
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

Amendment No. 2
TO
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

GT BIOPHARMA, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

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

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Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box.

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant files 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, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold 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 where the offer or sale is not permitted.

SUBJECT TO COMPLETION DATED FEBRUARY 7, 2025

PRELIMINARY PROSPECTUS

Up to 3,361,344 Shares of Common Stock
Up to 3,361,344 Pre-Funded Warrants to Purchase up to 3,361,344 Shares of Common Stock
Up to 3,361,344 Common Warrants to Purchase up to 3,361,344 Shares of Common Stock
Up to 201,680 Placement Agent Warrants to Purchase up to 201,680 Shares of Common Stock
Up to 6,924,368 Shares of Common Stock underlying up to 3,361,344 Pre-Funded Warrants,
up to 3,361,344 Common Warrants and up to 201,680 Placement Agent Warrants



This is a reasonable best efforts public offering of up to 3,361,344 shares (the “shares”) of our common stock, par value \$0.001 per share (“common stock”) together with up to 3,361,344 common warrants to purchase up to 3,361,344 shares of common stock at an assumed combined public offering price of \$2.38 per share and common warrant (the last reported sale price per share of our common stock on the Nasdaq Capital Market, on January 23, 2025). Each share of common stock is being offered together with one common warrant to purchase one share of common stock. The shares of common stock and common warrants will be separately issued. Each common warrant will be immediately exercisable upon issuance with an exercise price of \$ _____ per share (100% of the combined public offering price of each share of common stock and accompanying common warrant in this offering) and will expire five years after the issuance date. This prospectus also covers the shares of common stock issuable from time to time upon the exercise of the common warrants. See “*Description of Securities we are Offering – Common Warrants*.”

We are also offering pre-funded warrants to those purchasers, whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock following the consummation of this offering in lieu of the shares of our common stock that would result in ownership in excess of 4.99% (or, at the election of the purchaser, 9.99%). Each pre-funded warrant will be exercisable for one share of common stock at an exercise price of \$0.0001 per share. Each pre-funded warrant is being offered together with the same common warrant to purchase one share of common stock described above that is being offered with each share of common stock. The purchase price of each pre-funded warrant will equal the combined public offering price per share of common stock and common warrants being sold in this offering, less the \$0.0001 per share exercise price of each such pre-funded warrant. Each pre-funded warrant will be exercisable upon issuance and will expire when exercised in full. The pre-funded warrants and common warrants will be separately issued. For each pre-funded warrant that we sell, the number of shares of common stock that we are selling will be decreased on a one-for-one basis. This prospectus also covers the shares of common stock issuable from time to time upon the exercise of the pre-funded warrants. See “*Description of Securities we are Offering – Pre-Funded Warrants*.”

We have engaged Roth Capital Partners, LLC, or the placement agent, to act as our exclusive placement agent in connection with this offering. The placement agent has agreed to use its reasonable best efforts to arrange for the sale of the securities offered by this prospectus. The placement agent is not purchasing or selling any of the securities we are offering and the placement agent is not required to arrange the purchase or sale of any specific number or dollar amount of securities. We have agreed to pay to the placement agent the placement agent fees set forth in the table below, which assumes that we sell all of the securities offered by this prospectus. There is no arrangement for funds to be received in escrow, trust or similar arrangement. There is no minimum number of shares of securities or minimum aggregate amount of proceeds that is a condition for this offering to close. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund if we do not sell all of the securities offered hereby. Because there is no escrow account and no minimum number of securities or amount of proceeds, investors could be in a position where they have invested in us, but we have not raised sufficient proceeds in this offering to adequately fund the intended uses of the proceeds as described in this prospectus. We will bear all costs associated with the offering. See “*Plan of Distribution*” on page 36 of this prospectus for more information regarding these arrangements. This offering will terminate no later than February 28, 2025, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. The securities will be offered at a fixed price and are expected to be issued in a single closing. Investors purchasing securities offered hereby will have the option to execute a securities purchase agreement with us. We expect that the closing of the offering will occur one trading day after we price the securities offered hereby. When we price the securities, we will simultaneously enter into securities purchase agreements relating to the offering with those investors who so choose. The offering will settle delivery versus payment (“DVP”)/receipt versus payment (“RVP”). That is, on the closing date, we will issue the shares of common stock directly to the account(s) at the placement agent identified by each purchaser; upon receipt of such shares, the placement agent shall promptly electronically deliver such shares to the applicable purchaser, and payment therefor shall be made by the placement agent (or its clearing firm) by wire transfer to us.

Our common stock is listed on the Nasdaq Capital Market under the symbol “GTBP.” On January 23, 2025, the last reported sale price of our common stock on the Nasdaq Capital Market was \$2.38 per share. All share, common warrant and pre-funded warrant numbers are based on an assumed combined public offering price of \$2.38 per share or pre-funded warrant, as applicable, and common warrants. The actual combined public offering price per share and common warrants and the actual combined public offering price per common warrants and pre-funded warrants will be determined between us and investors based on market conditions at the time of pricing, and may be at a discount to the current market price of our common stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price.

You should read this prospectus, together with additional information described under the headings “*Incorporation of Certain Information By Reference*” and “*Where You Can Find More Information*,” carefully before you invest in any of our securities.

Investing in our securities involves a high degree of risk. See the section entitled “*Risk Factors*” beginning on page 9 of this prospectus and in the documents incorporated by reference into this prospectus for a discussion of risks that should be considered in connection with an investment in our securities.

	Per Share and Common Warrant	Per Pre-Funded Warrant and Common Warrant	Total
Public offering price	\$	\$	\$
Placement Agent fees ⁽¹⁾	\$	\$	\$

Proceeds to us, before expenses⁽²⁾ \$ \$ \$

(1) Includes a cash fee up to 6% of the gross proceeds raised in this offering; provided, however, the cash fee shall equal 3% of the gross proceeds raised in this offering for securities purchased by certain excluded investors, to be paid to the placement agent. We have also agreed to reimburse the placement agent for certain of its offering-related expenses in an aggregate amount up to \$100,000. In addition, we have agreed to issue the placement agent or its designees warrants to purchase up to 201,680 shares of common stock (equal to 6% of the aggregate number of shares of common stock and pre-funded warrants sold in this offering, subject to a partial adjustment in the event certain investors participate) at an exercise price of \$ per share, which represents 125% of the public offering price per share of common stock and common warrants. We refer to these warrants in this prospectus as the “placement agent warrants.” See “*Plan of Distribution*” for a complete description of the compensation to be received by the placement agent.

(2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above. We estimate the total expenses of this offering payable by us, excluding the placement agent fee, will be approximately \$390,531.

The delivery of the shares of common stock any pre-funded warrants and common warrants to purchasers is expected to be made no later than , 2025, subject to the satisfaction of customary closing conditions.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

Roth Capital Partners

The date of this prospectus is , 2025.

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ABOUT THIS PROSPECTUS

We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under “*Where You Can Find More Information.*” You should carefully read this prospectus as well as additional information described under “*Incorporation of Certain Information by Reference,*” before deciding to invest in our securities.

We have not, and the placement agent has not, authorized anyone to provide any information or to make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

The information incorporated by reference or provided in this prospectus contains statistical data and estimates, including those relating to market size and competitive position of the markets in which we participate, that we obtained from our own internal estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third parties. Industry publications, studies and surveys generally state that they have been obtained from sources believed to be reliable. While we believe our internal company research is reliable and the definitions of our market and industry are appropriate, neither this research nor these definitions have been verified by any independent source.

For investors outside the United States: We have not, and the placement agent has not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities and the distribution of this prospectus outside the United States.

