stockholders

The following table sets forth:

- the names of the Selling Stockholders;
- the number of shares of common stock that can be acquired by each of the Selling Stockholders through the conversion of notes and preferred stock before the offering;
- the number of shares of common stock being registered with respect to each Selling Stockholder;
- the number of shares of common stock owned by each of the Selling Stockholders after the offering assuming all notes and applicable shares of preferred stock are converted and all common shares acquired are sold; and
- the person with voting or investment control if the stockholder is not a natural person.

As of June 14, 2019, there were 51,374,417 shares of common stock outstanding. To the extent that any successor(s) to the named selling stockholder(s) wish to sell under this prospectus, we will file a prospectus supplement identifying such successors as selling stockholders.

Selling Stockholders	Shares Acquireable upon Conversion of Notes and Preferred Stock	Shares Being Registered	Shares Owned After the Offering Assuming all Notes and Preferred Stock are Converted and all Shares Sold	Person with Voting or Investment Control
Bristol Investment Fund, Ltd.	6,312,245	6,312,243	4,447,689	Paul Kessler
Bristol Capital LLC	4,500,926	4,500,926	*	Paul Kessler
James Heavener	5,218,013	5,218,013	3,892,882	
Adam Kasower	2,140,229	2,140,229	1,091,664	
Red Mango Enterprises Limited	2,388,486	2,388,486	1,365,180	Chris Parker
Alpha Capital Anstalt	3,406,667	3,406,667	*	Nicola Feuerstein
The Rosalinde and Arthur Gilbert Foundation	4,639,828	4,639,828	2,360,565	Martin H. Blank
Hewlett Fund LP	1,341,905	1,341,905	*	Martin Chopp
Clearview Bio LLC	1,277,500	1,277,500	*	Tisno Onggara
Brio Capital Master Fund, Ltd	1,008,810	1,008,810	*	Shaye Hirsch
Jeffrey Bronfman Revocable Living Trust	851,950	851,950	*	Jeffrey Bronfman
Robert H. Lipp Separate Property Trust	938,643	938,643	*	Robert H. Lipp
The RSZ Trust	1,778,798	1,778,798	*	Richard Ziman
Diane S. Lipp Separate Property Trust	173,656	173,656	*	Diane S. Lipp
Lipp Irrevocable Trust	173,656	173,656	*	Diane S. Lipp
Martin H. Blank and Linda M. Blank Rev Trust	135,548	135,548	*	Martin H. Blank
The Runnels Family Trust DTD 1-11-2000	1,296,429	1,296,429	*	G. Tyler Runnels
District 2 Capital Fund LP	1,294,524	1,294,524	*	Eric J. Schlanger
Michael Breen	259,286	259,286	*	
Greg Suess	259,286	259,286	*	
Jeff Bronfman Revocable Living Trust	505,381	505,381	*	Jeffrey Bronfman
Contreras Family Trust	314,286	314,286	*	

*It is unknown to the Company whether the Selling Stockholder holds shares other than those being registered.

PLAN OF DISTRIBUTION

We are registering 40,216,064 shares of our common stock for possible sale by the selling stockholders.

We will not receive any of the proceeds from the sale by the selling stockholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

The selling stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of common stock are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of common stock may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the- counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- sales pursuant to Rule 144;
- broker-dealers may agree with the selling security holders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If the selling stockholders effect such transactions by selling shares of common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of common stock for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of the shares of common stock or otherwise, the selling stockholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of the shares of common stock in the course of hedging in positions they assume. The selling stockholders may also sell shares of common stock short and deliver shares of common stock covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling stockholders may also loan or pledge shares of common stock to broker-dealers that in turn may sell such shares.

The selling stockholders may pledge or grant a security interest in some or all of the senior convertible notes, warrants or shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of the shares of common stock is made, a prospectus supplement, if required, willbe distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling stockholders and any discounts, commissions or concessions allowed or reallowed or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that any selling stockholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling stockholders and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing ofpurchases and sales of any of the shares of common stock by the selling stockholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will pay all expenses of the registration of the shares of common stock pursuant to the registration rights agreement, including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with state securities or “blue sky” laws; provided, however, that a selling stockholder will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling stockholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreements, or the selling stockholders will be entitled to contribution. We may be indemnified by the selling stockholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling stockholder specifically for use in this prospectus, in accordance with the related registration rights agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock, together with any additional information we include in any applicable prospectus supplement or any related free writing prospectus, summarizes the material terms and provisions of our common stock. For the complete terms of our common stock, please refer to our amended andrestated certificate of incorporation, the and our amended and restated bylaws that are incorporated by reference into the registration statement of which this prospectus is a part or may be incorporated by reference in this prospectus or any applicable prospectus supplement. The terms of these securities may also be affected by Delaware General Corporation Law. The summary below and that contained in any applicable prospectus supplement or any related free writing prospectus are qualified in their entirety by reference to our amended and restated certificate of incorporation and our amended and restated bylaws.

General

As of the date of this Prospectus, our authorized capital stock consists of 750,000,000 shares of common stock, par value $0.001 per share, and 15,000,000 shares of preferred stock, par value $0.001 per share. As of June 15, 2019, there were approximately 51.3 million shares of our common stock issued and outstanding.

Common Stock

Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by our board of directors out of legally available funds, subject to any preferential dividend rights of any preferred stock then outstanding. In the event of our dissolution, liquidation or winding up, holders of our common stock are entitled to share ratably in our net assets legally available after the payment of all of our debts and other liabilities, subject to the liquidation preferences of any preferred stock then outstanding. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock that we may designate and issue in the future. All outstanding shares of our common stock are fully paid and nonassessable. Except as described below in “Anti-Takeover Provisions Under Our Charter and Bylaws and Delaware Law,” a majority vote of common stockholders is generally required to take action under our amended and restated certificate of incorporation and amended and restated bylaws.

Anti-Takeover Provisions Under Our Charter and Bylaws and Delaware Law

Certain provisions of Delaware law, our amended and restated certificate of incorporation and our bylaws contain provisions that could have the effect of delaying, deferring or discouraging another party from acquiring control of us. These provisions, which are summarized below, may have the effect of discouraging coercive takeover practices and inadequate takeover bids. These provisions are also designed, in part, to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with an unfriendly or unsolicited acquirer outweigh the disadvantages of discouraging a proposal to acquire us because negotiation of these proposals could result in an improvement of their terms.

Amended and Restated Certificate of Incorporation

Undesignated Preferred Stock. Our board of directors has the ability to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Special Meetings of Stockholders. Our bylaws provide that special meetings of our stockholders may be called only by our chairman of the board, our president or our board of directors, thus prohibiting a stockholder from calling a special meeting. This provision might delay the ability of our stockholders to force consideration of a proposal or for stockholders controlling a majority of our capital stock to take any action, including the removal of directors.

