

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

FORM S-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  
incorporation or organization

**2834**  
(Primary Standard Industrial  
Classification Code Number)

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

**9350 Wilshire Blvd. Suite 203**  
**Beverly Hills, CA 90212**  
**(800) 304-9888**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Anthony J. Cataldo**  
**Chief Executive Officer**  
**9350 Wilshire Blvd. Suite 203**  
**Beverly Hills, CA 90212**  
**(800) 304-9888**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable 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 of 1933, check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please 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.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act.

## CALCULATION OF REGISTRATION FEE

<i>Title of Each Class of Securities To Be Registered</i>	Proposed Maximum Aggregate Offering Price <sup>(1)(2)</sup> (3)	Amount of Registration Fee
Units consisting of:	\$ 10,000,000	\$ 1,091.00
Shares of common stock, par value \$0.001 per share (the "Common Stock"), included in the Units	— <sup>(4)</sup>	—
Warrants to purchase common stock included in the Units	— <sup>(4)</sup>	—
Pre-Funded Units consisting of:	\$ 10,000,000	\$ 1,091.00
Warrants to purchase common stock included in the Pre-Funded Units	— <sup>(4)</sup>	—
Pre-funded warrants to purchase common stock included in the Pre-Funded Units	— <sup>(4)</sup>	—
Underwriter's over-allotment option (5)	\$ 3,000,000	\$ 327.30
Underwriter's warrants (5)	\$ 1,250,000	\$ 136.39
Shares of common stock issuable upon exercise of the Underwriter's warrants (5)	— <sup>(4)</sup>	—
Shares of common stock issuable upon exercise of the warrants included in the Units and Pre-Funded Units	— <sup>(4)</sup>	—
Shares of common stock issuable upon exercise of the pre-funded warrants included in the Pre-Funded Units	— <sup>(4)</sup>	—
Shares of common stock issuable upon exercise of the warrants included in the Underwriter's over-allotment option (5)	— <sup>(4)</sup>	—
<b>Total</b>	<b>\$ 24,250,000</b>	<b>\$ 2,645.68</b>

- (1) Pursuant to Rule 416 promulgated under the Securities Act of 1933, as amended (the "Securities Act"), this registration statement shall also cover any an indeterminate number of additional shares of the registrant's common stock as may be issuable because of any future stock dividends, stock distributions, stock splits, similar capital readjustments or other anti-dilution adjustments.
- (2) All amounts in this table are estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) under the Securities Act. The registrant may increase or decrease the size of the offering prior to effectiveness.
- (3) The proposed maximum aggregate offering price of the Units and Pre-Funded Units, if any, is \$24,000,000. This registration fee table shows a proposed maximum aggregate offering price of \$24,000,000 solely for purposes of complying with guidance of the Securities and Exchange Commission (the "SEC") relating to the payment of registration fees, as we are required by the SEC to register separately the Units, the Pre-Funded Units, the shares of common stock included in the Units, the warrants included in the Units and Pre-Funded Units, the pre-funded warrants included in the Pre-Funded Units, the shares of common stock issuable upon exercise of the warrants included in the Units and Pre-Funded Units, the shares of common stock issuable upon exercise of the pre-funded warrants included in the Pre-Funded Units. The aggregate offering price of the Units proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the aggregate offering price of the Pre-Funded Units offered and sold in the offering (plus the aggregate exercise price of the shares of common stock issuable upon exercise of the pre-funded warrants included in the Pre-Funded Units).
- (4) No additional registration fee is payable pursuant to Rule 457(i) under the Securities Act.
- (5) Includes additional Units which may be issued upon the exercise of a 45-day option granted to the underwriter to cover over-allotments, if any, up to 15% of the total number of Units to be offered. We have calculated the proposed maximum aggregate offering price of the common stock underlying the underwriter's warrants to purchase up to 5% of the securities sold in this offering by assuming that such warrants are exercisable at a price per share equal to 125% of the public offering price of the common stock in the units sold in this offering.

**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 Securities and Exchange Commission acting pursuant to said section 8(a), may determine.**

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 DECEMBER 11, 2020

PRELIMINARY PROSPECTUS



Up to Units  
(Each Unit Consisting of One Share of Common Stock and One Common Warrant to Purchase Shares of Common Stock)

Up to Pre-Funded Units  
(Each Pre-funded Unit Consisting of One Pre-Funded Warrant to Purchase One Share of Common Stock and One Common Warrant to Purchase Shares of Common Stock)

We are offering up to units (the “Units”), with each Unit consisting of (i) one share of common stock, par value \$0.001 per share (the “Common Stock”), of GT Biopharma, Inc., a Delaware corporation (the “Company”), and (ii) one warrant to purchase shares of common stock (a “Common Warrant”). The Common Warrants will have an exercise price of \$per share, will be exercisable at any time after the date of issuance and will expire years from the date of issuance. Each Unit will be sold at a price to the public of \$per Unit.

We are also offering to those purchasers, if any, whose purchase of Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, in lieu of Units that would otherwise result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, pre-funded units (the “Pre-Funded Units”), with each Pre-Funded Unit consisting of (i) a pre-funded warrant to purchase one share of Common Stock (the “Pre-Funded Warrant”), and (ii) one Common Warrant. Because we will issue a Common Warrant as part of each Unit or Pre-Funded Unit, the number of Common Warrants sold in this offering will not change as a result of a change in the mix of the Units and Pre-Funded Units sold. Each Pre-Funded Warrant contained in a Pre-Funded Unit will be exercisable for one share of Common Stock. The purchase price of each Pre-Funded Unit will equal the price per Unit being sold to the public in this offering, less \$0.001, and the exercise price of each Pre-Funded Warrant included in the Pre-Funded Unit will be \$0.001 per share. Each Pre-Funded Warrant is exercisable for one share of our Common Stock at any time at the option of the holder, provided that the holder will be prohibited from exercising Pre-Funded Warrants for shares of our Common Stock if, as a result of such exercise, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our Common Stock then issued and outstanding. However, any holder may increase such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us. Otherwise, the Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until exercised in full.

For each Pre-Funded Unit we sell, the number of Units we are offering will be decreased on a one-for-one basis. Units and the Pre-Funded Units will not be issued or certificated. The Common Stock or Pre-Funded Warrants, as the case may be, and the Common Warrants included in the Units or the Pre-Funded Units, can only be purchased together in this offering, but the securities contained in the Units or Pre-Funded Units will be issued separately and will be immediately separable upon issuance. The shares of Common Stock issuable from time to time upon exercise of the Common Warrants and the Pre-Funded Warrants are also being offered by this prospectus. We refer to the shares of Common Stock issued or issuable upon exercise of the Common Warrants and Pre-Funded Warrants, and the shares of Common Stock, the Common Warrants and Pre-Funded Warrants being offered hereby, collectively, as the “securities.”

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Our Common Stock is presently quoted on the OTCQB, one of the OTC Markets Group over-the-counter markets, under the trading symbol "GTBP." On December 10, 2020, the closing sale price for our Common Stock was \$0.26. We intend to apply to list our Common Stock on the Nasdaq Capital Market under the symbol "GTBP." No assurance can be given that our application will be approved or that the trading prices of our Common Stock on the OTCQB market will be indicative of the prices of our Common Stock if our Common Stock were traded on the Nasdaq Capital Market.

There is no established public trading market for the Common Warrants or the Pre-Funded Warrants, and we do not expect such a market to develop. In addition, we do not intend to apply for a listing of the Common Warrants or the Pre-Funded Warrants on any national securities exchange or other nationally recognized trading system.

Unless otherwise noted and other than in our financial statements and the notes thereto, the share and per share information in this prospectus reflects a proposed reverse stock split of the outstanding common stock and treasury stock of the Company at an assumed ratio to occur immediately following the effective date but prior to the closing of the offering.

**Investing in our securities involves a high degree of risk. You should carefully review and consider "Risk Factors" beginning on page 17 of this prospectus.**

**Neither the Securities and Exchange Commission (the "SEC") 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.**

	Per Unit	Per Pre-Funded Unit	Total <sup>(2)</sup>
<b>Public offering price</b>	\$	\$	\$
<b>Underwriter discounts and commissions <sup>(1)</sup></b>	\$	\$	\$
<b>Proceeds, before expenses, to us</b>	\$	\$	\$

- (1) The underwriters will receive compensation in addition to the underwriting discount and commissions. We have agreed to issue upon the closing of this offering common stock purchase warrants to the underwriters entitling them to purchase up to 5% of the aggregate shares of the units sold in this offering. The exercise price of such warrants is equal to 125% of the public offering price of the units offered hereby. The warrants will be exercisable commencing six months after the date of effectiveness of this Registration Statement and will terminate five years after the date of effectiveness of this Registration Statement. See "Underwriting" beginning on page 83 of this prospectus for additional information regarding underwriting compensation.
- (2) The public offering corresponds to an assumed public offering price per share of common stock and per pre-funded warrant of \$ and an assumed public offering price per warrant of \$0.01.

We have granted the underwriter a 45-day option to purchase additional Units up to 15% of the total number of Units to be offered solely to cover over-allotments, if any.

Delivery of the securities is expected to be made on or about \_\_\_\_\_, 2020, subject to customary closing conditions.

**DAWSON JAMES SECURITIES, INC.**

The date of this prospectus is \_\_\_\_\_, 2020.

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## CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus are “forward-looking statements” within the meaning of the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. 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,” “may,” “guidance,” “estimate,” “potential,” “outlook,” “target,” “forecast,” “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 under “*Risk Factors*” and “*Management’s Discussion and Analysis of Financial Condition and Results of Operations*” in this prospectus or under similar headings in any accompanying prospectus supplement. 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.

## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-1 that we filed with the SEC under the Securities Act. This prospectus does not contain all of the information included in the registration statement. For further information, we refer you to the registration statement, including its exhibits, filed with the SEC. Statements contained in this prospectus about the contents of any document are not necessarily complete. If SEC rules require that a document be filed as an exhibit to the registration statement, please see such document for a complete description of these matters. You should carefully read this prospectus, together with the additional information described under the headings “*Where You Can Find More Information.*”

Neither we nor the underwriter have authorized anyone to provide you with any information or to make any representations other than that contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. Neither we nor the underwriter are making an offer to sell securities in any jurisdiction in which the offer or sale is not permitted. The information in this prospectus is accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of our shares of common stock and the information in any free writing prospectus that we may provide to you in connection with this offering is accurate only as of the date of that free writing prospectus. Our business, financial condition, results of operations and prospects may have changed since those dates.

**For investors outside the United States:** We have not and the underwriter has not, done anything that would permit this offering, or possession or distribution of this prospectus, in any jurisdiction where action for that purpose is required, other than in the United States. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions 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 Notice 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, or will be, filed or incorporated by reference 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 More Information.*”

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 ™ 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” and “the Company” refer to GT Biopharma, Inc., a Delaware corporation, and/or its related subsidiaries, as the context may require.

## PROSPECTUS SUMMARY

*This summary highlights certain information about us, this offering and selected information contained elsewhere 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 the information under "Risk Factors" set forth in this prospectus and the information included in any prospectus supplement or 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 under "Risk Factors," as well as other matters described in this prospectus. See "Cautionary Notice Regarding Forward-Looking Statements."*

### Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-therapeutic products based on our proprietary Tri-specific Killer Engager (TriKE™) and Tetra-specific Killer Engager (TetraKE™) platform technologies. Our TriKE and TetraKE platforms generate proprietary therapeutic candidates that are designed to harness and enhance the immune response of a patient's endogenous natural killer cells ("NK cells"). Once bound to an NK cell, our platform moieties are designed to enhance the activity of NK cells, with targeted direction to one or more proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in targeted cell death. We have constructed our TriKEs and TetraKEs of recombinant fusion proteins that can be designed to target a wide array of tumor antigen that may be located on hematologic malignancies, sarcomas or solid tumors. Our TriKEs and TetraKEs do not require patient-specific or autologous customization.

We are using our TriKE and TetraKE platforms with the intent to bring to market products that treat a range of hematologic malignancies, sarcomas, solid tumors and selected infectious diseases. Our platforms are scalable, and in addition to our first clinical indication of our TriKE platform in relapsed or refractory acute myelogenous leukemia ("AML"), we are preparing investigational new drug applications ("IND") based on a specific TriKE or TetraKE design. We intend to continue to advance into the clinic, on our own or through potential collaborations with larger companies, multiple TriKE or TetraKE product candidates. We believe our TriKEs and TetraKEs may have the ability, if approved for marketing, to be used as monotherapy, be dosed concomitantly with current monoclonal antibody therapeutics, be used in conjunction with more traditional cancer therapy, and potentially overcome certain limitations of current chimeric antigen receptor ("CAR-T") therapy.

We are also using our TriKE and TetraKE platforms to develop therapeutics for the treatment of infectious diseases such as human immunodeficiency virus ("HIV") and COVID-19 infection. For example, while the use of anti-retroviral drugs has substantially improved the morbidity and mortality of individuals infected with HIV, these drugs are designed to suppress virus replication and to help modulate progression to AIDS and to limit further transmission of the virus. Despite the use of anti-retroviral drugs, infected individuals retain reservoirs of latent HIV-infected cells that, upon cessation of anti-retroviral drug therapy, can reactivate and reestablish an active HIV infection. Destruction of these latent HIV infected cells is the primary objective of curative therapy. Our HIV-TriKE contains the antigen binding fragment (Fab) from a broadly-neutralizing antibody targeting the HIV-Env protein. The HIV-TriKE is designed to target HIV while redirecting NK cell killing specifically to actively replicating HIV infected cells. The HIV-TriKE induced NK cell proliferation and demonstrated the ability in vitro to reactivate and kill HIV-infected T-cells. These findings indicate a potential role for the HIV-TriKE in the reactivation and elimination of the latently infected HIV reservoir cells by harnessing the NK cell's ability to mediate the antibody-directed cellular cytotoxicity ("ADCC").

We have licensed the exclusive rights from the University of Minnesota to the TriKE and TetraKE platforms.



## **Immuno-Oncology Product Candidates**

### ***GTB-3550***

GTB-3550 is our first TriKE product candidate. It is a tri-specific single-chain variable fragment (“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, in a novel conformational construct. We have commenced clinical trials of this anti-CD16-IL-15-anti-CD33 TriKE in CD33 positive leukemias, a marker expressed on tumor cells in AML, and we intend to study this TriKE in myelodysplastic syndrome (“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 was derived from the M195 humanized anti-CD33 scFV and has been used in human clinical studies. We believe the recent approval of the antibody-drug conjugate gemtuzumab validates this targeted approach.

Patients who are diagnosed with AML typically receive frontline therapy—usually chemotherapy—including cytarabine and an anthracycline, a therapy that has not changed in over 40 years. Approximately 50% of patients will relapse and require alternative therapies. In addition, MDS incidence rates in the U.S. have dramatically increased 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.

We filed an IND amendment in June 2018 and announced on November 1, 2018 that we received notification from the FDA that the IND was open and that the Company was authorized to initiate a first-in-human Phase I clinical trial with GTB-3550 in AML, MDS and severe mastocytosis. We began our Phase I clinical trial in January 2020.

### ***GTB-C3550***

GTB-C3550 is a next-generation, follow-on, to our lead TriKE, GTB-3550. GTB-C3550 contains a modified CD16 moiety which has improved binding characteristics and enhanced tumoricidal activity 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 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 clinical trials.

### ***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 trials for certain of our solid tumor product candidates later this year.

## Recent Developments

### *Collaboration Agreement*

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

### *Financings*

#### November 2020 Financing

In November, 2020, we entered into a securities purchase agreement with three purchasers pursuant to which we issued convertible debentures in an aggregate principal amount of \$350,000 (the “November 2020 Notes”).

The November 2020 Notes are convertible at any time, at the holder’s option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The November 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the November 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above.

The November 2020 Notes each have a term of six months and mature in May, 2021, unless earlier converted or repurchased. The November 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder’s option, in shares of common stock based on the conversion price then in effect. We may not prepay the November 2020 Notes without the prior written consent of the applicable holder.

#### September 2020 Financing

On September 16, 2020, we entered into a securities purchase agreement with two purchasers pursuant to which we issued convertible debentures in an aggregate principal amount of \$250,000 (the “September 2020 Notes”).

The September 2020 Notes are convertible at any time, at the holder’s option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The September 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the September 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above.

The September 2020 Notes each have a term of six months and mature on March 16, 2021, unless earlier converted or repurchased. The September 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder’s option, in shares of common stock based on the conversion price then in effect. We may not prepay the September 2020 Notes without the prior written consent of the applicable holder.

#### July 2020 Financing

On July 7, 2020, we entered into a securities purchase agreement with ten purchasers pursuant to which we issued convertible notes in an aggregate principal amount of approximately \$3.2 million (collectively, the "July 2020 Notes").

The July 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The July 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the July 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above.

The July 2020 Notes each have a term of six months and mature on January 7, 2021, unless earlier converted or repurchased. The July 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder's option, in shares of common stock based on the conversion price then in effect. We may not prepay the July 2020 Notes without the prior written consent of the applicable holder.

#### May 2020 Financing

Between April 20, 2020 and May 7, 2020, we entered into securities purchase agreements with eight purchasers pursuant to which we issued convertible notes in an aggregate principal amount of approximately \$2.0 million (collectively, the "May 2020 Notes").

The May 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The May 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the May 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above.

The May 2020 Notes each have a term of six months and mature between October 20, 2020 and November 7, 2020, unless earlier converted or repurchased. The May 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder's option, in shares of common stock based on the conversion price then in effect. We may not prepay the May 2020 Notes without the prior written consent of the applicable holder.

#### January 2020 Financing

On January 30, 2020, we entered into a securities purchase agreement with one purchaser pursuant to which we issued convertible notes in an aggregate principal amount of \$0.2 million (the "January 2020 Notes").

The January 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect.

The January 2020 Notes have a term of eight months and mature on September 30, 2020, unless earlier converted or repurchased. The January 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder's option, in shares of common stock based on the conversion price then in effect. We may not prepay the January 2020 Notes without the prior written consent of the holder.

The January 2020 Notes, together with the September 2020 Notes, July 2020 Notes, the May 2020 Notes and the \$0.2 million aggregate principal amount of convertible notes issued in December 2019 (the "December 2019 Notes") pursuant to a securities purchase agreement, dated December 19, 2019, between the Company and one purchaser, are referred to herein as the "Bridge Notes."

For additional information about our convertible notes and debentures, see Note 2 to our unaudited financial statements, *Debt*.

#### ***Forbearance Agreements***

Effective as of June 23, 2020, we entered into Standstill and Forbearance Agreements (as amended, collectively, the "Forbearance Agreements") with the holders of approximately \$13.2 million aggregate principal amount of our outstanding convertible notes and debentures (including certain of the convertible notes issued pursuant to the Bridge Financing) (collectively, the "Default Notes"), which are currently in default. Pursuant to the Forbearance Agreements, the holders of the Default Notes have agreed to forbear from exercising their rights and remedies under the Default Notes (including declaring such Default Notes (together with default amounts and accrued and unpaid interest) immediately due and payable) until the earlier of (i) the date that we complete a future financing in the amount of at least \$15 million and, in connection therewith, commences listing on NASDAQ (collectively, the "New Financing") or (ii) January 31, 2020 (the "Termination Date").

Pursuant to the Forbearance Agreement, the holders of the Default Notes have also agreed that the Default Notes (together with default amounts and accrued and unpaid interest) will be converted into common stock upon the closing of a New Financing at a conversion price equal to the lesser of (i) the conversion price in effect for the Default Notes on the date of such New Financing or (ii) 75% of the lowest per share price at which common stock is or may be issued in connection with such New Financing, in each case, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). Shares of our preferred stock, which will be convertible into the Company's common stock, will be issued in lieu of common stock to the extent that conversion of the Default Notes is prohibited by such beneficial ownership limitations.

For additional information regarding the terms of the Forbearance Agreements, see [ ].

#### ***Extensions of Certain Bridge Notes***

Effective as of November 9, 2020, we entered into extensions with the holders of approximately \$1.2 million aggregate principal amount of our outstanding convertible notes and debentures to extend the maturity date thereof until the earlier of (i) the date that we complete a future financing in the amount of at least \$15 million and, in connection therewith, commences listing on NASDAQ (collectively, the "New Financing") or (ii) January 31, 2020 (the "Termination Date").

## ***Settlement with Empery Funds***

### **Settlement Agreement**

On June 19, 2020, we entered into a settlement agreement (the “Settlement Agreement”) with Empery Asset Master Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP (collectively, the “Empery Funds”), Anthony Cataldo and Paul Kessler resolving all remaining disputes between the parties pertaining to certain convertible notes (the “Original Notes”) and warrants to purchase common stock, par value \$0.001 per share, of the Company (the “common stock”) (the “Original Warrants” and, together with the Original Notes, the “Original Securities”) issued by the Company to the Empery Funds in January 2018 pursuant to a securities purchase agreement. As previously disclosed, the Empery Funds made various allegations regarding failures by the Company to take certain actions required by the terms of the Original Securities, all of which the Company denied. See “*Description of Business—Legal Proceedings.*”

As a result of the Settlement Agreement, the Company paid the Empery Funds cash payments in an aggregate amount of \$0.2 million. In addition, pursuant to the Settlement Agreement, the Company issued to the Empery Funds, solely in exchange for the outstanding Original Securities, (i) an aggregate of 3.5 million shares of common stock (the “Settlement Shares”), (ii) pre-funded warrants to purchase an aggregate of 5.5 million shares of common stock (the “Settlement Warrants”) and (iii) senior convertible notes in an aggregate principal amount of \$0.45 million (the “Settlement Notes” and, together with the Settlement Shares and the Settlement Notes, the “Settlement Securities”).

### **Settlement Notes**

The Settlement Notes are convertible at any time, at the holder’s option, into shares of common stock at an initial conversion rate of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect.

The Settlement Notes have a term of six months, maturing on December 19, 2020, and bear interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder’s option, in shares of common stock based on the conversion price then in effect.

Pursuant to the terms of the Settlement Notes, the Company is required to make an offer to repurchase, at the holder’s option, the Settlement Notes at price in cash equal to 100% of the aggregate principal amount of the Settlement Note plus accrued and unpaid interest, if any, to, but excluding, the date of repurchase following the consummation by the Company of a capital raising transactions, or a series of transactions, resulting in aggregate gross proceeds to the Company in excess of \$7.5 million. The Company may not otherwise prepay the Settlement Notes without the prior written consent of the applicable Empery Funds.

For additional information regarding the terms of the Settlement Notes and Settlement Agreement, see [ ].

### **Settlement Warrants**

The Settlement Warrants provide for the purchase of up to an aggregate of 5.5 million shares of common stock at an exercise price of \$0.20 per share, subject to adjustment in certain circumstances, and expire on June 19, 2025. Exercise of the warrant is subject to certain additional terms and conditions, including certain beneficial ownership limitations (with a maximum ownership limit of 4.99%).

***Listing on the Nasdaq Capital Market***

Our common stock is presently quoted on the OTCQB, one of the OTC Markets Group over-the-counter markets, under the trading symbol "GTBP." In connection with this offering, we intend to apply to list our common stock on the Nasdaq Capital Market ("Nasdaq") under the symbols "[●]." If our listing application is approved, we expect to list our common stock upon consummation of the offering, at which point our common stock will cease to be traded on the OTCQB. No assurance can be given that our listing application will be approved. This offering will occur only if Nasdaq approves the listing of our common stock. Nasdaq listing requirements include, among other things, a stock price threshold. As a result, prior to effectiveness, we will need to take the necessary steps to meet Nasdaq listing requirements, including but not limited to a reverse split of our outstanding common stock. If Nasdaq does not approve the listing of our common stock, we will not proceed with this offering. There can be no assurance that our common stock will be listed on the Nasdaq.

