

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT  
UNDER THE SECURITIES ACT OF 1933

**GT Biopharma, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation or organization)

**94-1620407**

(IRS Employer Identification Number)

**1825 K Street NW, Suite 510**

**Washington, D.C. 20006**

**Phone: (800) 3049888**

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

**Corporation Service Company**

**Corporation Trust Center**

**1209 Orange Street Wilmington, DE**

**Phone: (302) 6587581**

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

Copies to:

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DLA Piper LLP (US)

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**Steven Weldon**

Chief Financial Officer

1825 K Street NW, Suite 510

Washington, D.C. 20006

(800) 304-9888

**Approximate date of commencement of proposed sale to public:** As soon as practicable after this registration statement is declared effective. [ ]

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

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, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box. [X]

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

If this Form is a posteffective 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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. [ ]

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. [ ]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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  (Do not check if a smaller reporting company)

Smaller reporting company

Emerging growth company

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



## CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Amount to be Registered <sup>(1)</sup>	Proposed maximum offering price per security <sup>(2)</sup>	Proposed Maximum Aggregate Offering Price <sup>(2)</sup>	Amount of Registration Fee <sup>(1) (2)</sup>
Common stock, par value \$0.001 per share	3,388,884	\$ 1.95	\$6,608,323.80	\$ 822.74

- (1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, this registration also covers such additional number of shares of common stock issuable upon stock splits, stock dividends, reclassifications, recapitalizations, combinations or similar events, with respect to the shares of common stock being registered pursuant to this registration statement.
- (2) Estimated solely for the purposes of calculating the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low per-share prices of the registrant's common stock as quoted on the OTCQB on February 22, 2018.

**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 (the "Act") or until the registration statement shall become effective on such date as the Securities and Exchange Commission (the "SEC"), acting pursuant to said Section 8(a), may determine.**

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**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 MARCH 1, 2018**

**PRELIMINARY PROSPECTUS**

**GT BIOPHARMA, INC.**

**3,388,884 Shares**

**Common Stock**

The selling stockholders named herein are offering, from time to time, in one or more offerings, up to 3,388,884, shares of our common stock. You should read this prospectus and any accompanying prospectus supplement before you decide to invest in any of these securities.

The selling stockholder shares consist of shares of our common stock issued pursuant to a private placement of warrants and senior convertible notes. This prospectus describes the general manner in which the shares of common stock may be offered and sold by the selling stockholders.

We are not selling any common stock under this prospectus and we will not receive any proceeds from the sale of shares by the selling stockholders, but we do incur expenses in connection with the registration of these shares of our common stock.

Our common stock is listed on the OTCQB under the symbol GTBP. The last reported sale price of our common stock on the OTCQB on February 28, 2018, was \$1.90 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). The applicable prospectus supplement will contain information, where applicable, as to any other quotation on the OTCQB or any securities market or other exchange of the securities, if any, covered by the prospectus supplement.

**Investing in our common stock involves a high degree of risk. Please read “Risk Factors” beginning on page 4 of this prospectus for a discussion of factors you should consider before deciding to invest in shares of our common stock.**

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

**The date of this prospectus is March 1, 2018.**

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission utilizing a “shelf” registration process. Under this shelf registration process, the selling stockholders may offer from time to time up to an aggregate of 3,388,884 shares of common stock in one or more offerings. The registration statement of which this prospectus is a part is being filed in accordance with the registration rights agreement, dated as of January 22, 2018, by and among GT Biopharma, Inc. and the selling stockholders party thereto. Pursuant to the registration rights agreement, we have agreed to indemnify and hold harmless, to the extent permitted by law, each of the selling stockholders party to the registration rights agreement and each of such selling stockholder’s directors, officers, partners, members, employees, agents, representatives of and each other person, if any, who controls such selling stockholder within the meaning of the Securities Act of 1933, as amended (the “Securities Act”), from and against certain losses, claims, damages and liabilities, including certain liabilities under the Securities Act.

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

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

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

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

All references to the number of shares issued or outstanding in this prospectus, and all per share and other similar data, reflect a 1for300 reverse stock split that we effected on August 21, 2017.

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

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

## PROSPECTUS SUMMARY

*This summary highlights certain information about us, this offering and selected information contained elsewhere in or incorporated by reference in this prospectus. Because this is only a summary, it does not contain all of the information that may be important to you or that you should consider before investing in our common stock. You should read the entire prospectus carefully, especially "Risk Factors" beginning on page 4 of this prospectus, and in the section titled "Risk Factors" in the documents incorporated herein by reference, including our Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, the other information incorporated by reference in this prospectus, and the information included in any free writing prospectus that we have authorized for use in connection with this offering. This prospectus contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may vary materially from those discussed in the forward-looking statements as a result of various factors, including, without limitation, those set forth in "Risk Factors" as well as other matters described in this prospectus. See "Cautionary Note Regarding Forward-Looking Statements."*

### Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE), Tetra-specific Killer Engager (TetraKE) and bi-specific Antibody Drug Conjugate (ADC) technology platforms. Our TriKE and TetraKE platforms generate proprietary moieties designed to harness and enhance the cancer killing abilities of a patient's own natural killer, or NK, cells. Once bound to a NK cell, our moieties are designed to enhance the NK cell and precisely direct it to one or more specifically-targeted proteins (tumor antigens) expressed on a specific type of cancer, ultimately resulting in the cancer cell's death. TriKEs and TetraKEs are made up of recombinant fusion proteins, can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization. They are designed to be dosed in a common outpatient setting similar to modern antibody therapeutics and are expected to have reasonably low cost of goods. Our ADC platform generates product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of ADCs.