Board Vacancies Filled Only by Majority of Directors. Vacancies and newly created seats on our board may be filled only by a majority of the directors then in office. Only our board of directors may determine the number of directors on our board. The inability of stockholders to determine the number of directors or to fill vacancies or newly created seats on our board of directors makes it more difficult to change the composition of our board of directors, but these provisions promote a continuity of existing management.

No Cumulative Voting. The Delaware General Corporation Law, or DGCL, provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless our amended and restated certificate of incorporation provides otherwise. Our amended and restated certificate of incorporation and bylaws do not expressly provide for cumulative voting.

Directors Removed Only by Special Meeting of Stockholders. A director can be removed only by the affirmative vote of a majority of the votes of the issued and outstanding stock entitled to vote for the election of directors of the corporation given at a special meeting of the stockholders called and held for this purpose.

Amendment of Charter Provisions. In order to amend certain of the above provisions in our amended and restated certificate of incorporation and our bylaws, the board of directors is expressly authorized to adopt, alter or repeal the bylaws, subject to the rights of the stockholders entitled to vote. Stockholders can vote at any stockholder meeting and repeal, alter, or amend the bylaws by the affirmative vote of a majority of the stockholders entitled to vote in such meeting.

Delaware Anti-takeover Statute

We are subject to Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interest stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales and other transactions in which the interested stockholder receives or could receive a financial benefit on other than a *pro rata* basis with other stockholders. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's outstanding voting stock. This provision has an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging takeover attempts that might result in a premium over the market price for the shares of our market price. With approval of our stockholders, we could amend our amended and restated certificate of incorporation in the future to avoid the restrictions imposed by this anti-takeover law.

The provisions of Delaware law and our amended and restated certificate of incorporation could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Transfer Agent and Registrar

Our transfer agent and registrar for our capital stock is ComputerShare. The transfer agent's address is 350 Indiana Street, Golden, Colorado 80401, and its telephone number is (303) 262-0600.

Listing

Our common stock is listed on the OTCQB under the symbol "GTBP." The last reported sale price of our common stock on the OTCQB on June 14, 2019, was $0.29 per share. 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).

LEGAL MATTERS

Certain legal matters in connection with this offering will be passed upon for us by Gary R. Henrie, Attorney at Law, Nauvoo, Illinois. These legal matters include that shares of common stock to be sold by the Selling Shareholders are validly issued, fully paid and non-assessable. Mr. Henrie's address is P.O. Box 107, 315 Kimball's Garden Circle, Nauvoo, IL 62354. Mr. Henrie is licensed to practice law in the states of Nevada and Utah.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is therefore unenforceable**.**

EXPERTS

The consolidated financial statements, and the related financial statement schedule, incorporated in this Prospectus by reference to our Annual Report on Form 10-K have been audited by Seligson & Giannattasio, LLP, an independent registered public accounting firm, as stated in their report, which is incorporated herein by reference. Such financial statements and financial statement schedule have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 under the Securities Act with the Securities and Exchange Commission with respect to the sale or resale of an aggregate of 40,216,064 shares of common stock. This prospectus was filed as a part of that registration statement but does not contain all of the information contained in the registration statement and exhibits. Reference is thus made to the omitted information. Statements made in this prospectus are summaries of the material terms of contracts, agreements and documents and are not necessarily complete; however, all information we considered material has been disclosed. Reference is made to each exhibit for a more complete description of the matters involved and these statements are qualified in their entirety by the reference. You may inspect the registration statement, exhibits and schedules filed with the Securities and Exchange Commission at the Securities and Exchange Commission's principle office in Washington, D.C. Copies of all or any part of the registration statement may be obtained from the Public Reference Section of the Securities and Exchange Commission, 100 F. Street, N.E., Washington, D.C. 20549. The Securities and Exchange Commission also maintains a web site (http://www.sec.gov) that contains this filed registration statement, reports, proxy statements and information regarding us that we have filed electronically with the Commission. For more information pertaining to our company and the sale or resale of an aggregate of 40,216,064 shares of common stock, reference is made to the registration statement.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

GT Biopharma, Inc. and Subsidiaries
as of March 31,2019 and December 31, 2018
Consolidated Balance Sheets
(in Thousands, Except Par Value and Share Data)

	March 31, 2019	December 31, 2018
ASSETS	(unaudited)	
Current Assets:		
Cash and cash equivalents	$ 51	$ 60
Prepaid expenses	27	30
Total Current Assets	78	90
Intangible assets	25,262	25,262
Deposits	12	12
Operating lease right-to-use asset	153	-
Fixed assets, net	34	35
Total Other Assets	25,461	25,309
TOTAL ASSETS	$ 25,539	$ 25,399
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,898	$ 1,762
Accrued expenses	2,136	1,455
Deferred rent	-	8
Operating lease liability	161	-
Note payable to related party	-	100
Line of credit	31	31
Convertible debentures	11,297	10,673
Total Current Liabilities	15,523	14,029
Total liabilities	15,523	14,029
Stockholders' Equity:		
Convertible preferred stock - $0.001 par value; 15,000,000 shares authorized:		
Series C - 96,230 and 96,230 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	1	1
Series J – 1,163,548 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	1	1
Common stock - $0.001 par value; 750,000,000 shares authorized; and 51,374,417and 50,650,478 shares issued and outstanding at March 31, 2019 and December 31, 2018, respectively	51	51
Additional paid-in capital	543,327	540,171
Accumulated deficit	(533,195)	(528,685)
Noncontrolling interest	(169)	(169)
Total Stockholders' Equity	10,016	11,370
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 25,539	$ 25,399

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

GT Biopharma, Inc. and Subsidiaries
March 31, 2019 and 2018
Statements of Operations
(in Thousands, Except per Share Data)

	March 31,	
	2019	**2018**
Revenue:	(unaudited)	(unaudited)
License revenues	$ -	$ -
TOTAL REVENUE	-	-
Cost of License Revenue	-	-
Gross profit	-	-
Operating Expenses:		
Research and development	834	3,473
Selling, general and administrative	3,222	3,687
Total operating expenses	4,056	7,160
Loss from Operations	(4,056)	(7,160)
Other income (expense)		
Interest expense/income	(454)	(2,931)
Total Other Income (Expense)	(454)	(2,931)
Loss before minority interest and provision for income taxes	(4,510)	(10,091)
Less: Loss attributable to the noncontrolling interests	-	-
Loss before provision for income taxes	(4,510)	(10,091)
Provision for income taxes	-	-
Net loss	(4,510)	(10,091)
Loss per share		
Basic	$ (0.09)	$ (0.20)
Diluted	$ (0.09)	$ (0.20)
Weighted Average Shares Outstanding – basic and diluted		
Basic	51,092,886	50,117,977
Diluted	51,092,886	50,117,977