***Reverse Stock Split***

On December [●], 2020, we filed a consent solicitation statement on Schedule 14A in connection with a solicitation of consents from our stockholders to approve an amendment to our restated certificate of incorporation to effect a reverse stock split of our common stock at a ratio to be determined by our Board prior to the effective time of the amendment of not less than 1-for-5 and not more than 1-for-30. If approved by our stockholders, the reverse stock split will not impact the number of authorized shares of common stock which will remain at 750,000,000 shares. Unless otherwise noted, the share and per share information in this prospectus reflects, other than in our financial statements and the notes thereto, a proposed reverse stock split of the outstanding common stock and treasury stock of the Company at an assumed ratio to occur immediately following the effective date but prior to the closing of the offering.

## Summary Risk Factors

Participating in this offering involves substantial risk. Our ability to execute our strategy is also subject to certain risks. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under the heading “*Risk Factors*” in deciding whether to invest in our securities. These risks include, but are not limited to, the following:

- Our business is at an early stage of development and we may not develop therapeutic products that can be commercialized.
- 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.
- Our independent auditor’s report for the years ended December 31, 2019 and 2018 is qualified as to our ability to continue as a going concern.
- We will need additional capital to conduct our operations and develop our products, and our ability to obtain the necessary funding is uncertain.
- Our current and future indebtedness may impose significant operating and financial restrictions on us and affect our ability to access liquidity.
- The cost of our research and development programs may be significantly higher than expected and there is no assurance that they will be successful in a timely manner, or at all.
- We have identified material weaknesses in our internal controls over financial reporting and have not yet remedied these weaknesses. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.
- 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.
- Claims that we infringe the intellectual property rights of others may prevent or delay our drug discovery and development efforts.
- 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.
- If we are unsuccessful in obtaining or maintaining patent protection for intellectual property in development or licensed from third parties, our business and 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 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.

- Clinical drug development is costly, time-consuming and uncertain, and we may suffer setbacks in our clinical development program that could harm our business.
- 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.
- Obtaining regulatory approval even after clinical trials that are believed to be successful is an uncertain process.
- 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.
- 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.
- 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.
- 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.
- Our products may be expensive to manufacture, and they may not be profitable if we are unable to control the costs to manufacture them.
- We currently lack manufacturing capabilities to produce our therapeutic product candidates at commercial-scale quantities and do not have an alternate manufacturing supply, which would negatively impact our ability to meet any demand for the product.
- 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.
- 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 rely on third parties to supply candidates for clinical testing and 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.

#### **Corporate Information**

Our principal executive offices are located at 9350 Wilshire Blvd. Suite 203, Beverly Hills, CA 90212, and our telephone number is (800) 304-9888. We maintain a website at [www.gtbiopharma.com](http://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

Units offered by us

Units, each consisting of (i) one share of common stock and (ii) one Common Warrant to purchase share of common stock. The Units will not be certificated, and the share of common stock and Common Warrant comprising each Unit are immediately separable and will be issued separately in this offering.

This prospectus also relates to the offering of shares of common stock issuable upon the exercise of the Common Warrants included in the Units.

Pre-Funded Units offered by us

We are also offering to those purchasers whose purchase of Units in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, in lieu of Units that would otherwise result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock, Pre-Funded Units. The purchase price of each Pre-Funded Unit will equal the public offering price at which the Units are being sold to the public in this offering, minus \$0.001, and the exercise price of each Pre-Funded Warrant included in each Pre-Funded Unit will be \$0.001 per Common Share.

Each Pre-Funded Unit will consist of (i) one Pre-Funded Warrant to purchase one share of common stock and (ii) one Common Warrant to purchase share of common stock. The Pre-Funded Units will not be certificated and the Pre-Funded Warrants and the Common Warrants comprising each Pre-Funded Unit are immediately separable and will be issued separately in this offering.

This prospectus also relates to the offering of shares of common stock issuable upon exercise of the Pre-Funded Warrants and the Common Warrants included in the Pre-Funded Units.

Common Warrants offered by us

Each Common Warrant will have an exercise price of \$ per share of common stock, will be exercisable at any time after the date of issuance and will expire on the anniversary of the date of issuance. To better understand the terms of the Common Warrants, you should carefully read the "Description of Securities We are Offering" section of this prospectus.

Pre-Funded Warrants offered by us

Each Pre-Funded Warrant will have an exercise price of \$0.001 per share of common stock and will be exercisable any time after the date of issuance and may be exercised at any time until exercised in full. To better understand the terms of the Pre-Funded Warrants, you should carefully read the "Description of Securities We are Offering" section of this prospectus.

Offering Price

The offering price is \$ per Unit and \$ per Pre-Funded Unit.

Total shares of common stock outstanding immediately after this offering	shares of common stock, assuming that the maximum number of Units offered by this prospectus is sold in this offering and no sale of any Pre-Funded Units and assuming none of the Common Warrants or Underwriter Warrants (as defined below) issued in this offering are exercised.
Over Allocation Option	Pursuant to the underwriting agreement, we granted to the underwriter an option, exercisable within 45 days after the closing of this offering to acquire up to an additional 15% of the total Units to be offered, solely for the purpose of covering over-allotments, if any.
Use of Proceeds	We intend to use the net proceeds of this offering for general corporate purposes, which includes, among other purposes, the funding and expansion of our ongoing clinical trials and the continued development of our pipeline of candidate products. See “ <i>Use of Proceeds.</i> ”
Existing Trading Market	Our common stock is currently quoted on the OTCQB, one of the OTC Markets Group over-the-counter markets, under the trading symbol “GTBP.” In connection with this offering, we have applied to have our shares of our common stock listed for trading on the Nasdaq Capital Market under the symbol “[●].” we do not intend to list the Common Warrants or the Pre-Funded Warrants on any securities exchange or nationally recognized trading system.
Reverse Stock Split	On December [●], 2020, we filed a consent solicitation statement on Schedule 14A in connection with a solicitation of consents from our stockholders to approve an amendment to our restated certificate of incorporation to effect a reverse stock split of our common stock at a ratio to be determined by our Board prior to the effective time of the amendment of not less than 1-for-5 and not more than 1-for-30. We intend to effectuate the reverse split of our common stock in a ratio to be determined by the Board immediately following the effective date but prior to the closing of the offering. Unless otherwise stated and other than in our financial statements and the notes thereto, all share and per share information in this prospectus reflects a proposed reverse stock split of the outstanding common stock and treasury stock of the Company at an assumed ratio to occur immediately following the effective date but prior to the closing of the offering.
Risk Factors	Investing in our securities involves a high degree of risk. You should carefully review and consider “ <i>Risk Factors</i> ” beginning on page 17 of this prospectus and any risks described in any accompanying prospectus supplement.
Dividend Policy	We have never declared or paid any cash dividends on our common stock. We do not anticipate paying any cash dividends in the foreseeable future.

### Assumptions Used Throughout This Prospectus

Unless otherwise stated in this prospectus, the number of shares of our common stock to be outstanding after this offering is based on 77,518,614 shares of our common stock outstanding as of November 30, 2020, after giving effect to the following:

(1) The conversion of the approximately \$14.1 million of Bridge Notes (plus approximately \$0.7 million in accrued and unpaid interest) into 74 million shares of our common stock immediately prior to the completion of this offering (based on the assumed public offering price of \$ per Unit). The number of shares of our common stock actually issued upon the conversion of our outstanding Bridge Notes depends on the actual public offering price of our Units in this offering. The Bridge Notes are subject to mandatory conversion in the event of the completion of a financing in the amount of at least \$15 million (for which we expect this offering to qualify) at a conversion price equal to the lesser of (i) the conversion price in effect for the Bridge Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above. In the event the actual initial public offering price is lower than \$ per share, the Bridge Notes will convert into a larger number of shares of common stock. A \$0.25 decrease in the public offering price would increase by [●], and a \$0.25 increase in the public offering price would decrease by [●], the number of shares of common stock issuable upon conversion of the Bridge Notes.

(2) The conversion of the approximately \$13.2 million of Default Notes (plus approximately \$3.7 million aggregate principal amount of default amounts and accrued and unpaid interest) into 84.5 million shares of our common stock immediately prior to the completion of this offering (based on the assumed public offering price of \$ per Unit). The number of shares of our common stock actually issued upon the conversion of our outstanding Default Notes depends on the actual public offering price of our Units in this offering. Pursuant to the Forbearance Agreement, the Default Notes (together with default amounts and accrued and unpaid interest) will be converted into common stock upon the closing of a New Financing (of which we expect this offering to qualify) at a conversion price equal to the lesser of (i) the conversion price in effect for the Default Notes on the date of such New Financing or (ii) 75% of the lowest per share price at which common stock is or may be issued in connection with such New Financing, in each case, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). In the event the actual initial public offering price is lower than \$ per share, the Default will convert into a larger number of shares of common stock. A \$0.25 decrease in the public offering price would increase by [●], and a \$0.25 increase in the public offering price would decrease by [●], the number of shares of common stock issuable upon conversion of the Default Notes.

(3) The conversion of 2.3 million shares of Series J-1 Preferred Stock into 11.8 million shares of our common stock immediately prior to the completion of this offering (based on the assumed public offering price of \$ per Unit). The number of shares of our common stock actually issued upon the conversion of our outstanding Series J-1 Preferred Stock depends on the actual public offering price of our Units in this offering. Pursuant to the Forbearance Agreement, the Series J-1 Preferred Stock will be converted into common stock upon the closing of a New Financing (of which we expect this offering to qualify) at a conversion price equal to the lesser of (i) the conversion price in effect for the Default Notes on the date of such New Financing or (ii) 75% of the lowest per share price at which common stock is or may be issued in connection with such New Financing, in each case, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). In the event the actual initial public offering price is lower than \$ per share, the Series J-1 Preferred Stock will convert into a larger number of shares of common stock. A \$0.25 decrease in the public offering price would increase by [●], and a \$0.25 increase in the public offering price would decrease by [●], the number of shares of common stock issuable upon conversion of the Series J-1 Preferred Stock.

Unless otherwise stated in this prospectus, the total number of shares of common stock outstanding after this offering is based on shares outstanding as of November 30, 2020, assumes the sale of Units based on an assumed public offering price of \$[●], the last reported sales price of our shares of common stock on the OTCQB on December 11, 2020, and excludes the following other securities as of November 30, 2020:

- 6.8 million shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$0.20 per share;
- [●] shares of common stock issuable upon the exercise of outstanding stock options and deferred share units at a weighted average exercise price of \$[●] per share;
- [●] shares of common stock reserved for future issuance under our 2014 Stock Incentive Plan;
- [●] shares of common stock issuable upon the exercise of Common Warrants to be issued to investors in this offering at an exercise price of \$[●] per share; and
- [●] shares of common stock, equal to 5% of the aggregate number of Units sold pursuant to this offering (the “Underwriter Warrants”) at an exercise price of \$[●] per share.

Unless otherwise stated, outstanding share information throughout this prospectus excludes such outstanding securities. Except as otherwise indicated, all information in this prospectus assumes the full exercise of the Pre-Funded Warrants sold in this offering.

(1) The assumed public offering price of \$[●] per Unit is the mid-point of the range described on the cover of this prospectus. The actual number of Units we will offer will be determined based on the actual public offering price and the reverse split ratio will be determined based on the stock price.

(2) Unless we indicate otherwise, the number of shares of our common stock outstanding is based on 77,518,614 of common stock outstanding on November 30, 2020, and gives effect to our planned reverse stock split at an assumed ratio of not less than 1-for-5 and not more than 1-for-30 but does not include, as of that date:

- 6.8 million shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$[●] per share;
- [●] shares of our common stock issuable upon exercise of outstanding options at a weighted average exercise price of \$[●] per share;
- [●] shares of our common stock that are reserved for equity awards that may be granted under our existing equity incentive plans;
- [●] shares of common stock issuable upon conversion of our outstanding Series [J-1] Convertible Preferred Stock; and
- [●] shares of common stock issuable upon exercise of outstanding debentures assuming an exercise price of \$[●] per share.

(3) The number of shares of our common stock outstanding after the offering includes an estimated [●] shares of common stock potentially issuable upon the automatic conversion of the Bridge Notes, [●] shares potentially issuable upon the cancellation of the Settlement Warrants, gives effect to our planned reverse stock split at an assumed ratio of [50-to-1], but does not include:

- 6.8 million shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$[●] per share (including warrants for [●] shares to be issued in this offering, warrants for [●] shares to be issued upon the automatic conversion of the Bridge Notes, and currently outstanding warrants to purchase [●] shares of common stock);
- [●] shares of our common stock issuable upon exercise of outstanding options at a weighted average exercise price of \$[●] per share;
- [●] shares of our common stock that are reserved for equity awards that may be granted under our existing equity incentive plans; and
- [●] shares of common stock issuable upon conversion of our outstanding Series [●] Convertible Preferred Stock.

Except as otherwise indicated, all information in this prospectus assumes:

- that the assumed public offering price is \$[●] per Unit which is the mid-point of the estimated offering price range described on the cover of this prospectus;

- a reverse stock split being effected at a ratio of not less than 1-for-5 and not more than 1-for-30;
- no exercise of the outstanding warrants described above;
- no exercise of the warrants included in the Units;
- no exercise of the Underwriter's Warrants;
- no exercise of the Underwriter's over-allotment option to purchase additional shares and/or warrants from us in this offering; and
- each debenture holder signs the agreement described above under "[●]"; as of December [●], 2020, [●] holders representing \$[●] in the aggregate of the outstanding Bridge Notes automatically convertible into an aggregate of [●] shares of common stock at an exercise price of \$[●] per share (based on an assumed public offering price of \$[●] per Unit) and who hold Settlement Warrants to purchase an aggregate of [●] shares of common stock, or [●] shares of common stock after the offering at the assumed public offering price of \$[●] per Unit, have not yet signed the agreement.

## Summary Financial Information

The tables and information below are derived from the Company's unaudited consolidated financial statements as of September 30, 2020, and for the nine months ended September 30, 2020 and 2019, and also as of December 31, 2019.

<b>Balance Sheet Summary (in thousands)</b>	<b>September 30, 2020</b>	<b>December 31, 2019</b>
Cash and cash equivalents	\$ 350	\$ 28
Total assets	\$ 917	\$ 396
Total current liabilities	\$ 30,694	\$ 19,706
Total (deficit) equity	\$ (29,777)	\$ (19,310)

<b>Statement of Operations Summary (in thousands except per share data)</b>	<b>September 30, 2020</b>	<b>September 30, 2019</b>
Revenue	\$ -	\$ -
Selling, general and administrative expenses	\$ 4,321	\$ 8,932
Research and development	\$ 252	\$ 1,659
Loss from operations	\$ (4,573)	\$ (15,190)
Net loss	\$ (13,363)	\$ (31,177)
Net loss per share – basic and diluted	\$ (0.18)	\$ (0.69)

The tables and information below are derived from the Company's audited consolidated financial statements for the years ended December 31, 2019 and 2018.

<b>Balance Sheet Summary (in thousands)</b>	<b>December 31, 2019</b>	<b>December 31, 2018</b>
Cash and cash equivalents	\$ 28	\$ 60
Total assets	\$ 396	\$ 25,399
Total current liabilities	\$ 19,706	\$ 14,029
Total (deficit) equity	\$ (19,310)	\$ 11,370

<b>Statement of Operations Summary (in thousands except per share data)</b>	<b>December 31, 2019</b>	<b>December 31, 2018</b>
Revenue	\$ —	\$ —
Selling, general and administrative expenses	\$ 9,790	\$ 12,487
Research and development	\$ 1,667	\$ 9,067
Loss from operations	\$ (16,056)	\$ (250,069)
Net loss	\$ (38,674)	\$ (259,186)
Net loss per share – basic and diluted	\$ (0.67)	\$ (5.16)

## RISK FACTORS

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

### **Risks Related to Our Business**

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

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

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

As of September 30, 2020, we had an accumulated deficit of approximately \$581 million. We have not generated any significant revenue to date, 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, of which there can be no assurances. 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.

***Our independent auditor's report for the years ended December 31, 2019 and 2018 is qualified as to our ability to continue as a going concern.***

Due to the uncertainty of our ability to meet our current operating and capital expenses, in our audited consolidated financial statements for the years ended December 31, 2019 and 2018, our independent auditors included a note to our consolidated financial statements regarding our ability to continue as a going concern. Recurring losses from operations and the dependence upon our ability to meet future financing needs and succeed in our future operations in order to realize a major portion of our assets have raised a substantial doubt about our ability to continue as a going concern. The presence of the going concern note to our consolidated financial statements may have an adverse impact on the relationships we are developing and plan to develop with third parties as we continue the commercialization of our products and could make it challenging and difficult for us to raise additional financing, all of which could have a material adverse impact on our business and prospects.

***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 to 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 as a going concern. The timing and degree of any future capital requirements will depend on many factors, including:

- the accuracy of the assumptions underlying our estimates for capital needs in 2020 and beyond;
- scientific and clinical progress in our research and development programs;
- the magnitude and scope of our research and development programs and our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with pre-clinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

Additional financing through strategic collaborations, public or private equity or debt financings or other financing sources may not be available on acceptable terms, or at all. The completion of financings involving the issuance of additional common stock or other securities convertible into, or exchangeable for, common stock (such as warrants or additional convertible notes) could also result in significant dilution to our stockholders.

Further, if we obtain additional funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize on our own.

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

***Our current and future indebtedness may impose significant operating and financial restrictions on us and affect our ability to access liquidity.***

As of the date of this prospectus, after giving effect to (i) the issuance of the July 2020 Notes and the May 2020 Notes and (ii) the issuance of the Settlement Notes pursuant to the Settlement Agreement, we had approximately \$23.3 million aggregate principal amount of convertible notes and debentures outstanding, a portion of which are secured by a first priority security interest in substantially all of the assets of the Company and its subsidiaries. Our existing convertible notes and debentures do, and any future instruments governing our indebtedness may, contain a number of restrictive covenants that impose significant operating and financial restrictions on us. For example, our existing convertible notes and debentures include restrictions on our ability to, among other things:

- incur additional indebtedness;
- place liens on our or our subsidiaries' assets;
- repurchase shares of our common stock or repay existing indebtedness;
- pay cash dividends or distributions on our equity securities;
- engage in certain fundamental change transactions; and
- engage in transactions with affiliates.



A failure by us or our subsidiaries to comply with the covenants and restrictions contained in the agreements governing our indebtedness could result in an event of default under such indebtedness, which could adversely affect our ability to respond to changes in our business and manage our operations. Upon the occurrence of an event of default under any of the agreements governing our indebtedness, the holders could elect to declare all amounts outstanding to be due and payable and exercise other remedies as set forth in the agreements. Further, an event of default or acceleration of indebtedness under one instrument may constitute an event of default—or cross-default—under another instrument. For example, in June 2020, we entered into the Forbearance Agreements with holders of the Default Notes pursuant to which such holders have agreed to forbear from exercising their rights and remedies under the Default Notes (including declaring such Default Notes (together with default amounts and accrued and unpaid interest) immediately due and payable) for a specified period of time.

If any of our indebtedness (including the Default Notes) were to be accelerated, there can be no assurance that our assets would be sufficient to repay this indebtedness in full, which could have a material adverse effect on our ability to continue to operate as a going concern.

***The cost of our research and development programs may be significantly higher than expected and there is no assurance that they will be successful in a timely manner, or at all.***

Our currently projected expenditures for 2021 include approximately \$12 million to \$15 million for research and development. The actual cost of our programs could differ significantly from our current projections if we change our planned development process. In the event that actual costs of our clinical program, or any of our other ongoing research activities, are significantly higher than our current estimates, we may be required to significantly modify our planned level of operations.

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

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

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

We have identified material weaknesses in our internal control over financial reporting as a company. As defined in Regulation 12b-2 under the Securities Exchange Act of 1934, as amended (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 as of December 31, 2019: (i) inadequate segregation of duties; (ii) risks of executive override; and (iii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both generally accepted accounting principles in the United States of America (“GAAP”) and SEC regulations.

As of the date of this prospectus, we have not remediated these material weaknesses. We are taking steps, and intend to take additional steps, to mitigate the issues identified and implement a functional system of internal controls over financial reporting. Such measures will include, but not be limited to: hiring of additional employees in our finance and accounting department, although the timing of such hires is largely dependent on our securing additional financing to cover such costs; preparation of risk-control matrices to identify key risks and develop and document policies to mitigate those risks; and identification and documentation of standard operating procedures for key financial and SEC reporting activities. The implementation of these initiatives may not fully address any material weakness or other deficiencies that we may have in our internal control over financial reporting.

Even if we develop effective internal control over financial reporting, such controls may become inadequate due to changes in conditions or the degree of compliance with such policies or procedures may deteriorate, which could result in the discovery of additional material weaknesses and deficiencies. In any event, the process of determining whether our existing internal control over financial reporting is compliant with Section 404 of the Sarbanes-Oxley Act ("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.

***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 intellectual property.

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.

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 enter into intellectual property assignment agreements, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other proprietary information may be disclosed or competitors may otherwise gain access to such information or independently develop substantially equivalent information. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant difficulty in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the trade secret intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, which could materially adversely affect our market position and business and operational results.

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

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware, with claims that cover the use or manufacture of our product candidates or the practice of our related methods. Because patent applications can take many years to issue and remain confidential for a period of time after filing, 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 licensors 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, consultants, advisors and other third parties. We also require all of our employees and certain consultants and advisors to enter into intellectual property assignment agreements. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such disclosure. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose the trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

***We will have to hire additional executive officers and employees to operate our business. If we are unable to hire qualified personnel, we may not be able to implement our business strategy.***

We currently have only two full-time employees. The loss of the services of any one of our employees could delay our product development programs and our research and development efforts. We do not maintain key person life insurance on any of our officers, employees, consultants or advisors. In order to develop our business in accordance with our business strategy, we will have to hire additional qualified personnel, including in the areas of manufacturing, clinical trials management, regulatory affairs, finance and business development. We will need to raise sufficient funds to hire the necessary employees and have commenced our search for additional key employees.

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

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

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

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

Many of our employees, consultants and advisors 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, consultants and advisors 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, consultants or advisors have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's, consultant's or advisor's former employers. Litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees, consultants and advisors 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, consultants and advisors 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 fraud or other misconduct by our employees, consultants or advisors. Misconduct by employees, consultants or advisors could include intentional failures to comply with regulations of governmental authorities, such as the FDA or the European Medicines Agency (the "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. Such 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 such misconduct, and the precautions we currently take and the procedures we may establish in the future as our operations and employee base expand to detect and prevent this type of activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure by our employees, consultants or advisors 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 (“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 (“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 consultants or advisors, 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 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;
- the proximity and availability of clinical trial sites for prospective patients.
- 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 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 III trial. We will also need to agree on a protocol with the FDA for a clinical trial before commencing the trial. Phase III clinical trials frequently produce unsatisfactory results even though prior clinical trials were successful. Therefore, even if the results of our Phase II 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 III clinical trials. The FDA or other foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. Any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a clinical trial. The FDA or other regulatory agencies may require that we conduct additional clinical, nonclinical, manufacturing validation or drug product quality studies and submit those data before considering or reconsidering the application. Depending on the extent of these or any other studies, approval of any applications that we submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA or other regulatory agencies.