This prospectus and the information incorporated by reference into this prospectus contain references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus and the information incorporated by reference into 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 we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. 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 company.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements in this prospectus are “forward-looking statements” within the meaning of the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our current beliefs, goals and expectations about matters such as our expected financial performance and condition, operating results, our business strategy and our financing plans. The forward-looking statements in this prospectus are not based on historical facts, but rather reflect the current expectations of our management concerning future results and events. The forward-looking statements generally can be identified by the use of terms such as “believe,” “expect,” “anticipate,” “intend,” “plan,” “foresee,” “may,” “guidance,” “estimate,” “potential,” “outlook,” “target,” “forecast,” “likely” or other similar words or phrases. Similarly, statements that describe our objectives, plans or goals are, or may be, forward-looking statements.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be different from any future results, performance and achievements expressed or implied by these statements. We cannot guarantee that our forward-looking statements will turn out to be correct or that our beliefs and goals will not change. Our actual results could be very different from and worse than our expectations for various reasons. The risk factors and cautionary language discussed in this prospectus provide examples of risks, uncertainties and events that may cause actual results to differ materially from the expectations described by us in such forward-looking statements, including among other things:

- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials;
- our financial condition raises substantial doubt as to our ability to continue as a going concern;
- our financial performance and our ability to effectively manage our anticipated growth;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the impact of laws and regulations;
- general economic conditions;
- the effects of the coronavirus and other communicable diseases on the continued or resumed disruption of supply chains, the global economy, on the global financial markets and on our business;
- the timing, scope and likelihood of regulatory filings and approvals;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering product candidates we may develop, including the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- the rate and degree of market acceptance and clinical utility of our product candidates we may develop;
- our ability to hire additional qualified personnel and attract and retain key employees; and
- the result of any future financing efforts; and
- our failure to maintain compliance with the Nasdaq Capital Market’s (“Nasdaq”) continued listing requirements could result in the delisting of our common stock.

These risks, among others, could cause actual results to differ materially from those implied by the forward-looking statements contained in this prospectus. You should review carefully all information, including the discussion under “Risk Factors” in this prospectus and in the documents incorporated by reference herein. Any forward-looking statements in this prospectus are made only as of the date hereof and, except as may be required by law, we do not have any obligation to publicly update any forward-looking statements contained in this prospectus to reflect subsequent events or circumstances.

You should read this prospectus with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements whether as a result of new information, future events or otherwise, except as required by applicable law.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read this entire prospectus carefully, including the “Risk Factors” section in this prospectus and under similar captions in the documents incorporated by reference into this prospectus. In this prospectus, unless otherwise stated or the context otherwise requires, references to the terms “GTBP,” “the Company,” “we,” “us” and “our” refer to GT Biopharma, Inc., together with its subsidiaries, unless the context otherwise requires. This prospectus and the information incorporated herein by reference include trademarks, service marks and trade names owned by us or other companies. All trademarks, service marks and trade names included or incorporated by reference into this prospectus and the information incorporated herein by reference are the property of their respective owners.

Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based on our proprietary Tri-specific Killer Engager (TriKE®), and Tetra-specific Killer Engager (Dual Targeting TriKE®) fusion protein immune cell engager technology platforms. Our TriKE® and Dual Targeting TriKE® platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient’s own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to activate the NK cell to direct it to one or more specifically targeted proteins expressed on a specific type of cancer cell or virus infected cell, resulting in the targeted cell’s death. TriKE®s can be designed to target any number of tumor antigens, including B7-H3, HER2, CD33 and PDL1, on hematologic malignancies or solid tumors and do not require patient-specific customization. We believe our TriKE® and Dual Targeting TriKE® platforms that activate endogenous NK cells are potentially safer than T-cell immunotherapy because there is less cytokine release syndrome (CRS) and fewer neurological complications. Our preclinical data suggests that this is explained by the TriKE® dependent CD16 directed IL-15 proliferation of NK cells but little effect endogenous T cells.

We are using our TriKE® platform with the intent to bring to market immuno-oncology products that can treat a range of hematologic malignancies, solid tumors, and potentially autoimmune disorders. The platform is scalable, and we are implementing processes to produce investigational new drug (IND) ready moieties in a timely

manner after a specific TriKE® conceptual design. Specific drug candidates can then be advanced into the clinic on our own or through potential collaborations with partnering companies. We believe our TriKE®s may have the ability, if approved for marketing, to be used as both monotherapy and in combination with other standard-of-care therapies.

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

Product Pipeline

Our current product candidate pipeline is summarized in the table below



TriKE® Pipeline

TriKE® Product Candidates	Approach	Target	Indication	Pre-Clinical	IND-Enabling/ GMP Manufacturing	Phase 1	Phase 2
GTB-3650 2 nd Generation Camelid	Monotherapy	CD33	Leukemia – AML MDS			GTB-3650 Phase 1 trial initiated: First patient dosed on 01/21/2025	
	Combination with Chemotherapy	CD33	Leukemia – AML MDS				
GTB-5550	Monotherapy & Combination	B7H3	Solid Tumors			GTB-5550 IND submission expected H1 2025	
GTB-6550	Monotherapy & Combination	HER2	Solid Tumors				
GTB-7550	Monotherapy & Combination	CD19	B-Cell Malignancies				
GTB-1050	Monotherapy & Combination		HIV				
Undisclosed Candidates	Monotherapy & Combination		Solid & Hematological Malignancies				
GTB-3550	Monotherapy	CD33	Leukemia – AML MDS				GTB-3550 supplanted by second generation GTB-3650

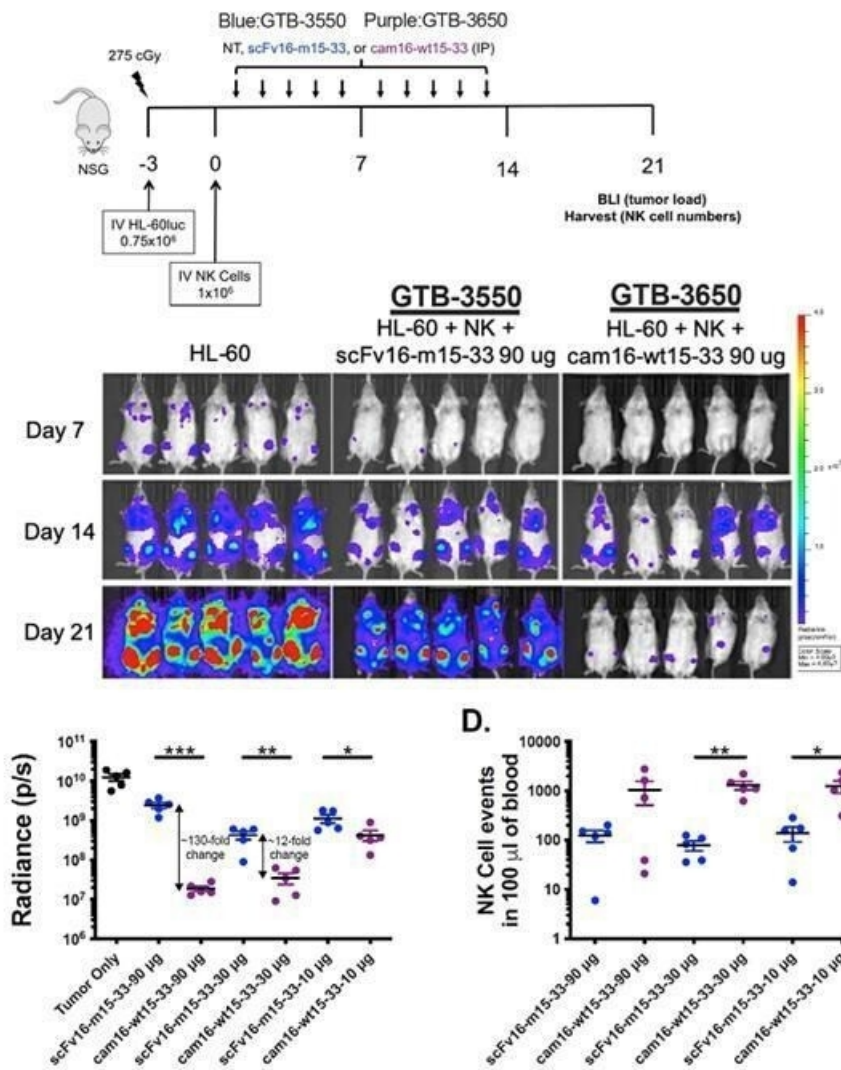
Clinical Product Candidates
 Preclinical Product Candidates
 Development abandoned

GTB-3550

GTB-3550 was our first TriKE® product candidate and its clinical development was suspended so that we could focus resources on second-generation TriKEs®. GTB-3550 is a tri-specific killer engager (TriKE) comprised of two single-chain variable fragments (“scFv”) composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. We studied this anti-CD16-IL-15-anti-CD33 TriKE® in CD33 positive leukemias, a marker expressed on tumor cells in acute myelogenous leukemia, or AML, and myelodysplastic syndrome, or MDS. The anti-CD33 antibody fragment in GTB-3550 was derived from the M195 humanized anti-CD33 scFv. We believe the approval of the antibody-drug conjugate gemtuzumab validates the targeting of CD33.