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

GT Biopharma, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
For the Three Months Ended March 31, 2019 and 2018
(in Thousands)

	March 31, 2019 (unaudited)	2018 (unaudited)
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (4,510)	$ (10,091)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	1	1
Stock compensation expense for options and warrants issued to employees and non-employees	2,565	3,060
Amortization of debt discounts	163	2,665
Non-cash interest expense	-	266
Amortization of loan costs	-	407
Changes in operating assets and liabilities:		
Other assets	3	-
Accounts payable and accrued liabilities	817	(534)
Net cash used in operating activities	(961)	(4,226)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of fixed assets	-	(2)
Net cash used by investing activities	0	(2)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable	1,052	7,055
Loan costs	-	(533)
Repayment of note payable	(100)	-
Net cash provided by financing activities	952	6,522
Minority interest	-	-
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(9)	2,294
CASH AND CASH EQUIVALENTS - Beginning of period	60	576
CASH AND CASH EQUIVALENTS - End of period	$ 51	$ 2,870
Supplemental disclosures:		
Interest paid	$ -	$ -
Income taxes paid	$ -	$ -
Supplemental disclosures:		
Issuance of common stock upon conversion of convertible notes	$ 430	$ -
Issuance of common stock upon conversion of accrued interest	$ 4	$ -

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
CONDENSED NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
MARCH 31, 2019

(UNAUDITED)

1. The Company and Summary of Significant Accounting Policies

Business

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

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Natural Killer (NK) cell engager (Tri-specific Killer Engager (TriKE) & Tetra-specific Killer Engager (TetraKE)) and bi-specific Antibody Drug Conjugate (bispecific-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 stimulate 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 tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization. They are designed to be dosed in an outpatient setting and are expected to have reasonably low cost of goods. Our bispecific-ADC platform can generate product candidates that are ligand-directed single-chain fusion proteins that simultaneously target two tumor antigens. We believe our bispecific-ADC moieties represents the next generation of ADCs.

Going Concern

The Company's current operations have focused on business planning, raising capital, establishing an intellectual property portfolio, hiring, and conducting preclinical studies and clinical trials. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future.

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

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of $533.3 million and cash of $51 thousand as of March 31, 2019. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: public offerings of equity and/or debt securities, payments from potential strategic research and development, and licensing and/or marketing arrangements with pharmaceutical companies. Management has also implemented cost saving efforts, including reduction in executive salaries and reduced travel. Management believes that these ongoing and planned financing endeavors, if successful, will provide adequate financial resources to continue as a going concern for at least the next six months from the date the financial statements are issued. however, there can be no assurance in this regard. If the Company is unable to secure adequate additional funding, its business, operating results, financial condition and cash flows may be materially and adversely affected.

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.

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.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U.S. (“U.S. GAAP”) and the rules and regulations of the U.S. Securities and Exchange Commission (“SEC”). Certain information and disclosures required by U.S. GAAP for complete consolidated financial statements have been condensed or omitted herein. The interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Form 10-K for the year ended December 31, 2018. The unaudited interim condensed consolidated financial information presented herein reflects all normal adjustments that are, in the opinion of management, necessary for a fair statement of the financial position, results of operations and cash flows for the periods presented. The Company is responsible for the unaudited interim consolidated financial statements included in this report. The results of operations of any interim period are not necessarily indicative of the results for the full year.

Cash and Cash Equivalents

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

Concentrations of Credit Risk

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

Stock Based Compensation to Employees

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

The Company granted no stock options during the quarters ended March 31, 2019 and 2018, respectively

Long-Lived Assets

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

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

Impairment of Long-Lived Assets

The Company's long-lived assets currently consist of indefinite lived intangible assetsassociated with IPR&D ("In-Process Research & Development") projects and related capitalized patents acquired in the acquisition of Georgetown Translational Pharmaceuticals, Inc. as described in Note 2 below. Intangible assets associated with IPR&D projects are not amortized until approval by the Food and Drug Administration (FDA) is obtained in a major market subject to certain specified conditions and management judgment. The useful life of an amortizing asset generally is determined by identifying the period in which substantially all of the cash flows are expected to be generated.

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

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

Income Taxes

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

Net Income (Loss) per Share

Basic net income (loss) per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period. Diluted net income (loss) per share is computed by dividing the net loss for the period by the weighted average number of common shares outstanding during the period, plus the potential dilutive effect of common shares issuable upon exercise or conversion of outstanding stock options and warrants during the period. The weighted average number of potentially dilutive common shares excluded from the calculation of net income (loss) per share totaled in 22,731,781 and 4,553,668 as of March 31, 2019 and 2018, respectively.

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 is 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 Black-Scholes valuation model based on observable market inputs, such as share price data and a discount rate consistent with that of a government-issued security of a similar maturity. There were not such liabilities at March 31, 2019.

- 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 $.8 million and $3.5 million for the years ended March 31, 2019 and 2018, 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. As of March 31, 2019, the Company has not generated any licensing revenue.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB") issued new guidance related to accounting for leases, Accounting Standards codification Topic 842 (ASC 842). We adopted the new guidance on January 1, 2019 using the modified retrospective approach and the optional transition method. Under this adoption method, comparative prior periods were not adjusted and continue to be reported with our historical accounting policy. The primary impact of adopting this standard was the recognition of $173 thousand in operating lease liabilities and $165 thousand in right of use assets.

2. Intangibles

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

As of September 30, 2018, the Company recorded an intangible asset impairment charge of $228.5 million related to the portfolio of CNS IPR&D assets within Operating Expenses, which represents the excess carrying value compared to fair value. The impairment charge was the result of both internal and external factors. In the 3rd quarter of 2018, the Company experienced changes in key senior management, led by the appointment of a new CEO with extensive experience in oncology drug development. These changes resulted in the prioritization of immuno-oncology development candidates relative to CNS development candidates. In conjunction with these strategic changes, limited internal resources have delayed the development of the CNS IPR&D assets. The limited resources, changes in senior leadership, and favorable market conditions for immuno-oncology development candidates have resulted in the Company choosing to focus on development of its immuno-oncology portfolio. In light of this shift in market strategy, the Company performed a commercial assessment and a valuation of the CNS IPR&D assets, both to assess fair value and support potential future licensing efforts. The valuation indicated an excess carrying value over the fair value of these assets, resulting in the impairment charge noted above.

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

3. Debt

Convertible Notes

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

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

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

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

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

Senior Convertible Debentures

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

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

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

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

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

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

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

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

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 March 31, 2019.