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

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

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

Our TetraKE product candidates are single-chain fusion proteins composed of human single-domain anti-CD16 antibody, wild-type IL-15 and the variable regions of the heavy and light chains of two antibodies that target two specific tumor antigens expressed on specific types of cancer cells. An example of a TetraKE product candidate is OXS-1615 which targets EpCAM and CD133 positive solid tumors. EpCAM is found on many solid tumor cells of epithelial origin and CD133 is a marker for cancer stem cells. OXS-1615 is designed to enable a patient's NK cells to kill not only the heterogeneous population of cancer cells found in many solid tumors but also kill the cancer stem cells that are typically responsible for recurrences. We intend to initiate human clinical testing for certain of our solid tumor product candidates in 2019.

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

We are using our TriKE and TetraKE platforms with the intent to bring to market multiple immuno-oncology products that can treat a wide range of hematologic malignancies, sarcoma and solid tumors. The platforms are scalable and we are putting processes in place to be able to produce IND-ready moieties in approximately 90-120 days after a specific TriKE or TetraKE conceptual design. After conducting market and competitive research, specific moieties can then be rapidly advanced into the clinic on our own or through potential collaborations with larger companies. We are currently evaluating over a dozen moieties and intend to announce additional clinical product candidates in the second half of 2018. We believe our TriKEs and TetraKEs will have the ability, if approved for marketing, to be used on a stand-alone basis, augment the current monoclonal antibody therapeutics, be used in conjunction with more traditional cancer therapy and potentially overcome certain limitations of current chimeric antigen receptor, or CAR-T, therapy.

We also believe our bi-specific, ligand-directed single-chain fusion proteins represents the next generation of ADCs. Our lead bi-specific ADC, OXS-1550, which targets CD19+ and/or CD22+ hematological malignancies is currently in a Phase 2 trial being conducted at the University of Minnesota Masonic Cancer Center in patients with relapsed/refractory B-cell leukemias or lymphomas. We believe OXS-1550 has certain properties that could result in competitive advantages over recently approved ADC products targeting leukemias and lymphomas. In a Phase 1 trial, of nine patients that achieved adequate blood levels, we saw a durable complete response, or CR, in two heavily pretreated patients. One patient, who had failed multiple previous treatment regimens, has been cancer free since early 2015.

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

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

#### **Summary Risk Factors**

Investing in our common stock involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties discussed under the section titled "Risk Factors" beginning on page 4, as well as any amendments thereto reflected in subsequent filings with the SEC, which are incorporated by reference into this prospectus in their entirety, together with other information in this prospectus, the documents incorporated by reference and any free writing prospectus that we may authorize for use in connection with a specific offering.

#### **Our Offices**

Our principal executive offices are located at 1825 K Street NW, Suite 510, Washington, D.C. 20006, and our telephone number is (800) 3049888.

#### **Our Website**

Our website is located 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

<b>Securities offered by the selling stockholders</b>	Up to 3,388,884 shares of common stock
<b>Offering Price</b>	Fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices.
<b>Use of proceeds</b>	We will not receive any proceeds from the sale of common stock by the selling stockholders. See "Use of Proceeds."
<b>Common stock outstanding before this offering</b>	50,117,978 shares
<b>Common stock outstanding after this offering</b>	50,117,978 shares
<b>OTC Markets symbol</b>	GTBP

The number of shares of common stock to be outstanding after this offering is based on 50,117,978 shares of common stock outstanding as of February 28, 2018, which includes shares of common stock subject to stock options and preferred stock that are currently exercisable or exercisable within 60 days of February 20, 2018.

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

## RISK FACTORS

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

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

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

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

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

As of December 31, 2017, we had an accumulated deficit of \$267,896,000. We have not generated any significant revenue to date and are not profitable, and have incurred losses in each year since our inception. We do not expect to generate any product sales or royalty revenues for at least four years. We expect to incur significant additional operating losses for the foreseeable future as we expand research and development and clinical trial efforts.

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

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

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

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

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

- the accuracy of the assumptions underlying our estimates for capital needs in 2018 and beyond;
- scientific and clinical progress in our research and development programs;
- the magnitude and scope of our research and development programs and our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with pre-clinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

Additional financing through strategic collaborations, public or private equity or debt financings or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to our stockholders, and any debt financings will likely involve covenants restricting our business activities. Additional financing may not be available on acceptable terms, or at all. Further, if we obtain additional funds through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize on our own.

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

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

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

We have identified material weaknesses in our internal control over financial reporting as a company. As defined in Regulation 12b-2 under the Securities Exchange Act of 1934, or the Exchange Act, a “material weakness” is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented, or detected on a timely basis. Specifically, we determined that we had the following material weaknesses in our internal control over financial reporting: (i) inadequate segregation of duties; and (ii) insufficient written policies and procedures for accounting and financial reporting with respect to the requirements and application of both generally accepted accounting principles in the United States of America, or GAAP, and the U.S. Securities and Exchange Commission, or the SEC, guidelines.

As of the date of this report, we have not remediated these material weaknesses. We are continuing to adopt and implement written policies and procedures for accounting and financial reporting. We plan to hire additional qualified personnel to address inadequate segregation of duties, although the timing of such hires is largely dependent on our securing additional financing to cover such costs. The implementation of these initiatives may not fully address any material weakness or other deficiencies that we may have in our internal control over financial reporting.

Even if we develop effective internal control over financial reporting, such controls may become inadequate due to changes in conditions or the degree of compliance with such policies or procedures may deteriorate, which could result in the discovery of additional material weaknesses and deficiencies. In any event, the process of determining whether our existing internal control over financial reporting is compliant with Section 404 of the Sarbanes-Oxley Act, or Section 404, and sufficiently effective requires the investment of substantial time and resources, including by certain members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete. In addition, we cannot predict the outcome of this process and whether we will need to implement remedial actions in order to establish effective controls over financial reporting. The determination of whether or not our internal controls are sufficient and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. We may also fail to timely complete our evaluation, testing and any remediation required to comply with Section 404.