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

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

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

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

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

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

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

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

Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of healthcare pharmaceutical companies and others in the healthcare space, as well as their executives and managers. In addition, amendments to the Federal False Claims Act, have made it easier for private parties to bring qui tam (whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. In addition, the Patient Protection and Affordable Care and Health Care and Education Affordability Reconciliation Act of 2010 (collectively, the "Affordable Care Act") amended the federal civil False Claims Act to provide that a claim that includes items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and/or exclusion from the Medicare program. In addition, a majority of states have adopted similar state whistleblower and false-claims provision. There can be no assurance that our activities will not come under the scrutiny of regulators and other government authorities or that our practices will not be found to violate applicable laws, rules and regulations or prompt lawsuits by private citizen "relators" under federal or state false claims laws. Any future investigations of our business or executives, or enforcement action or prosecution, could cause us to incur substantial costs and result in significant liabilities or penalties, as well as damage to our reputation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We do not currently have any alternate supply for our products. If the facilities where our products are currently being manufactured or equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity or availability of drug supply, including, but not limited to, if such facilities are deemed not in compliance with current Good Manufacturing Practice (“cGMP”) requirements, future clinical studies and commercial production for our products could 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 could have a material adverse impact on our business and ability to achieve profitability from future sales of our approved product candidates, if any.

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

Our therapeutic immuno-oncology development programs face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities or funding, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates. According to a recent analysis by InVentiv Health, there are over 800 companies developing approximately 1,500 cancer immunotherapies via 4,000 development projects across 535 targets. According to the Pharmaceutical Manufacturers Research Association Medicines in Development for Cancer 2018 Report, there were 135 drugs in development for the treatment of lymphoma, including non-Hodgkin lymphoma, which accounts for nearly five percent of all new cancer diagnoses.

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

We will have only limited control over the activities of the CRO we will engage to conduct our clinical trials including the University of Minnesota for our Phase II clinical trial for GTB-1550 and Phase I clinical trial for GTB-3550. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on any CRO does not relieve us of our regulatory responsibilities. Based on our present expectations, we, our CROs and our clinical trial sites are required to comply with good clinical practices (“GCPs”) for all of our product candidates in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in the applicable trial may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a product candidate for marketing, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from any sales of such product candidate. In addition, our clinical trials are required to be conducted with product produced in compliance with 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 affected product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

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

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

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

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

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

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

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

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

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

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

The occurrence of one or more natural disasters, such as tornadoes, hurricanes, fires, floods and earthquakes, unusual weather conditions, epidemic outbreaks, terrorist attacks or disruptive political events in certain regions where our operations are located could adversely affect our business. Epidemic or pandemic outbreaks, such as COVID-19 (coronavirus) could impact our management and our ability to conduct clinical trials. For example, we were required to temporarily halt our Phase I clinical trial with GTB-3550 for 30 days in March 2020 as result of restrictions on hospital operation implemented in reaction to the coronavirus pandemic. This also may affect the market conditions that would limit our ability to raise additional capital. This could have a sustained material adverse effect on our business, financial condition and results of operations.

***We have not held regular annual meetings in the past, and if we are required by the Delaware Court of Chancery to hold an annual meeting pursuant to Section 211(c) of the Delaware General Corporation Law (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 (the “Board”), and Section 211(b) of the DGCL provides for an annual meeting of stockholders to be held for the election of directors. Section 211(c) of the DGCL provides that if there is a failure to hold the annual meeting for a period of 13 months after the latest to occur of the organization of the corporation, its last annual meeting or last action by written consent to elect directors in lieu of an annual meeting, the Delaware Court of Chancery may order a meeting to be held upon the application of any stockholder or director. Section 211(c) also provides that the failure to hold an annual meeting shall not affect otherwise valid corporate acts or result in a forfeiture or dissolution of the corporation.

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

#### **Risks Related to this Offering and Our Common Stock**

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

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

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

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

The volatility of the price of our common stock may also be impacted by the risks discussed under this “Risk Factors” section, in addition to other factors, including:

- developments in the financial markets and worldwide or regional economies;
- announcements of innovations or new products or services by us or our competitors;
- announcements by the government relating to regulations that govern our industry;
- significant sales of our common stock or other securities in the open market;
- variations in interest rates;
- changes in the market valuations of other comparable companies; and
- changes in accounting principles.

***Our outstanding warrants and preferred stock may affect the market price and liquidity of the common stock.***

As of the date of this prospectus, after giving effect to the issuance of the Settlement Shares and the Settlement Warrants pursuant to the Settlement Agreement, we had approximately 77.5 million shares of common stock outstanding and had outstanding warrants for the purchase of up to approximately 7.8 million additional shares of common stock at an exercise price of \$0.20 per share, all of which are exercisable as of the date of this prospectus (subject to certain beneficial ownership limitations). We also had outstanding 96,230 shares of Series C preferred stock (the “Series C Preferred Stock”) and 2,353,548 shares of Series J-1 Preferred Stock as of the date of this prospectus, which preferred stock is convertible into up to approximately 11.8 million additional shares of common stock at any time (subject to certain beneficial ownership limitations). In addition, as described more fully below, holders of our convertible notes and debentures may elect to receive a substantial number of shares of common stock upon conversion of the notes and, at each holder’s option, we will pay accrued interest on such notes in shares of our common stock. The amount of common stock reserved for issuance may have an adverse impact on our ability to raise capital and may affect the price and liquidity of our common stock in the public market. In addition, the issuance of these shares of common stock will have a dilutive effect on current stockholders’ ownership.

***The conversion of outstanding convertible notes and debentures into shares of common stock, and the issuance of common stock by us as payment of accrued interest upon our convertible notes and debentures, could materially dilute our current stockholders.***

As of the date of this prospectus, after giving effect to (i) the issuance of the September 2020 Notes, the July 2020 Notes and the May 2020 Notes and (ii) the issuance of the Settlement Notes pursuant to the Settlement Agreement, we had approximately \$23.3 million aggregate principal amount of convertible notes and debentures outstanding. The convertible notes and debentures are convertible into shares of our common stock at fixed conversion prices, which may be less than the market price of our common stock at the time of conversion, and which may be subject to future adjustment due to certain events, including the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. If the entire principal is converted into shares of common stock (including approximately \$3.9 million in default amounts accrued with respect to the Default Notes), we would be required to issue an aggregate of no less than 84.5 million shares of common stock. If we issue all of these shares, the ownership of our current stockholders will be diluted.

Further, at each holder's option, we will pay interest on the convertible notes and debentures in shares of common stock based on the then current conversion price. To date, we have issued approximately [●] million shares of common stock as in-kind interest payments on our convertible notes and debentures. Such interest payments could further dilute our current stockholders.

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

Historically, the trading price of our common stock has been \$5.00 per share or lower, and deemed a penny stock, as defined in Rule 3a51-1 under the Exchange Act, and subject to the penny stock rules of the Exchange Act specified in rules 15g-1 through 15g-100. Those rules require broker-dealers, before effecting transactions in any penny stock, to:

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

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

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

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

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

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock may be negatively affected. In the event that we receive securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

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

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

*An investment in this offering may result in uncertain U.S. federal income tax consequences.*

An investment in this offering may result in uncertain U.S. federal income tax consequences. For instance, because there are no authorities that directly address instruments similar to the Units part of this offering, the allocation an investor makes with respect to the purchase price of a Unit between the common stock and Common Warrant included in each Unit (or between the Pre-Funded Warrant and Common Warrant included in each Pre-Funded Unit) could be challenged by the IRS or courts. See “*Material United States Federal Income Tax Considerations*” for a summary of the U.S. federal income tax considerations of an investment in our securities. Prospective investors are urged to consult their tax advisors with respect to these and other tax consequences when acquiring, owning or disposing of our securities.

**Risks Relating to this Offering and our Reverse Stock-Split**

***Our Bridge Notes automatically convert at the closing of this offering at the lower of \$4.00 per Unit or a 30% discount to the offering price of the Units, and our Settlement Warrants will be cancelled and shares issued as a result, all of which could negatively impact trading in our securities.*** On March 6, 2020, we completed the offering of \$1,992,000 of the Bridge Notes that provided for the automatic conversion into shares of our common stock at the closing of this offering at the lower of \$4.00 per share or a 30% discount to the offering price of the Units. Purchasers of the Bridge Notes also received warrants (the “Settlement Warrants”) in the private placement. On June 15, 2020, we entered into agreements with the holders of the Bridge Notes to provide that the Bridge Notes will automatically convert upon the closing of this offering into shares of our common stock and warrants underlying the Units at the lower of \$4.00 per Unit or a 30% discount to the public offering price of the Units. As of June 15, 2020, two holders representing \$200,000 in the aggregate of the outstanding Bridge Notes automatically convertible into an aggregate of 51,948 shares of common stock at an exercise price of \$3.85 per share (based on an assumed public offering price of \$5.50 per Unit) and who hold Settlement Warrants to purchase an aggregate of 50,000 shares of common stock, or 68,182 shares of common stock after the offering at the assumed public offering price of \$5.50 per Unit, have not yet signed the agreement. The agreements further provide that, immediately upon the closing of this offering, the Settlement Warrants will be cancelled and in lieu thereof each holder will receive 0.4 of a share of common stock for each share formerly underlying such cancelled 2020 Warrant. As a result, the investors in this offering will experience immediate dilution when the Bridge Notes are automatically converted into shares of our common stock and warrants and the Settlement Warrants are cancelled and shares in lieu thereof are issued at the closing of this offering. We estimate that approximately 517,403 shares and warrants to purchase 517,403 shares will be issuable upon conversion of the Bridge Notes, assuming a \$3.85 conversion price and not taking into account interest earned, and 199,200 shares will be issued to holders upon cancellation of the Settlement Warrants. We have agreed to register the shares and warrants underlying the Bridge Notes, as well as the shares underlying the warrants issued upon automatic conversion of the Bridge Notes, and the shares issued upon cancellation of the Settlement Warrants for resale under the Securities Act. The holders of the Bridge Notes and Settlement Warrants have agreed to certain lock-up provisions with respect to the securities received upon conversion of the Bridge Notes and Settlement Warrants as described below under “*Underwriting—Lock-up Agreements.*” The automatic conversion of the Bridge Notes into shares of our common stock and warrants and issuance of shares upon cancellation of the Settlement Warrants will be dilutive to our holders and could negatively impact the trading market and price of our common stock following the offering.

***Our management team will have immediate and broad discretion over the use of net proceeds from this offering and may not use them effectively.***

We intend to use the net proceeds of this offering for general corporate purposes, which includes, among other purposes, the [●]. See “*Use of Proceeds.*” However, our management will still have broad discretion in the application of such proceeds. Our shareholders may not agree with the manner in which our management chooses to allocate the net proceeds from this offering. The failure by our management to apply these funds effectively could have a material adverse effect on our business, financial condition and results of operation. Pending their use, management may invest the net proceeds from this offering in a manner that does not produce income. The decisions made by our management may not result in positive returns on your investment, and you will not have an opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

***You may experience immediate and substantial dilution in the net tangible book value of the common shares you purchase.***

The offering price of the common shares underlying the Units and the Pre-Funded Units offered pursuant to this prospectus is substantially higher than the net tangible book value per share. Therefore, if you purchase Units or Pre-Funded Units, you will incur immediate and substantial dilution in the pro forma net tangible book value per common share from the price per unit that you pay for the underlying share. If the holders of outstanding options or warrants exercise those options or warrants at prices below the offering price, you will incur even further dilution. See “*Dilution.*”

***There is no public market for the Common Warrants or Pre-Funded Warrants being offered.***

There is no established public trading market for the Common Warrants or Pre-Funded Warrants being offered pursuant to this offering, nor do we expect such a market to develop. We do not intend to apply to list any Common Warrants or Pre-Funded Warrants on any securities exchange or other nationally recognized trading system, including NASDAQ. Without an active market, the liquidity of such Common Warrants and Pre-Funded Warrants will be limited.

***Holders of the Common Warrants and Pre-Funded Warrants purchased pursuant to this offering will have no rights as common shareholders until such holders exercise the Common Warrants and Pre-Funded Warrants and acquire our common shares.***

Holders of Common Warrants and Pre-Funded Warrants purchased in this offering only acquire our common shares upon exercise thereof, meaning holders will have no rights with respect to the shares of our common shares underlying such warrants. Upon the exercise of any of the warrants purchased, such holders will be entitled to exercise the rights of a shareholder only as to matters for which the record date occurs after the exercise date. The Common Warrants and the Underwriter Warrants are speculative in nature. The Common Warrants being sold in this offering have an exercise price of \$[●] per common share, the Pre-Funded Warrants \$[●], and the Underwriter Warrants have an exercise price of \$[●]. The Common Warrants will expire on the [●] anniversary from the issuance date, and the Underwriter Warrants will expire on the [●] anniversary from the effective date of this offering. In the event our common share price does not exceed the per share exercise price of the Common Warrants or the Underwriter Warrants during the period when such warrants are exercisable, such warrants will not have any value.

## USE OF PROCEEDS

We estimate that our net proceeds from this offering will be approximately \$

million, based on the sale of the maximum amount of Units in this offering at an assumed public offering price of \$ per Unit after deducting the underwriter fees and estimated offering expenses payable by us.

If a holder of Common Warrants elects to exercise the Common Warrants issued in this offering, we may also receive proceeds from the exercise of the Common Warrants. We cannot predict when or if the Common Warrants will be exercised. It is possible that the Common Warrants may expire and may never be exercised.

Each \$[●] increase or decrease in the assumed public offering price of \$ per Unit would increase or decrease, respectively, our net proceeds by approximately \$ million, assuming the maximum number of Units offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting underwriter fees and estimated offering expenses payable by us. We may also increase or decrease the number of Units we are offering. An increase or decrease of 1,000,000 in the number of Units we are offering would increase or decrease, respectively, the net proceeds from this offering, after deducting underwriter fees and estimated offering expenses payable by us, by approximately \$ million, assuming the assumed public offering price stays the same.

We intend to use the net proceeds of this offering for general corporate purposes, which includes, among other purposes, the [ ].

Our expected use of net proceeds from the offering represents our current intentions based upon our present plans and business condition. Investors are cautioned, however, that expenditures may vary substantially from these uses. Investors will be relying on the judgment of our management, who will have broad discretion regarding the application of the proceeds of this offering. The amounts and timing of our actual expenditures will depend upon numerous factors, including the amount of cash generated by our operations, the amount of competition and other operational factors. We may find it necessary or advisable to use portions of the proceeds from this offering for other purposes.



## UNDERWRITING

We have entered into an underwriting agreement with Dawson James Securities, Inc. with respect to the offering. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriter, and the underwriter has agreed to purchase from us on a firm commitment basis, the number of units set forth opposite its name in the table below.

Underwriter	Number of Units (1)
Dawson James Securities, Inc.	
Total	

(1) The shares and warrants comprising the Units will be separately issued but will be purchased together in this offering.

The underwriting agreement provides that the obligations of the underwriter are subject to certain conditions precedent and that the underwriter has agreed to purchase all of the Units sold under the underwriting agreement if any of these Units are purchased. The underwriter proposes to offer to the public the Units purchased pursuant to the underwriting agreement at the public offering price per Unit on the cover page of this prospectus supplement. The underwriter may offer some of the Units to other securities dealers at such price less a concession of \$[ ] per Unit.

The underwriter may also allow, and such dealers may re-allow, a concession not in excess of \$[ ] per Unit to other dealers. After the Units are released for sale to the public, the underwriter may change the offering price and other selling terms at various times.

The factors considered in determining the public offering price included the recent market price of our common stock, the general condition of the securities market at the time of this offering, the history of, and the prospects for, the industry in which we compete, our past and present operations and our prospects for future revenues. Dawson James Securities, Inc., its officers and its registered representatives may participate in this offering on the same terms and conditions as the investors participating in this offering.

The following table shows the per Unit price and total underwriting discounts and commissions we will pay in connection with the sale of the Units.

Per Unit underwriting discount	\$
Total	\$

In addition, we have agreed to reimburse the underwriter for its expenses in an amount not to exceed \$25,000.

Pursuant to the underwriting agreement, for a period of twelve months from the closing of this offering, we will grant Dawson James Securities, Inc. the right of first refusal to act as lead managing underwriter and book runner, for future equity, or convertible debt (excluding non-convertible debt, at the market financing and strategic investments) offerings during such period.

We have also agreed to issue to the underwriter or its designees a five-year Unit purchase option to purchase 5% of the aggregate number of Units sold in this offering at an exercise price equal to \$ [ ] per Unit (125% of the public offering price per Unit). The Unit purchase option will be exercisable at any time and from time to time, in whole or in part, during the period commencing six months following the commencement date of this offering, and ending five years from the commencement date of this offering.

The Unit purchase option provides for a cashless exercise provision, registration rights (including a one-time demand registration right and unlimited piggyback rights) and customary anti-dilution provisions (for stock dividends and splits and recapitalizations) consistent with FINRA Rule 5110. The Unit purchase option and the underlying securities are deemed compensation by FINRA, and are therefore subject to FINRA Rule 5110(g)(1). In accordance with FINRA Rule 5110(g)(1), neither the Unit purchase option nor any securities issued upon exercise of the Unit purchase option may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities by any person for a period of 180 days immediately following the date of commencement of sales of the offering pursuant to which the Unit purchase option is being issued, except the transfer of any security: (i) by operation of law or by reason of reorganization of our company; (ii) to any FINRA member firm participating in this offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period; (iii) if the aggregate amount of our securities held by either a underwriter or a related person do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

We have granted to the underwriter a 45-day option to purchase up to an additional 15% of the total Units offered pursuant to this the offering.

We will pay the expenses associated with the exercise of the over-allotment option.

In connection with this offering, the underwriter may engage in stabilizing transactions, over-allotment transactions, syndicate covering transactions, penalty bids and purchases to cover positions created by short sales.

- Stabilizing transactions permit bids to purchase Units so long as the stabilizing bids do not exceed a specified maximum, and are engaged in for the purpose of preventing or retarding a decline in the market price of the Units while the offering is in progress.
- Syndicate covering transactions involve purchases of Units in the open market after the distribution has been completed in order to cover syndicate short positions. If the underwriters sell more shares than set forth herein and, therefore, have a naked short position, the position can be closed out only by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that after pricing there could be downward pressure on the price of the shares in the open market that could adversely affect investors who purchase in the offering.
- Penalty bids permit the representative to reclaim a selling concession from a syndicate member when the common stock originally sold by that syndicate member are purchased in stabilizing or syndicate covering transactions to cover syndicate short positions.

This prospectus may be made available in electronic format on Internet sites or through other online services maintained by the underwriter or its affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. Other than this prospectus in electronic format, any information on the underwriter's or its affiliates' websites and any information contained in any other website maintained by the underwriter or any affiliate of the underwriter is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriter and should not be relied upon by investors.

The underwriter or its affiliates have in the past and may in the future engage in transactions with, and may perform, from time to time, investment banking and advisory services for us in the ordinary course of their business and for which they would receive customary fees and expenses. In addition, in the ordinary course of their business activities, the underwriter and its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for its own account and for the accounts of its customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates.

The underwriting agreement provides that our directors and executive officers will agree for a period of six months from the date of this offering, not to (a) offer, sell, or otherwise transfer or dispose of, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; or (b) file or caused to be filed any registration statement relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock.

The foregoing description of the underwriting agreement is only a summary, does not purport to be complete and is qualified in its entirety by reference to the underwriting agreement and underwriter Unit purchase option, copies of which are included as exhibits to the registration statement of which this prospectus forms a part.

## MARKET INFORMATION

Our common stock is quoted on the OTCQB under the symbol “GTBP.” Our common stock is also quoted on several European based exchanges, including Berlin (GTBPBE), Frankfurt (GTBP.DE), the Euronext (GTBP.NX) and Paris (GTBP.PA).

### Stockholders

As of November 30, 2020, there were 33 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 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 during such time.

## CONSOLIDATED CAPITALIZATION

The following table presents the number of our issued and outstanding shares of common stock and our consolidated cash and cash equivalents and capitalization as at September 30, 2020; (i) on an actual basis; and (ii) on an as adjusted basis to give effect to the sale by us of [●] Units in this offering at the public offering price of \$[●] per Unit, and the sale of [●] Pre-Funded Units at the public offering price of \$[●] per Pre-Funded Unit and assuming the full exercise of the Pre-Funded Warrants sold in this offering, after deducting estimated underwriter fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the Common Warrants and Underwriter Warrants issued pursuant to this offering.

The information below has been derived from and should be read in conjunction with, and is qualified in its entirety by, our unaudited consolidated financial statements as at September 30, 2020, and for the six-month periods ended June 30, 2020 and 2019, and the Management's Discussion and Analysis thereon, incorporated by reference into this prospectus supplement. Figures are in thousands of U.S. dollars except share data.

(in thousands except per share data)	September 30, 2020	
	Actual	As Adjusted
Number of Common Shares issued and outstanding	77,518	
Cash and cash equivalents	350	
Shareholders' equity	(29,777)	
Share capital		
Other capital		
Deficit		
Accumulated other comprehensive income		
Total shareholders' equity and total capitalization		

The number of shares of common stock that will be outstanding both before and immediately after this offering is based on 77,518,614 shares outstanding as of September 30, 2020, and excludes as of such date:

- 7.8 million shares of common stock issuable upon the exercise of outstanding warrants at a weighted average exercise price of \$0.20 per share;
- [●] shares of common stock issuable upon the exercise of outstanding stock options and deferred share units at a weighted average exercise price of \$[●] per share;
- [●] shares of common stock reserved for future issuance under our 2014 Stock Incentive Plan;
- [●] shares of common stock reserved for future issuance under our [Stock Option Plan] adopted by our Board of Directors on [●], and ratified by the shareholders on [●];
- [●] shares of common stock issuable upon the exercise of warrants to be issued to investors in this offering at an exercise price of \$[●] per share; and
- [●] shares of common stock issuable upon the exercise of the Underwriter Warrants to be issued to the underwriter at an exercise price of \$[●] per share.

## DILUTION

If you invest in our common stock and warrants, your interest will be diluted immediately to the extent of the difference between the public offering price per unit and the as-adjusted net tangible book value per share after this offering.

The net tangible book value (deficit) of our common stock as of November 30, 2020 was approximately \$[●], or approximately \$[●] per share. Net tangible book value per share represents the amount of our total tangible assets less total liabilities divided by the total number of our shares of common stock outstanding as of November 30, 2020.

After giving effect to the sale of Units in this offering at the public offering price of \$ per Unit, and the sale of Pre-Funded Units at the public offering price of \$ per Pre-Funded Unit and assuming the full exercise of the Pre-Funded Warrants sold in this offering, after deducting estimated underwriter fees and estimated offering expenses payable by us, and excluding the proceeds, if any, from the exercise of the Common Warrants and Underwriter Warrants issued pursuant to this offering, our as adjusted net tangible book value as of November 30, 2020 would have been approximately \$ , or approximately \$ per share. This represents an immediate increase in net tangible book value of approximately \$ per share to our existing security holders and an immediate dilution in as-adjusted net tangible book value of approximately \$ per share to purchasers of units in this offering, as illustrated by the following table:

Public offering price per Unit
Consolidated net tangible book value per Common Share
Increase in consolidated net tangible book value per Common Share
As adjusted consolidated net tangible book value per Common Share
Dilution per Common Share to new investors participating in this offering

**If the underwriter exercises in full its option to purchase additional Units in full, the as adjusted net tangible book value of our common stock after this offering would be \$ per share, representing an immediate increase in net tangible book value of approximately \$ per share to existing stockholders and an immediate dilution of \$ per share to the investors in this offering, after deducting the underwriting discount and estimated offering expenses payable by us. To the extent that outstanding options or warrants outstanding as of November 30, 2020, have been or may be exercised or other shares issued, investors participating in this offering may experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.**

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

**Overview**

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

**Recent Developments**

*Financings*

November 2020 Financing

In November, 2020, we entered into a securities purchase agreement with three purchasers pursuant to which we issued convertible debentures in an aggregate principal amount of \$350,000 (the "November 2020 Notes").

The November 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The November 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the November 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above.

The November 2020 Notes each have a term of six months and mature in May, 2021, unless earlier converted or repurchased. The November 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder's option, in shares of common stock based on the conversion price then in effect. We may not prepay the November 2020 Notes without the prior written consent of the applicable holder.