4. Stockholders' Equity

Common Stock

In the first quarter of 2019, the Company issued 723,940 shares of common stock upon conversion of $434,271 in principal and interest on senior convertible notes.

Preferred 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 208,224 shares of Series J Preferred Stock in exchange for the conversion of debt in the total amount of $250,000.

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.

5. Stock Options and Warrants

Stock Options

The following table summarizes stock option transactions for the quarter ended March 31, 2018:

	Number of Options	Weighted Average Exercise Price
Outstanding, December 31, 2018	1,133	$ 1,320.00
Granted	-	-
Exercised	-	-
Expired	-	-
Outstanding, March 31, 2019	1,133	$ 1,320.00
Exercisable, March 31, 2019	1,133	$ 1,320.00

Common Stock Warrants

Warrant transactions for the quarter ended March 31, 2019 are as follows:

	Number of Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2018:	1,813,053	$2.00
Granted	-	-
Forfeited	-	-
Exercised	-	-
Outstanding at March 31, 2019	1,813,053	$2.00
Exercisable at March 31, 2019	1,813,053	$2.00

6. Commitments and Contingencies

Leases

As described in *Note 1. Nature of Operations and Summary of Significant Accounting Policies*, we adopted new lease accounting guidance effective January 1, 2019.

We determine if a contractual arrangement is a lease at inception. Our lease arrangements provide the Company the right to utilize certain specified tangible assets for a period of time in exchange for consideration. Our leases primarily relate to building office space. Our leases currently consist solely of operating leases. Leases with an initial term of 12 months or less are not recorded on the balance sheet.

We recognize a lease liability and a right of use asset at the lease commencement date based on the present value of the future lease payments over the lease term discounted using our incremental borrowing rate. Implicit interest rates within our lease arrangements are rarely determinable. Right of use assets also include, if applicable, prepaid lease payments and initial direct costs, less incentives received.

We recognize operating lease expense on a straight-line basis over the term of the lease within selling general and administrative expenses.

Our leases do not contain any material residual value guarantees or material restrictive covenants. Some of our leases include optional renewal periods or termination provisions which we assess at inception to determine the term of the lease, subject to reassessment in certain circumstances.

The following table summarizes the Company's future minimumpayments under operating leases as of December 31, 2018:

Year ending December 31:	
2019	69,000
2020	71,000
2021	61,000
Total minimum lease payments	$201,000

Lease expense for the quarters ended March 31, 2019 and 2018 was $17,000 and $24,000, respectively.

Employment Agreements

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

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

8. Subsequent Events

Preferred Stock

On April 4, 2019, the Company filed a Certificate of Designation with the Office of the Secretary of State of the State of Delaware. The Certificate of Designation designated 3,000,000 shares of preferred stock as Series J-1 Preferred Stock. A copy of the Certificate of Designation detailing the rights and preferences of the stock is attached hereto as Exhibit 3.1. In the State of Delaware, the Certificate of Designation has the effect of amending the Certificate of Incorporation by adding to the Certificate of Incorporation the terms and conditions of the Designation and the stock designated.

On April 19, 2019, the Company issued a total of 2,353,548 shares of Series J-1 Preferred Stock (the "Shares") to a total of two entities. The Shares are convertible into shares of common stock of the Registrant at the rate of $0.60 per share. The issuance was exempt from the registration requirements of Section 5 of the Securities Act of 1933 pursuant to Section 4(2) of the same Act since the issuance of the Shares did not involve any public offering.

In addition, the Company entered into a letter agreement with the two entities, pursuant to which the Company has agreed toinclude the shares of common stock issuable upon full conversion of the Series J-1 Preferred Stock in the next registration statement that the Company files (the "Piggyback Registration Statement"). The Company must file the Piggyback Registration Statement on or before August 30, 2019.

Common Stock

In April 2019, the Company issued 656,181 shares of common stock upon conversion of $393,709 in principal and interest on convertible notes.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of GT Biopharma, Inc. and subsidiaries ,(the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2018, 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, 2018 and 2017 and the consolidated results of its operations and its consolidated cash flows for each of the years in the two-year period ended December 31, 2018, 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 29, 2019

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

	December 31, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 60	$ 576
Prepaid expenses	30	-
Total Current Assets	90	576
Intangible assets	25,262	253,777
Deposits	12	9
Fixed assets, net	35	6
Total Other Assets	25,309	253,792
TOTAL ASSETS	$ 25,399	$ 254,368
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,762	$ 2,546
Accrued expenses	1,455	102
Line of credit	31	31
Note Payable to Related Party	100	-
Deferred Rent	8	-
Convertible debentures	10,673	-
Total Current Liabilities	14,029	2,679
Total liabilities	14,029	2,679
Stockholders' Equity:		
Convertible preferred stock - $0.001 par value; 15,000,000 shares authorized:		
Series C - 96,230 and 96,230 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	1	1
Series J – 1,163,548 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	1	1
Common stock - $0.001 par value; 750,000,000 shares authorized; and 50,650,478 and 50,117,977 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	51	50
Additional paid-in capital	540,171	521,305
Accumulated deficit	(528,685)	(269,499)
Noncontrolling interest	(169)	(169)
Total Stockholders' Equity	11,370	251,689
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 25,399	$ 254,368

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

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

	December 31	
	2018	**2017**
Operating expenses:		
Research and development	$ 9,067	$ 1,068
Selling, general and administrative expenses	12,487	134,502
Loss on impairment	228,515	-
Total operating expenses	250,069	135,570
Loss from operations	(250,069)	(135,570)
Other income (expense):		
Interest expense	(9,117)	(8,602)
Total other income (expense)	(9,117)	(8,602)
Loss before provision for income taxes	(259,186)	(144,172)
Provision for income tax	-	-
Net loss	$ (259,186)	$ (144,172)
Net loss per common share – basic and diluted	$ (5.16)	$ (8.60)
Weighted average common shares outstanding – basic and diluted	50,240	16,769

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

GT Biopharma, Inc. and Subsidiaries
Consolidated Statement of Stockholders' Equity
For the Years Ended December 31, 2018 and 2017
(in thousands)