We are required, pursuant to Section 404, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. However, for as long as we are a “smaller reporting company,” our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. While we could be a smaller reporting company for an indefinite amount of time, and thus relieved of the above-mentioned attestation requirement, an independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Such undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

***Our intellectual property may be compromised.***

Part of our value going forward depends on the intellectual property rights that we have been and are acquiring. There may have been many persons involved in the development of our intellectual property, and we may not be successful in obtaining the necessary rights from all of them. It is possible that in the future, third parties may challenge our intellectual property rights. We may not be successful in protecting our intellectual property rights. In either event, we may lose the value of our intellectual property, and if so, our business prospects may suffer.

***If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market and our business would be harmed.***

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any disclosure to or misappropriation by third parties of our trade secret or other confidential information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding any competitive advantage we may derive from this information.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications we own or license may fail to result in issued patents in the United States or in foreign countries. Third parties may challenge the validity, enforceability or scope of any issued patents we own or license or any applications that may issue as patents in the future, which may result in those patents being narrowed, invalidated or held unenforceable. Even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from developing similar products that do not fall within the scope of our patents. If the breadth or strength of protection provided by the patents we hold or pursue is threatened, our ability to commercialize any product candidates with technology protected by those patents could be threatened. Further, if we encounter delays in our clinical trials, the period of time during which we would have patent protection for any covered product candidates that obtain regulatory approval would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain at the time of filing that we are the first to file any patent application related to our product candidates.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our discovery platform and drug development processes that involve proprietary know-how, information or technology that is not covered by patents or not amenable to patent protection. Although we require all of our employees and certain consultants and advisors to assign inventions to us, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, our trade secrets and other proprietary information may be disclosed or competitors may otherwise gain access to such information or independently develop substantially equivalent information. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant difficulty in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the trade secret intellectual property related to our technologies to third parties, we may not be able to establish or maintain the competitive advantage that we believe is provided by such intellectual property, which could materially adversely affect our market position and business and operational results.

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

Our research, development and commercialization activities, as well as any product candidates or products resulting from those activities, may infringe or be accused of infringing a patent or other form of intellectual property under which we do not hold a license or other rights. Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware of, with claims that cover the use or manufacture of our product candidates or the practice of our related methods. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes one or more claims of these patents. If our activities or product candidates infringe the patents or other intellectual property rights of third parties, the holders of such intellectual property rights may be able to block our ability to commercialize such product candidates or practice our methods unless we obtain a license under the intellectual property rights or until any applicable patents expire or are determined to be invalid or unenforceable.

Defense of any intellectual property infringement claims against us, regardless of their merit, would involve substantial litigation expense and would be a significant diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties, limit our business to avoid the infringing activities, pay royalties and/or redesign our infringing product candidates or methods, any or all of which may be impossible or require substantial time and monetary expenditure. Further, if we were to seek a license from the third party holder of any applicable intellectual property rights, we may not be able to obtain the applicable license rights when needed or on commercially reasonable terms, or at all. The occurrence of any of the above events could prevent us from continuing to develop and commercialize one or more of our product candidates and our business could materially suffer.

***We may desire, or be forced, to seek additional licenses to use intellectual property owned by third parties, and such licenses may not be available on commercially reasonable terms or at all.***

A third party may hold intellectual property, including patent rights, that are important or necessary to the development of our product candidates, in which case we would need to obtain a license from that third party or develop a different formulation of the product that does not infringe upon the applicable intellectual property, which may not be possible. Additionally, we may identify product candidates that we believe are promising and whose development and other intellectual property rights are held by third parties. In such a case, we may desire to seek a license to pursue the development of those product candidates. Any license that we may desire to obtain or that we may be forced to pursue may not be available when needed on commercially reasonable terms or at all. Any inability to secure a license that we need or desire could have a material adverse effect on our business, financial condition and prospects.

***The patent protection covering some of our product candidates may be dependent on third parties, who may not effectively maintain that protection.***

While we expect that we will generally seek to gain the right to fully prosecute any patents covering product candidates we may in-license from third-party owners, there may be instances when platform technology patents that cover our product candidates remain controlled by our licensors. If any of our current or future licensing partners that retain the right to prosecute patents covering the product candidates we license from them fail to appropriately maintain that patent protection, we may not be able to prevent competitors from developing and selling competing products or practicing competing methods and our ability to generate revenue from any commercialization of the affected product candidates may suffer.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.***

Competitors may infringe our patents or the patents of our current or potential licensors. To attempt to stop infringement or unauthorized use, we may need to enforce one or more of our patents, which can be expensive and time-consuming and distract management. If we pursue any litigation, a court may decide that a patent of ours or our licensor's is not valid or is unenforceable, or may refuse to stop the other party from using the relevant technology on the grounds that our patents do not cover the technology in question. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, which could reduce the likelihood of success of any infringement proceeding we pursue in any such jurisdiction. An adverse result in any infringement litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing, which could limit our ability to exclude competitors from directly competing with us in the applicable jurisdictions.

Interference proceedings provoked by third parties or brought by the U.S. PTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to use it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

***If we are unsuccessful in obtaining or maintaining patent protection for intellectual property in development, our business and competitive position would be harmed.***

We are seeking patent protection for some of our technology and product candidates. Patent prosecution is a challenging process and is not assured of success. If we are unable to secure patent protection for our technology and product candidates, our business may be adversely impacted.

In addition, issued patents and pending international applications require regular maintenance. Failure to maintain our portfolio may result in loss of rights that may adversely impact our intellectual property rights, for example by rendering issued patents unenforceable or by prematurely terminating pending international applications.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We currently, and expect in the future to continue to, seek to protect these trade secrets, in part, by entering into confidentiality agreements with parties who have access to them, such as our employees, collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for any such disclosure. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they disclose the trade secrets, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

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

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

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

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

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

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

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

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

Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, with contractual provisions and other procedures, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employers. Litigation may be necessary to defend against any such claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact contributes to the development of intellectual property that we regard as our own. Further, the terms of such assignment agreements may be breached and we may not be able to successfully enforce their terms, which may force us to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of intellectual property rights we may regard and treat as our own.

***Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could cause our business to suffer.***

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with regulations of governmental authorities, such as the FDA or the European Medicines Agency, or EMA, to provide accurate information to the FDA or EMA, to comply with manufacturing standards we have established, to comply with federal, state and international healthcare fraud and abuse laws and regulations as they may become applicable to our operations, to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we currently take and the procedures we may establish in the future as our operations and employee base expand to detect and prevent this type of activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure by our employees to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



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

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

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

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

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

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

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

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

***We intend to pursue Section 505(b)(2) regulatory approval filings with the FDA for at least three of our product candidates. If the FDA concludes that certain of our product candidates fail to satisfy the requirements under Section 505(b)(2), or if the requirements for such product candidates under Section 505(b)(2) are not as we expect, the approval pathway for such product candidates may take significantly longer, cost substantially more and entail greater complications and risks than anticipated and, in either case, may not be successful. In addition, if under certain circumstances, exclusivity of competitors would delay approval of our product candidates, then we may pursue approval through the Section 505(b)(1) regulatory pathway, which may require us to conduct additional preclinical or clinical trials or obtain a right to reference the preclinical or clinical data of others.***

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our therapeutic immuno-oncology development programs face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities or funding, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We will have only limited control over the activities of the CRO we will engaged to continue conduct our clinical trials including the University of Minnesota for our phase 2 clinical trial for OXS-1550. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on any CRO does not relieve us of our regulatory responsibilities. Based on our present expectations, we, our CROs and our clinical trial sites are required to comply with good clinical practices, or GCPs, for all of our product candidates in clinical development. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in the applicable trial may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving a product candidate for marketing, which we may not have sufficient cash or other resources to support and which would delay our ability to generate revenue from any sales of such product candidate. In addition, our clinical trials are required to be conducted with product produced in compliance with current good manufacturing practice requirements, or cGMPs. Our or our CROs' failure to comply with those regulations may require us to repeat clinical trials, which would also require significant cash expenditures and delay the regulatory approval process.

Agreements governing relationships with CROs generally provide those CROs with certain rights to terminate a clinical trial under specified circumstances. If a CRO that we have engaged terminates its relationship with us during the performance of a clinical trial, we would be forced to seek an engagement with a substitute CRO, which we may not be able to do on a timely basis or on commercially reasonable terms, if at all, and the applicable trial would experience delays or may not be completed. In addition, our CROs are not our employees, and except for remedies available to us under any agreements we enter with them, we are unable to control whether or not they devote sufficient time and resources to our clinical, nonclinical and preclinical programs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to a failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for, or successfully commercialize, the affected product candidates. As a result, our operations and the commercial prospects for the effected product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.



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

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

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

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

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

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

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

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

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

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

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

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

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

***Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.***

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. In addition, the sale of substantial amounts of our common stock could adversely impact its price.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains or incorporates by reference documents containing certain statements that are, or may be deemed to be, “Forward-Looking Statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are “Forward-Looking Statements” for purposes of these provisions, including our plans of operation, any projections of revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All Forward-Looking Statements included in this document are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any Forward-Looking Statement. In some cases, Forward-Looking Statements can be identified by the use of terminology such as “may,” “will,” “expects,” “plans,” “anticipates,” “intends,” “believes,” “estimates,” “potential,” or “continue,” or the negative thereof or other comparable terminology.

Although we believe that the expectations reflected in the Forward-Looking Statements contained herein are reasonable, there can be no assurance that such expectations or any of the Forward-Looking Statements will prove to be correct, and actual results could differ materially from those projected or assumed in the Forward-Looking Statements. Future financial condition and results of operations, as well as any Forward-Looking Statements are subject to inherent risks and uncertainties, including any other factors referred to in our press releases and reports filed with the Securities and Exchange Commission. All subsequent Forward-Looking Statements attributable to the company or persons acting on its behalf are expressly qualified in their entirety by these cautionary statements. Additional factors that may have a direct bearing on our operating results are incorporated by reference as described under the heading “Incorporation of Certain Information by Reference” including, without limitation, 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.
- 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 identified material weaknesses in our internal control over financial reporting, which may negatively impact our ability to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financials 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.
- 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.
- Clinical drug development is costly, time-consuming and uncertain, and we may suffer setbacks in our clinical development program that could harm our business.
- We have limited clinical testing and regulatory capabilities, and human clinical trials are subject to extensive regulatory requirements, very expensive, time-consuming and difficult to design and implement. Our products may fail to achieve necessary safety and efficacy endpoints during clinical trials, which may limit our ability to generate revenues from therapeutic products.
- 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 operate in a very competitive and rapidly changing environment and new risks emerge from time to time. As a result, it is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this prospectus may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. You are cautioned not to place undue reliance upon such forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-looking statements will be achieved or occur.

## USE OF PROCEEDS

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

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

## DESCRIPTION OF SECURITIES TO BE REGISTERED

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

### General

As of the date of this Prospectus, our authorized capital stock consists of 750,000,000 shares of common stock, par value \$0.001 per share, and 15,000,000 shares of preferred stock, par value \$0.001 per share. As of February 28, 2018, there were 50,117,978 shares of our common stock outstanding, and [●] shares of our preferred stock outstanding.

### Common Stock

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

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

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

### *Amended and Restated Certificate of Incorporation*

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

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

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

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

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

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

#### ***Delaware Anti-takeover Statute***

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

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

#### **Transfer Agent and Registrar**

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

#### **Listing**

Our common stock is listed on the OTCQB under the symbol “GTBP.” The last reported sale price of our common stock on the OTCQB on February 28, 2018, was \$1.90 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).