September 2020 Financing

On September 16, 2020, we entered into a securities purchase agreement with two purchasers pursuant to which we issued the September 2020 Notes in an aggregate principal amount of \$250,000.

The September 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The September 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the September 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above.

The September 2020 Notes each have a term of six months and mature on March 16, 2021, unless earlier converted or repurchased. The September 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder's option, in shares of common stock based on the conversion price then in effect. We may not prepay the September 2020 Notes without the prior written consent of the applicable holder.

#### July 2020 Financing

On July 7, 2020, we entered into a securities purchase agreement with ten purchasers pursuant to which we issued the July 2020 Notes in an aggregate principal amount of approximately \$3.2 million.

The July 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The July 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the July 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above.

The July 2020 Notes each have a term of six months and mature on January 7, 2021, unless earlier converted or repurchased. The July 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder's option, in shares of common stock based on the conversion price then in effect. We may not prepay the July 2020 Notes without the prior written consent of the applicable holder.

#### May 2020 Financing

Between April 20, 2020 and May 7, 2020, we entered into securities purchase agreements with eight purchasers pursuant to which we issued convertible notes in an aggregate principal amount of approximately \$2.0 million.

The May 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The May 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the May 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above.

The May 2020 Notes each have a term of six months and mature between October 20, 2020 and November 7, 2020, unless earlier converted or repurchased. The May 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder's option, in shares of common stock based on the conversion price then in effect. We may not prepay the May 2020 Notes without the prior written consent of the applicable holder.

#### January 2020 Financing

On January 30, 2020, we entered into a securities purchase agreement with one purchaser pursuant to which we issued the January 2020 Notes in an aggregate principal amount of \$0.2 million.

The January 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect.

The January 2020 Notes have a term of eight months and mature on September 30, 2020, unless earlier converted or repurchased. The January 2020 Notes accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder's option, in shares of common stock based on the conversion price then in effect. We may not prepay the January 2020 Notes without the prior written consent of the holder.

For additional information regarding the terms of our convertible notes and debentures, including the Bridge Notes, and the securities purchase agreements pursuant to which they were issued, see "*Indebtedness—Convertible Notes/Debentures*" below.

#### **Manufacturing Agreement**

Effective October 5, 2020, the Company entered into a Master Services Agreement (the "MSA"), with Cytovance Biologics, Inc., ("Cytovance"), a subsidiary of Shenzhen Hepalink Pharmaceutical Group Co., Ltd. Cytovance is headquartered in Oklahoma City, Oklahoma.

Under the MSA, the Company will engage Cytovance as the exclusive manufacturer for three of the Company's TriKE™ therapeutic product candidates. Cytovance will manufacture TriKE™ using Cytovance's proprietary Keystone® bacterial or mammalian expression systems. Subject to the completion of certain milestones by Cytovance, GT Biopharma has the option to pay Cytovance up to \$6 million for its manufacturing services in either cash or in shares of the Company's common stock valued at the time Cytovance achieves each of several milestones over the next 12 months.

#### ***Forbearance Agreements***

Effective as of June 23, 2020, we entered into the Forbearance Agreements with the holders of approximately \$13.2 million aggregate principal amount of the Default Notes, which are currently in default. Pursuant to the Forbearance Agreements, the holders of the Default Notes have agreed to forbear from exercising their rights and remedies under the Default Notes (including declaring such Default Notes (together with default amounts and accrued and unpaid interest) immediately due and payable) until the earlier of (i) the date that we complete a New Financing or (ii) the Termination Date.

Pursuant to the Forbearance Agreement, the holders of the Default Notes have also agreed that the Default Notes (together with default amounts and accrued and unpaid interest) will be converted into common stock upon the closing of a New Financing at a conversion price equal to the lesser of (i) the conversion price in effect for the Default Notes on the date of such New Financing or (ii) 75% of the lowest per share price at which common stock is or may be issued in connection with such New Financing, in each case, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). Shares of our Series J-1 Preferred Stock, which are convertible into the Company's common stock, will be issued in lieu of common stock to the extent that conversion of the Default Notes is prohibited by such beneficial ownership limitations.

For additional information regarding the terms of the Forbearance Agreements, see "*Indebtedness—Forbearance Agreements*" below.

#### ***Extension Agreements***

Effective as of November 9, 2020, we entered into the New Financing with the holders of approximately \$[●] million aggregate principal amount of our outstanding convertible notes and debentures to extend the maturity date thereof until the earlier of (i) the date that we complete a future financing in the amount of at least \$15 million and, in connection therewith, commences listing on NASDAQ or (ii) the Termination Date.



## ***Settlement with Empery Funds***

### **Settlement Agreement**

On June 19, 2020, we entered into the Settlement Agreement with the Empery Funds, Anthony Cataldo and Paul Kessler resolving all remaining disputes between the parties pertaining to the Original Securities issued by the Company to the Empery Funds in January 2018 pursuant to a securities purchase agreement. See “*Description of Business—Legal Proceedings.*”

As a result of the Settlement Agreement, the Company paid the Empery Funds cash payments in an aggregate amount of \$0.2 million. In addition, pursuant to the Settlement Agreement, the Company issued to the Empery Funds, solely in exchange for the outstanding Original Securities, (i) an aggregate of 3.5 million shares of common stock, (ii) pre-funded warrants to purchase an aggregate of 5.5 million shares of common stock and (iii) senior convertible notes in an aggregate principal amount of \$0.45 million.

### **Settlement Notes**

The Settlement Notes are convertible at any time, at the holder’s option, into shares of common stock at an initial conversion rate of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%). The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect.

The Settlement Notes have a term of six months, maturing on December 19, 2020, and bear interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder’s option, in shares of common stock based on the conversion price then in effect.

Pursuant to the terms of the Settlement Notes, the Company is required to make an offer to repurchase, at the holder’s option, the Settlement Notes at price in cash equal to 100% of the aggregate principal amount of the Settlement Note plus accrued and unpaid interest, if any, to, but excluding, the date of repurchase following the consummation by the Company of a capital raising transactions, or a series of transactions, resulting in aggregate gross proceeds to the Company in excess of \$7.5 million. The Company may not otherwise prepay the Settlement Notes without the prior written consent of the applicable Empery Funds.

For additional information regarding the terms of the Settlement Notes and Settlement Agreement, see “*Indebtedness—Convertible Notes/Debentures*” below.

### **Settlement Warrants**

The Settlement Warrants provide for the purchase of up to an aggregate of 5.5 million shares of common stock at an exercise price of \$0.20 per share, subject to adjustment in certain circumstances, and expire on June 19, 2025. Exercise of the warrant is subject to certain additional terms and conditions, including certain beneficial ownership limitations (with a maximum ownership limit of 4.99%).

### ***Collaboration Agreement***

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

## Results of Operations

### Comparison of the Three Months Ended September 30, 2020 and 2019

#### *Research and Development Expenses*

During the three months ended September 30, 2020 and 2019, we incurred \$0 and \$.6 thousand of research and development expenses, respectively. Research and development costs decreased less clinical expenses. We anticipate our direct clinical costs will increase in the last quarter of 2020 with the continuation of our Phase I clinical trial of our most advanced TriKe product candidate, GTB-3550.

#### *Selling, general and administrative expenses*

During the three months ended September 30, 2020 and 2019, we incurred \$2 million and \$3.6 million of selling, general and administrative expenses, respectively. The decrease in selling, general and administrative expenses is primarily attributable the reduction of payroll and stock compensation expenses.

#### *Loss on impairment*

For the three months ended September 30, 2019, the Company recorded an intangible asset impairment charge of \$4.6 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 the sale of certain assets and prioritization for immuno-oncology development candidates.

#### *Interest Expense*

Interest expenses were \$.9 million and \$.6 million for the three months ended September 30, 2020 and 2019, respectively. The increase is primarily due to the accrual of default interest under the Default Notes.

### Comparison of the Nine Months Ended September 30, 2020 and 2019

#### *Research and Development Expenses*

During the nine months ended September 30, 2020 and 2019, we incurred \$252 thousand and \$1.7 million of research and development expenses, respectively. Research and development costs decreased due primarily to the reduction of employee, consultant and preclinical expenses. We anticipate our direct clinical costs will increase in the 4<sup>th</sup> quarter of 2020 upon the continuation of our Phase I clinical trial of our most advancedTriKE product candidate, GTB-3550.

#### *Selling, general and administrative expenses*

During the nine months ended September 30, 2020 and 2019, we incurred \$4.3 million and \$8.9 million of selling, general and administrative expenses, respectively. The decrease in selling, general and administrative expenses is primarily attributable the reduction of payroll and stock compensation expenses.

#### *Loss on impairment*

For the three months ended September 30, 2019, the Company recorded an intangible asset impairment charge of \$4.6 million related to the portfolio of CNS IPR&D assets, which represents the excess carrying value compared to the fair value. The impairment charge was the result of the sale of certain assets and prioritization for immuno-oncology development candidates.

#### *Interest Expense*

Interest expenses were \$6.2 million and \$1.5 million for the nine months ended September 30, 2020 and 2019 respectively. The increase is primarily due to the accrual of default interest under the Default Notes.

## **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 nine months ended September 30, 2020, the Company raised \$5.7 million through a series of issuances 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 Company is pursuing several alternatives to address this situation, including the raising of additional funding through equity or debt financings. In order to finance existing operations and pay current liabilities over the next 12 months, the Company will need to raise an additional \$18 million of capital.

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 \$580 million and cash of \$350 thousand as of September 30, 2020. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales or revenue from out-licensing of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern.

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

## **Indebtedness**

### ***Convertible Notes/Debentures***

As of the date of this prospectus, after giving effect to (i) the issuance of the July 2020 Notes and the May 2020 Notes and (ii) the issuance of the Settlement Notes pursuant to the Settlement Agreement, we had approximately \$18.8 million aggregate principal amount of convertible notes and debentures outstanding that were issued pursuant to securities purchase agreements (or, in the case of the Settlement Notes, the Settlement Agreement) entered into with numerous investors.

The convertible notes and debentures are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion rate, subject to certain beneficial ownership limitations (which vary between maximum ownership of between 4.99% and 9.99%). The conversion price is also generally subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The conversion price for each of our outstanding convertible notes and debentures is currently \$0.20 per share. In addition, the July 2020 Notes and the May 2020 Notes will be subject to mandatory conversion in connection with the completion of a future financing in the amount of at least \$15 million, subject to the beneficial ownership limitations described above.

The convertible notes and debentures generally have terms of six months to one year. The convertible notes and debentures each accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default with respect to certain of our convertible notes and debentures. Interest is payable in cash or, with respect to certain of our convertible notes and debentures, and at the holder's option, in shares of common stock based on the conversion price then in effect.

Pursuant to the terms of the Settlement Notes, the Company is required to make an offer to repurchase, at the holder's option, the Settlement Notes at price in cash equal to 100% of the aggregate principal amount of the Settlement Note plus accrued and unpaid interest, if any, to, but excluding, the date of repurchase following the consummation by the Company of a capital raising transactions, or a series of transactions, resulting in aggregate gross proceeds to the Company in excess of \$7.5 million. Generally, we otherwise do not have the right to prepay any of the convertible notes and debentures without the prior written consent of the holders of such securities.

The convertible notes and debentures contain a number of affirmative and negative covenants and customary events of default. See *"Risk Factors—Risks Related to Our Business—Our current and future indebtedness may impose significant operating and financial restrictions on us and affect our ability to access liquidity."*

The securities purchase agreements and Settlement Agreement, as applicable, also generally contain certain ongoing covenants of the Company, including rights of participation in certain future financing transactions, limitations on future variable rate transactions at "at-the-market" offerings and "most favored nation" provisions giving holders of certain of the convertible notes and debentures 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 holder under the applicable securities purchase agreement and the transactions contemplated thereby.

The convertible notes and debentures are senior obligations of the Company. In addition, approximately \$1.4 million aggregate principal amount of the convertible note and debenture are secured by a first priority security interest in substantially all of the assets of the Company and its subsidiaries. Certain convertible note and debentures are also secured by individual pledges by certain of our current and former officers and directors of our common stock owned by such officer and directors.

For additional information about our convertible notes and debentures, see Note 2 to our unaudited financial statements, *Debt*.

#### ***Forbearance Agreements***

Effective as of June 23, 2020, we entered into the Forbearance Agreements with the holders of \$13.2 million aggregate principal amount of the Default Notes, which are currently in default. Pursuant to the Forbearance Agreements, the holders of the Default Notes have agreed to forbear from exercising their rights and remedies under the Default Notes (including declaring such Default Notes (together with default amounts and accrued and unpaid interest) immediately due and payable) until the earlier of (i) the date that we complete a New Financing or (ii) the Termination Date. As a result of the ongoing default, the Default Notes are currently accruing interest at the default rate of 18% per annum and have also accrued defaults in an aggregate amount of \$3.9 million.

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

The Forbearance Agreements contain various customary and other representations, warranties and covenants of the Company and the holders of the Default Notes, including an agreement that the Default Notes (together with default amounts and accrued and unpaid interest) will be converted into common stock upon the closing of a New Financing at a conversion price equal to the lesser of (i) the conversion price in effect for the Default Notes on the date of such New Financing or (ii) 75% of the lowest per share price at which common stock is or may be issued in connection with such New Financing, in each case, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). Shares of our Series J-1 Preferred Stock, which are convertible into the Company's common stock, will be issued in lieu of common stock to the extent that conversion of the Default Notes is prohibited by such beneficial ownership limitations.

### ***Gemini 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 bear interest at the rate of interest of prime plus 2% per annum. There is \$31,000 due on this credit line at September 30, 2020.

### **Critical Accounting Policies**

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

#### *Basis of Consolidation*

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

#### *Long-Lived Assets*

Our long-lived assets include property, plant and equipment, capitalized costs of filing patent applications and goodwill and other assets. We evaluate our long-lived assets for impairment in accordance with Accounting Standards Codification ("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 November 30, 2020.

## 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™) and Tetra-specific Killer Engager (TetraKE™). Our TriKE and TetraKE platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell and precisely direct it to one or more specifically-targeted proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in the targeted cell's death. TriKEs and TetraKEs are made up of recombinant fusion proteins, can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization.

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

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

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

### **Immuno-Oncology Platform**

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

The generation of chimeric antigen receptor ("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, ("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 CAR-T therapy, it has certain limitations for broad potential applicability because it can require an individual approach that is expensive and time consuming, and may be difficult to apply on a large scale. NK cells represent an important immunotherapeutic target as they are involved in tumor immune-surveillance, can mediate ADCC, contain pre-made granules with perforin and granzyme B and can quickly secrete inflammatory cytokines, and unlike T cells they do not require antigen priming and can kill cells in the absence of major histocompatibility complex ("MHC") presentation of antigens. We believe there is a continued unmet medical need for targeted immuno-oncology therapies that can have the potential to be dosed in a patient-friendly outpatient setting, can be used on a stand-alone basis, augment the current monoclonal antibody therapeutics or be used in conjunction with more traditional cancer therapy. We believe our TriKE and TetraKE constructs have this potential and therefore we have generated, and intend to continue to generate, a pipeline of product candidates to be advanced into the clinic on our own or through potential collaborations with larger companies.

### ***GTB-3550 TriKE™ and GTB-3550 TriKE™ Phase I/II Clinical Trial***

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

NK cells represent an important immunotherapeutic target as they are involved in tumor immune-surveillance, can mediate 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 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 ("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.

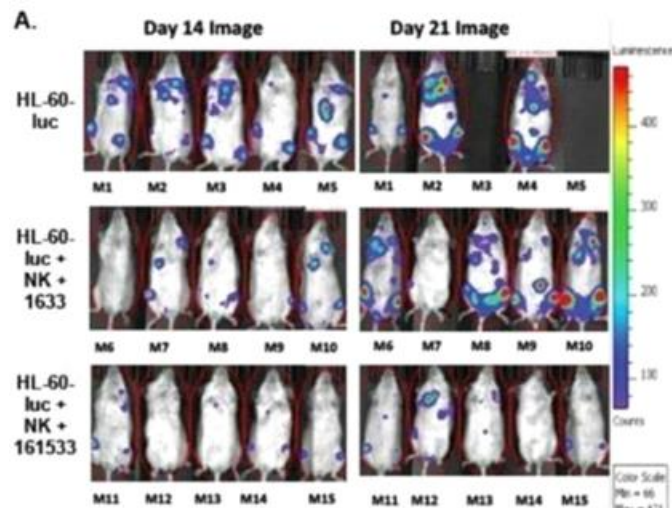
When compared to the CD16 x CD33 BiKE, the CD16 x IL-15 x CD33 TriKE is also capable of potentially restoring killing capacity of post-transplant NK cells against CD33-expressing HL-60 targets and primary AML blasts. These results demonstrated the ability to functionally incorporate an IL-5 cytokine into the BiKE platform and also demonstrated the possibility of targeting a variety of cytokines directly to NK cells while reducing off-target effects and the amount of cytokines needed to obtain biologically relevant function.

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

The TriKE constructs were also tested against three separate human tumor cell lines: HL-60 (promyelocytic 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.

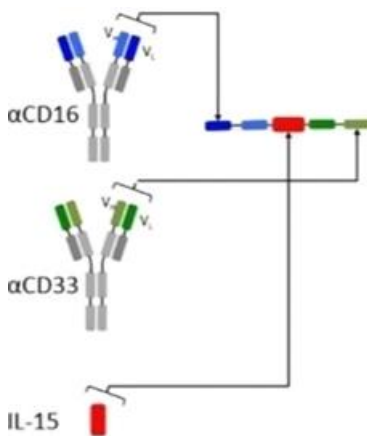




Based on these results, and others, the IND for GTB-3550 was filed in June 2017 by the University of Minnesota. The FDA requested that additional preclinical toxicology be conducted prior to initiating clinical trials. The FDA also requested some additional information and clarifications on the manufacturing 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 I study with GTB-3550 in AML, MDS and severe mastocytosis. We began the Phase I clinical trial in January 2020.

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

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



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

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

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

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

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

### **Immuno-Oncology Product Candidates**

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 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.

In addition, we have recently terminated further development of GTB-1550, which targets CD19+ and/or CD22+ hematological malignancies following completion of the Phase II component of a Phase I/II NHL/ALL trial.

#### ***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 AML, MDS, and other hematopoietic malignancies. CD33 is primarily a myeloid differentiation antigen with endocytic properties broadly expressed on AML blasts and, possibly, some leukemic stem cells. CD33 or Siglec-3 (sialic acid binding Ig-like lectin 3, SIGLEC3, SIGLEC3, gp67, p67) is a transmembrane receptor expressed on cells of myeloid lineage. It is usually considered myeloid-specific, but it can also be found on some lymphoid cells. The anti-CD33 antibody fragment that will be used for these studies was derived from the M195 humanized anti-CD33 scFv and has been used in multiple human clinical studies. It has been exploited as target for therapeutic antibodies for many years. We believe the recent approval of the antibody-drug conjugate gemtuzumab validates this targeted approach.

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

The IND for GTB-3550 was filed in June 2017 by the University of Minnesota. The 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 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 I study with GTB-3550 in AML, MDS and severe mastocytosis. We began the Phase I clinical trial in January 2020.

### **GTB-C3550**

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

### **GTB-1615**

GTB-1615 is an example of our first-generation TetraKEs designed for the treatment of solid tumors. It is a single-chain fusion protein composed of CD16-IL15EpCAM-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 later this year.

### **Our Strategy**

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

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

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

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

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

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

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

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

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

## **Oncology Markets**

### ***B-cell Lymphomas/Leukemias***

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

### ***Acute Lymphoblastic Leukemia***

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

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

### ***Multiple Myeloma***

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

## ***Myeloid Leukemias***

### **Acute Myeloid Leukemia**

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

## ***Sarcomas***

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

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

## **Manufacturing**

We do not currently own or operate manufacturing facilities for the production of clinical or commercial quantities of any of our product candidates. We rely on a small number of third-party manufacturers to produce our compounds and expect to continue to do so to meet the preclinical and clinical requirements of our potential product candidates as well as for all of our commercial needs. We do not have long-term agreements with any of these third parties. We require in our manufacturing and processing agreements that all third-party contract manufacturers and processors produce active pharmaceutical ingredients and finished products in accordance with the FDA's cGMPs 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.

## **Intellectual Property**

We seek to protect our proprietary information by means of United States and foreign patents, trademarks and copyrights. In addition, we rely upon trade secret protection and contractual license agreements to protect certain of our proprietary information and products. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally or licensed or acquired from third parties. We also plan to rely on regulatory protection afforded through orphan drug designations, available regulatory exclusivities and patent term extensions where available. To achieve this objective, a strategic focus for us has been to develop our own intellectual property, while also identifying and licensing patents that provide protection and serve as an optimal platform to enhance our intellectual property and technology base.

### ***University of Minnesota Licensed Intellectual Property***

We are party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, to further develop and commercialize cancer therapies using TriKE technology developed by researchers at the university to target NK cells to cancer. Under the terms of the agreement, we receive exclusive rights to conduct research and to develop, make, use, sell, and import TriKE technology worldwide for the treatment of any disease, state or condition in humans. We are responsible for obtaining all permits, licenses, authorizations, registrations and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as the TriKE technology, including without limitation the FDA in the United States and the European Agency for the Evaluation of Medicinal Products in the European Union. We are presently evaluating GTB-3550, our lead TriKE therapeutic product candidate in a Phase I/II clinical trial. Under the agreement, the University of Minnesota will receive an upfront license fee, royalty fees ranging from 4% to 6%, minimum annual royalty payments of \$0.25 million beginning in 2022, \$2.0 million in 2025, and \$5.0 million in 2027 and certain milestone payments totaling \$3.1 million.

The TriKE™ patent estate licensed from the Regents of the University of Minnesota includes more than 18 patent applications and the following foundational patent application:

<b>Appl. No.</b>	<b>Title</b>	<b>Country</b>	<b>Status</b>
PCT Patent Application Number PCT/US2016/055722	Therapeutic compounds and methods	Worldwide	Pending

***Daniel A. Vallera, Ph.D. Licensed Intellectual Property***

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 received exclusive rights to conduct research and to develop, make, use, sell, and import DT2219ARL worldwide for the treatment of any disease, state or condition in humans. We shall be responsible for obtaining all permits, licenses, authorizations, registrations and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as DT2219ARL, including without limitation the FDA in the United States and the European Agency for the Evaluation of Medicinal Products in the European Union. . Under the agreement, Dr. Vallera will receive an upfront license fee, royalty fees ranging from 3% for net sales and 25% of net sublicensing revenues, and certain milestone payments totaling \$1.5 million.

The patent estate licensed from the Dr. Vallera includes more than 16 patent applications and the following issued U.S. patent and U.S. patent application:

<b>Pat./Pub. No.</b>	<b>Title</b>	<b>Country</b>	<b>Status</b>
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

**Employees**

As of November \_\_\_\_, 2020, we had two employees. Many of our activities are outsourced to consultants who provide services to us on a project basis. As business activities require and capital resources permit, we will hire additional employees to fulfill our company’s needs.

**Legal Proceedings**

On December 24, 2018, the Empery Funds 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 the Empery Funds and the Company pursuant to which the Company issued the Original Securities to the Empery Funds in or around January 2018. On June 19, 2020, the Company and the Empery Funds, among others, entered into the Settlement Agreement resolving all remaining disputes between the parties pertaining to the Original Securities. See “*Prospectus Summary—Recent Developments—Settlement with Empery Funds.*”

On August 28, 2019, a complaint was filed in the Superior Court of California, County of Los Angeles, West Judicial District, Santa Monica Courthouse, Unlimited Civil Division by Jeffrey Lion and Daniel Vallera. Lion and Vallera are referred to jointly as the “Plaintiffs”. The complaint was filed against the Company and its subsidiary Oxis Biotech, Inc. (either of them or jointly, the “Defendant”). The Plaintiffs allege breach of a license agreement between the Plaintiffs and the Defendant entered into on or about September 3, 2015. Lion alleges breach of a consulting agreement between Lion and the Defendant entered into on or about September 1, 2015. Vallera alleges breach of a consulting agreement between Vallera and the Defendant entered into in or around October, 2018. The complaint seeks actual damages of \$1,670,000, for the fair market value of the number of shares of the Company’s common stock that at the time of judgment represent 15,000,000 shares of such stock as of September 1, 2015, and that the Company issue Lion the number of common shares the Company’s common stock that at the time of judgment represent 15,000,000 such shares as of September 1, 2015.