We previously announced the interim clinical trial results for GTB-3550, which showed significantly reduced CD 33+ bone marrow blast levels by 33.3%, 61.7%, 63.6%, 50% in Patient 5 (25 µg/kg/day), Patient 7 (50 µg/kg/day), Patient 9 (100 µg/kg/day), and Patient 11 (150 µg/kg/day), respectively. After the end of infusion, GTB-3550 and IL-15 concentrations declined rapidly with overall geometric mean terminal phase elimination half-life (T1/2) of 2.2 and 2.52 hours, respectively. There was minimal CRS resulting from hyperactivation of patient’s T-cell population at doses 5–150 µg/kg/day.

Despite the positive interim clinical trial results, GTB-3550 was replaced by a more potent next-generation camelid nanobody TriKE®, GTB-3650, that similarly targets CD33 on relapsed/refractory AML and high-risk MDS. A key difference between GTB-3550 and GTB-3650 is the incorporation of camelid antibody technology instead of a scFv; our preclinical experience showed markedly enhanced potency of TriKEs® comprised of camelid components. This is illustrated below by better tumor control of AML bearing animals with GTB-3650 (purple dots) compared to GTB-3550 (blue dots). This provided the rationale for pausing further development of GTB-3550 and moving over to solely develop the second-generation, camelid-based TriKE® platform.

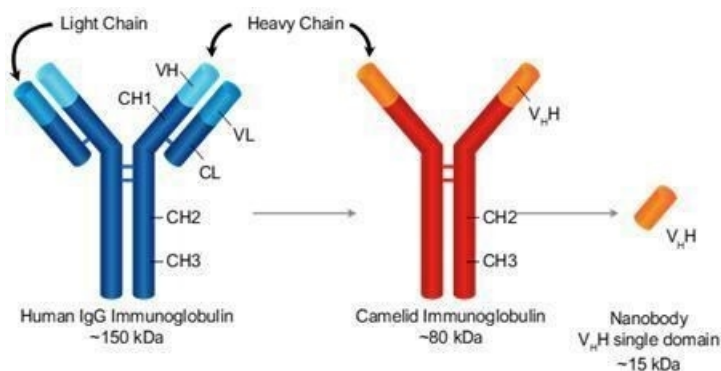


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Second Generation TriKE®s Utilize Camelid Nanobody Technology

Our goal is to be a leader in immuno-oncology therapies targeting a broad range of indications including hematological malignancies and solid tumors. A key element of our strategy includes introducing a next-generation camelid nanobody platform. Camelid antibodies (often referred as nanobodies) are smaller than human immunoglobulin, consisting of two heavy chains instead of two heavy and two light chains. These nanobodies have the potential to have greater affinity to target antigens, potentially resulting in greater potency. We are utilizing this camelid antibody structure for all of our new TriKE® product candidates.

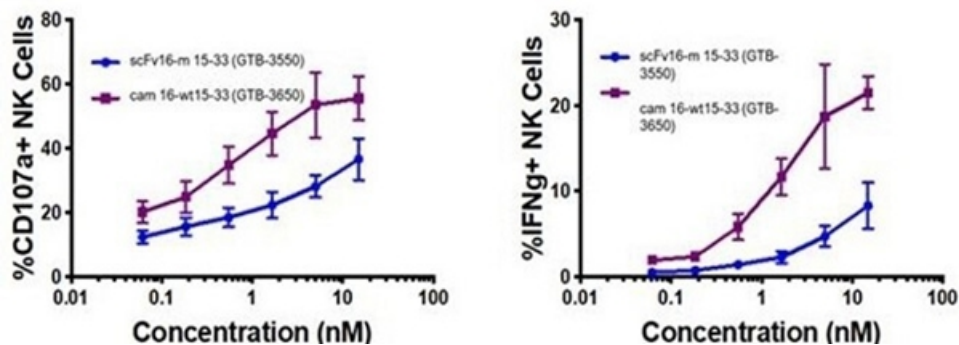
To develop second generation TriKE®, we designed a new humanized CD16 engager derived from a single-domain antibody. While scFvs consist of a heavy and a light variable chain joined by a linker, single-domain antibodies consist of a single variable heavy chain capable of engaging without the need of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



These single-domain antibodies are thought to have certain attractive features for antibody engineering, including physical stability, ability to bind deep grooves, and increased production yields, amongst others. Pre-clinical studies demonstrated increased NK cell activation against CD33+ targets including enhanced NK cell degranulation (% CD107a+) and IFNγ with the single-domain CD16 TriKE® (cam 16-wt15-33; GTB-3650) compared to the original TriKE® (scFv16-m 15-33; GTB-3550) (see figure below). This data was published by Dr. Felices M et al (2020) in Cancer Immunol Res.

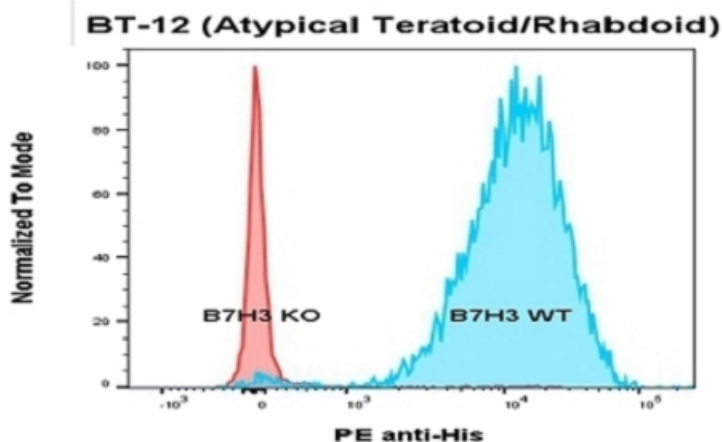
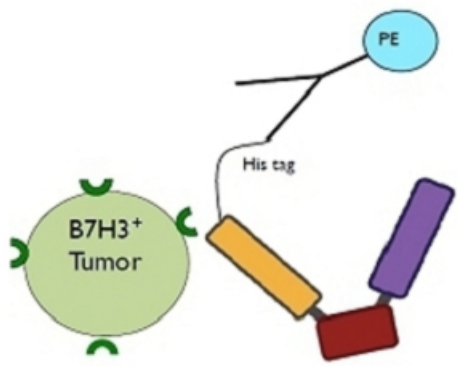
CD33+ HL60 Targets in Killing Assays

The purple line represents the GTB-3650 and the blue line represents GTB-3550.