## SELLING STOCKHOLDERS

This prospectus relates to the possible resale by certain of our stockholders, who we refer to in this prospectus as the “selling stockholders,” of shares of our common stock described in this prospectus that were issued and outstanding prior to the filing of the registration statement of which this prospectus forms a part.

### 2018 Private Placement Financing

On January 22, 2018, we entered into a securities purchase agreement with certain institutional and other accredited investors relating to a private placement of our senior convertible notes and warrants representing the right to acquire a number of shares of our common stock. Each senior convertible note is convertible into our common stock, par value, \$0.001 per share, at the current conversion price at any time or times on or after January 23, 2018. Each warrant represents the right to purchase one share of common stock at a price of \$4.58 per share and are exercisable at any time or times on or after January 23, 2018. The investors purchased an aggregate principal amount of \$7,760,510 of senior convertible notes and warrants to purchase 1,694,442 shares of our common stock. Each of the investors in the private placement is a selling stockholder.

In connection with the private placement, we entered into a registration rights agreement, dated January 22, 2018, with the investors, pursuant to which we agreed to register for resale by the investors the shares of common stock issuable upon conversion of the senior convertible notes and the shares of common stock issuable upon exercise of the warrants, purchased by the investors pursuant to the securities purchase agreement. We committed to file the registration statement no later than March 2, 2018. The registration rights agreement provides for liquidated damages upon the occurrence of certain events, including our failure to file the registration statement or cause it to become effective prior to the applicable deadlines. The amount of liquidated damages payable to an investor would be 2.0% of the aggregate amount invested by such investor for each 30-day period, or pro rata portion thereof, during which the default continues. We filed the registration statement of which this prospectus is a part with the SEC pursuant to the registration rights agreement.

The shares of common stock being offered by the selling stockholders are those issuable to the selling stockholders pursuant to the terms of the senior convertible notes and upon exercise of the warrants. We are registering the shares of common stock in order to permit the selling stockholders to offer the shares for resale from time to time. Except for the ownership of the senior convertible notes and the warrants issued pursuant to the securities purchase agreement, the selling stockholders have not had any material relationship with us within the past three years.

### Selling Stockholder Table

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of common stock by each of the selling stockholders. The second column lists the number of shares of common stock beneficially owned by each selling stockholder, based upon information provided to us by each selling stockholder for use in this prospectus, assuming conversion of all senior convertible notes and exercise of all warrants held by the selling stockholders on that date, without regard to any limitations on the issuance of shares of common stock pursuant to the terms of the convertible notes or exercise of the warrants.

The third column lists the shares of common stock being offered by this prospectus by the selling stockholders.

In accordance with the terms of a registration rights agreement with the selling stockholders, this prospectus generally covers the resale of at least the sum of (i) 200% of the maximum number of shares of common stock issued and issuable pursuant to the senior convertible notes as of the Trading Day immediately preceding the date the registration statement is initially filed with the SEC, and (ii) the maximum number of shares of common stock issued and issuable upon exercise of the related warrants as of the trading day immediately preceding the date the registration statement is initially filed with the SEC. Because the conversion price of the senior convertible notes, the number of shares that will actually be issued may be more or less than the number of shares being offered by this prospectus. The fourth column assumes the sale of all of the shares offered by the selling stockholders pursuant to this prospectus. The fifth column lists the percentage ownership of our common stock by each selling stockholder after completion of this offering, assuming that each selling stockholder sells all of the shares covered by this prospectus, to the extent such percentage will exceed 1% of the total number of shares of common stock outstanding.

Under the terms of the senior convertible notes and the warrants, a selling stockholder may not convert the senior convertible notes or exercise the warrants to the extent such conversion or exercise would cause such selling stockholder, together with its affiliates, to beneficially own a number of shares of common stock that would exceed 4.99% of our then-outstanding shares of common stock following such conversion or exercise, excluding for purposes of such determination shares of common stock issuable pursuant to the terms of the senior convertible notes that have not been converted and upon exercise of the warrants that have not been exercised. The number of shares in the second column does not reflect this limitation. The selling stockholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

Name of Selling Stockholder	Number of Shares of Common Stock Beneficially Owned Prior to Offering	Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus	Number of Shares of Common Stock Beneficially Owned After Offering (15)	Percentage of Shares of Common Stock Owned After Offering
Adam Kasower (1)	2,754,434	240,176	2,514,258	5.01%
Alto Opportunity Master Fund, SPC – Segregated Master Portfolio (2)	960,700	960,700	0	0%
Diane S. Lipp Separate Property Trust (3)	19,214	19,214	0	0%
Empery Asset Master, Ltd. (4)	420,788	420,788	0	0%
Empery Tax Efficient, LP (5)	159,958	159,958	0	0%
Empery Tax Efficient II, LP (6)	379,958	379,958	0	0%
James Heavener (7)	2,958,662	401,094	2,584,568	5.16%
Jeffrey Bronfman Revocable Living Trust (8)	72,054	72,054	0	0%
Lipp Irrevocable Trust (9)	19,214	19,214	0	0%
Red Mango Enterprises Limited (10)	2,571,854	401,094	2,170,760	4.33%
Robert H. Lipp Separate Property Trust (11)	67,250	67,250	0	0%
Siesta Fiesta Holdings, LLC (12)	152,387	24,018	128,369	0.26%
The Rosalinde and Arthur Gilbert Foundation (13)	168,124	168,124	0	0%
The RSZ Trust (14)	55,242	55,242	0	0%

- (1) Consists of (i) 120,088 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 120,088 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (2) Consists of (i) 48,350 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 48,350 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (3) Consists of (i) 9,607 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 9,607 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (4) Consists of (i) 210,394 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 210,394 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share. Empery Asset Management LP, the authorized agent of Empery Asset Master Ltd (“EAM”), has discretionary authority to vote and dispose of the shares held by EAM and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by EAM. EAM, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares except to the extent of their pecuniary interest therein. The business address for each of EAM, Empery Asset Management LP and Messrs. Hoe and Lane is c/o Empery Asset Management, LP, 1 Rockefeller Plaza, Suite 1205, New York, NY 10020.