#### **Form and Year of Organization**

In 1965, the corporate predecessor of the Company, Diagnostic Data, Inc., was incorporated in the State of California. Diagnostic Data, Inc. 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.



## DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

Name	Age	Position
Anthony J. Cataldo	68	Chief Executive Officer and Chairman of the Board
Michael Handelman	61	Chief Financial Officer
Bruce Wendel	67	Director
Greg Berk	62	Director

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

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

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

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

#### **Board Committees, Compensation Committee Interlocks and Insider Participation**

At the present time the duties of an Audit Committee, Nominating and Governance Committee and Compensation Committee (including with respect to setting executive officer compensation) are performed by the Board as a whole. However, as a result of the appointment of Mr. Wendel and Dr. Berk to our Board, these committees will be reconstituted.

#### **Director Independence**

Mr. Wendel and Dr. Berk each qualify as an “independent director” as defined by Item 407 of Regulation S-K.

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

## EXECUTIVE COMPENSATION

As a “smaller reporting company” under SEC rules, our named executive officers for the fiscal year ended December 31, 2019 (collectively, the “Named Executive Officers”) were as follows:

- Anthony J. Cataldo, our current Chief Executive Officer;
- Steven Weldon, was appointed Chief Financial Officer on March 20, 2019, and resigned on November 10, 2020; and
- Raymond Urbanski, M.D., Ph.D., our former Chief Executive Officer who resigned from the Company on March 15, 2019.

No other executive officers received total annual compensation during the fiscal year ended December 31, 2019 in excess of \$100,000.

### Summary Compensation Table

The following table sets forth certain information relating to the total compensation earned for services rendered to us in all capacities by our Named Executive Officers.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards (\$) (1)	All Other Compensation (\$) (2)	Total (\$)
<b>Anthony J. Cataldo</b> (3)	2019	225,000	—	1,281,000	75,000	1,581,000
Chief Executive Officer	2018	190,000	—	-	404,151	594,151
<b>Steven Weldon</b> (4)	2019	230,000	—	823,500	—	1,053,500
Chief Financial Officer	2018	230,000	—	-	—	230,000
<b>Raymond Urbanski, M.D., Ph.D.</b> (5)	2019	318,000	—	-	—	318,000
Former Chief Executive Officer	2018	321,154	—	7,644,490	—	7,965,644

- (1) The amounts in this column represent the aggregate grant date fair value of the stock awards, determined in accordance with Financial Accounting Standards Board ASC Topic 718. The Company determines the grant date fair value of the awards by multiplying the number of shares granted by the closing market price of one share of the Company’s 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 sale of these awards.
- (2) The amount in this column represents compensation earned under a consultant agreement with the Company described in more detail below under “—Employment Arrangements.”
- (3) Mr. Cataldo was appointed Chief Executive Officer on March 15, 2019. Prior to his appointment as Chief Executive Officer, Mr. Cataldo provided services to the Company under a consulting agreement from February 14, 2018. Mr. Cataldo also served as Executive Chairman of the Board until February 2018 for which service he received salary in 2018.
- (4) Mr. Weldon was appointed Chief Financial Officer on March 20, 2019, and resigned on November 10, 2020.
- (5) Dr. Urbanski resigned as Chief Executive Officer on March 15, 2019.

## Employment Arrangements

On October 18, 2018, the Company entered into a consultant agreement with Anthony Cataldo (the "Consulting Agreement"). The Consulting Agreement terminated in March 2019 in connection with Mr. Cataldo's appointment as Chief Executive Officer of the Company. The Consulting Agreement replaced an earlier consulting agreement, dated February 14, 2018, and provide for payments of \$25,000 per month to Mr. Cataldo during the term of the agreement.

On April 1, 2019, the Company entered into a settlement agreement and general release with Mr. Urbanski (as amended, the "Severance Agreement") in connection with his resignation as Chief Executive Officer. Pursuant to the Severance Agreement, Mr. Urbanski received a cash severance payment of approximately \$170,000 in two installments. In consideration for the severance payment, Mr. Urbanski provided a general release of claims in favor of the Company, including an acknowledgement that Mr. Urbanski was not entitled to any further compensation, remuneration or benefits under his executive employment agreement as a result of his resignation from the Company.

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

Effective August 11, 2020, the Company and Mr. Weldon entered into the Weldon Agreement with respect to Mr. Weldon's continued employment as the Chief Financial Officer of the Company. The Initial Term of the Weldon Agreement is three years with the option of automatic one-year renewals thereafter. Mr. Weldon will be paid a cash salary of \$25,000 per month, together with customary benefits, expense reimbursement and the possibility of performance bonuses. Mr. Cataldo will receive a stock grant equal to seven percent of the fully diluted shares of common stock of the Company (calculated with the inclusion of the current stock holdings of Mr. Weldon) upon conversion of options, warrants and Convertible Notes in association with a national markets qualified financing as consideration for entering into the Weldon Agreement (with such stock to vest and be delivered within 30 days after the national markets qualified financing). Mr. Weldon will be entitled to certain additional severance payments and other benefits in connection with a Change in Control Period Involuntary Termination or a Non Change in Control Period Involuntary Termination (each as defined in the Weldon Agreement) or his registration as a result of a Change in Control Period Good Reason or Non Change in Control Period Good Reason (each as defined in the Weldon Agreement). Following the Effective Date, Mr. Weldon will also continue to serve as the principal accounting officer and as a director of the Company.

## Outstanding Equity Awards at Fiscal Year End

As of December 31, 2019, there were no unexercised options, unvested stock awards or outstanding equity incentive plan awards held by our Named Executive Officers.

## Director Compensation

The following table summarizes the total compensation we paid to our non-employee directors for the fiscal year ended December 31, 2019:

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

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

Effective January 2018, the following annual compensation for non-employee directors was approved by the Compensation Committee of our Board:

- \$42,500 cash payment;
- an additional cash payment of \$15,000 for acting as chair of a committee and \$5,000 for acting as a member of a committee; and
- upon approval of a stock option plan, a grant of options to purchase 150,000 shares of our common stock, vesting over a three year period (with vesting accelerating if the Company undergoes a change of control transaction for cash).

A director who is one of our employees receives no additional compensation for his service as a director or as a member of a committee of the Board.

## VOTING SECURITIES AND PRINCIPAL HOLDERS

The following table sets forth certain information regarding beneficial ownership of our common stock and Preferred Stock as of November 30, 2020 (a) by each person known by us to own beneficially 5% or more of any class of our voting securities, (b) by each of our Named Executive Officers, (c) by each of our directors and (d) by all our current executive officers and directors as a group. As of November 30, 2020, there were (a) 77,518,614 shares of common stock, (b) 96,230 shares of Series C Preferred Stock and (c) 2,353,548 shares of Series J-1 Preferred Stock issued and outstanding.

Shares of common stock subject to stock options, Preferred Stock, convertible notes and debentures and warrants that are currently exercisable or convertible, or exercisable or convertible within 60 days of November 30, 2020, are deemed to be outstanding for purposes of computing the percentage ownership of that person but are not treated as outstanding for computing the percentage ownership of any other person. Unless indicated below, the persons and entities named in the table have sole voting and sole investment power with respect to all shares beneficially owned, subject to community property laws where applicable.

Except as otherwise indicated, the address of each stockholder is c/o GT Biopharma, Inc. at 9350 Wilshire Blvd., Suite 203, Beverly Hills, CA 90212.

Name and Address of Beneficial Owner <sup>(1)</sup>	Shares of Common Stock Beneficially Owned	Percentage of Class Outstanding	Shares of Series J-1 Preferred Stock Beneficially Owned <sup>(2)</sup>	Percentage of Class Outstanding
<b>Security Ownership of Certain Beneficial Owners:</b>				
Alpha Capital Anstalt <sup>(3)</sup>	7,648,430 <sup>(4)</sup>	9.99% <sup>(5)</sup>	—	
Bristol Capital, LLC <sup>(6)</sup>	— <sup>(7)</sup>	—	1,575,324	66.9%
Bristol Investment Fund, Ltd. <sup>(6)</sup>	6,619,779 <sup>(8)</sup>	9.99% <sup>(9)</sup>	778,224	33.1%
James Heavener <sup>(10)</sup>	7,648,430 <sup>(11)</sup>	9.99% <sup>(17)</sup>	—	—
Adam Kasower	7,625,485 <sup>(11)</sup>	9.96%	—	—
Bigger Capital Fund, LP <sup>(12)</sup>	4,500,000 <sup>(11)</sup>	5.88%	—	—
District 2 Capital Fund LP <sup>(13)</sup>	4,289,077 <sup>(11)</sup>	5.60%	—	—
GT Bio Partners LLC <sup>(14)</sup>	7,500,000 <sup>(11)</sup>	9.80%	—	—
Kevin Young	5,000,000 <sup>(11)</sup>	6.53%	—	—
Red Mango Enterprises Limited <sup>(15)</sup>	7,648,430 <sup>(16)</sup>	9.99% <sup>(17)</sup>	—	—
The Rosalinde and Arthur Gilbert Foundation <sup>(18)</sup>	7,648,430 <sup>(16)</sup>	9.99% <sup>(17)</sup>	—	—
The RSZ Trust <sup>(19)</sup>	5,938,566 <sup>(11)</sup>	7.76%	—	—
Steven Weldon	4,500,000	5.89%	—	—
<b>Security Ownership of Management and Directors:</b>				
Anthony J. Cataldo	7,013,345	9.16%	—	—
Executive officers and directors as a group - 4 people	7,013,345	9.16%	—	—

(1) The Company is not aware of any holder beneficially owning in excess of 5% of the outstanding shares of Series C Preferred Stock.

(2) Each holder of Series J-1 Preferred Stock is entitled to the number of votes equal to the number of shares of common stock into which the shares of Series J-1 Preferred Stock held by such holder could be converted as of November 30, 2020 (voting together, as a single class, with the holders of common stock and Series C Preferred Stock). Each share of our Series J-1 Preferred Stock is currently convertible into five shares of our common stock, subject to a “blocker provision” which prohibits conversion if such conversion would result in the holder being the beneficial owner of in excess of 9.99% of our common stock.

- (3) The address of Alpha Capital Anstalt (“Alpha Capital”) is Lettstrasse 32, FL-9490 Vaduz, Furstentums, Liechtenstein. We have been advised Konrad Ackermann exercises voting and investment power over securities held by Alpha Capital.
- (4) As reported on Schedule 13G/A filed with the SEC on January 16, 2020, Alpha Capital holds shares of our common stock plus other securities that are convertible or exercisable for shares of our common stock only if such conversion or exercise does not result in Alpha Capital (together with its affiliates) holding more than 9.99% of our outstanding shares of common stock. The full conversion or exercise of such securities of the Company held by Alpha Capital would exceed such beneficial ownership limitation. This represents the maximum number of shares of common stock that Alpha Capital could beneficially own as of November 30 , 2020.
- (5) Calculated based on the maximum number of shares of common stock that Alpha Capital could have beneficially owned on November 30 , 2020 following conversion or exercise of securities held by Alpha Capital, subject to the beneficial ownership limitation described in note (4) above.
- (6) Paul Kessler, as manager of Bristol Capital Advisors, LLC, the investment advisor to Bristol Investment Fund, Ltd. (“BIF”), has voting and investment control over the securities held by BIF. Mr. Kessler, as manager of Bristol Capital, LLC (“Bristol Capital”), also has voting and investment control over the securities held by Bristol Capital. 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.
- (7) As reported on Schedule 13G filed with the SEC on June 10, 2020. Excludes shares of our common stock that may be issued upon conversion of the Series J-1 Preferred Stock held by Bristol Capital. Such Series J-1 Preferred Stock may be converted into shares of our common stock only if such conversion does not result in Bristol Capital (together with its affiliates, including BIF) holding more than 9.99% of our outstanding shares of common stock.
- (8) As reported on Schedule 13G filed with the SEC on June 10, 2020. As disclosed in the Schedule 13G, BIF also holds Series J-1 Preferred Stock and convertible notes which may be converted into shares of our common stock only if such conversion does not result in BIF (together with its affiliates, including Bristol Capital) holding more than 9.99% of our outstanding shares of common stock. The full conversion of such securities would exceed such beneficial ownership limitation. As of November 30 , 2020, the maximum number of shares of common stock that BIF could beneficially own was 7,648,430 shares.
- (9) Calculated based on the maximum number of shares of common stock that BIF could have beneficially owned on November 30 , 2020 following conversion of the Series J-1 Preferred Stock or convertible notes, subject to the beneficial ownership limitation described in note (8) above.
- (10) The address of Mr. Heavener is 3300 University Blvd, Suite 218 Winter Park, FL 32792.
- (11) Represents or includes shares of common stock that may be issuable to the stockholder upon conversion of certain convertible notes or other securities that are convertible into, or exercisable for, shares of our common stock and excludes additional shares of common stock that may be issuable to the stockholder (i) in lieu of cash payments of interest on convertible notes or (ii) in connection with any default amounts with respect to convertible notes. Such convertible notes are only convertible if such conversion does not result in the stockholder (together with its affiliates) holding more than 9.99% of our outstanding shares of common stock.
- (12) We have been advised that Michael Bigger exercises voting and investment power over the securities held by Bigger Capital Fund, LP.

- (13) We have been advised that Eric H Schlanger exercises voting and investment power over the securities held by District 2 Capital Fund LP.
- (14) We have been advised that Philip G. Werthman exercises voting and investment power over the securities held by of GT Bio Partners LLC.
- (15) We have been advised that Chi Kan Tang exercises voting and investment power over the securities held by Red Mango Enterprises Limited.
- (16) The full conversion or exercise of convertible notes or other securities convertible into, or exercisable for, our common stock held by the stockholder would exceed the beneficial ownership limitation described in note (11) above. This represents the maximum number of shares of common stock that the stockholder could beneficially own as of November 30, 2020.
- (17) Calculated based on the maximum number of shares of common stock that the stockholder could have beneficially owned on the Exercise Date following conversion or exercise of convertible notes or other securities convertible into, or exercisable for, our common held by the stockholder, subject to the beneficial ownership limitation described in note (11) above.
- (18) We have been advised that Martin H. Blank exercises voting and investment power over the securities held by The Rosalinde and Arthur Gilbert Foundation.
- (19) We have been advised that Richard Ziman exercises voting and investment power over the securities held by RSZ Trust.



## 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 capital stock. For the complete terms of our capital stock, please refer to our certificate of incorporation 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 the DGCL. 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 certificate of incorporation and bylaws.

### General

As of the date of this prospectus, our authorized capital stock consists of 750.0 million shares of common stock, par value \$0.001 per share, and 15.0 million shares of preferred stock, par value \$0.001 per share. As of November 30, 2020, there were 77,518,614 shares of our common stock, 96,230 shares of Series C Preferred Stock and 2,353,548 shares of Series J-1 Preferred 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 the Board 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 currently outstanding or that we may designate and issue in the future. All outstanding shares of our common stock are fully paid and non-assessable. Except as described below in "Anti-Takeover Provisions Under Our Charter and Bylaws and Delaware Law," holders of a majority of the outstanding shares of stock entitled to vote shall constitute a quorum for the transaction of business, and a vote of the majority of the voting power represented at such meeting at which a quorum is generally required to take action under our certificate of incorporation and bylaws.

### Preferred Stock

Our Board is authorized, without action by the stockholders, to designate and issue up to 15.0 million shares of preferred stock in one or more series. In the past the Board has designated series lettered A through J-1 and issued shares in those series. As of the date of this prospectus, only preferred shares in the series designated C and J-1 have shares issued and outstanding. Our Board can fix or alter the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting a class or series. The issuance of preferred stock could, under certain circumstances, result in one or more of the following adverse effects:

- decreasing the market price of our common stock;
- restricting dividends on our common stock;
- diluting the voting power of our common stock;
- impairing the liquidation rights of our common stock;  
or
- delaying or preventing a change in control of us without further action by our stockholders.

Our Board will make any determination to issue such shares based on its judgment as to our best interests and the best interests of our stockholders.

### *Series C Preferred Stock*

For a discussion of the terms of our Series C Preferred Stock, see Note 7 to our audited financial statements, *Stockholders' Equity*.

### *Series J-1 Preferred Stock*

Shares of our Series J-1 Preferred Stock are convertible at any time, at the option of the holders, into shares of our common stock at an effective conversion price of \$0.20 per share, subject to adjustment for, among other things, stock dividends, stock splits, combinations, reclassifications of our capital stock and mergers or consolidations, and subject to a "blocker provision" which prohibits conversion if such conversion would result in the holder being the beneficial owner of in excess of 9.99% of our common stock. Shares of our Series J-1 Preferred Stock have the same voting rights as shares of our common stock, with the holders of the Series J-1 Preferred Stock entitled to vote on an as-converted-to-common stock basis, subject to the "blocker provision" described above, together with the holders of our common stock on all matters presented to our stockholders. The Series J-1 Preferred Stock are not entitled to any dividends (unless specifically declared by our Board), but will participate on an as-converted-to-common stock basis in any dividends to the holders of our common stock. In the event of our dissolution, liquidation or winding up, the holders of our Series J-1 Preferred Stock will be on parity with the holders of our common stock and will participate, on an as-converted-to-common stock basis, in any distribution to holders of our common stock.

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

Certain provisions of Delaware law, our 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. 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 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, 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 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 makes it more difficult to change the composition of our Board, but these provisions promote a continuity of existing management.

*No Cumulative Voting.* The DGCL provides that stockholders are not entitled to the right to cumulate votes in the election of directors unless our certificate of incorporation provides otherwise. Our 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 certificate of incorporation and our bylaws, the Board 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, 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 8742 Lucent Blvd., Suite 225, Highland Ranch, CO 80129, and its telephone number is (303) 262-0600.

#### **Existing Trading Markets**

Our common stock is quoted on the OTCQB, one of the OTC Markets Group over-the-counter markets, under the trading symbol “GTBP.” The closing sale price of our common stock on the OTCQB on December 10, 2020, was \$0.26 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).

## MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS TO NON-U.S. HOLDERS

The following is a summary of certain material U.S. federal income tax considerations that may be relevant to the acquisition, ownership and disposition of Units or Pre-Funded Units. This description addresses only the U.S. federal income tax considerations to Non-U.S. Holders (as defined below) that will hold the Units, Pre-Funded Units and the components thereof as capital assets within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended (the "Code"). This description does not address all of the tax considerations applicable to particular investors in light of their individual circumstances, including holders that may be subject to special tax rules, including, but not limited to:

- certain financial institutions, banks, thrifts or insurance companies;
- real estate investment trusts;
- regulated investment companies;
- brokers, dealers or traders in securities;
- a trader in securities who elects to use a mark-to-market method of accounting for its securities holdings;
- investors subject to special tax accounting rules as a result of any item of gross income with respect to our ordinary shares being taken into account in an applicable financial statement;
- partnerships or other entities or arrangements classified as partnerships for U.S. federal income tax purposes or other pass-through entities (and investors therein);
- tax-exempt entities;
- individual retirement and other tax-deferred accounts;
- persons that will hold our securities as part of a "straddle," "hedging," "constructive sale," "conversion" or other integrated transaction or as a position in a "straddle" for U.S. federal income tax purposes;
- persons who acquire our securities pursuant to the exercise of compensatory options or compensatory warrants or in other compensatory transactions;
- persons that may be liable for the alternative minimum tax;
- certain former citizens or long-term residents of the United States;
- persons that have a "functional currency" other than the U.S. dollar;  
or
- persons that own or are deemed to own directly, indirectly, or constructively 10% or more, by voting power or value, of our stock.

Moreover, this description does not address the U.S. federal estate, gift or alternative minimum tax consequences or any state, local or non-U.S. tax consequences, of the acquisition, ownership and disposition of our Units, Pre-Funded Units, and the components thereof, or the U.S. federal Medicare tax on net investment income. This description is for general information purposes only and does not purport to be a complete analysis or summary of all potential U.S. federal income tax consequences that may apply as a result of the acquisition, ownership and disposition of our Units, Pre-Funded Units or the components thereof. Each Non-U.S. Holder (as defined below) is urged to consult its own tax advisor regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of their investment in our ordinary shares.

This description is based on the Code, and existing, proposed and temporary U.S. Treasury regulations, and judicial and administrative interpretations thereof, in each case as of the date hereof. The U.S. tax laws and the interpretation thereof are subject to change, which change could apply retroactively and could affect the tax consequences described below.

A “U.S. Holder” is a beneficial owner of our Units, Pre-Funded Units, common stock, Common Warrants, or Pre-Funded Warrants that is, for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation, created or organized in or under the laws of the United States, any state thereof, or the District of Columbia;
- an estate the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust (A) the administration of which is subject to the primary supervision of a court within the United States and which has one or more U.S. persons who have the authority to control all of the substantial decisions of such trust or (B) that has otherwise validly elected to be treated as a U.S. person under applicable U.S. Treasury regulations.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our Units or Pre-Funded Units or the components thereof, the tax treatment of the partnership and a partner in such partnership will generally depend on the status of the partner (or other interest holder) and the activities of the partnership. Such a partnership or partner in such a partnership should consult its own tax advisor as to its own tax consequences of acquiring, holding, or disposing of our ordinary shares.

For purposes of this discussion, a “Non-U.S. Holder” is a holder of our Units, Pre-Funded Units, common stock, Common Warrants, or Pre-Funded Warrants that is not a U.S. Holder and is not an entity or arrangement treated as a partnership for U.S. federal income tax purposes.

Prospective purchasers should consult their own tax advisors concerning the U.S. federal, state, local, foreign and other tax consequences of acquiring, owning and disposing of our units and the components thereof in light of their particular circumstances.

#### **Characterization of Units and Allocation of Purchase Price**

No statutory, administrative or judicial authority directly addresses the treatment of a Unit, a Pre-Funded Unit, or any instrument similar to these units for U.S. federal income tax purposes, and therefore, that treatment is not entirely clear. We intend to take the position that the acquisition or disposition of a Unit is treated for U.S. federal income tax purposes as the acquisition or disposition of the underlying common stock and Common Warrants and that the acquisition or disposition of a Pre-Funded Unit is treated for U.S. federal income tax purposes as the acquisition or disposition of the underlying Pre-Funded Warrants and Common Warrants. By purchasing a Unit or Pre-Funded Unit, you will agree to adopt such treatment for U.S. federal income tax purposes. For U.S. federal income tax purposes, each holder of a Unit or Pre-Funded Unit must allocate the purchase price paid by such holder for such unit between the underlying common stock, Common Warrant or Pre-Funded Warrant based on the relative fair market value of each at the time of issuance. Under U.S. federal income tax law, each investor must make his or her own determination of such value based on all the relevant facts and circumstances. Therefore, we urge each investor to consult his or her tax advisor regarding the determination of value for these purposes. The price allocated to each share of common stock, each Common Warrant, and each Pre-Funded Warrant should be the shareholder’s initial tax basis in such shares of common stock or such Common Warrant or Pre-Funded Warrant. We also intend to take the position that the separation of the common stock and Common Warrant constituting a Unit and the separation of a Common Warrant and Pre-Funded Warrant constituting a Pre-Funded Unit is not a taxable event for U.S. federal income tax purposes.