	Preferred Shares		Common Shares		Additional Paid-in	Accumulated
	Shares	Amount	Shares	Amount	Capital	Deficit
Balance at December 31, 2016	**1,788**	**$ 2**	**104**	**$ 0**	**$ 105,891**	**$ (124,649)**
Issuance of common stock for acquisition			16,928	17	253,901	
Issuance of common and preferred stock for convertible notes and interest	909	1	17,678	18	25,254	
Issuance of common and preferred stock for warrants	5	0	497	0	5,819	
Issuance of common for preferred stock	(2,042)	(2)	5,678	6	(4)	
Issuance of common and preferred stock for compensation	600	1	9,233	9	129,766	
Change in accounting method for debt and warrants					678	(678)
Net loss						(144,172)
Balance at December 31, 2017	**1,260**	**$ 2**	**50,118**	**$ 50**	**$ 521,305**	**$ (269,499)**
Issuance of warrants					8,304	
Issuance of common stock for convertible notes			162	0	325	
Beneficial conversion feature on convertible notes					544	
Issuance of common stock for compensation			370	1	9,693	
Net loss						(259,186)
Balance at December 31, 2018	**1,260**	**$ 2**	**50,650**	**$ 51**	**$ 540,171**	**$ (528,685)**

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

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

	Twelve Months Ended December 31,	
	2018	**2017**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (259,186)	$ (144,172)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	7	2
Loss on impairment of long-lived assets	228,515	-
Stock compensation expense for options and warrants issued to employees and non-employees	9,696	130,124
Amortization of debt discounts	8,663	4,914
Note Allonge	-	100
Non-cash interest expense	441	2,197
Amortization of loan costs	1,076	-
Changes in operating assets and liabilities:		
Prepaid Expenses	(30)	-
Other assets	(3)	(7)
Other liabilities	8	
Accounts payable and accrued liabilities	136	1,412
Net cash used in operating activities	(10,677)	(5,430)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Acquisition of fixed assets	(36)	(4)
Net cash used by investing activities	(36)	(4)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from notes payable	15,145	5,991
Loan costs	(533)	-
Repayment of note payable	(4,415)	-
Net cash provided by financing activities	10,197	5,991
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(516)	557
CASH AND CASH EQUIVALENTS - Beginning of period	576	19
CASH AND CASH EQUIVALENTS - End of period	$ 60	$ 576
Supplemental cash flow disclosures:		
Issuance of common stock upon conversion of convertible notes	$ 325	$ -
Acquisition of intangibles through issuance of common stock	$ -	$ 253,777
Issuance of common stock for interest expense	$ -	$ 5,179
Issuance of common stock for debt	$ -	$ 19,166

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

1. The Company

Business

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

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Natural Killer (NK) cell engager (Tri-specific Killer Engager (TriKE) & Tetra-specific Killer Engager (TetraKE)) and bi-specific Antibody Drug Conjugate (bispecific-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 an NK cell, our moieties are designed to stimulate 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 tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization. They are designed to be dosed in an outpatient setting and are expected to have reasonably low cost of goods. Our bispecific-ADC platform can generate product candidates that are ligand-directed single-chain fusion proteins that simultaneously target two tumor antigens. We believe our bispecific-ADC moieties represents the next generation of ADCs.

Also, in connection with the acquisition of Georgetown Translational Pharmaceuticals on September 1, 2017, we acquired a portfolio of IPR&D CNS assets consisting of innovative reformulations and/or repurposing of existing therapies. These CNS assets address disease states such as chronic neuropathic pain, myasthenia gravis and motion sickness.

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.

Going Concern

As shown in the accompanying consolidated financial statements, the Company has incurred an accumulated deficit of $528,685,000 through December 31, 2018. On a consolidated basis, the Company had cash and cash equivalents of $60,000 at December 31, 2018. 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.

Use of Estimates

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

Segment Information

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

2. Summary of Significant Accounting Policies

Advertising and promotional fees

Advertising expenses consist primarily of costs incurred in the design, development, and printing of Company literature and marketing materials. The Company expenses all advertising expenditures as incurred. There were no advertising expenses for the years ended December 31, 2018 and 2017, respectively.

Cash and Cash Equivalents

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

Concentrations of Credit Risk

The Company's cash and cash equivalents, marketable securities and accounts receivable are monitored for exposure to concentrations of credit risk. The Company maintains substantially all of its cash balances in a limited number of financial institutions. The balances are each insured by the Federal Deposit Insurance Corporation up to $250,000. The Company had no balances in excess of this limit at December 31, 2018.

Stock Based Compensation to Employees

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

The Company granted no stock options during the years ended December 31, 2018 and 2017, respectively.

Long-Lived Assets

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

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

Impairment of Long-Lived Assets

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

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

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

Income Taxes

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

Net Income (Loss) per Share

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

The computation of basic and diluted net loss per share for the years ended December 31, 2018 and 2017 excludes the common stock equivalents of the following potentially dilutive securities because their inclusion would be anti-dilutive:

	December 31,	
	2018	2017
Exercise of common stock warrants	1,813,053	-
Conversion of preferred stock into common stock	1,163,659	1,163,659
Conversion of convertible debentures into common stock	5,704,543	-
Exercise of common stock options	1,113	1,246
	8,682,368	1,164,905

Patents

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

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

Fixed Assets

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

Fair Value

The carrying amounts reported in the balance sheets for 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 Black-Scholes valuation model based on observable market inputs, such as share price data and a discount rate consistent with that of a government-issued security of a similar maturity. There were no such liabilities at December 31, 2018.

- 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 totaled $9.1 million and $1.1 million for the years ended December 31, 2018 and 2017, respectively. Research and development costs for the year ended December 31, 2018 included non-cash compensation of $6.8 million.

Recently Issued Accounting 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, 2018, the Company's undiscounted future minimum payments outstanding for lease obligations (including those currently included as capital lease obligations) were approximately $200,878.

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 adopted the standard using the modified retrospective approach beginning January 1, 2018. Adoption of this ASU did not have a significant impact on the Company's consolidated financial position, results of operations and cash flows.

3. Intangibles

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

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

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

4. Debt

Convertible Notes

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

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

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

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

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

Senior Convertible Debentures

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

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

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

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

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, 2018.

5. Accrued Expenses

Accrued Expenses are comprised of the following:

	December 31,	
	2018	**2017**
Research & Development	585,000	-
Accrued Interest	432,000	-
Professional Fees	162,000	62,000
Consulting and Advisory Services	161,000	-
Board of Directors Service Costs	94,000	-
Payroll and Benefits	21,000	39,000
Accrued Expenses	**1,455,000**	**101,000**

6. Related Party Transactions

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

7. Stockholders' Equity

Stock Split

In July 2017, the Company approved a one for three hundred reverse stock split.

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

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 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.

During the quarter ended September 30, 2018, the Company issued 110,000 shares of common stock upon conversion of $220,000 of senior convertible notes.

During the quarter ended December 31, 2018, the Company issued 52,500 shares of common stock upon conversion of $105,000 of senior convertible notes.

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

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, 2018.

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.