- (5) Consists of (i) 79,979 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 79,979 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share. Empery Asset Management LP, the authorized agent of Empery Tax Efficient, LP (“ETE”), has discretionary authority to vote and dispose of the shares held by ETE and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE. ETE, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares except to the extent of their pecuniary interest therein. The business address for each of ETE, Empery Asset Management LP and Messrs. Hoe and Lane is c/o Empery Asset Management, LP, 1 Rockefeller Plaza, Suite 1205, New York, NY 10020.
- (6) Consists of (i) 189,979 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 189,979 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share. Empery Asset Management LP, the authorized agent of Empery Tax Efficient II, LP (“ETE II”), has discretionary authority to vote and dispose of the shares held by ETE II and may be deemed to be the beneficial owner of these shares. Martin Hoe and Ryan Lane, in their capacity as investment managers of Empery Asset Management LP, may also be deemed to have investment discretion and voting power over the shares held by ETE II. ETE II, Mr. Hoe and Mr. Lane each disclaim any beneficial ownership of these shares except to the extent of their pecuniary interest therein. The business address for each of ETE II, Empery Asset Management LP and Messrs. Hoe and Lane is c/o Empery Asset Management, LP, 1 Rockefeller Plaza, Suite 1205, New York, NY 10020.
- (7) Consists of (i) 200,547 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 200,547 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (8) Consists of (i) 36,027 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 36,027 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (9) Consists of (i) 9,607 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 9,607 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (10) Consists of (i) 1,085,380 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 1,085,380 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (11) Consists of (i) 33,625 shares of common stock that may be acquired from us upon exercise of warrant and (ii) 33,625 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (12) Consists of (i) 12,009 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 12,009 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (13) Consists of (i) 84,062 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 84,062 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (14) Consists of (i) 27,621 shares of common stock that may be acquired from us upon exercise of warrants and (ii) 27,621 shares of common stock that may be acquired from us upon conversion of a senior convertible note at the current conversion price of \$4.58 per share.
- (15) The selling stockholders have not informed us, and we do not know, when or in what amounts the selling stockholders may offer for sale the shares of common stock pursuant to this offering. The selling stockholders may choose not to sell any of the shares offered by this prospectus. Because the selling stockholders may offer all, some or none of the common stock that they own pursuant to this offering, and because there are currently no agreements, arrangements or undertakings with respect to the sale of any such shares, we cannot provide any information or estimates as to the number of shares of our common stock that the selling stockholders will hold after completion of this offering. For purposes of this table, we have assumed that the selling stockholders will have sold all of the shares of common stock issuable upon conversion of the notes and exercise of the warrants covered by this prospectus upon the completion of this offering.

## PLAN OF DISTRIBUTION

We are registering 3,388,884 shares of our common stock for possible sale by the selling stockholders.

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

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

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

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

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

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

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

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

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

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

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

## LEGAL MATTERS

The validity of the shares of common stock offered through this prospectus has been passed on by DLA Piper LLP (US), Austin, Texas.

## EXPERTS

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

## WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-3 under the Securities Act with the Securities and Exchange Commission with respect to the shares of our common stock offered by this prospectus. This prospectus was filed as a part of that registration statement but does not contain all of the information contained in the registration statement and exhibits. Reference is thus made to the omitted information. Statements made in this prospectus are summaries of the material terms of contracts, agreements and documents and are not necessarily complete; however, all information we considered material has been disclosed. Reference is made to each exhibit for a more complete description of the matters involved and these statements are qualified in their entirety by the reference. You may inspect the registration statement, exhibits and schedules filed with the Securities and Exchange Commission at the Securities and Exchange Commission's principal office in Washington, D.C. Copies of all or any part of the registration statement may be obtained from the Public Reference Section of the Securities and Exchange Commission, 100 F. Street, N.E., Washington, D.C. 20549. The Securities and Exchange Commission also maintains a website (<http://www.sec.gov>) that contains this filed registration statement, reports, proxy statements and information regarding us that we have filed electronically with the Commission. For more information pertaining to our company and the common stock offered in this prospectus, reference is made to the registration statement.

Upon the effective date of this registration statement and thereafter, we will file with the Securities and Exchange Commission annual and quarterly periodic reports on forms 10-K and 10-Q respectively and current reports on form 8-K as needed. We are not required to deliver annual reports to our shareholders and at this time we do not intend to do so. We encourage our shareholders, however, to access and review all materials that we will file with the Securities and Exchange Commission at <http://www.sec.gov>. Our SEC file number is 000-08092.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" information into this prospectus, which means that we can disclose important information about us by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be a part of this prospectus. This prospectus incorporates by reference the documents and reports listed below (other than portions of these documents deemed to have been furnished and not filed in accordance with SEC rules):

- our Annual Report on Form 10-K for the year ended December 31, 2016, filed with the SEC on March 31, 2017, as amended on Form 10-K/A, filed with the SEC on February 28, 2018 (File No. 000-08092);
- our quarterly report on Form 10-Q for the quarter ended September 30, 2017, filed with the SEC on November 14, 2017, as amended on Form 10Q/A, filed with the SEC on February 28, 2018 (File No. 000-08092);
- our current reports on Form 8-K filed with the SEC on October 12, 2017, November 16, 2017, January 16, 2018, January 23, 2018 and February 21, 2018 (File No. 000-08092);
- our information statement filed pursuant to Section 14 of the Exchange Act in connection with our Notice of Action by Written Consent of Stockholders filed with the SEC on May 12, 2017 (File No. 000-08092); and
- the description of our common stock contained in our Prospectus dated June 18, 1969 (File No. 0361150), filed with the SEC on June 23, 1969, including any amendment or report filed for the purpose of updating such description.