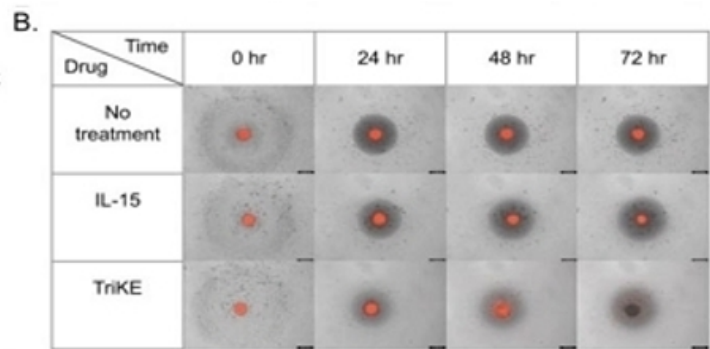
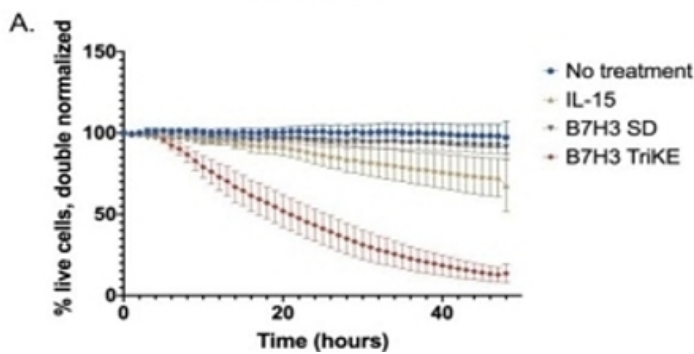
GTB-3650

GTB-3650 is a TriKE® which targets CD33 on the surface of myeloid leukemias and an agonistic camelid engager to the potent activating receptor on NK cells, CD16. Use of this engager enhances the activity of wild type IL-15 included in GTB-3650. The TriKE® approach provides a novel way to specifically target these tumors by leveraging NK cells, which have been shown to mediate relapse protection in this setting, in an anti-CD33-targeted fashion. We are advancing GTB-3650 to clinical studies based on pre-clinical data showing a marked increase in potency compared to GTB-3550, which we anticipate could lead to an enhanced efficacy signal in AML and MDS. We advanced GTB-3650 through requisite preclinical studies and filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) in December 2023. In late June 2024, the FDA cleared our IND Application for GTB-3650. We started study enrollment targeting patients with relapsed/refractory AML and high grade MDS on January 21, 2025. This initial study is testing GTB-3650 as monotherapy testing administration 2 weeks on and two weeks off (to prevent NK cell exhaustion) for at least 2 cycles of therapy, as agreed on with the FDA.



GTB-5550

GTB-5550 is a B7-H3 targeted TriKE® which targets B7-H3 on the surface of advanced solid tumors (figure above). GTB-5550 is our first dual camelid TriKE®. B7-H3 is expressed on a broad spectrum of solid tumor malignancies, allowing our team to target these malignancies through GTB-5550. Pre-clinical work has shown that this molecule has NK-cell targeted activity against a variety of solid tumors, including head and neck cancer squamous cell carcinoma (figure below), prostate cancer, breast cancer, ovarian cancer, glioblastoma, and lung cancer (amongst others). We are advancing GTB-5550 through preclinical studies and initiated a GMP manufacturing campaign in anticipation of filing an IND in the first half of 2025. A pre-IND packet was submitted to the FDA in October 2023 with a written response from the FDA in December 2023. The main question from the FDA was regarding pre-clinical toxicology and a pivot to subcutaneous dosing. The initial trial expected in 2025 is designed as a basket trial for patients with B7-H3+ solid tumors using Monday through Friday dosing (2 weeks on and 2 weeks off to prevent immune exhaustion), and is dependent on manufacturing of clinical materials.



GTB-7550

GTB-7550 TriKE® is a product candidate in development for the treatment of lupus and other autoimmune disorders. GTB-7550 TriKE® is a tri-specific molecule composed of a camelid nanobody that binds the CD16 receptor on NK cells, a scFv engager against CD19 on malignant and normal B cells, and a human IL-15 sequence between them.

Published data shows that GTB-7550 effectively targets CD19+ malignant cell lines and primary chronic lymphocytic leukemia (CLL). Preliminary data shows that GTB-7550 can target and eliminate normal B cells, which we are continuing to test in mice. We are currently exploring and assessing potential manufacturers of GTB-7550.

Litigation Update

As disclosed in our third quarter report on Form 10-Q for the period ended September 30, 2024, on November 14, 2023, former interim Chief Executive Officer, Dr. Gregory Berk filed a lawsuit in the U.S. District Court for the District of Massachusetts alleging that the Company discriminated and retaliated against Dr. Berk for engaging in protected whistleblowing activity in violation of the Sarbanes Oxley Act (“SOX”). Although the Company vigorously defended this matter and believes it to be without merit, the lawsuit was dismissed with prejudice on December 4, 2024 as a result of the parties’ settlement.

As disclosed in our third quarter report on Form 10-Q for the period ended September 30, 2024, on May 24, 2023, TWF Global, LLC (“TWF”) filed a Complaint in the California Superior Court for the County of Los Angeles naming the Company as defendant. The Complaint alleges that TWF is the holder of two Convertible Promissory Notes (“Notes”) and that the Company did not deliver shares of common stock due on conversion in February 2021. TWF was seeking per diem liquidated damages based on the terms of alleged Notes. On July 14, 2023, the Company filed a motion to dismiss for improper forum because the terms of the Notes, as alleged, require disputes to be filed in New York state and federal courts. TWF voluntarily dismissed its Complaint before the California Superior Court of Los Angeles without prejudice. The Company subsequently filed a Summons and Complaint for Interpleader against TWF and Z-One LLC before the Supreme Court of the State of New York County of New York, asking the Supreme Court to determine if the Company’s shares of common stock are properly registered to TWF or Z-One LLC, as both of these entities have made conflicting demands for registration of the shares of common stock. On February 5, 2024, the Company filed a motion for entry of default against TWF, seeking an order directing the Company to register the shares of common stock in the name of Z-One and that the Company be released from all associated liability and claims. The Court denied the motion without prejudice to reconsider the motion without further briefing upon the filing of a supplemental party affidavit. On May 9, 2024, Z-One filed a motion for summary judgement seeking dismissal of the action, representing that Z-One and TWF have settled their dispute over the entitlement to the Company’s shares of common stock and there is no remaining dispute before the Court. On May 21, 2024, the Company filed a supplemental affidavit in support of its motion for entry of default. On November 14, 2024, the Court held a hearing on the parties’ motions, at which the Court found that the motion for entry of default was mooted by the settlement agreement between Z-One and TWF. The Court ordered that the case be dismissed.

Implications of Being a Smaller Reporting Company

We are a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and have elected to take advantage of certain of the scaled disclosures available to smaller reporting companies. Accordingly, we may provide less public disclosure than larger public companies, including the inclusion of only two years of audited consolidated financial statements and only two years of management’s discussion and analysis of financial condition and results of operations disclosure and the inclusion of reduced disclosure about our executive compensation arrangements. As a smaller reporting company, we are also exempt from compliance with the auditor attestation requirements pursuant to the Sarbanes-Oxley Act. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests. We will continue to be a “smaller reporting company” until we have \$250 million or more in public float (based on our common stock) measured as of the last business day of our most recently completed second fiscal quarter or, in the event we have no public float or a public float (based on our common stock) that is less than \$700 million, annual revenues of \$100 million or more during the most recently completed fiscal year.

Corporate Information

Our common stock currently trades on the Nasdaq under the symbol “GTBP.” Our principal executive offices are located at 315 Montgomery Street, 10th Floor, San Francisco, CA 94104, and our telephone number is (415) 919-4040. We maintain a website at www.gtbiopharma.com. Information contained on or accessible through our website is not, and should not be considered, part of, or incorporated by reference into, this prospectus.

THE OFFERING

Common Stock to be Offered Up to 3,361,344 shares of common stock.

Common Warrants to be Offered Common warrants to purchase up to 3,361,344 shares of our common stock. Each common warrant has an exercise price of \$ _____ per share of common stock. Common warrants will become exercisable immediately after issuance and will expire five years from the date of issuance.

The shares of common stock and pre-funded warrants, and the accompanying common warrant, as the case may be, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. This prospectus also relates to the offering of the shares of common stock issuable upon exercise of the common warrants.

Pre-funded Warrants to be Offered We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if such purchasers so choose, pre-funded warrants to purchase shares of common stock, in lieu of shares of common stock that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant and accompanying common warrants will equal the price at which the share of common stock and accompanying common warrants are being sold to the public in this offering, minus \$0.0001, and the exercise price of each pre-funded warrant will be \$0.0001 per share. The pre-funded warrants will be exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. Because we will also issue one common warrant to purchase one share of common stock for each share of our common stock and for each pre-funded warrant to purchase one share of our common stock sold in this offering, the number of common warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold.