The foregoing treatment of the Units, Pre-Funded Units, common stock, Common Warrants, and Pre-Funded Warrants and a holder’s purchase price allocation is not binding on the U.S. Internal Revenue Service (“IRS”) or the courts. Because there are no authorities that directly address instruments that are similar to the Units or Pre-Funded Units, no assurance can be given that the IRS or the courts will agree with the characterization described above or the discussion below. Accordingly, each prospective investor is urged to consult its tax advisors regarding the tax consequences of an investment in a Unit or Pre-Funded Unit (including alternative characterizations of the same). The remainder of this discussion assumes that the characterization of the Units and Pre-Funded Units described above will be respected for U.S. federal income tax purposes.

## Characterization of Pre-Funded Warrants

Although the characterization of the Pre-Funded Warrants for U.S. federal income tax purposes is not entirely clear, because the exercise price of the Pre-Funded Warrants is a nominal amount, the Company expects to treat the Pre-Funded Warrants as common stock of the Company for U.S. federal income tax purposes. Except where noted, the remainder of this discussion assumes that the Pre-Funded Warrants will be so treated. Each holder should consult its own tax advisor regarding the proper characterization of the Pre-Funded Warrants for U.S. federal, state and local, and non-U.S. tax purposes, and the consequences to them of such treatment given their individual circumstances.

## Distributions

We have never declared or paid any cash dividends on our common stock. However, if we do make distributions with respect to our common stock of cash or other property (other than certain distributions of common stock), such distributions will constitute dividends for U.S. federal income tax purposes to the extent of our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. To the extent any distributions exceed our current and accumulated earnings and profits, such distributions will first be treated as a tax-free return of capital to the extent of a Non-U.S. Holder's U.S. federal income tax basis in the common stock, and then will be treated as gain from the sale of common stock.

Dividends paid to a Non-U.S. Holder will generally be subject to withholding tax at a 30% rate unless the Non-U.S. Holder is eligible for the benefits of an income tax treaty that provides for a reduced rate of withholding and the Non-U.S. Holder establishes its eligibility for the reduced rate by providing a properly executed IRS Form W-8BEN or W-8BEN-E (or applicable successor form) claiming an exemption from or reduction of the withholding tax under the benefit of an applicable income tax treaty.

Additionally, a Non-U.S. Holder will not be subject to withholding tax if such Non-U.S. Holder holds our common stock in connection with the conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), dividends are paid in connection with that trade or business, and such Non-U.S. Holder provides a properly executed IRS Form W-8ECI (or applicable successor form) stating that the dividends are effectively connected with the conduct by the Non-U.S. Holder of a trade or business within the United States. Instead, such Non-U.S. Holder will generally be subject to U.S. federal income tax at the rates applicable to U.S. persons and, in the case of a corporate Non-U.S. Holder, a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty.

If a Non-U.S. Holder is eligible for a reduced rate of withholding, such Non-U.S. Holder may file a refund claim with the IRS for a refund of any amounts withheld in excess of such reduced rate.

## Sale or Exchange of Common Stock and Common Warrants

Non-U.S. Holders will generally not be subject to U.S. federal income tax on any gain realized upon the sale or exchange of common stock or Common Warrants unless:

- The gain is effectively connected with the conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gains are attributable);
- The Non-U.S. Holder is an individual present in the United States for a period or periods aggregating 183 days or more during the calendar year in which the sale or disposition occurs and certain other conditions are met; or
- We are or have been within the five year period ending on the date of disposition a "United States real property holding corporation" (a "USRPHC").

If a Non-U.S. Holder is described in the first bullet above, such Non-U.S. Holder will generally be subject to U.S. federal income tax at the rates applicable to U.S. persons and, in the case of a corporate Non-U.S. Holder, a branch profits tax at a rate of 30% or such lower rate as may be specified by an applicable income tax treaty. If a Non-U.S. Holder is described in the second bullet above, such Non-U.S. Holder will be required to pay a flat 30% tax on the gain derived from the sale, which tax may be offset by U.S.-source capital losses for the year.

With respect to the third bullet above, we believe that we are not currently, and have not been a USRPHC. However, because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property relative to the fair market value of certain of our other assets, there can be no assurance that we will not become a USRPHC in the future. Even if we become a USRPHC, however, as long as our common stock is regularly traded on an established securities market, such common stock will be treated as U.S. real property interests only if you actually or constructively hold more than five percent of such regularly traded common stock at any time during the shorter of the five-year period preceding your disposition of, or your holding period for, our common stock. Special rules may apply to the determination of the five percent threshold in the case of a holder of a Common Warrant or Pre-Funded Warrant. Non-U.S. Holders are urged to consult their own tax advisors regarding the effect of holding our Common Warrants or Pre-Funded Warrants on the calculation of such five percent threshold.

#### **Exercise or Lapse of a Common Warrant or Pre-Funded Warrant**

In general, a Non-U.S. Holder will not recognize gain or loss for U.S. federal income tax purposes upon the exercise of a Common Warrant or Pre-Funded Warrant, except to the extent the Non-U.S. Holder receives a cash payment for any such fractional share that would otherwise have been issuable upon exercise of the Common Warrant or Pre-Funded Warrant, which will be treated as a sale subject to the rules described under “—Sale or Other Disposition of Common Stock or Common Warrants” above. Upon the lapse or expiration of a Common Warrant or Pre-Funded Warrant, a Non-U.S. Holder will recognize a loss equal to such Non-U.S. Holder’s U.S. federal income tax basis in the Common Warrant or Pre-Funded Warrant if the loss is (i) effectively connected with the conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such loss is attributable) or (ii) treated as a loss from sources within the United States and the Non-U.S. Holder is present 183 days or more in the taxable year of disposition and certain other conditions are met. The deductibility of capital losses is subject to limitations.

#### **Certain Adjustments to the Common Warrants or Pre-Funded Warrants**

Under Section 305(c) of the Code, an adjustment (or a failure to make an adjustment) to the conversion ratio of a Common Warrant or Pre-Funded Warrant that has the effect of increasing a Non-U.S. Holder’s proportionate interest in our assets or earnings may, in some circumstances, result in a deemed distribution to a Non-U.S. Holder for U.S. federal income tax purposes. Adjustments to the conversion rate made pursuant to a bona fide, reasonable, adjustment formula that has the effect of preventing the dilution of the interest of the holders of our Common Warrants or Pre-Funded Warrants, however, generally will not be deemed to result in a distribution to a Non-U.S. Holder. Any such deemed distribution would be taxable to a Non-U.S. Holder as described above under “—Distributions.”

In addition, regulations governing “dividend equivalents” under Section 871(m) of the Code may apply to the Pre-Funded Warrants. Under those regulations, an implicit or explicit payment under the Pre-Funded Warrants that references a dividend distribution on our common stock would possibly be taxable to a Non-U.S. Holder as described under “—Distributions” above. Such dividend equivalent amount would be taxable and subject to withholding whether or not there is actual payment of cash or other property. Non-U.S. Holders are encouraged to consult their own tax advisors regarding the application of Section 871(m) of the Code to the Pre-Funded Warrants.

## Information Reporting and Backup Withholding

Payments to Non-U.S. Holders of dividends will generally not be subject to backup withholding, and payments of proceeds made to Non-U.S. Holders by brokers upon a sale of common stock, Common Warrants, and Pre-Funded Warrants will generally not be subject to information reporting or backup withholding, in each case so long as the Non-U.S. Holders certifies its non-resident status (and we or our paying agent do not have actual knowledge or reason to know that the Non-U.S. Holders is a U.S. person or that the conditions of any other exemption are not, in fact, satisfied) or otherwise establishes an exemption. The certification procedures to claim a reduced rate of withholding under an income tax treaty described above in "Distributions" will generally satisfy the certification requirements necessary to avoid backup withholding. Copies of information returns with respect to dividends that are filed with the IRS may also be made available to tax authorities of the country in which the Non-U.S. Holder resides.

Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a Non-U.S. Holder's US federal income tax liability. A Non-U.S. Holder generally may obtain a refund of any amounts withheld under the backup withholding rules in excess of such Non-U.S. Holder's U.S. federal income tax liability by filing the appropriate claim for refund with the U.S. Internal Revenue Service in a timely manner and furnishing any required information.

## FATCA

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (commonly referred to as the Foreign Account Tax Compliance Act or "FATCA") on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on payments of dividends if paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution enters into an agreement with the United States Department of the Treasury to undertake certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution which entered into the agreement in (1) above, the diligence and reporting requirements include, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. An intergovernmental agreement governing FATCA between the United States and an applicable foreign country may modify the requirements described in this paragraph.

The FATCA withholding tax will apply to all withholdable payments without regard to whether the beneficial owner of the payment would otherwise be entitled to an exemption from withholding tax pursuant to an applicable tax treaty with the United States or under other provisions of the Code. Non-U.S. Holders are urged to consult their tax advisors regarding the potential application of withholding under FATCA.

**THE US FEDERAL INCOME TAX SUMMARY SET FORTH ABOVE IS INCLUDED FOR GENERAL INFORMATION ONLY. HOLDERS OF UNITS, PRE-FUNDED UNITS, COMMON STOCK, COMMON WARRANTS, AND PRE-FUNDED WARRANTS SHOULD CONSULT THEIR TAX ADVISORS TO DETERMINE THE PARTICULAR TAX CONSEQUENCES TO SUCH HOLDERS, INCLUDING THE APPLICABILITY AND EFFECT OF STATE, LOCAL, AND NON-US TAX LAWS.**



## UNDERWRITING

Dawson James Securities, Inc. is acting as lead book-running manager of the offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has severally and not jointly agreed to purchase, and we have agreed to sell to that underwriter, the number of units described in this prospectus.

Underwriter	Number of Units
Dawson James Securities, Inc.	
Total	

The underwriting agreement provides that the obligations of the underwriters to purchase the units of the Company's securities included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all of such units of common stock and warrants (other than those covered by the over-allotment option described below) if they purchase any of the shares of common stock and warrants.

Shares of common stock and warrants sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover of this prospectus. Any shares of common stock and warrants sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed \$ \_\_\_\_\_ per share and warrant. If all the shares of common stock and warrants are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms.

Pursuant to the underwriting agreement, we granted to the underwriter an option, exercisable within 45 days after the closing of this offering to acquire up to an additional \_\_\_\_\_ of the total units to be offered, solely for the purpose of covering over-allotments, if any. If the underwriter exercises all or any part of this option, it will purchase shares and/or warrants covered by the option at the public offering price per share and the public offering price per warrant, respectively, less the underwriting discount. If this option is exercised in full, the total offering price to the public will be \$ \_\_\_\_\_ and the total net proceeds, before expenses, to us will be \$ \_\_\_\_\_. We will pay the expenses associated with the exercise of the over-allotment option.

### Underwriting discounts and commissions

The following table shows the per unit price and total underwriting discounts and commissions we will pay in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters' over-allotment option:

	Per Shares	Total without O/A Option	Total with O/A Option
Public offering price	\$ _____	\$ _____	\$ _____
Underwriting discount (8%)	\$ _____	\$ _____	\$ _____
Proceeds, before expenses, to us	\$ _____	\$ _____	\$ _____

We have also agreed to reimburse the underwriter for its expenses in connection with this offering, including all reasonable fees and expenses of the underwriters' outside legal counsel, up to \$125,000. We estimate the total expenses of this offering which will be payable by us, excluding the underwriting discount and the underwriter's expenses payable by us, will be approximately \$ \_\_\_\_\_.

### Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

### Right of First Refusal; Tail Financing

Provided this offering is completed, for a period of twelve months from the closing date of this offering, Dawson James has a right of first refusal to act as our exclusive placement agent or lead underwriter and sole book runner, as applicable, in the event we decide to pursue an offering of our equity, equity-linked or debt securities during such period.

Dawson James will be entitled to compensation as discussed above with respect to any public or private offering or other financing or capital-raising transaction of any kind (“Tail Financing”) to the extent that such Tail Financing is consummated by the Company during the term of Dawson James’ engagement for this offering or nine months following the completion thereof.

#### **Underwriters’ Warrants**

We have also agreed to issue to the underwriters’ a warrant to purchase a number of our shares of common stock equal to 5% of the common stock underlying the units sold in this offering. The underwriters’ warrant will have an exercise price equal to 125% of the public offering price of the combination of shares and warrants set forth on the cover of this prospectus (or \$ per share and accompanying warrant) and may be exercised on a cashless basis. The underwriters’ warrant is not redeemable by us. This prospectus also covers the sale of the underwriters’ warrant and the shares of common stock underlying such warrant. The underwriters’ warrant and the underlying securities have been deemed compensation by FINRA, and are therefore subject to FINRA Rule 5110(g)(1). In accordance with FINRA Rule 5110(g)(1), neither the underwriters’ warrant nor any securities issued upon exercise of the underwriters’ warrant may be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put, or call transaction that would result in the effective economic disposition of such securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of the offering pursuant to which the underwriters’ warrant is being issued, except the transfer of any security: (i) by operation of law or by reason of reorganization of our company; (ii) to any FINRA member firm participating in this offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction described above for the remainder of the time period; (iii) if the aggregate amount of our securities held by either an underwriter or a related person do not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro-rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund, and participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities received remain subject to the lock-up restriction set forth above for the remainder of the time period.

#### **Lock-up Agreements**

We, our executive officers and directors, and certain holders of at least 5% or more of our common stock have agreed to enter into lock-up agreements in connection with this offering. Under the lock-up agreements, subject to certain exceptions, we and each of these persons may not, without the prior written approval of the Underwriter, offer, sell, contract to sell, pledge, or otherwise dispose of, directly or indirectly, or hedge our common stock or securities convertible into or exchangeable or exercisable for our common stock. These restrictions remain in effect and will generally terminate on the six-month anniversary after the closing date. In connection with this offering, we agreed that we will not: (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; (ii) file or cause to be filed any registration statement with the SEC relating to the offering of any shares of our capital stock or any securities convertible into or exercisable or exchangeable for shares of our capital stock; or (iii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our capital stock, whether any such transaction described in clause (i), (ii) or (iii) above is to be settled by delivery of shares of our capital stock or such other securities, in cash or otherwise, in each case without the prior consent of the Underwriter for a period of six months after the date of the Underwriting Agreement, other than (A) the securities sold in this offering, or (B) the issuance by us of shares of our common stock upon the exercise of a stock option or warrant or the conversion of a security outstanding on the date of this prospectus, hereafter issued pursuant to our currently existing or hereafter adopted equity compensation plans or employment or consulting agreements or arrangements of which the Underwriter has been advised in writing or which have been filed with the SEC.

#### **Stabilization, Short Positions and Penalty Bids**

The representatives may engage in stabilizing transactions, short sales and purchases to cover positions created by short sales, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Exchange Act:

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.
- A short position involves a sale by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase in the offering, which creates the syndicate short position. This short position may be either a covered short position or a naked short position. In a covered short position, the number of shares involved in the sales made by the underwriters in excess of the number of shares they are obligated to purchase is not greater than the number of shares that they may purchase by exercising their option to purchase additional shares. In a naked short position, the number of shares involved is greater than the number of shares in their option to purchase additional shares. The underwriters may close out any short position by either exercising their option to purchase additional shares and/or purchasing shares in the open market. In determining the source of shares to close out the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through their option to purchase additional shares. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.
- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions.
- Penalty bids permit the representatives to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction to cover syndicate short positions.

These stabilizing transactions, syndicate covering transactions and penalty bids may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of the common stock. As a result, the price of the common stock may be higher than the price that might otherwise exist in the open market. These transactions may be effected on the Nasdaq Capital Market or otherwise and, if commenced, may be discontinued at any time.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of the common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these stabilizing transactions or that any transaction, once commenced, will not be discontinued without notice.

#### **Electronic Distribution**

A prospectus in electronic format may be made available on the Internet sites or through other online services maintained by one or more of the underwriters and/or selling group members participating in this offering, or by their affiliates. In those cases, prospective investors may view offering terms online and, depending upon the particular underwriter or selling group member, prospective investors may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares for sale to online brokerage account holders. Any such allocation for online distributions will be made by the representatives on the same basis as other allocations.

Other than the prospectus in electronic format, the information on any underwriter's or selling group member's web site and any information contained in any other web site maintained by an underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

#### **Other Relationships**

The underwriters and certain of their affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for the issuer and its affiliates, for which they received or may in the future receive customary fees and expenses. Dawson James Securities, Inc., the representative of the underwriters, served as the lead book-running manager of our initial public offering.

In the ordinary course of their various business activities, the underwriters and certain of their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments of the issuer or its affiliates. If the underwriters or their affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the shares of common stock offered hereby. Any such credit default swaps or short positions could adversely affect future trading prices of the shares of common stock offered hereby. The underwriters and certain of their affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

#### **Selling Restrictions**

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the shares of common stock or possession or distribution of this prospectus or any other offering or publicity material relating to the shares of common stock in any country or jurisdiction (other than the United States) where any such action for that purpose is required. Accordingly, each underwriter has undertaken that it will not, directly or indirectly, offer or sell any shares of common stock or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of shares of common stock by it will be made on the same terms.

## LEGAL MATTERS

The validity of the common stock offered by this prospectus will be passed upon for us by Baker & McKenzie LLP, Dallas, Texas. Certain legal matters in connection with the offering will be passed upon for the underwriter by Schiff Hardin LLP.

## DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act 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 SEC such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

## EXPERTS

The financial statements of GT Biopharma, Inc. at December 31, 2019 and 2018, and for each of the two years in the period ending December 31, 2019, appearing in this prospectus have been audited by Seligson & Giannattasio, LLP, an independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and are included in reliance upon such report given on the authority of such firm 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 SEC with respect to this offering. 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. The SEC also maintains a web site (<http://www.sec.gov>) that contains this filed registration statement, reports and other information regarding us that we have filed electronically with the SEC. For more information pertaining to our company and this offering, reference is made to the registration statement.

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### **Audited Consolidated Financial Statements of GT Biopharma, Inc.**

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### **Unaudited Consolidated Financial Statements of GT Biopharma, Inc.**

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## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

### Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of GT Biopharma, Inc. and subsidiaries (the "Company") as of December 31, 2019 and 2018, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the two-year period ended December 31, 2019, and the related notes (collectively referred to as the financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2019 and 2018 and the consolidated results of its operations and its consolidated cash flows for each of the years in the two-year period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

### Basis of Opinion

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

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

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

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred significant recurring losses. The realization of a major portion of its assets is dependent upon its ability to meet its future financing needs and the success of its future operations. These factors raise substantial doubt about the Company's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from this uncertainty.

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

We have served as the Company's auditor since 2008.

White Plains, New York  
March 27, 2020

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

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

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



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

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

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

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

	Preferred Shares		Common Shares		Paid-in Capital	Accumulated Deficit
	Shares	Amount	Shares	Amount		
<b>Balance at December 31, 2018</b>	<b>1,260</b>	<b>\$ 2</b>	<b>50,118</b>	<b>\$ 50</b>	<b>\$ 521,305</b>	<b>\$ (269,499)</b>
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)
<b>Balance at December 31, 2018</b>	<b>1,260</b>	<b>\$ 2</b>	<b>50,650</b>	<b>\$ 51</b>	<b>\$ 540,171</b>	<b>\$ (528,685)</b>
Issuance of preferred stock	1,190	1			1,139	
Issuance of common stock for convertible notes			3,484	3	1,357	
Beneficial conversion feature on convertible notes					158	
Issuance of common stock for compensation			15,650	16	5,293	
Net loss						(38,647)
<b>Balance at December 31, 2019</b>	<b>2,450</b>	<b>\$ 3</b>	<b>69,784</b>	<b>\$ 70</b>	<b>\$ 548,118</b>	<b>\$ (567,332)</b>

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

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

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

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

## 1. The Company

### *Business*

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

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE™), Tetra-specific Killer Engager (TetraKE™) and bi-specific ligand-directed single-chain fusion protein technology platforms. Our TriKE and TetraKE platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell and precisely direct it to one or more specifically-targeted proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in the targeted cell's death. TriKEs and TetraKEs are made up of recombinant fusion proteins, can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization.

### *Basis of Consolidation*

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

### *Going Concern*

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

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

The Company has incurred substantial losses and negative cash flows from operations since its inception and has an accumulated deficit of \$567 million and cash of \$28 thousand as of December 30, 2019. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: public offerings of equity and/or debt securities, payments from potential strategic research and development, and licensing and/or marketing arrangements with pharmaceutical companies. If the Company is unable to secure adequate additional funding, its business, operating results, financial condition and cash flows may be materially and adversely affected.

### *Use of Estimates*

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

### *Segment Information*

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

## **2. Summary of Significant Accounting Policies**

### *Advertising and promotional fees*

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

### *Cash and Cash Equivalents*

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

### *Concentrations of Credit Risk*

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

### *Stock Based Compensation to Employees*

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

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

### *Long-Lived Assets*

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

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

### *Impairment of Long-Lived Assets*

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

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

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

#### *Income Taxes*

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

#### *Net Income (Loss) per Share*

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

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

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

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

#### *Patents*

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

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

#### *Fixed Assets*

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

#### *Fair Value*

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

- Level 1 inputs to the valuation methodology are quoted prices (unadjusted) for identical assets or liabilities in active markets. The Company's Level 1 assets include cash equivalents, primarily institutional money market funds, whose carrying value represents fair value because of their short-term maturities of the investments held by these funds.
- Level 2 inputs to the valuation methodology include quoted prices for similar assets and liabilities in active markets, and inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the financial instrument. The Company's Level 2 liabilities consist of liabilities arising from the issuance of convertible securities and in accordance with ASC 815-40. These liabilities are remeasured each reporting period if required by ASC 815-40. Fair value is determined using the Black-Scholes valuation model based on observable market inputs, such as share price data and a discount rate consistent with that of a government-issued security of a similar maturity. There were no such liabilities at December 31, 2019 ..
- Level 3 inputs to the valuation methodology are unobservable and significant to the fair value measurement. The Company does not have any assets or liabilities measured using Level 3 inputs.

#### *Research and Development*

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

#### *Leases*

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

### **3. Intangibles**

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

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

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

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

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

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

#### **4. Debt**

##### *Convertible Notes*

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

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

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



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

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

#### *Senior Convertible Debentures*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The Purchase Agreement contains customary representations, warranties and covenants, including covenants, subject to certain exceptions, that the Company, until the date on which less than 10% of the Notes are outstanding, shall not 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 30 days after December 19, 2019, one or more registration statements on Form S-3 (or, if Form S-3 is not then available to the Company, such form of registration that is then available to effect a registration for resale of the subject securities) covering the resale of all Conversion Shares, subject to certain penalties set forth in the Registration Rights Agreement.

#### *Financing Agreement*

On November 8, 2010, the Company entered into a financing arrangement with Gemini Pharmaceuticals, Inc., a product development and manufacturing partner of the Company, pursuant to which Gemini Pharmaceuticals made a \$250,000 strategic equity investment in the Company and agreed to make a \$750,000 purchase order line of credit facility available to the Company. The outstanding principal of all Advances under the Line of Credit will bear interest at the rate of interest of prime plus 2 percent per annum. There is \$31,000 due on this credit line at December 31, 2019.