We also incorporate by reference the information contained in all other documents we file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act (other than documents or portions of these documents that are deemed to have been furnished and not filed in accordance with SEC rules, unless otherwise indicated therein) after the date of the initial registration statement of which this prospectus forms a part and prior to the effectiveness of such registration statement, and after the date of this prospectus and prior to the termination of this offering. The information contained in any such document will be considered part of this prospectus from the date the document is filed with the SEC.

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed to be modified or superseded to the extent that a statement contained herein or in any other subsequently filed document which also is or is deemed to be incorporated by reference in this prospectus modifies or supersedes that statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

We will provide you, without charge, a copy of any or all of the information incorporated by reference into this prospectus, if requested in writing or by telephone, any such request should be directed to:

GT Biopharma, Inc.  
1825 K Street NW, Suite 510  
Washington, D.C. 20006  
(800) 3049888

**Transfer Agent and Registrar**

The Transfer Agent and Registrar for our common stock is ComputerShare, whose address is 350 Indiana Street, Colorado 80401.

**Listing**

Our common stock is listed on the OTCQB under the symbol "GTPB".

## PART II

### INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 14. Other Expenses of Issuance and Distribution.

The following table sets forth all costs and expenses, other than underwriter discounts, payable in connection with the sale of the shares of common stock to be registered. Except as otherwise noted, GT Biopharma, Inc. (the “company,” “we,” “us,” or “our”) will pay all of the costs and expenses set forth in the following table.

<b>Item</b>	<b>Amount</b>
<b>SEC registration fee</b>	<b>\$ 822.74</b>
<b>Accountants' fees and expenses</b>	<b>*</b>
<b>Legal fees and expenses</b>	<b>*</b>
<b>Printing</b>	<b>*</b>
<b>Miscellaneous</b>	<b>*</b>
<b>Total</b>	<b>\$ *</b>

\* To be filed by amendment.

#### Item 15. 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 the corporation. 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.

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 for any breach of the director's duty of loyalty to the corporation or its stockholders, for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, for unlawful payments of dividends or unlawful stock repurchases, redemptions or other distributions, or for any transaction from which the director derived an improper personal benefit.

Our amended and restated certificate of incorporation and amended and restated by-laws include provisions to (i) eliminate the personal liability of our directors for monetary damages resulting from breaches of their fiduciary duty to the extent permitted by Section 102(b)(7) of the DGCL and (ii) require the registrant to indemnify its directors and officers to the fullest extent permitted by Section 145 of the DGCL, including circumstances in which indemnification is otherwise discretionary. Pursuant to Section 145 of the DGCL, a corporation generally has the power to indemnify its present and former directors, officers, employees and agents against expenses incurred by them in connection with any suit to which they are, or are threatened to be made, a party by reason of their serving in such positions so long as they acted in good faith and in a manner they reasonably believed to be in or not opposed to, the best interests of the corporation and with respect to any criminal action, they had no reasonable cause to believe their conduct was unlawful. We believe that these provisions are necessary to attract and retain qualified persons as directors and officers. These provisions do not eliminate the directors' duty of care, and, in appropriate circumstances, equitable remedies such as injunctive or other forms of non-monetary relief will remain available under DGCL. In addition, each director will continue to be subject to liability for breach of the director's duty of loyalty to the registrant, for acts or omissions not in good faith or involving intentional misconduct, for knowing violations of law, for acts or omissions that the director believes to be contrary to the best interests of the registrant or its stockholders, for any transaction from which the director derived an improper personal benefit, for acts or omissions involving a reckless disregard for the director's duty to the registrant or its stockholders when the director was aware or should have been aware of a risk of serious injury to the registrant or its stockholders, for acts or omissions that constitute an unexcused pattern of inattention that amounts to an abdication of the director's duty to the registrant or its stockholders, for improper transactions between the director and the registrant and for improper distributions to stockholders and loans to directors and officers. The provision also does not affect a director's responsibilities under any other law, such as the federal securities law or state or federal environmental laws.

Insofar as indemnification for liabilities arising under the Act may be permitted to directors, officers or persons controlling us pursuant to the foregoing, we have been informed that in the opinion of the SEC such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable.

At present, there is no pending litigation or proceeding involving any of our directors or officers as to which indemnification is being sought nor are we aware of any threatened litigation that may result in claims for indemnification by any officer or director.

We have an insurance policy covering our officers and directors with respect to certain liabilities, including liabilities arising under the Act or otherwise.

The foregoing statements are subject to the detailed provisions of the DGCL, our articles and our bylaws.

**Item 16. Exhibits and Financial Statement Schedules.**

(a) Exhibits: The list of Exhibits is set forth on page 36 of this registration statement and is incorporated herein by reference.

**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 of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the 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) promulgated under the Securities Act of 1933, 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.

(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;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, 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.

(6) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(7) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by 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 Securities Act of 1933 and will be governed by the final adjudication of such issue.

(8) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus 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.