Common Stock to be Outstanding Before this Offering 2,234,328 shares.

Common Stock to be Outstanding Immediately After this Offering 5,595,672 shares, (assuming full exercise of the pre-funded warrants and assuming no exercise of the common warrants).

Use of Proceeds We estimate that the net proceeds from this offering will be approximately \$7.1 million, excluding the proceeds, if any, from the cash exercise of the common warrants in this offering. We currently intend to use the net proceeds from this offering for working capital and general corporate purposes, including the further development of our product candidates that are currently undergoing clinical trials, our product candidates that we expect to submit an investigational new drug application for in the near term, and our product candidates that are pre-clinical. See "Use of Proceeds" for additional information.

Risk Factors An investment in our securities involves a high degree of risk. See "Risk Factors" beginning on page 9 of this prospectus and the other information included and incorporated by reference in this prospectus for a discussion of the risk factors you should carefully consider before deciding to invest in our securities.

Nasdaq Symbol Our common stock is listed on the Nasdaq Capital Market under the symbol "GTBP." There is no established public trading market for the common warrants or pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants or pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active trading market, the liquidity of the common warrants and pre-funded warrants will be limited.

Unless otherwise stated in this prospectus, the number of shares of our common stock to be outstanding as of the date of this prospectus and after this offering is based on 2,234,328 shares outstanding as of September 30, 2024, and excludes (a) placement agent warrants to purchase up to 201,680 shares of our common stock issuable upon the exercise of warrants to be issued to the placement agent in connection with this offering having an exercise price of \$ per share, (b) the shares of common stock issuable upon exercise of the common warrants and pre-funded warrants being offered by us in this offering, (c) previously issued and outstanding warrants to purchase up to 1,133,762 shares of our common stock, and (d) outstanding stock options to purchase up to 101,264 shares of our common stock. See "Note 7 – Common Stock Warrants and Options" to our Third Quarter Report filed on Form 10-Q that is incorporated by reference into this prospectus.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information contained in this prospectus and any prospectus supplement before deciding whether to invest in shares of our common stock. The risks summarized below and others are discussed more fully in the section titled "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, which is incorporated herein by reference. If any of the following risks or the risks incorporated by reference occur, our business, financial condition or operating results could be harmed. In that case, the trading price of our common stock could decline and you may lose part or all of your investment. In the opinion of management, the risks discussed below and incorporated by reference represent the material risks known to us. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, financial condition and operating results and adversely affect the market price of our common stock.

Risks Related to Our Business

Risks related to our business risks include, but are not limited to, the following:

- Our financial condition raises substantial doubt as to our ability to continue as a going concern.
- 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. 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.
- Our current and future indebtedness may impose significant operating and financial restrictions on us and affect our ability to access liquidity.
- The cost of our research and development programs may be significantly higher than expected, and there is no assurance that they will be successful in a timely manner, or at all.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market and our business would be harmed.
- Claims that we infringe the intellectual property rights of others may prevent or delay our drug discovery and development efforts.

- We may desire, or be forced, to seek additional licenses to use intellectual property owned by third parties, and such licenses may not be available on commercially reasonable terms, or at all.
- If we are unsuccessful in obtaining or maintaining patent protection for intellectual property in development or licensed from third parties, our business and competitive position would be harmed.
- If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends.
- Our reliance on the activities of our non-employee consultants, research institutions and scientific contractors, whose activities are not wholly within our control, may lead to delays in development of our proposed products.
- Clinical drug development is costly, time-consuming and uncertain, and we may suffer setbacks in our clinical development program that could harm our business.
- If we experience delays or difficulties in the enrollment of patients in clinical trials, those clinical trials could take longer than expected to complete and our receipt of necessary regulatory approvals could be delayed or prevented.
- Obtaining regulatory approval, even after clinical trials that are believed to be successful, is an uncertain process.

- We will continue to be subject to extensive FDA regulation following any product approvals, and if we fail to comply with these regulations, we may suffer a significant setback in our business.
- Many of our business practices are subject to scrutiny and potential investigation by regulatory and government enforcement authorities, as well as to lawsuits brought by private citizens under federal and state laws. We could become subject to investigations, and our failure to comply with applicable law or an adverse decision in lawsuits may result in adverse consequences to us. If we fail to comply with U.S. healthcare laws, we could face substantial penalties and financial exposure, and our business, operations and financial condition could be adversely affected.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- We may expend our limited resources to pursue a particular product candidate or indication that does not produce any commercially viable products and may fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.
- Our products may be expensive to manufacture, and they may not be profitable if we are unable to control the costs to manufacture them.
- We currently lack manufacturing capabilities to produce our therapeutic product candidates at commercial-scale quantities and do not have an alternate manufacturing supply, which would negatively impact our ability to meet any demand for the product.
- Our business is based on novel technologies that are inherently expensive and risky and may not be understood by or accepted in the marketplace, which could adversely affect our future value.
- We could be subject to product liability lawsuits based on the use of our product candidates in clinical testing or, if obtained, following marketing approval and commercialization. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to cease clinical testing or limit commercialization of our product candidates.
- We rely on third parties to supply candidates for clinical testing and to conduct preclinical and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates. As a result, our business could be substantially harmed.
- Our failure to maintain compliance with the Nasdaq Capital Market's ("Nasdaq") continued listing requirements could result in the delisting of our common stock.

These risks are described more fully in our Annual Report on Form 10-K for the year ended December 31, 2023, which is incorporated herein by reference.

Risks Related to our Business

Our financial condition raises substantial doubt as to our ability to continue as a going concern.

As of September 30, 2024, we had approximately \$6.5 million in cash and cash equivalents and restricted cash, and working capital of \$2.1 million, and we have incurred and expect to continue to incur significant costs in pursuit of our drug candidates. For the nine months ended September 30, 2024, we recorded a net loss of approximately \$9.4 million and used cash in operations of approximately \$10.4 million. Our unaudited consolidated condensed financial statements for the nine month period ended September 30, 2024 have been prepared assuming that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. To date, we have not generated substantial product revenues from our activities and have incurred substantial operating losses. We expect that we will continue to generate substantial operating losses for the foreseeable future until we complete development and approval of our product candidates. We will continue to fund our operations primarily through utilization of our current financial resources and additional raises of capital.

These conditions raise substantial doubt about our ability to continue as a going concern. For further information, please see Note 1 to our third quarter unaudited condensed consolidated financial statements for the nine-months ended September 30, 2024. The Company has evaluated the significance of the uncertainty regarding the Company's financial condition in relation to its ability to meet its obligations, which has raised substantial doubt about the Company's ability to continue as a going concern. While it is very difficult to estimate the Company's future liquidity requirements, the Company believes if it is unable to obtain additional financing, existing cash resources will not be sufficient to enable it to fund the anticipated level of operations through one year from the date the accompanying unaudited condensed consolidated financial statements are issued. There can be no assurances that the Company will be able to secure additional financing on acceptable terms. In the event the Company does not secure additional financing, the Company will be forced to delay, reduce, or eliminate some or all of its discretionary spending, which could adversely affect the Company's business prospects, ability to meet long-term liquidity needs and the ability to continue operations.

Risks Related to this Offering and Our Common Stock

There has been a limited public market for our common stock, and we do not know whether one will develop to provide you adequate liquidity. Furthermore, the trading

price for our common stock, should an active trading market develop, may be volatile and could be subject to wide fluctuations in per-share price.

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

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

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

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

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

Our outstanding warrants and options may affect the market price of our common stock

As of the date of this prospectus, we had 2,234,328 shares of common stock outstanding and issued and had outstanding warrants for the purchase of up to 1,120,429 additional shares of common stock at a weighted average exercise price of \$18.85 per share, all of which are exercisable as of the date of this prospectus (subject to certain beneficial ownership limitations). In addition, we had outstanding options for the purchase of up to 124,600 additional shares of common stock at a weighted average exercise price of \$32.69 per share, 105,154 of which are exercisable as of the date of this prospectus. The amount of common stock reserved for issuance may have an adverse impact on our ability to raise capital and may affect the price and liquidity of our common stock in the public market. In addition, the issuance of these shares of common stock will have a dilutive effect on current stockholders’ ownership.