## 5. Accrued Expenses

Accrued Expenses are comprised of the following:

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

## 6. Related Party Transactions

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

## 7. Stockholders' Equity

### *Common Stock*

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

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

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

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

### *Preferred Stock*

The 96,230 shares of Series C preferred stock are convertible into 111 shares of the Company's common stock at the option of the holders at any time. The conversion ratio is based on the average closing bid price of the common stock for the fifteen consecutive trading days ending on the date immediately preceding the date notice of conversion is given, but cannot be less than .20 or more than .2889 common shares for each Series C preferred share. The conversion ratio may be adjusted under certain circumstances such as stock splits or stock dividends. The Company has the right to automatically convert the Series C preferred stock into common stock if the Company lists its shares of common stock on the Nasdaq National Market and the average closing bid price of the Company's common stock on the Nasdaq National Market for 15 consecutive trading days exceeds \$3,000.00. Each share of Series C preferred stock is entitled to the number of votes equal to .26 divided by the average closing bid price of the Company's common stock during the fifteen consecutive trading days immediately prior to the date such shares of Series C preferred stock were purchased. In the event of liquidation, the holders of the Series C preferred stock shall participate on an equal basis with the holders of the common stock (as if the Series C preferred stock had converted into common stock) in any distribution of any of the assets or surplus funds of the Company. The holders of Series C preferred stock are entitled to noncumulative dividends if and when declared by the Company's board of directors. No dividends to Series C preferred stockholders were issued or unpaid through December 31, 2019.

On September 1, 2017, the Company designated 2,000,000 shares of Series J Preferred Stock. Shares of Series J Preferred Stock will have the same voting rights as shares of common stock with each share of Series J Preferred Stock entitled to one vote at a meeting of the shareholders of the Corporation. Shares of Series J Preferred Stock will not be entitled to receive any dividends, unless and until specifically declared by our board of directors. The holders of the Series J Preferred Stock will participate, on an as-if-converted-to-common stock basis, in any dividends to the holders of common stock. Each share of the Series J Preferred Stock is convertible into one share of our common stock at any time at the option of the holder.

On the same day, the Board issued 1,513,548 of those shares in exchange for the cancellation of debt. In the first quarter of 2019, it was discovered that a certificate of designation with respect to the Series J Preferred Stock had never been filed with the Office of the Secretary of State for the State of Delaware. Legal research determined that despite the fact the Company had issued shares of Series J Preferred Stock, those shares had, in fact, never existed.

To remedy the situation, on April 4, 2019, the Company filed a certificate of designation with the Office of the Secretary State for the State of Delaware designating a series of preferred stock as Series J-1 Preferred Stock. On April 19, 2019, the Company issued 2,353,548 of those shares. The issuance was in lieu of the preferred stock that should have been issued on September 1, 2017, and in settlement for not receiving preferred stock until 20 months after the debt for which the stock was issued was cancelled. The Company reflected an expense in general and administrative costs in the year ended December 31, 2019 totaling \$1,140,000.

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

#### *Common Stock Warrants*

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

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

#### *Stock Options*

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

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

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

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

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

## 8. Income Taxes

### Deferred Taxes

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

	December 31,	
	2019	2018
Deferred tax assets:		
Federal net operating loss carryforward	36,803,000	25,306,000
Intellectual property	58,504,000	61,787,000
Accrued expense	1,262,000	129,000
Patent amortization	4,000	5,000
Deferred tax assets before valuation	96,573,000	87,227,000
Valuation allowance	(96,573,000)	(87,227,000)
Net deferred income tax assets	-	-

Generally accepted accounting principles requires that the tax benefit of net operating losses, temporary differences and credit carryforwards be recorded as an asset to the extent that management assesses that realization is "more likely than not." Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Because of the Company's history of operating losses, management has provided a valuation allowance equal to its net deferred tax assets. The valuation allowance increased by approximately \$9,346,000 during the year ended December 31, 2019.

### *Tax Carryforward*

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

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

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

## **9. Commitments and Contingencies**

### *Leases*

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

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

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

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

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

### *Employment Agreements*

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

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

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



## 10. Subsequent Events

### *Financing*

On January 30, 2020 GT Biopharma, Inc. (the “Company”) entered into a Securities Purchase Agreement (the “Purchase Agreement”) with the one purchaser (individually, a “Purchaser,” and collectively, the “Purchasers”), pursuant to which the Company issued to the Purchasers, between April 20 and May 7, 2020, Secured Convertible Notes in an aggregate principal amount of \$200,000 (the “Notes”), which Notes shall be convertible at any time after issuance into shares (the “Conversion Shares”) of the Company’s common stock, par value \$0.001 per share (the “Common Stock”), at an initial conversion price of \$0.20 per share (the “Conversion Price”).

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

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

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

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

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

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

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

#### *Common Stock*

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

**GT BIOPHARMA, INC. AND SUBSIDIARIES**  
**As of September 30, 2020 and December 31, 2019**  
**Consolidated Balance Sheets**  
(In Thousands, Except Par Value and Share Data)

	June 30, 2020 (unaudited)	December 31, 2020
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 350	\$ 28
Prepaid expenses	483	246
Total Current Assets	<u>833</u>	<u>274</u>
Deposits	12	12
Operating lease right-to-use asset	72	110
Total Other Assets	<u>84</u>	<u>122</u>
<b>TOTAL ASSETS</b>	<u>\$ 917</u>	<u>\$ 396</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 2,171	\$ 1,940
Accrued expenses	1,228	2,379
Accrued interest	4,182	2,029
Operating lease liability	82	120
Line of credit	31	31
Convertible notes	23,000	13,207
Total Current Liabilities	<u>30,694</u>	<u>19,706</u>
<b>Total liabilities</b>	<u>30,694</u>	<u>19,706</u>
Stockholders' Deficit:		
Convertible preferred stock - \$0.01 par value; 15,000,000 shares authorized:		
Series C - 96,230 and 96,230 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	1	1
Series J-1 - 2,353,548 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	24	24
Common stock - \$0.001 par value; 750,000,000 shares authorized; and 77,518,614 and 69,784,699 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively		
Additional paid-in capital	550,984	548,096
Accumulated deficit	(580,695)	(567,332)
Noncontrolling interest	(169)	(169)
Total Stockholders' Deficit	<u>(29,777)</u>	<u>(19,310)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' DEFICIT</b>	<u>\$ 917</u>	<u>\$ 396</u>

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

**GT BIOPHARMA, INC. AND SUBSIDIARIES**  
**Consolidated Statements of Operations**  
(Unaudited)  
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
<b>Operating expenses:</b>				
Research and development	(84)	671	252	1,659
Selling, general and administrative expenses	2,029	3,585	4,321	8,932
Loss on impairment	-	4,599	-	4,599
Total operating expenses	<u>1,945</u>	<u>8,855</u>	<u>4,573</u>	<u>15,190</u>
Loss from operations	<u>(1,945)</u>	<u>(8,855)</u>	<u>(4,573)</u>	<u>(15,190)</u>
<b>Other income (expense):</b>				
Loss on disposal of assets	-	(20,463)	-	(20,494)
Settlement expense	-	-	(2,563)	-
Interest expense	(931)	(560)	(6,227)	(1,493)
Total other income (expense)	<u>(931)</u>	<u>(21,023)</u>	<u>(8,790)</u>	<u>(21,987)</u>
Loss before provision for income taxes	(2,876)	(29,878)	(13,363)	(31,177)
Provision for income tax	-	-	-	-
Net loss	<u>(2,876)</u>	<u>(29,878)</u>	<u>(13,363)</u>	<u>(31,177)</u>
Net loss per common share – basic and diluted	<u>\$ (0.04)</u>	<u>\$ (0.51)</u>	<u>\$ (0.18)</u>	<u>\$ (0.69)</u>
Weighted average common shares outstanding – basic and diluted	<u>76,730,076</u>	<u>58,805,997</u>	<u>72,909,738</u>	<u>53,967,298</u>

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

**GT Biopharma, Inc. and Subsidiaries**  
**Consolidated Statement of Stockholders' Deficit**  
(In thousands)

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit
	Shares	Amount	Shares	Amount		
<b>Balance at January 1, 2020</b>	2,450	\$ 25	69,785	\$ 70	\$ 548,096	\$ (567,332)
Issuance of common stock for convertible notes			3,147	3	626	
Beneficial conversion feature of convertible notes					27	
Issuance of common stock for settlement of litigation			3,500	4	1,909	
Issuance of warrants for compensation					180	
Issuance of common stock for compensation			1,086	1	146	
Net loss						(13,363)
<b>Balance at September 30, 2020</b>	<u>2,450</u>	<u>\$ 25</u>	<u>77,518</u>	<u>\$ 78</u>	<u>\$ 550,984</u>	<u>\$ (580,695)</u>

	Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Deficit
	Shares	Amount	Shares	Amount		
<b>Balance at January 1, 2019</b>	1,260	\$ 13	50,650	\$ 51	\$ 540,160	\$ (528,685)
Issuance of preferred stock	1,190	12			1,128	
Issuance of common stock for convertible notes			2,741	3	1,160	
Beneficial conversion feature of convertible notes					158	
Issuance of common stock for compensation			13,500	13	5,047	
Net loss						(37,177)
<b>Balance at September 30, 2019</b>	<u>2,450</u>	<u>\$ 25</u>	<u>66,891</u>	<u>\$ 67</u>	<u>\$ 547,653</u>	<u>\$ (565,862)</u>

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

**GT Biopharma, Inc. and Subsidiaries**  
**Consolidated Statements of Cash Flows**  
**For the Nine Months Ended September 30, 2020 and 2019**  
**(in Thousands)**

	<b>2020</b>	<b>2019</b>
	(unaudited)	(unaudited)
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (13,363)	\$ (37,177)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	-	10
Stock compensation expense for options and warrants issued to employees and non-employees	327	6,202
Amortization of debt discounts	-	451
Non-cash interest expense	3,970	1,140
Loss on disposal of assets	-	20,494
Impairment of intangible assets	-	4,599
Settlement expense	2,363	-
Changes in operating assets and liabilities:		
Other assets	3	6
Accounts payable and accrued liabilities	1,365	1,101
Net cash used in operating activities	<u>(5,335)</u>	<u>(3,174)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Disposal of fixed assets	-	200
Net cash used by investing activities	<u>0</u>	<u>200</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from notes payable	5,657	3,327
Repayment of note payable	-	(100)
Net cash provided by financing activities	<u>5,657</u>	<u>3,227</u>
Minority interest	-	-
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>322</u>	<u>253</u>
CASH AND CASH EQUIVALENTS - Beginning of period	28	60
CASH AND CASH EQUIVALENTS - End of period	<u>\$ 350</u>	<u>\$ 313</u>
Supplemental disclosures:		
Interest paid	\$ 69	\$ -
Income taxes paid	\$ -	\$ -
Supplemental disclosures:		
Issuance of common stock upon conversion of convertible notes	\$ 598	\$ 1,150
Issuance of common stock upon conversion of accrued interest	\$ 32	\$ 14

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

## **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.

The Company is a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE™), Tetra-specific Killer Engager (Dual Targeting TriKEDual Targeting TriKE) platforms. The Company's TriKE and Dual Targeting TriKE platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells, or NK cells. Once bound to an NK cell, the Company's moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically-targeted proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in the targeted cell's death. TriKEs and Dual Targeting TriKEs 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.

### *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 \$580 million and cash of \$350 thousand as of September 30, 2020. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates. These factors raise substantial doubt about the Company's ability to continue as a going concern.

Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to: public offerings of equity and/or debt securities, payments from potential strategic research and development, and licensing and/or marketing arrangements with pharmaceutical companies. If the Company is unable to secure adequate additional funding, its business, operating results, financial condition and cash flows may be materially and adversely affected.

### *Use of Estimates*

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

### *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, 2019 filed with the SEC on March 27, 2020. 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 a balance of approximately \$100,000 in excess of this limit at September 30, 2020.

### *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 nine months ended September 30, 2020 and 2019, 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 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 income (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 income (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, convertible notes and debentures (including shares issuable upon conversion of accrued interest or other default amounts with respect to such convertible notes or debentures), 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 114,887,906 and 73,520,680 as of September 30, 2020 and 2019, 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 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. There were not such liabilities at September 30, 2020.
- Level 3 inputs to the valuation methodology are unobservable and significant to the fair value measurement. There were no such assets or liabilities as of September 30, 2020.

#### *Research and Development*

Research and development costs are expensed as incurred and reported as research and development expense. Research and development costs totaled \$0.3 million and \$1.6 million for the nine months ended September 30, 2020 and 2019, 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 September 30, 2020, the Company has not generated any licensing revenue.

#### *Leases*

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, *Leases (Topic 842)* (“Topic 842”). Topic 842 requires the entity to recognize the assets and liabilities for the rights and obligations created by leased assets. Leases will be classified as either finance or operating, with classification affecting expense recognition in the income statement.

On January 1, 2019, the Company adopted Topic 842 applying the optional transition method, which allows an entity to apply the new standard at the adoption date with a cumulative effect adjustment to the opening balance of retained earnings in the period of adoption. As a result of adopting Topic 842, the Company recognized assets and liabilities for the rights and obligations created by operating leases totaling approximately \$174 thousand.

The Company determines if a contract contains a lease at inception based on whether it conveys the right to control the use of an identified asset. Substantially all of the Company’s leases are classified as operating leases. The Company records operating lease right-of-use assets within “Other assets” and lease liabilities are recorded within “current and noncurrent liabilities” in the consolidated balance sheets. Lease expenses are recorded within “General and administrative expenses” in the consolidated statements of operations. Operating lease payments are presented within “Operating cash flows” in the consolidated statements of cash flows.

Operating lease right-of-use assets and lease liabilities are recognized based on the net present value of future minimum lease payments over the lease term starting on the commencement date. The Company generally is not able to determine the rate implicit in its leases and, as such, applies an incremental borrowing rate based on the Company’s cost of borrowing for the relevant terms of each lease. Lease expense for minimum lease payments is recognized on a straight-line basis over the lease term. Lease terms may include an option to extend or terminate a lease if it is reasonably certain that the Company will exercise such options. The Company has elected the practical expedient to not separate lease components from non-lease components, and also has elected not to record a right-of-use asset or lease liability for leases which, at inception, have a term of twelve months or less. Variable lease payments are recognized in the period in which the obligation for those payments is incurred.

## **2. Debt**

#### *Convertible Notes/Debentures*

As of September 30, 2020, the Company had approximately \$23 million aggregate principal amount of convertible notes and debentures (collectively, the “Convertible Notes”) outstanding that were issued pursuant to securities purchase agreements (or, in the case of the Settlement Notes (as defined herein), the Settlement Agreement (as defined herein)) entered into with numerous investors.

The Convertible Notes are convertible at any time, at the holder's option, into shares of the Company's common stock at an initial conversion price, subject to certain beneficial ownership limitations (which vary between maximum ownership of between 4.99% and 9.99%). The conversion price of the Convertible Notes is also generally subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion price then in effect. The conversion price for each of the Company's outstanding Convertible Notes is currently \$0.20 per share. In addition, approximately \$5.3 million aggregate principal amount of the Company's Convertible Notes will be subject to mandatory conversion in connection with the completion of a future financing in the amount of at least \$15 million, subject to the beneficial ownership limitations described above.

The Convertible Notes generally have terms of six months to one year and mature between August 2, 2019 and January 7, 2021, unless earlier converted or repurchased. The Convertible Notes each accrue interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default with respect to certain of the Convertible Notes. Interest is payable in cash or, with respect to certain of the Convertible Notes, and at the holder's option, in shares of common stock based on the conversion price then in effect.

Pursuant to the terms of the Settlement Notes, the Company is required to make an offer to repurchase, at the holder's option, the Settlement Notes at price in cash equal to 100% of the aggregate principal amount of the Settlement Note plus accrued and unpaid interest, if any, to, but excluding, the date of repurchase following the consummation by the Company of a financing transaction, or a series of transactions, resulting in aggregate gross proceeds to the Company in excess of \$7.5 million. Generally, the Company otherwise does not have the right to prepay any of the Convertible Notes without the prior written consent of the holders of such securities.

The Convertible Notes contain a number of affirmative and negative covenants and customary events of default. As of September 30, 2020, approximately \$13.2 million aggregate principal amount of our Convertible Notes were in default. See "*Forbearance Agreements*" below.

The securities purchase agreements and Settlement Agreement, as applicable, also generally contain certain ongoing covenants of the Company, including rights of participation in certain future financing transactions, limitations on future variable rate transactions and "at-the-market" offerings and "most favored nation" provisions giving holders of certain of the Convertible Notes 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 holder under the applicable securities purchase agreement and the transactions contemplated thereby.

The Convertible Notes are senior obligations of the Company. In addition, approximately \$8.9 million aggregate principal amount of the Convertible Notes are secured by a first priority security interest in substantially all of the assets of the Company and its subsidiaries. Convertible Notes are also secured by individual pledges by certain of our current and former officers and directors of our common stock owned by such officer and directors.

For additional information about the Convertible Notes, see Note 4, *Debt* to the Company's audited consolidated financial statements included in the Company's Form 10-K for the year ended December 31, 2019.

#### Forbearance Agreements

Effective as of June 23, 2020, the Company entered into Standstill and Forbearance Agreements (collectively, the "Forbearance Agreements") with the holders of \$13.2 million aggregate principal amount of the Convertible Notes (the "Default Notes"), which are currently in default. Pursuant to the Forbearance Agreements, the holders of the Default Notes have agreed to forbear from exercising their rights and remedies under the Default Notes (including declaring such Default Notes (together with any default amounts and accrued and unpaid interest) immediately due and payable) until the earlier of (i) the date that the Company completes a future financing in the amount of \$15 million and, in connection therewith, commences listing on NASDAQ (collectively, the "New Financing") or (ii) January 31, 2021 (the "Termination Date"). As a result of the ongoing default, the Default Notes are currently accruing interest at the default rate of 18% per annum and have accrued additional default amounts of approximately \$3.9 million in the aggregate as of September 30, 2020.

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

The Forbearance Agreements contain various customary and other representations, warranties and covenants of the Company and the holders of the Default Notes, including an agreement that the Default Notes (together with default amounts and accrued and unpaid interest) will be converted into common stock upon the closing of a New Financing at a conversion price equal to the lesser of (i) the conversion price in effect for the Default Notes on the date of such New Financing or (ii) 75% of the lowest per share price at which common stock is or may be issued in connection with such New Financing, in each case, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%). Shares of the Company's preferred stock, which are convertible into the Company's common stock, will be issued in lieu of common stock to the extent that conversion of the Default Notes is prohibited by such beneficial ownership limitations.

#### Settlement Notes

On June 19, 2020, the Company entered into a settlement agreement (the "Settlement Agreement") with Empery Asset Master Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP (collectively, the "Empery Funds"), Anthony Cataldo and Paul Kessler resolving all remaining disputes between the parties pertaining to certain Convertible Notes and warrants to purchase common stock of the Company (collectively, the "Original Securities") issued by the Company to the Empery Funds in January 2018 pursuant to a securities purchase agreement. In connection with the Settlement Agreement, the Company issued Convertible Notes in an aggregate principal amount of \$450,000 (the "Settlement Notes") to the Empery Funds on June 19, 2020. The Settlement Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 4.99%).

The Settlement Notes mature on December 19, 2020, unless earlier converted or repurchased. The terms of the Settlement Notes are generally the same as the Company's other Convertible Notes, except that the Company is required to make an offer to repurchase, at the option of each holder, the Settlement Notes at price in cash equal to 100% of the aggregate principal amount of the Settlement Notes plus accrued and unpaid interest, if any, to, but excluding, the date of repurchase following the consummation by the Company of a financing transaction, or a series of transactions, resulting in aggregate gross proceeds to the Company in excess of \$7.5 million.

#### Fiscal 2019 and Fiscal 2020 Convertible Notes Transactions

On February 4, 2019, the Company entered into a securities purchase agreement with certain purchasers pursuant to which it issued secured Convertible Notes in an aggregate principal amount of \$1,352,224, consisting of gross proceeds of \$1,052,224 and settlement of existing debt of \$300,000, which Convertible Notes were convertible into common stock at an initial conversion price of \$0.60 per share.

On May 22, 2019, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued Convertible Notes in an aggregate principal amount of \$1,300,000, which Convertible Notes were convertible into the Company's common stock at an initial conversion price of \$0.35 per share.

Between July 31 and August 28, 2019, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued Convertible Notes in an aggregate principal amount of \$975,000, which Convertible Notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.

On December 19, 2019, the Company entered into a securities purchase agreement with one purchaser pursuant to which the Company issued Convertible Notes in an aggregate principal amount of \$200,000, which Convertible Notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.

On January 30, 2020, the Company entered into a securities purchase agreement with one purchaser pursuant to which the Company issued Convertible Notes in an aggregate principal amount of \$200,000, which Convertible Notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.

Between April 20 and May 7, 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued Convertible Notes in an aggregate principal amount of \$2,017,000, which Convertible Notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.

On June 19, 2020, the Company entered into the Settlement Agreement pursuant to which the Company issued the Settlement Notes in an aggregate principal amount of \$450,000, which Settlement Notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.

On July 7, 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued Convertible Notes in an aggregate principal amount of \$3,190,000, which Convertible Notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.

On September 16, 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued Convertible Notes in an aggregate principal amount of \$250,000, which Convertible Notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.

#### *Gemini 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% per annum. There is \$31,000 due on this credit line at September 30, 2020.

### **3. Stockholders' Equity**

#### *Common Stock*

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 \$0.01 per share. As of September 30, 2020, 77,518,614 shares of common stock were issued and outstanding.

During the nine months ended September 30, 2020, the Company issued 3,147,486 shares of common stock upon conversion of \$629,497 in principal and interest on Convertible Notes.

On May 1, 2020, the Company issued 1,086,429 shares of common stock for consulting services.

On June 19, 2020, the Company issued 3,500,000 shares of common stock pursuant to the Settlement Agreement.

## *Preferred Stock*

The 96,230 shares of Series C preferred stock, par value \$0.01 per share (the "Series C Preferred Stock"), are convertible into 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 0.20 or more than 0.2889 common shares for each share of Series C Preferred Stock. The conversion ratio may be adjusted under certain circumstances such as stock splits or stock dividends. The Company has the right to automatically convert the Series C Preferred Stock into common stock if the Company lists its shares of common stock on the Nasdaq National Market and the average closing bid price of the Company's common stock on the Nasdaq National Market for 15 consecutive trading days exceeds \$3,000.00. Each share of Series C Preferred Stock is entitled to the number of votes equal to 0.26 divided by the average closing bid price of the Company's common stock during the fifteen consecutive trading days immediately prior to the date such shares of Series C Preferred Stock were purchased. In the event of liquidation, the holders of the Series C Preferred Stock shall participate on an equal basis with the holders of the common stock (as if the Series C Preferred Stock had converted into common stock) in any distribution of any of the assets or surplus funds of the Company. The holders of Series C Preferred Stock are entitled to noncumulative dividends if and when declared by the Company's board of directors (the "Board"). No dividends to holders of the Series C Preferred Stock were issued or unpaid through September 30, 2020.

On September 1, 2017, the Board designated 2,000,000 shares of Series J preferred stock (the "Series J Preferred Stock"). On the same day, the Board issued 1,513,548 shares of Series J Preferred Stock in exchange for the cancellation of certain indebtedness. In the first quarter of 2019, it was discovered that a certificate of designation with respect to the Series J Preferred Stock had never been filed with the Office of the Secretary of State for the State of Delaware. Despite the fact the Company had issued shares of Series J Preferred Stock, the issuance of those shares was not valid and was of no legal effect.

To remedy the situation, on April 4, 2019, the Company filed a certificate of designation with the Office of the Secretary State for the State of Delaware designating a series of preferred stock as the Series J-1 preferred stock, par value \$0.01 per share (the "Series J-1 Preferred Stock"). On April 19, 2019, the Company issued 2,353,548 shares of Series J-1 Preferred Stock. The issuance was in lieu of the Series J Preferred Stock that should have been issued on September 1, 2017, and in settlement for not receiving preferred stock until 20 months after the debt for which the stock was issued was cancelled. The Company reflected an expense in general and administrative costs in the quarter ended September 30, 2019 totaling \$1,140,000.