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:

a. 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.
b. 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.
c. 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, 2018 and 2017 are as follows:

	Number of Warrants	Weighted-Average Exercise Price
Outstanding, December 31, 2016	15,550	135.00
Granted	486,351	15.00
Exercised	(501,901)	15.00
Expired	-	-
Outstanding, December 31, 2017	-	-
Granted	1,813,053	2.00
Exercised	-	
Expired	-	
Outstanding, December 31, 2018	1,813,053	2.00
Exercisable Warrants:		
December 31, 2018	1,813,053	2.00
December 31, 2017	-	-

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, 2018, 87 shares of common stock were available for grant and options to purchase 1,246 shares of common stock are outstanding under the 2014 Plan.

The following table summarizes stock option transactions for the years ended December 31, 2018 and 2017:

	Number of Options	Weighted-Average Exercise Price
Outstanding, December 31, 2016	1,246	1,320.00
Granted	-	-
Exercised	-	-
Expired	-	-
Outstanding, December 31, 2017	1,246	1,320.00
Granted	-	-
Exercised	-	-
Expired	(133)	1,020.00
Outstanding, December 31, 2018	1,113	1,320.00
Exercisable Options:		
December 31, 2018	1,113	1,320.00
December 31, 2017	1,246	1,428.00

The weighted-average fair value of options granted was approximately $1,469,000 and $1,780,000 for 2018 and 2017, respectively.

The following table summarizes information about all outstanding and exercisable stock options at December 31, 2018:

	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	1,113	0.49	$ 1,320.00	1,113	$ 1,320.00

8. Income Taxes

Deferred Taxes

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

	December 31,	
	2018	2017
Deferred tax assets:		
Federal net operating loss carryforward	25,306,000	15,949,000
Intellectual Property	61,787,000	
Accrued Interest	129,000	-
Patent amortization	5,000	6,000
Deferred tax asseets before valuation	87,227,000	15,955,000
Valuation allowance	(87,227,000)	(15,955,000)
Net deferred income tax assets	-	-

Generally accepted accounting principles requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is “more likely than not.” Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's history of operating losses, management has provided a valuation allowance equal to its net deferred tax assets. The valuation allowance increased by approximately $71,270,000 during the year ended December 31, 2018.

Tax Carryforward

At December 31, 2018, the Company had net operating loss carryforwards of approximately $84,354,000 to reduce United States federal taxable income in future years. These carryforwards expire from 2019 through 2038.

The Company is no longer subject to U.S. and state tax examinations for years ending before the fiscal year ended December 31, 2014. 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, 2018 and 2017.

9. Commitments and Contingencies

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

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

Leases

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

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

The following table summarizes the Company's future minimum lease commitments as of December 31, 2018 (in thousands):

Year ending December 31:	
2019	69,000
2020	71,000
2021	61,000
Total minimum lease payments	201,000

Rent expense for the years ended December 31, 2018 and 2017 was $69,000 and $9,000, respectively.

Employment Agreements

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

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

10. Change of Accounting Method

Adoption of ASU 2017-11

In connection with the securities purchase agreements and debt transactions during the year ended December 31, 2017, the Company issued warrants to purchase common stock with a five-year term. Upon issuance of the warrants, the Company evaluated the note agreement to determine if the agreement contained any embedded components that would qualify the agreement as a derivative. The Company identified certain put features embedded in the warrants that potentially could result in a net cash settlement in the event of a fundamental transaction, requiring the Company to classify the warrants as a derivative liability. The Company changed its method of accounting for the debt and warrants through the early adoption of ASU 2017-11 on January 1, 2018 on a retrospective basis. Accordingly, the Company recorded the warrant derivative and conversion option derivative liabilities to additional paid in capital upon issuance.

The following table provides a summary of the derivative liability activity as a result of the adoption of ASU 2017-11 (in thousands, except per share data):

	Consolidated Balance Sheet December 31, 2017		
	Previously Reported	Revisions	Revised Report
Additional Paid-in Capital	$ 519,702,000	$ 1,603,000	$ 521,305,000
Accumulated Deficit	$ (267,896,000)	$ (1,603,000)	$ (269,499,000)

	Consolidated Statement of Operations For the Year Ended December 31, 2017		
	Previously Reported	Revisions	Revised Report
Change in Warrant Liability	$ 925,000	$ (925,000)	$ -
Earnings per Share	$ (8.54)	$ (0.06)	$ (8.60)

During 2018, the down round provisions of certain of the notes was triggered. The Company calculated the value of the down round feature on that date and determined there to be no additional cost to be reported.

11. Subsequent Events

Financing

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

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

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

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

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

Common Stock

In the first quarter of 2019, the Company issued 723,940 shares of common stock upon conversion of $437,271 in principal and interest on senior convertible notes.

PART II
INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 13. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION

The following table sets forth the expenses expected to be incurred in connection with the issuance and distribution of common stock registered hereby, all of which expenses, except for the Securities and Exchange Commission registration fee, are estimated.

Securities and Exchange Commission registration fee	$ 1,177.16
Miscellaneous expenses	500.00
Legal	10,000.00
Accounting fees and expenses	5,000.00
Total	$ 16,677.16

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Seligson & Giannattasio, LLP was our independent registered public accounting firm for the fiscal years ending December 31, 2018 and 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 2018 and 2017 fiscal years.

	Fiscal 2018	Fiscal 2017
Audit Fees[1]	$ 69,000	$ 64,000
Audit-Related Fees[2]	-	-
Tax Fees[3]	4,000	4,000
Subtotal	$ 73,000	68,000
All other Fees[4]	-	-
Total	$ 73,000	$ 68,000

(1)Audit fees represent fees for professional services provided in connection with the audit of our annual financial statements and the review of our financial statements included in our Form 10-Q quarterly reports and services that are normally provided in connection with statutory or regulatory filings for the 2018 and 2017 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.

ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES

In January 2015, the Company agreed to issue 39,657 shares of common stock as a price protection to a note holder that originally converted notes at a price of $2.50 and continues to hold these shares. These additional shares would have been issued if the conversion shares price was $1.75. As of December 31, 2015, 33,142 shares of common stock have been issued and $247,000 of interest expense was recorded for this issuance. During January 2016 the remaining 6,515 share were issued and $20,000 of interest expense was recorded.

During the six months ending June 30, 2016, the Company issued an aggregate of 12,580,183 shares of common stock to a total of 34 persons or entities in exchange of the cancellation of warrants on a cashless basis. The shares issued 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.

During the six months ending June 30, 2016, the Company also issued an aggregate of 2,022,230 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 $2.00 per share. These shares were also exempt from the registration requirements of Section 5 of the Act pursuant to Section 4(2) of the Act since the shares were also issued to persons closely associated with the Company and there was no public offering of the shares.