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

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

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

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

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

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

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

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have research coverage by only one securities analyst, and we may never obtain research coverage by additional analysts. If no or few securities or industry analysts

commence coverage of us, the trading price for our common stock may be negatively affected. In the event that we receive additional securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

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

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

Purchasers of our common stock in this offering will experience immediate and substantial dilution in the book value of their investment.

The offering price per share in this offering is substantially higher than the net tangible book value per share of our ordinary shares before giving effect to this offering. Accordingly, purchasers of our securities in this offering will incur immediate dilution of approximately \$0.73 per share, representing the difference between the public offering price per share and our as-adjusted net tangible book value per share as of September 30, 2024. Furthermore, if outstanding options or warrants are exercised, purchasers could experience further dilution. For more information, including how these amounts were calculated, see “Dilution.”

Our management will have broad discretion as to the use of the proceeds from this offering, and may not use the proceeds effectively.

Our management will have broad discretion as to the application of the net proceeds from this offering. Currently, we intend to use the net proceeds from this offering for working capital and general corporate purposes, including the further development of our product candidates that are currently undergoing clinical trials, our product candidates that we expect to submit an investigational new drug application for in the near term, and our product candidates that are pre-clinical. See “Use of Proceeds.” Purchasers will not have the opportunity, as part of their investment decision, to assess whether these proceeds are being used appropriately. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value, which could cause the price of our securities to decline.

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 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 commercialization of our product candidates. 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:

- accuracy of the assumptions underlying our estimates for capital needs in 2025 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. 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.

There is no public market for the common warrants or pre-funded warrants being offered by us in this offering.

There is no established public trading market for the common warrants or the pre-funded warrants, and we do not expect a market to develop. In addition, we do not intend to apply to list the common warrants or pre-funded warrants on any national securities exchange or other nationally recognized trading system. Without an active market, the liquidity of the common warrants and pre-funded warrants will be limited.

Holders of warrants purchased in this offering will have no rights as common stockholders until such holders exercise their warrants and acquire our common stock.

Until holders of warrants acquire shares of our common stock upon exercise thereof, holders of warrants will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of the warrants, the holders will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

This is a reasonable best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans, including our near-term business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to support our continued operations, including our near-term continued operations. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

Purchasers who purchase our securities in this offering pursuant to a securities purchase agreement may have rights not available to purchasers that purchase without the benefit of a securities purchase agreement.

In addition to rights and remedies available to all purchasers in this offering under federal securities and state law, the purchasers that enter into a securities purchase agreement will also be able to bring claims of breach of contract against us. The ability to pursue a claim for breach of contract provides those investors with the means to enforce the covenants uniquely available to them under the securities purchase agreement including, but not limited to: (i) timely delivery of shares; (ii) agreement to not issue any shares or securities convertible into shares for a period of sixty days from closing of the offering, subject to certain exceptions; and (iii) indemnification for breach of contract.

Our common stock may be at risk for delisting from the Nasdaq Capital Market in the future if we do not maintain compliance with Nasdaq's continued listing requirements. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease.

Our common stock is currently listed on Nasdaq. Nasdaq has minimum requirements that a company must meet in order to remain listed on Nasdaq, including corporate governance standards and a requirement that we maintain a stockholders' equity above \$2,500,000 as set forth in Nasdaq Listing Rule 5550(b)(1).

On November 21, 2024, the Company received a letter from Nasdaq notifying the Company that its amount of stockholders' equity has fallen below the \$2,500,000 required minimum for continued listing set forth in Nasdaq Listing Rule 5550(b)(1).

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Nasdaq's Letter has no immediate effect on the listing of the Company's common stock, and its common stock will continue to trade on The Nasdaq Capital Market under the symbol "GTBP" at this time. Pursuant to Nasdaq Listing Rules, the Company provided Nasdaq with a plan to achieve and sustain compliance on December 31, 2024. If Nasdaq accepts the Company's plan to regain compliance, Nasdaq may grant an extension of up to 180 calendar days from the date of the Letter to evidence compliance. If Nasdaq does not accept the Company's plan to regain compliance, the Company will have the opportunity to appeal the decision to a Nasdaq Hearings Panel. The Company intends to submit to Nasdaq, within the requisite time period, a plan to regain compliance with Listing Rule 5550(b)(1). There can be no assurance that Nasdaq will accept the Company's plan, that the Company will be able to regain compliance with Listing Rule 5550(b)(1) or that the Company will be able to meet the continued listing requirements during any compliance period that may be granted by Nasdaq.

In the future, if we fail to maintain such minimum requirements and a final determination is made by Nasdaq that our common stock must be delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease. In addition, if delisted, we would no longer be subject to Nasdaq rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards. Our failure to be listed on Nasdaq or another established securities market would have a material adverse effect on the value of our investment in us.

USE OF PROCEEDS

We estimate that the net proceeds from the offering will be approximately \$7.1 million, based on the assumed public offering price of \$2.38 per share and common warrant, which is the last reported sales price of our common stock on Nasdaq on January 23, 2024 after deducting the placement agent fees and estimated offering expenses payable by us, assuming no sale of any fixed combinations of warrants and pre-funded warrants offered hereunder. We may only receive additional proceeds from the exercise of the common warrants issuable in connection with this offering and, if such common warrants are exercised in full for cash, the estimated net proceeds will increase to \$15.1 million. However, because this is a reasonable best-efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, the placement agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus. Based on the assumed public offering price set forth above, we estimate that our net proceeds from the sale of 75%, 50%, and 25% of the securities offered in this offering would be approximately \$5.2 million, \$3.4 million, and \$1.5 million, respectively, after deducting the estimated placement agent fees and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering for working capital to fund our clinical programs and general corporate purposes, including the further development of: our product candidates that are currently undergoing clinical trials, our product candidates that we expect to submit an investigational new drug application for in the near term, and our product candidates that are pre-clinical. This expected use of proceeds from this offering represents our intentions based upon our current plans and prevailing business conditions, which could change in the future as our plans and prevailing business conditions evolve. The amounts and timing of our use of proceeds will vary depending on a number of factors, including the amount of cash generated or used by our operations. As a result, we will retain broad discretion in the allocation of the net proceeds of this offering.

CAPITALIZATION

The following table presents a summary of our cash and cash equivalents and capitalization as of September 30, 2024:

- on an actual basis; and
- on an as adjusted basis to reflect the issuance and sale of common stock and accompanying common warrants in this offering, after deducting placement agent fees and estimated offering expenses payable by us. The as adjusted basis assumes no pre-funded warrants are sold in this offering and excludes the proceeds, if any, from the exercise of any common warrants issued in this offering.

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The unaudited as adjusted information below is prepared for illustrative purposes only and our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read the following table in conjunction with Management's Discussion and Analysis of Financial Condition and Results of Operations and the historical financial statements and related notes in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and our Quarterly Report on Form 10-Q for the period ended September 30, 2024, incorporated herein by reference.