Shares of the Series J-1 Preferred Stock are convertible at any time, at the option of the holders, into shares of the Company's common stock at an effective conversion price of \$0.20 per share, subject to adjustment for, among other things, stock dividends, stock splits, combinations, reclassifications of our capital stock and mergers or consolidations, and subject to a beneficial ownership limitation which prohibits conversion if such conversion would result in the holder (together with its affiliates) being the beneficial owner of in excess of 9.99% of the Company's common stock. Shares of the Series J-1 Preferred Stock have the same voting rights a shares of the Company's common stock, with the holders of the Series J-1 Preferred Stock entitled to vote on an as-converted-to-common stock basis, subject to the beneficial ownership limitation described above, together with the holders of the Company's common stock on all matters presented to the Company's stockholders. The Series J-1 Preferred Stock are not entitled to any dividends (unless specifically declared by the Board), but will participate on an as-converted-to-common-stock basis in any dividends to the holders of the Company's common stock. In the event of the Company's dissolution, liquidation or winding up, the holders of the Series J-1 Preferred Stock will be on parity with the holders of the Company's common stock and will participate, on a on an as-converted-to-common stock basis, in any distribution to holders of the Company's common stock.

#### 4. Stock Options and Warrants

##### *Stock Options*

The following table summarizes stock option transactions for the nine months ended September 30, 2020:

	<b>Number of Options</b>	<b>Weighted Average Exercise Price</b>
Outstanding, December 31, 2019	40	\$ 877.50
Granted	-	-
Exercised	-	-
Expired	-	-
Outstanding, September 30, 2020	40	\$ 877.50
Exercisable, September 30, 2020	40	\$ 877.50

##### *Common Stock Warrants*

Warrant transactions for the nine months ended September 30, 2020 are as follows:

	<b>Number of Warrants</b>	<b>Weighted Average Exercise Price</b>
Outstanding at December 31, 2019:	1,813,053	\$ 0.20
Granted	6,500,000	\$ 0.20
Forfeited/canceled	480,352	\$ 0.20
Exercised	-	-
Outstanding at September 30, 2020	7,832,701	\$ 0.20
Exercisable at September 30, 2020	7,832,701	\$ 0.20

##### *Compensation Warrant*

On July 28, 2020, the Company issued a warrant to purchase up to an aggregate of 1,000,000 shares of common stock at an exercise price of \$0.20 per share, subject to adjustment in certain circumstances. The warrant expires on July 28, 2025. The warrant was issued as compensation for certain services provided to the Company.

##### *Settlement Warrants*

Pursuant to the Settlement Agreement, the Company issued pre-funded warrants to purchase up to an aggregate of 5,500,000 shares of common stock (the "Settlement Warrants") at an exercise price of \$0.20 per share, subject to adjustment in certain circumstances. The Settlement Warrants expire on June 19, 2025. The aggregate exercise price of the Settlement Warrants was deemed to be pre-funded to the Company in conjunction with exchange of previously issued warrants to purchase 480,352 shares of common stock pursuant to the Settlement Agreement. Exercise of the Settlement Warrant is subject to certain additional terms and conditions, including certain beneficial ownership limitations.



### ***Forbearance Agreements***

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

### **5. Commitments and Contingencies**

#### ***Leases***

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 September 30, 2020:

Year ending December 31:	
2020	18,000
2021	61,000
Total minimum lease payments	<u>\$ 79,000</u>

Rent expense for the nine months ended September 30, 2020 and 2019 was \$50,000 and \$50,000, respectively.

### **6. Subsequent Events**

#### ***Convertible Notes***

On November 5, 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued Convertible Notes in an aggregate principal amount of \$250,000 (the "November 2020 Notes"). The November 2020 Notes are convertible at any time, at the holder's option, into shares of our common stock at an initial conversion price of \$0.20 per share, subject to certain beneficial ownership limitations (with a maximum ownership limit of 9.99%).

The November 2020 Notes mature on May 5, 2021, unless earlier converted or repurchased. The terms of the July 2020 Notes are generally the same as the Company's other Convertible Notes, except that the November 2020 Notes will be subject to mandatory conversion in the event of the completion of a future financing in the amount of at least \$15 million at a conversion price equal to the lesser of (i) the conversion price in effect for the November 2020 Notes on the date of completion of such financing or (ii) 75% of the lowest per share price at which common stock may be issued in connection with any conversion rights associated with the financing, in each case, subject to the beneficial ownership limitations described above. See Note 2, *Debt* under the caption "Convertible Notes/Debentures" for additional information regarding the terms of the Company's Convertible Notes.

#### ***Common Stock***

In October 2020, the Company issued 750,000 shares of common stock upon conversion of \$150,000 aggregate principal amount of Convertible Notes.

### ***Theorem Settlement Agreement***

On November 9, 2020, the Company, entered into a settlement agreement (the “Theorem Settlement Agreement”) with Adam Kasower (“Kasower”), East Ventures, Inc., A British Virgin Islands company (“East Ventures”), SV Booth Investments III, LLC, a Delaware limited liability company (“SV Booth”) and Theorem Group, LLC, a California limited liability company (“Theorem Group” and, collectively with Kasower, East Ventures and SV Booth, the “Claimants”) resolving all remaining disputes and claims between the parties pertaining to certain securities purchase agreements pursuant to which the Claimants purchased from the Company convertible warrants and preferred stock.

As a result of the Theorem Settlement Agreement, the Company has agreed to issue each Claimant a convertible note in the following amounts (the “Theorem Settlement Notes”):

Theorem Group	\$ 303,726.40
East Venture	\$ 112,788.48
Kasower	\$ 500,078.58
SV Booth	\$ 294,245.54

The Theorem Settlement Agreement also contains certain representations and warranties and covenants, including limitations on future variable rate transactions and “at-the-market offerings.”

### ***Theorem Settlement Notes***

The Theorem Settlement Notes are convertible, at the option of the applicable Claimant, at any time into shares of common stock at an initial conversion rate of \$0.20 per share, subject to certain beneficial ownership limitations. The conversion price is also subject to adjustment due to certain events, including stock dividends, stock splits and in connection with the issuance by the Company of common stock or common stock equivalents at an effective price per share lower than the conversion rate then in effect. The Theorem Settlement Notes mature on January 31, 2021, and bear interest at a rate of 10% per annum, subject to increase to 18% per annum upon and during the occurrence of an event of default. Interest is payable in cash or, at the holder’s option, in shares of common stock based on the conversion price then in effect. The Company may not prepay the Theorem Settlement Notes without the prior written consent of the applicable Claimant.

The Theorem Settlement Notes contain a number of other affirmative and negative covenants and events of default (including events of default related to certain change of control and other fundamental change transactions). Following an event of default, the Theorem Settlement Notes will become immediately due and payable in cash at a mandatory default amount equal to 130% of the outstanding principal amount of the Theorem Settlement Notes plus all other amounts, costs and expenses due in respect of the Theorem Settlement Notes.

### ***Resignation of Chief Financial Officer***

On November 11, 2020, Steven Weldon resigned from the Board and from his office as Chief Financial Officer of the Company, effective immediately. His resignation was the result of general disagreement regarding the Company’s decision making process. Pursuant to Mr. Weldon’s Employment Contract, dated August 11, 2020, Mr. Weldon is only entitled to such stock options, restricted stock awards and other Company stock-based awards granted which have vested as of the date of his resignation. He is not entitled to any other compensation or benefits.

### ***Appointment of New Interim Chief Financial Officer***

Anthony Cataldo, Chief Executive Officer and Chairman of the Board, assumed the additional role of Chief Financial Officer on an interim basis, and will be succeeded as Chief Financial Officer on an interim basis by Michael Handelman immediately after the filing of this report.

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

Mr. Handelman will receive a monthly consulting fee of \$15,000.00.

Mr. Handelman has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K, has no arrangement or understanding between him and any other person required to be disclosed pursuant to Item 401(b) of Regulation S-K and has no family relationships required to be disclosed pursuant to Item 401(d) of Regulation S-K.

Mr. Handelman has entered into a Consulting Agreement with the Company, effective as of November 13, 2020.

#### ***Appointment of New Directors***

On November 12, 2020, the Board appointed Bruce Wendel, age 67, and Greg Berk, age 62, as directors of the Company. Following the filing of this Quarterly Report on Form 10-Q, Mr. Cataldo will resign as interim Chief Financial Officer, and Michael Handelman, age 61, will be appointed as the interim Chief Financial Officer in his place.

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

Mr. Wendel has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K, has no arrangement or understanding between him and any other person required to be disclosed pursuant to Item 401(b) of Regulation S-K and has no family relationships required to be disclosed pursuant to Item 401(d) of Regulation S-K.

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

Dr. Berk has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K, has no arrangement or understanding between him and any other person required to be disclosed pursuant to Item 401(b) of Regulation S-K and has no family relationships required to be disclosed pursuant to Item 401(d) of Regulation S-K.

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

Mr. Wendel and Dr. Berk have each entered into Board Service Agreements with the Company, effective as of November 11, 2020, which supplement the indemnification provisions of the Company's bylaws and obligate the company to insure them both under the Company's director and officer's insurance policy.



**Up to**                      **Units**  
**(Each Unit Consisting of One Share of Common Stock and One Common Warrant to Purchase Shares of Common Stock)**

**Up to**                      **Pre-Funded Units**  
**(Each Pre-funded Unit Consisting of One Pre-Funded Warrant to Purchase One Share of Common Stock and One Common Warrant to Purchase Shares of Common Stock)**

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**PRELIMINARY PROSPECTUS**

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**, 2020**

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**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 SEC registration fee, are estimated.

SEC registration fee	\$ 2,645.68
Miscellaneous expenses	-
Legal	94,000
Accounting fees and expenses	1,500
Total	<u>\$ 96,121.58</u>

**ITEM 14. INDEMNIFICATION OF DIRECTORS AND OFFICERS**

Section 145 of the DGCL provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending or completed actions, suits or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee or agent to us. The DGCL provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors or otherwise. Our certificate of incorporation provides for indemnification by us of our directors, officers and employees to the fullest extent permitted by the DGCL.

Section 102(b)(7) of the DGCL permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) for unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions or (iv) for any transaction from which the director derived an improper personal benefit. Our certificate of incorporation provides for such limitation of liability.

**ITEM 15. RECENT SALES OF UNREGISTERED SECURITIES**

Since July 2017, the Company made the following issuances of its unregistered securities pursuant exemptions contained in Section 4(a)(2) or 3(a)(9) of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder:

- In July 2017, the Company entered into a securities purchase agreement with one purchaser pursuant to which the Company issued (i) 10% senior convertible debentures in an aggregate principal amount of \$650,000, which debentures are convertible into the Company's common stock at an initial conversion price equal to the lesser of (x) \$15.00 or (y) the average of the three lowest intra-day trading prices of the common stock during the 20 trading days immediately prior to delivery of the notice of conversion, and (ii) 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 certain purchasers pursuant to which the Company issued (i) 10% senior convertible debentures in an aggregate principal amount of \$3,890,000, which debentures are convertible into the Company's common stock at an initial conversion price equal to the lesser of (x) \$15.00 or (y) the average of the three lowest intra-day trading prices of the common stock during the 20 trading days immediately prior to delivery of the notice of conversion, and (ii) warrants to acquire up to an aggregate of 259,333 shares of the Company's common stock at an initial exercise price of \$15.00 per share.

- In January 2018, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued (i) senior convertible notes in an aggregate principal amount of \$7,760,510, which notes are convertible into the Company's common stock at an initial conversion price of \$4.58 per share, and (ii) warrants to acquire up to an aggregate of 1,694,440 shares of the Company's common stock at an initial exercise price of \$4.58 per share.
- In August 2018, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued 10% senior convertible debentures in an aggregate principal amount of \$5,140,000, which debentures are convertible into common stock at an initial conversion price of \$2 per share.
- In September 2018, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued 10% senior convertible debentures in an aggregate principal amount of \$2,050,000, which debentures are convertible into common stock at an initial conversion price of \$2 per share.
- In September 2018, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued 10% senior convertible debentures in an aggregate principal amount of \$800,000, which debentures are convertible into common stock at an initial conversion price of \$2 per share.
- In February 2019, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued secured convertible notes in an aggregate principal amount of \$1,352,224, consisting of gross proceeds of \$1,052,224 and settlement of existing debt of \$300,000, which notes are convertible into common stock at an initial conversion price of \$0.60 per share.
- In April 2019, the Company issued 2,353,548 shares of Series J Preferred Stock to certain existing investors, which Series J Preferred Stock are convertible into shares of common stock at an initial rate of \$0.60 per share.
- In May 2019, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued convertible notes in an aggregate principal amount of \$1,300,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.35 per share.
- Between July and August 2019, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued convertible notes in an aggregate principal amount of \$975,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.
- In December 2019, the Company entered into a securities purchase agreement with one purchaser pursuant to which the Company issued convertible notes in an aggregate principal amount of \$200,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.
- In January 2020, the Company entered into a securities purchase agreement with one purchaser pursuant to which the Company issued convertible notes in an aggregate principal amount of \$200,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.
- Between April and May 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued convertible notes in an aggregate principal amount of \$2,017,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.
- In June 2020, the Company issued (i) an aggregate of 3,500,000 shares of common stock, (ii) pre-funded warrants to purchase an aggregate of 5,500,000 million shares of common stock at an initial exercise price of \$0.20 per share and (iii) convertible notes in an aggregate principal amount of \$450,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share, in each case, pursuant to the Settlement Agreement.

- In July 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued convertible notes in an aggregate principal amount of \$3,190,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.
- In September 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issued convertible notes in an aggregate principal amount of \$250,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.
- In November 2020, the Company entered into a securities purchase agreement with certain purchasers pursuant to which the Company issues convertible notes in an aggregate principal amount of \$350,000, which notes are convertible into the Company's common stock at an initial conversion price of \$0.20 per share.

In addition, since July 2017, the Company made the following issuances of its unregistered common stock pursuant exemptions from the registration requirements of the Securities Act:

- 20,934,347 shares of common stock in connection with (i) the conversion of the Company's convertible notes or debentures and (ii) payments of interest in lieu of cash with respect to the Company's convertible notes or debentures;
- 11,500,000 shares of common stock in connection with compensation of the Company's officers and directors; and
- 5,236,429 shares of common stock in connection with compensation of the Company's consultants.

## ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

### (a) Exhibits

The following exhibits are filed with this registration statement:

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Form</u>	<u>Date</u>	<u>Number</u>	<u>Filed Herewith</u>
<a href="#">3.1</a>	Restated Certificate of Incorporation of GT Biopharma, Inc., filed September 10, 1996 and amended through March 1, 2002	10-KSB	04/01/02	3.A	
<a href="#">3.2</a>	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., dated February 9, 2011	10-K	03/31/11	3.2	
<a href="#">3.3</a>	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of July 19, 2017	8-K/A	3/15/18	3.1	
<a href="#">3.4</a>	Bylaws, as restated effective September 7, 1994 and as amended through April 29, 2003	10-QSB	08/13/03	3	
<a href="#">4.1</a>	Certificate of Designation of Preferences, Rights and Limitations of Series J-1 Preferred Stock of GT Biopharma, Inc., dated April 3, 2019	8-K	04/04/2019	3.1	
4.2*	Form of Warrant				
4.3*	Form of Pre-Funded Warrant				
5.1*	Opinion of Baker & McKenzie LLP				
<a href="#">10.1</a>	Exclusive License Agreement, dated July 18, 2016, between the Regents of the University of Minnesota and Oxis Biotech, Inc.	10-Q	08/11/17	10.3	
<a href="#">10.2</a>	License Agreement, dated September 3, 2015, among Daniel A. Vallera, Jeffrey Lion and Oxis Biotech, Inc.	10-Q	08/11/17	10.4	



<a href="#">10.3</a>	Clinical Trial Agreement, dated September 2019, between the Regents of the University of Minnesota and GT Biopharma, Inc.	10-Q	5/15/20	10.7
<a href="#">10.4</a>	Note Conversion Agreement, dated as of August 29, 2017, among GT Biopharma, Inc. and the holders of the convertible notes and debentures named therein	10-Q	11/14/17	10.5
<a href="#">10.5</a>	Amendment Agreement related to Note Conversion Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the holders of the convertible notes and debentures named therein	10-Q	11/14/17	10.8
<a href="#">10.6</a>	Warrant Exercise Agreement, dated August 29, 2017, among GT Biopharma, Inc. and the warrant holders named therein	10-Q	11/14/17	10.6
	Amendment Agreement related to Warrant Exercise Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the warrant holders named therein	10-Q	11/14/17	10.9
<a href="#">10.7</a>	Preferred Stock Exchange Agreement, dated as of August 29, 2017, among GT Biopharma, Inc. and the holders of preferred stock named therein	10-Q	11/14/17	10.7
<a href="#">10.8</a>	Amendment Agreement related to Preferred Stock Exchange Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the holders of preferred stock named therein	10-Q	11/14/17	10.10
<a href="#">10.9</a>	Securities Purchase Agreement, dated January 9, 2017, among OXIS International, Inc. and the purchasers named therein	8-K	01/13/17	10.1
<a href="#">10.10</a>	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/17	10.2
<a href="#">10.11</a>	Form of Common Stock Purchase Warrant (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/17	10.3
<a href="#">10.12</a>	Securities Purchase Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	1/23/18	10.1
<a href="#">10.13</a>	Registration Rights Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	1/23/18	10.2
<a href="#">10.14</a>	Form of Senior Convertible Note (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	1/23/18	10.3
<a href="#">10.15</a>	Form of Warrant to Purchase Common Stock (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	1/23/18	10.4
<a href="#">10.16</a>	Securities Purchase Agreement, dated August 2, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/03/18	10.1
<a href="#">10.17</a>	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated August 2, 2018)	8-K	08/03/18	4.1
<a href="#">10.18</a>	Stock Pledge Agreement, dated August 2, 2018, by the Pledgors named therein for the benefit of Grushko & Mittman, P.C.	10-Q	08/14/18	10.10
<a href="#">10.19</a>	Security Purchase Agreement, dated September 7, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/07/18	10.1
<a href="#">10.20</a>	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 7, 2018)	8-K	09/07/18	4.1
<a href="#">10.21</a>	Security Purchase Agreement, dated September 24, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/28/18	10.1
<a href="#">10.22</a>	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 24, 2018)	8-K	09/28/18	4.1
<a href="#">10.23</a>	Securities Purchase Agreement, dated February 4, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	02/06/19	10.1
<a href="#">10.24</a>	Registration Rights Agreement, dated February 4, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	02/06/19	10.3
<a href="#">10.25</a>	Form of Secured Convertible Note (related to Securities Purchase Agreement, dated February 4, 2019)	8-K	02/06/19	4.1
<a href="#">10.26</a>	Security Agreement, dated February 4, 2019, among GT Biopharma, Inc. and Alpha Capital Anstalt, as collateral agent	8-K	02/06/19	10.2
<a href="#">10.27</a>	Securities Purchase Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/19	10.1
<a href="#">10.28</a>	Registration Rights Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/19	10.2
<a href="#">10.29</a>	Form of Convertible Note (related to Securities Purchase Agreement, dated August 20, 2019)	8-K	05/24/19	4.1

<a href="#">10.30</a>	Securities Purchase Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/19	10.1
<a href="#">10.31</a>	Registration Rights Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/19	10.2
<a href="#">10.32</a>	Form of Convertible Note (related to Securities Purchase Agreement, dated May 22, 2019)	8-K	05/15/20	4.1
<a href="#">10.33</a>	Securities Purchase Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/20	10.1
<a href="#">10.34</a>	Registration Rights Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/20	10.2
<a href="#">10.35</a>	Form of Convertible Note (related to Securities Purchase Agreement, dated January 30, 2020)	10-Q	05/15/20	10.3
<a href="#">10.36</a>	Form Securities Purchase Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/20	10.1
<a href="#">10.37</a>	Form of Registration Rights Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/20	10.2
<a href="#">10.38</a>	Form of Convertible Note (related to Securities Purchase Agreement executed in April/May 2020)	10-Q	05/15/20	10.3
<a href="#">10.39</a>	Securities Purchase Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/20	10.1
<a href="#">10.40</a>	Registration Rights Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/20	10.3
<a href="#">10.41</a>	Form of Convertible Note (related to Securities Purchase Agreement, dated July 7, 2020)	8-K	07/09/20	4.1
<a href="#">10.42</a>	Form of Standstill and Forbearance Agreement, dated June 23, 2020, between the Company and certain holders of convertible notes and debentures	8-K	06/23/20	10.1
<a href="#">10.43</a>	Settlement Agreement, dated June 19, 2020, among GT Biopharma, Inc., Empery Asset Master Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, Anthony Cataldo and Paul Kessler.	8-K	06/19/20	10.1
<a href="#">10.44</a>	Form of Convertible Note, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020)	8-K	06/19/20	10.1
<a href="#">10.45</a>	Form of Pre-Funded Warrant to Purchase Common Stock, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020)	8-K	06/19/20	10.1
<a href="#">10.46</a>	Executive Employment Agreement, dated October 19, 2018, among GT Biopharma, Inc. and Raymond W. Urbanski	10-Q	11/14/18	10.17
<a href="#">10.47</a>	Consultant Agreement, dated February 14, 2018, among GT Biopharma, Inc., Georgetown Translational Pharmaceuticals, Inc. and Anthony J. Cataldo	8-K	2/21/18	10.3
<a href="#">10.48</a>	Employment agreement with Anthony Cataldo	10-Q	8/14/20	10.11
<a href="#">10.49</a>	Employment agreement with Steven Weldon	10-Q	8/14/20	10.12
<a href="#">10.50</a>	Form of Convertible Note (related to Securities Purchase Agreement, dated September 16, 2020)	8-K	9/22/20	4.1
<a href="#">10.51</a>	Securities Purchase Agreement, dated September 16, 2020, among GT Biopharma, Inc. and the purchasers named therein	8-K	9/22/20	10.1
<a href="#">10.52</a>	Master Services Agreement, dated October 5, 2020, between Gt Biopharma, Inc. and Cytovance Biologics, Inc.	8-K	10/6/20	10.1
<a href="#">21.1</a>	Subsidiaries of GT Biopharma, Inc.	10-K	03/31/16	21.1
<a href="#">23.1</a>	Consent of Seligson & Giannattasio, LLP			X
<a href="#">23.2*</a>	Consent of Baker McKenzie LLP (included in Exhibit 5.1)			X
<a href="#">24.1</a>	Power of Attorney (included on signature page to this registration statement)			X
101.INS	XBRL Instance Document			X
101.SCH	XBRL Taxonomy Extension Schema Document			X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document			X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document			X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document			X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document			X

\*To be filed by amendment

(b) Financial Statement Schedules

See the Index to Financial Statements included on page F-1 for a list of the financial statements included in this prospectus.

## ITEM 17. 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:

- (i) To include any prospectus required by Section 10(a)(3) of the Securities Act;
- (ii) To reflect in the prospectus any facts or events arising after the effective date of this registration statement ( or most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the 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) (Section 230.424(b) of this chapter) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and
- (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

Provided, however, that:

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 therein, 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 which remain unsold at the termination of the offering.

Insofar as indemnification for liabilities arising under the Securities Act 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, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant 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 by it is against public policy as expressed in the Act and 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 Los Angeles, State of California, on December 11, 2020.

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 each of Anthony J. Cataldo and Michael Handelman his true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him and in his 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 attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or his 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, Chief Executive Officer and Director  
(principal executive officer)  
December 11, 2020

/s/ Michael Handelman  
Michael Handelman, Chief Financial Officer  
(principal financial officer and principal accounting officer)  
December 11, 2020

/s/ Bruce Wendel  
Bruce Wendel, Director  
December 11, 2020

/s/ Greg Berk  
Greg Berk, Director  
December 11, 2020



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 of GT Biopharma, Inc. of our report dated March 27, 2020, relating to our audit of the consolidated financial statements as of and for the years ended December 31, 2019 and 2018, which appears in the Annual Report on Form 10-K of GT Biopharma, Inc. for the year ended December 31, 2019. 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  
December 11, 2020

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