During the six months ending June 30, 2016, the Company also issued an aggregate of 4,612,341 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. These shares were also exempt from the registration requirements of Section 5 of the Act pursuant to Section 4(2) of the Act since the shares were also issued to persons closely associated with the Company and there was no public offering of the shares.

During the six months ending June 30, 2016, the Company also issued an aggregate of 4,275,186 shares of common stock to a total of 17 persons as payment for the conversion of certain note and the related accrued interest. The conversion price of these shares was $0.40 per share. These shares were also exempt from the registration requirements of Section 5 of the Act pursuant to Section 4(2) of the Act since the shares were also issued to persons closely associated with the Company and there was no public offering of the shares.

In August 2016, the Company issued 1,115,000 shares of common stock to H.C. Wainwright and Co., LLC as payment for investment banking services provided to the Company.

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 October 2016 the Company issued an aggregate of 453,431 shares of common stock to one noteholder as payment for the conversion of certain accrued interest. The conversion price of these shares was $0.40 per share. These shares were also exempt from the registration requirements of Section 5 of the Act pursuant to Section 4(2) of the Act since the shares were also issued to persons closely associated with the Company and there was no public offering of the shares.

In October 2016 the Company issued an aggregate of 594,530 shares of common stock to one noteholder as payment for the conversion of a certain note. The conversion price of these shares was $0.0841 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 These shares were also exempt from the registration requirements of Section 5 of the Act pursuant to Section 4(2) of the Act since the shares were also issued to persons closely associated with the Company and there was no public offering of the shares.

In November 2016 the Company issued an aggregate of 975,039 shares of common stock to one noteholder as payment for the conversion of a certain note. The conversion price of these shares was $0.0513 per share based on 60% of the average of the lowest three trading prices occurring at any time during the 20 trading dayspreceding conversion These shares were also exempt from the registration requirements of Section 5 of the Act pursuant to Section 4(2) of the Act since the shares were also issued to persons closely associated with the Company and there was no public offering of the shares.

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 42,240 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 46,666 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 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, the Company entered into a securities purchase agreement with one 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 $650,000 and warrants to acquire up to 43,333 shares of the Company's common stock at an exercise price of $15.00 per share.

In August 2017, the Company 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 (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 $3,890,000 and warrants to acquire up to 259,333 shares of the Company's common stock at an exercise price of $15.00 per share.

In January 22, 2018, the Company entered into a Securities Purchase Agreement (“SPA”) with the fourteen accredited investors (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”).

Pursuant to the terms of SPA the Notes are subject to an original issue discount of 10% resulting in proceeds to the Company of $7,055,000 from the transaction. The Notes are due on July 22, 2018. The Notes are convertible, at the option of the Buyers, at any time prior to payment in full, into shares of common stock of the Company at a price of $4.58 per share (“Conversion Price”). According to the terms of the note agreement, the Notes are subject to certain adjustments depending upon the price and structure of a subsequent financing, including a qualified financing with gross proceeds of at least $20 million, as defined in the agreements.

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

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

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

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

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

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

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

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

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

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

On May 22, 2019, GT Biopharma, Inc. (the "Company") entered into a Securities Purchase Agreement with ten purchasers (individually, a "Purchaser," and collectively, the "Purchasers") pursuant to which the Company has issued to the Purchasers Convertible Debentures in an aggregate principal amount of $1,300,000 (the "Debentures"), which Debentures are convertible into the Company's common stock (the "Common Stock") at a price of $0.35 per share. The Company and each Purchaser also entered into a Registration Rights Agreement.

The abovementioned equity securities were issued in reliance on the exemption from registration provided by Section 4(2) of the Securities Act of 1933 (the "Securities Act") and/or Rule 506 of Regulation D under the Securities Act, as amended.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Exhibits

The following exhibits are filed with this registration statement:

Exhibit Number	Exhibit Description	Form	Date	Number	Filed Herewith
2.1	Agreement and Plan of Merger	10-Q	11/14/17	2.1	
3.1	Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002	10-KSB	04/01/02	3.A	
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of GT Biopharma, Inc.	10-K	03/31/11	3.2	
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series H Convertible Preferred Stock of GT Biopharma, Inc., dated February 5, 2010	8-K	02/16/10	3.1	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series I Convertible Preferred Stock of GT Biopharma, Inc., dated March 18, 2011.	10-K	03/31/11	3.4	
3.5	Bylaws, as restated effective September 7, 1994 and as amended through April 29, 2003	10-QSB	08/13/03	3	
3.6	Certificate of Amendment to the Certificate of Incorporation of the Registrant, effective as of July 19, 2017.	8-K	03/15/18		
10.1	License Agreement with ID4 Pharma LLC	10-Q	08/11/17	10.1	
10.2	License Agreement with MultiCell Immunotherapeutics, Inc.	10-Q	08/11/17	10.2	
10.3	License Agreement with the University of Minnesota	10-Q	08/11/17	10.3	
10.4	License Agreement with Daniel A. Vallera, Ph.D.	10-Q	08/11/17	10.4	
10.5	Warrant Conversion Agreement	10-Q	11/14/17	10.6	
10.6	Preferred Conversion Agreement	10-Q	11/14/17	10.7	
10.7	Amended Note Conversion Agreement	10-Q	11/14/17	10.8	
10.8	Amended Warrant Conversion Agreement	10-Q	11/14/17	10.9	
10.9	Amended Preferred Conversion Agreement	10-Q	11/14/17	10.10	
10.10	Securities Purchase Agreement	8-K	01/13/17	10.1	
10.11	10% Senior Convertible Debenture	8-K	01/13/17	10.2	
10.12	Common Stock Purchase Warrant	8-K	01/13/17	10.3	
10.13	Securities Purchase Agreement by and among the Company and the Buyers, dated January 22, 2018.	8-K	01/23/18	10.1	
10.14	Form of Registration Rights Agreement by and among the Company and the Buyers, dated January 22, 2018	8-K	01/23/18	10.2	
10.15	Form of Note	8-K	01/23/18	10.3	
10.16	Form of Warrant	8-K	01/23/18	10.4	
10.17	First Amendment to the Employment Agreement, dated as of February 14, 2018, between the Company and Dr. Clarence-Smith.	8-K	02/21/18	2	
10.18	Consultant Agreement, dated as of February 14, 2018, between the Company and Mr. Cataldo.	8-K	02/21/18	3	