As of September 30, 2024

	Actual	As adjusted
Cash and cash equivalents	\$ 6,418,000	\$ 13,547,000
Stockholders' equity:		
Convertible preferred stock, \$0.01 par value, 15,000,000 shares authorized Series C, 96,230 shares issued and outstanding	\$ 1,000	\$ 1,000
Common stock: \$0.001 par value; 250,000,000 shares authorized; 2,234,328 shares issued and outstanding, actual; 5,595,672 shares issued and outstanding, pro forma as adjusted	\$ 2,000	\$ 6,000
Additional paid-in capital	\$ 693,546,000	\$ 700,671,000
Accumulated deficit	\$ (691,452,000)	\$ (691,452,000)
Total stockholders' equity	<u>\$ 2,097,000</u>	<u>\$ 9,226,000</u>

Each \$0.25 increase (decrease) in the assumed public offering price of \$2.38 per share would increase (decrease) each of cash and cash equivalents, additional paid-in capital and total shareholders' equity by approximately \$790,000, assuming the number of shares of common stock and common warrants offered, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated placement agent fees and estimated offering expenses. Similarly, each increase (decrease) of 100,000 shares in the number of shares of common stock and common warrants offered would increase (decrease) cash and cash equivalents, additional paid-in capital and total shareholders' equity by approximately \$223,720, assuming the assumed public offering price remains the same, and after deducting estimated placement agent fees and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

Unless otherwise stated in this prospectus, the number of shares of our common stock to be outstanding as of the date of this prospectus and after this offering is based on 2,234,328 shares outstanding as of September 30, 2024, and excludes (a) placement agent warrants to purchase up to 201,680 shares of our common stock issuable upon the exercise of warrants to be issued to the placement agent in connection with this offering having an exercise price of \$ per share, (b) the shares of common stock issuable upon exercise of the common warrants and pre-funded warrants being offered by us in this offering, (c) previously issued and outstanding warrants to purchase up to 1,133,762 shares of our common stock, and (d) outstanding stock options to purchase up to 101,264 shares of our common stock. See "Note 7 – Common Stock Warrants and Options" to our Third Quarter Report filed on Form 10-Q that is incorporated by reference into this prospectus.

DILUTION

If you purchase shares of our common stock, your interest will be diluted immediately to the extent of the difference between the offering price per share you will pay in this offering and the as adjusted net tangible book value per share of our common stock after this offering. Net tangible book value per share represents our total tangible assets less total liabilities, divided by the number of shares of our common stock outstanding.

As of September 30, 2024, our net tangible book value was \$2,097,000, or \$0.94 per share of Common Stock.

After giving effect to the foregoing pro forma adjustments and the sale by us of 3,361,344 shares of common stock and/or pre-funded warrants at an assumed public offering price of \$2.38 per share and accompanying common warrant, and after deducting the placement agent fees and estimated offering expenses payable by us, our as adjusted net tangible book value as of September 30, 2024, would have been \$9,226,469, or \$1.65 per share. This represents an immediate increase in as adjusted net tangible book value of approximately \$0.71 per share to our existing stockholders, and an immediate dilution of \$0.73 per share to purchasers of shares in this offering, as illustrated in the following table. The information below is illustrative only and will change based on actual pricing and other terms of this offering determined at pricing. The final public offering price will be determined through negotiation between us, the placement agent and the investors in the offering and may be at a discount to the current market price. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price.

Assumed public offering price	\$ 2.38
Net tangible book value per share as of September 30, 2024	\$ 0.94
Net increase in net tangible book value per share attributable to existing shareholders	\$ 0.71
As adjusted net tangible book value per share after this offering	\$ 1.65
Dilution in net tangible book value per share to new investors in the offering	\$ (0.73)

Unless otherwise stated in this prospectus, the number of shares of our common stock to be outstanding as of the date of this prospectus and after this offering is based on 2,234,328 shares outstanding as of September 30, 2024, and excludes (a) placement agent warrants to purchase up to 201,680 shares of our common stock issuable upon the exercise of warrants to be issued to the placement agent in connection with this offering having an exercise price of \$ per share, (b) the shares of common stock issuable upon exercise of the common warrants and pre-funded warrants being offered by us in this offering, (c) previously issued and outstanding warrants to purchase up to 1,133,762 shares of our common stock, and (d) outstanding stock options to purchase up to 101,264 shares of our common stock. See "Note 7 – Common Stock Warrants and Options" to our Third Quarter Report filed on Form 10-Q that is incorporated by reference into this prospectus.

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EXECUTIVE COMPENSATION

Summary Compensation Table

The following table summarizes all compensation for the last two fiscal years awarded to, earned by, or paid to our Chief Executive Officer (principal executive officer) and our two most highly compensated executive officers other than our CEO who were either serving as executive officers at the end of our last completed fiscal year or for whom disclosure would have been provided but for the fact that the individual was not serving as an executive officer at the end of our last completed fiscal year, whose total compensation exceeded \$100,000 during such fiscal year ends.

Name and Principal Position	Year	Salary (\$)	Bonus (\$)	Stock Awards ⁽¹⁾ (\$)	Option Awards ⁽²⁾ (\$)	All Other Compensation (\$)	Total (\$)
Michael Breen Chairman, Interim Chief Executive Officer, and President	2024	\$ 556,200	417,150	–	–	213,622 ⁽³⁾	1,186,972
	2023	\$ 556,200	312,863	57,600 ⁽⁶⁾	425,000 ⁽⁷⁾	174,171 ⁽³⁾	1,525,834
Alan Urban Chief Financial Officer	2024	\$ 187,500	87,500	–	40,681 ⁽⁸⁾	27,643 ⁽⁴⁾	343,324
	2023	\$ –	–	–	–	–	–
Manu Ohri Former Chief Financial Officer	2024	\$ 203,540	–	–	–	104,264 ⁽⁵⁾	307,804
	2023	\$ 432,000	172,800	57,600 ⁽⁹⁾	425,000 ⁽¹⁰⁾	42,271 ⁽⁵⁾	1,129,671

- (1) The amounts in this column represent the aggregate grant date fair value of restricted stock awards, determined in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. We determine the grant date fair value of the awards by multiplying the number of units granted by the closing market price of one share of our common stock on the award grant date. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting or the sale of the common stock awards.
- (2) This column represents option awards computed in accordance with FASB ASC Topic 718, excluding the effect of estimated forfeitures related to service-based vesting conditions. For additional information on the valuation assumptions with respect to the option grants, refer to Note 1 of our financial statements in the Annual Report. These amounts do not correspond to the actual value that will be recognized by the named executives from these awards.
- (3) Other compensation for 2024 includes \$131,374 in paid time off payout, \$60,000 in medical insurance, life insurance and long-term disability insurance premiums, and \$22,248 in employer pension contributions. Other compensation for 2023 includes \$128,833 in medical insurance, life insurance and long-term disability insurance premiums, and \$45,338 in employer pension contributions.
- (4) Other compensation for 2024 includes \$19,245 in medical insurance premiums, and \$8,398 employer 401(k) contributions.
- (5) Other compensation for 2024 includes \$78,300 in paid time off payout, and \$25,964 in medical insurance premiums, life insurance and long-term disability insurance premiums, and medical expense reimbursements. Other compensation for 2023 includes \$42,271 in medical insurance, life insurance and long-term disability insurance premiums, medical expense reimbursements and employer 401(k) contributions.
- (6) Represents the aggregate grant date fair value 6,666 shares of our common stock issued on August 11, 2023 at a closing market price of \$8.70 per share as compensation for service as our Interim Chief Executive Officer.
- (7) Represents the aggregate grant date fair value of options to purchase 16,666 shares of common stock issued on January 27, 2023, with 1/12th of the shares vesting on the monthly anniversary of January 1, 2023 as compensation for service on our Board of Directors.
- (8) Represents the aggregate grant date fair value of options to purchase 23,335 shares of common stock issued on October 17, 2024, with 1/36th of the shares vesting on the monthly anniversary of June 3, 2024 until fully vested, subject to acceleration
- (9) Represents the aggregate grant date fair value 6,666 shares of our common stock issued on August 11, 2023 at a closing market price of \$8.70 per share.
- (10) Represents the aggregate grant date fair value of options to purchase 16,666 shares of common stock issued on January 27, 2023, with 1/12th of the shares vesting on the monthly anniversary of January 1, 2023

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Outstanding Equity Awards at Fiscal Year End

The following table sets forth information regarding unexercised stock options for each named executive officer as of December 31, 2024.

Name	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)	Option exercise price (\$)	Option expiration date
Michael Breen	1,666 ⁽¹⁾	—	74.40	7/14/2032
	16,666 ⁽¹⁾	—	25.50	1/27/2033
Alan Urban	4,537 ⁽²⁾	18,798 ⁽²⁾	2.11	10/17/2034

- (1) Consists of options granted to Mr. Breen as compensation for service on our Board of Directors.
- (2) Consists of options granted to Mr. Urban that vest as follows: 1/36th of the shares vest on the monthly anniversary of June 3, 2024 until fully vested, subject to acceleration.