## EXHIBIT INDEX

Exhibit No.	Description	Form	File No.	Exhibit	Filing Date
<a href="#">2.1</a>	Agreement and Plan of Merger, dated September 1, 2017, by and among GT Biopharma, Inc., GT Biopharma Merger Co. and Georgetown Translational Pharmaceuticals, Inc., and Kathleen Clarence-Smith, Mark J. Silverman, and Richard P. Dulik	10-Q	000-08092	2.1	November 14, 2017
<a href="#">3.1</a>	Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002	10-KSB	000-08092	3.A	April 1, 2002
<a href="#">3.2</a>	Certificate of Amendment to Amended and Restated Certificate of Incorporation of GT Biopharma, Inc.	10-K	000-08092	3.2	March 31, 2011
<a href="#">3.3</a>	Bylaws, as restated effective September 7, 1994, and as amended through April 29, 2003	10-QSB	000-08092	3	August 13, 2003
<a href="#">4.1</a>	Registration Rights Agreement among the Company and the investors party thereto, dated as of January 22, 2018	8-K	000-08092	10.2	January 23, 2018
<a href="#">4.2</a>	Form of Warrant under Securities Purchase Agreement	8-K	000-08092	10.4	January 23, 2018
<a href="#">4.3</a>	Form of Note under Securities Purchase	8-K	000-08092	10.3	January 23, 2018
<a href="#">5.1</a>	Opinion of DLA Piper LLP (US)				
<a href="#">23.1</a>	Consent of Seligson & Giannattasio, LLP, Independent Registered Public Accounting Firm, relating to the Registrant				
23.2	Consent of DLA Piper LLP (US) (included in Exhibit 5.1)				
24.1	Power of Attorney (included on signature page hereto)				

\*To be filed by amendment or as an exhibit to a report pursuant to Section 13(a), 13(c) or 15(d) of the Exchange Act

## SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Washington, District of Columbia, on March 1, 2018.

### GT BIOPHARMA, INC.

By: /s/ Shawn Cross

\_\_\_\_\_  
Shawn Cross  
Chief Executive Officer and Chairman of the  
Board

## POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Shawn Cross, Steven Weldon and Dr. Kathleen Clarence-Smith, M.D., Ph.D., as his or her true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him or her and in his or her name, place and stead, in any and all capacities to sign any or all amendments (including, without limitation, post-effective amendments) to this Registration Statement, any related Registration Statement filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and any or all pre- or post-effective amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully for all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that said attorney-in-fact and agent, or any substitute or substitutes for him, may lawfully do or cause to be done by virtue hereof. Pursuant to the requirements of the Securities Act of 1933, the following persons in the capacities and on the dates indicated have signed this Registration Statement below.

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated .

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Shawn Cross</u> Shawn Cross	Chief Executive Officer and Chairman of the Board	March 1, 2018
<u>/s/ Steven Weldon</u> Steven Weldon	Chief Financial Officer (Principal Financial Officer), and Director	March 1, 2018
<u>/s/ Dr. Kathleen Clarence-Smith</u> Dr. Kathleen Clarence-Smith, M.D., Ph.D.	Vice Chairwoman and Director	March 1, 2018
<u>/s/ Anthony J. Cataldo</u> Anthony J. Cataldo.	Director	March 1, 2018
<u>/s/ Geoffrey Davis</u> Geoffrey Davis	Director	March 1, 2018



**DLA Piper LLP  
(US)**  
401 Congress  
Avenue, Suite 2500  
Austin, Texas  
78701-3799  
www.dlapiper.com  
T 512.457.7000  
F 512.457.7001

March 1, 2018

GT Biopharma, Inc.  
1825 K Street NW, Suite 510  
Washington, DC 20006

**Re: Registration Statement on Form S-3**

Ladies and Gentlemen:

We have acted as counsel to GT Biopharma, Inc., a Delaware corporation (the “*Company*”) in connection with the preparation and filing of a registration statement on Form S-3 (the “*Registration Statement*”) relating to the registration under the Securities Act of 1933, as amended (the “*Act*”), of up to an aggregate of 3,388,884 shares (the “*Shares*”) of the Company’s common stock, par value \$0.001 per share (the “*Common Stock*”), plus an indeterminate number of shares of Common Stock that may be issued upon stock splits, stock dividends or similar transactions in accordance with Rule 416 of the Act, which may be offered and sold from time to time by the selling stockholders named in the Registration Statement. The Shares consist of (i) 1,694,442 shares of Common Stock that may be acquired upon exercise of outstanding warrants (“*Warrants*”) and (ii) 1,694,442 shares of Common Stock issuable upon conversion of the senior convertible notes (the “*Notes*”).

As the basis for the opinions hereinafter expressed, we have examined: (i) originals, or copies certified or otherwise identified, of (a) the Registration Statement; (b) the Certificate of Incorporation of the Company, as amended to date; (c) the Bylaws of the Company; (d) certain resolutions of the Board of Directors of the Company; and (e) such other instruments and documents as we have deemed necessary or advisable for the purposes of this opinion; and (ii) such statutes, including the Delaware General Corporation Law, and regulations as we have deemed necessary or advisable for the purposes of this opinion. In such examination, we have assumed the genuineness of all signatures and the authenticity of all documents submitted to us as originals and the conformity to the originals of all documents submitted to us as copies.

Based on such examination, we are of the opinion that the Shares are, or will be, when and to the extent issued upon conversion of the Notes or exercise of the Warrants in accordance with the terms thereof, will be validly issued, fully paid and nonassessable.

We express no opinion other than as to the federal laws of the United States of America and the Delaware General Corporation Law (including the statutory provisions, the applicable provisions of the Delaware Constitution and reported judicial decisions interpreting the foregoing). We express no opinion as to any matter other than as expressly set forth above, and no opinion, other than the opinion given herein, may be inferred or implied herefrom.

We consent to the use of this opinion as an exhibit to the Registration Statement, and we consent to the reference of our name under the caption “Legal Matters” in the prospectus forming part of the Registration Statement. In giving our consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Act or the rules and regulations promulgated thereunder.

Very truly yours,

/s/ DLA Piper LLP (US)  
DLA Piper LLP (US)

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Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in this Registration Statement on Form S-3 of GT Biopharma, Inc. of our report dated March 1, 2018, relating to our audit of the consolidated financial statements as of and for the years ended December 2017 and 2016, which appears in the Annual Report on Form 10-K of GT Biopharma, Inc. for the year ended December 31, 2017. 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  
March 1, 2018

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