10.19	Form of 10% Senior Convertible Debenture	8-K	08/03/18	4.1	
10.20	Security Purchase Agreement	8-K	08/03/18	10.1	
10.21	Form of 10% Senior Convertible Debenture	8-K	09/07/18	4.1	
10.22	Security Purchase Agreement	8-K	09/07/18	10.1	
10.23	Form of 10% Senior Convertible Debenture	8-K	09/24/18	4.1	
10.24	Security Purchase Agreement	8-K	09/24/18	10.1	
10.25	Separation Agreement between the Company and Dr. Clarence-Smith	8-K	10/12/18	10.1	
10.26	Resignation of Steven Weldon	8-K	10/16/18		
10.27	Stock Pledge Agreement	10-Q	08/14/18	10.10	
10.28	Executive Employment Agreement with Dr. Urbanski	10-Q	11/14/18	10.17	
10.29	Secured Convertible Note	8-K	02/06/19	4.1	
10.30	Security Purchase Agreement	8-K	02/06/19	10.1	
10.31	Security Agreement	8-K	02/06/19	10.2	
10.32	Registration Rights Agreement	8-K	02/06/19	10.3	
10.33	Form of Note	8-K	05/24/19	4.1	
10.34	Security Purchase Agreement	8-K	05/24/19	10.1	
10.35	Form of Registration Rights Agreement	8-K	05/24/19	10.2	
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	
23.1	Opinion of Gary R. Henrie	S-1	06/21/19	23.1	
23.2	Consent of Seligson & Giannattasio, LLP, Independent Registered Public Accounting Firm, relating to the Registrant				X
23.3	Consent of Gary R. Henrie (included in Exhibit 5.1)	S-1	06/21/19	23.3	
24.1	Power of Attorney (included on signature page hereto)	S-1	06/21/19	24.1	
101	Interactive Data File	S-1	06/21/19	101	

(b) Financial Statement Schedules

See the Index to Financial Statements included on page 58 for a list of the financial statements included in this prospectus.

ITEM 24. INDEMNIFICATION OF DIRECTORS AND OFFICERS

Our officers and directors are indemnified as provided by Delaware Corporation Law and our bylaws. Under the Delaware Corporation Law, director immunity from liability to a company or its shareholders for monetary liabilities applies automatically unless it is specifically limited by a company's articles of incorporation that is not the case with our articles of incorporation. Excepted from that immunity are:

(1) a willful failure to deal fairly with the company or its shareholders in connection with a matter in which the director has a material conflict of interest;
(2) a violation of criminal law (unless the director had reasonable cause to believe that his or her conduct was lawful or no reasonable cause to believe that his or her conduct was unlawful);
(3) a transaction from which the director derived an improper personal profit; and
(4) willful misconduct.

Our bylaws provide that we will indemnify our directors and officers to the fullest extent not prohibited by Delaware law; provided, however, that we may modify the extent of such indemnification by individual contracts with our directors and officers; and, provided, further, that we shall not be required to indemnify any director or officer in connection with any proceeding (or part thereof) initiated by such person unless:

(1) such indemnification is expressly required to be made by law;
(2) the proceeding was authorized by our Board of Directors;
(3) such indemnification is provided by us, in our sole discretion, pursuant to the powers vested us under Delaware law; or
(4) such indemnification is required to be made pursuant to the bylaws.

Our bylaws provide that we will advance all expenses incurred to any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he is or was our director or officer, or is or was serving at our request as a director or executive officer of another company, partnership, joint venture, trustor other enterprise, prior to the final disposition of the proceeding, promptly following request. This advanced of expenses is to be made upon receipt of an undertaking by or on behalf of such person to repay said amounts should it be ultimately determined that the person was not entitled to be indemnified under our bylaws or otherwise.

Our bylaws also provide that no advance shall be made by us to any officer in any action, suit or proceeding, whether civil, criminal, administrative or investigative, if a determination is reasonably and promptly made: (a) by the board of directors by a majority vote of a quorum consisting of directors who were not parties to the proceeding; or (b) if such quorum is not obtainable, or, even if obtainable, a quorum of disinterested directors so directs, by independent legal counsel in a written opinion, that the facts known to the decision-making party at the time such determination is made demonstrate clearly and convincingly that such person acted in bad faith or in a manner that such person did not believe to be in or not opposed to our best interests.

ITEM 28. UNDERTAKINGS

The undersigned registrant hereby undertakes:

1. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(1) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(2) To reflect in the prospectus any facts or events arising after the effective date of this registration statement, or most recent post-effective amendment, which, individually or in the aggregate, represent a fundamental change in the information set forth in this registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(3) To include any material information with respect to the plan of distribution not previously disclosed in this registration statement or any material change to such information in the registration statement.

2. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered herein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

3. To remove from registration by means of a post-effective amendment any of the securities being registered hereby, which remain unsold at the termination of the offering.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to our directors, officers and controlling persons pursuant to the provisions above, or otherwise, we have been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933, and is, therefore, unenforceable.

In the event that a claim for indemnification against such liabilities, other than the payment by us of expenses incurred or paid by one of our directors, officers, or controlling persons in the successful defense of any action, suit or proceeding, is asserted by one of our directors, officers, or controlling persons in connection with the securities being registered, we will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification is against public policy as expressed in the Securities Act of 1933, and we will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Las Vegas, State of California, on July 11, 2019.

GT BIOPHARMA, INC.
By: */s/ Anthony J. Cataldo*
Anthony J. Cataldo
Chief Executive Officer

POWER OF ATTORNEY

Each person whose signature appears below hereby constitutes and appoints Anthony J. Cataldo his true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him or her and in his or her name, place, and stead, in any and all capacities, to sign any and all (1) amendments (including post-effective amendments) and additions to this Registration Statement and (2) Registration Statements, and any and all amendments thereto (including post-effective amendments), relating to the offering contemplated pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, and hereby grants to such attorney-in-fact and agent full power and authority to do and perform each and every actand thing requisite and necessary to be done, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or his or her substitute or substitutes may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the following persons in the capacities and on the dates indicated.

/s/ Anthony J. Cataldo
Anthony J. Cataldo, CEO and Director
July 11, 2019

/s/ Steven Weldon
Steven Weldon, CFO, Chief Accounting Officer and Director
July 11, 2019

SELIGSON & GIANNATTASIO, LLP
Certified Public Accountants and Consultants

14 Ver Valen Street
Closter, NJ 07624

723 N Broadway
White Plains, NY 10603

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in this Registration Statement on Form S-1/A of GT Biopharma, Inc. of our report dated March 29, 2019, relating to our audit of the consolidated financial statements as of and for the years ended December 2018 and 2017, which appears in the Annual Report on Form 10-K of GT Biopharma, Inc. for the year ended December 31, 2018. Our report included an explanatory paragraph expressing substantial doubt about the ability of GT Biopharma, Inc. to continue as a going concern.

We also consent to the reference to our Firm under the caption "Experts" in the Prospectus, which is part of this Registration Statement.

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

White Plains, New York
July 11, 2019