Pay Versus Performance

Year	Summary Compensation Table Total for PEO ⁽¹⁾	Compensation Actually Paid to PEO ⁽²⁾	Average Summary Compensation Table Total for Non-PEO NEO ⁽³⁾	Average Compensation Actually paid to Non-PEO NEOs ⁽⁴⁾	Value of Initial Fixed \$100 Investment Based on Total Shareholder Return ⁽⁵⁾	Net Loss (In Thousands) ⁽⁶⁾
2024	\$ 1,186,972	\$ 1,186,972	\$ 343,324	\$ 359,710	\$ 3.25	\$ (a)
2023	\$ 1,525,834	\$ 1,258,279	\$ 1,129,671	\$ 862,116	\$ 8.15	\$ 7,597
2022	\$ 1,892,293	\$ 1,498,165	\$ 944,544	\$ 1,029,311	\$ 28.31	\$ 20,884

- (a) Amount will be reported on the Company's 2024 Form 10-K.
- (1) The dollar amounts reported are the amounts of total compensation reported in our Summary Compensation Table for each of 2024, 2023, and 2022 for Mr. Breen, our Interim Chief Executive Officer (our principal executive officer (PEO) from and after March 2, 2022).
- (2) The dollar amounts reported represent the amount of "compensation actually paid," as computed in accordance with SEC rules. The dollar amounts do not reflect the actual amount of compensation earned by or paid during the applicable year. In accordance with SEC rules, the following adjustments were made to total compensation to determine the compensation actually paid:

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Year	Reported Summary Compensation Table Total for PEO	Reported Value of Equity Awards (a)	Equity Award Adjustments (b)	Compensation Actually Paid to PEO
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2024	\$	1,186,972	\$	—	\$	—	\$	1,186,972
2023	\$	1,525,834	\$	482,600	\$	215,045	\$	1,258,279
2022	\$	1,892,293	\$	800,584	\$	406,456	\$	1,498,165

- (a) The grant date fair value of equity awards represents the total of the amounts reported in the “Stock awards” and “Option awards” columns in the Summary Compensation Table for the applicable year.
- (b) The equity award adjustments for each applicable year include the addition (or subtraction, as applicable) of the following: (i) the year-end fair value of any equity awards granted in the applicable year that are outstanding and unvested as of the end of the year; (ii) the amount of change as of the end of the applicable year (from the end of the prior fiscal year) in fair value of any awards granted in prior years that are outstanding and unvested as of the end of the applicable year; (iii) for awards that are granted and vest in same applicable year, the fair value as of the vesting date; (iv) for awards granted in prior years that vest in the applicable year, the amount equal to the change as of the vesting date (from the end of the prior fiscal year) in fair value; (v) for awards granted in prior years that are determined to fail to meet the applicable vesting conditions during the applicable year, a deduction for the amount equal to the fair value at the end of the prior fiscal year; and (vi) the dollar value of any dividends or other earnings paid on stock or option awards in the applicable year prior to the vesting date that are not otherwise reflected in the fair value of such award or included in any other component of total compensation for the applicable year. The valuation assumptions used to calculate fair values did not materially differ from those disclosed at the time of grant. The amounts deducted or added in calculating the equity award adjustments are as follows:

Year	Year End Fair Value of Outstanding and Unvested Equity Awards Granted During the Year	Year over Year Change in Fair Value of Outstanding and Unvested Equity Awards Granted in Prior Years	Fair Value as of Vesting Date of Equity Awards Granted and Vested in the Year	Year over Year Change in Fair Value of Equity Awards Granted in Prior Years that Vested in the Year	Total Equity Award Adjustments
2024	\$ —	\$ —	\$ —	\$ —	\$ —
2023	\$ 10,641	\$ —	\$ 204,404	\$ —	\$ 215,045
2022	\$ 10,265	\$ (25,072)	\$ 997,908	\$ (576,645)	\$ 406,456

- (3) The dollar amounts reported represent the average of the amounts reported for the Company’s named executive officers (NEOs) as a group (excluding our CEO) in the “Total” column of the Summary Compensation Table in each applicable year. Mr. Urban is the only NEO included for purposes of calculating the average amounts in 2024, and Mr. Ohri is the only NEO included for purposes of calculating the average amounts in 2023 and 2022.
- (4) The dollar amounts reported represent the average amount of “compensation actually paid” to the NEOs as a group (excluding our CEO), as computed in accordance with SEC rules. The dollar amounts do not reflect the actual average amount of compensation earned by or paid to the NEOs as a group (excluding our CEO) during the applicable year. In accordance with the SEC rules, the following adjustments were made to average total compensation for the NEOs as a group (excluding our CEO) for each year to determine the compensation actually paid, using the same methodology described above in Note 2:

Year	Average Reported Summary Compensation Table Total for Non-PEO NEOs	Average Reported Value of Equity Awards	Average Equity Award Adjustments (a)	Average Compensation Actually Paid to Non-PEO NEOs
2024	\$ 343,324	\$ 40,681	\$ 57,067	\$ 359,710
2023	\$ 1,129,671	\$ 482,600	\$ 215,045	\$ 862,116
2022	\$ 944,544	\$ 448,515	\$ 533,282	\$ 1,029,311

- (a) The amounts deducted or added in calculating the total average equity award adjustments are as follows:

Year	Average Year End Fair Value of Outstanding and Unvested Equity Awards Granted During the Year	Year over Year Average Change in Fair Value of Outstanding and Unvested Equity Awards Granted in Prior Years	Average Fair Value as of Vesting Date of Equity Awards Granted and Vested in the Year	Year over Year Average Change in Fair Value of Equity Awards Granted in Prior Years that Vested in the Year	Total Average Equity Award Adjustments
2024	\$ 49,157	\$ —	\$ 7,910	\$ —	\$ 57,067
2023	\$ 10,641	\$ —	\$ 204,404	\$ —	\$ 215,045
2022	\$ 97,175	\$ —	\$ 436,107	\$ —	\$ 533,282

- (5) Cumulative total stockholder return is calculated by dividing the sum of the cumulative amount of dividends for the measurement period, assuming dividend reinvestment, and the difference between the Company’s share price at the end and the beginning of the measurement period, by the Company’s share price at the beginning of the measurement period. Represents the value on the last trading day of each of 2024, 2023 and 2022 of an investment of \$100 in our common stock on the last trading day of 2021.
- (6) The dollar amounts reported represent the amount of net loss reflected in our audited financial statements for the applicable year.

Analysis of Information Presented in the Pay versus Performance Table

The Company’s executive compensation program reflects a variable pay-for-performance philosophy. While the Company utilizes several performance measures to align executive compensation with Company performance, all of those Company measures are not presented in the Pay versus Performance table. Moreover, the Company generally seeks to incentivize long-term performance, and therefore does not specifically align the Company’s performance measures with compensation that is actually paid (as computed in accordance with SEC rules) for a particular year. In accordance with SEC rules, the Company is providing the following narrative disclosure regarding the relationships between information presented in the Pay versus Performance table.

Compensation Actually Paid and Cumulative Total Stockholder Return

During fiscal 2023 and 2024, compensation actually paid to our PEO decreased from \$1,258,279 in fiscal 2023 to \$1,186,972 in fiscal 2024, and average compensation actually paid to our named executive officers other than our PEO decreased from \$862,116 in fiscal 2023 to \$359,710 in fiscal 2024. During fiscal 2022 and 2023, compensation actually paid to our PEO decreased from \$1,498,165 in fiscal 2022 to \$1,258,279 in fiscal 2023, and average compensation actually paid to our named executive officers other than our PEO decreased from \$1,029,311 in fiscal 2022 to \$862,116 in fiscal 2023.

Over the same period, the value of an investment of \$100 in our common stock on the last trading day of 2021 decreased by \$71.69 to \$28.31 during fiscal 2022, further decreased by \$20.16 to \$8.15 during fiscal 2023, and further decreased by \$4.90 to \$3.25 during fiscal 2024, for a total decrease from fiscal 2022 through fiscal 2024 of \$96.75.

Compensation Actually Paid and Net Loss

During fiscal 2023 and 2024, compensation actually paid to our PEO decreased from \$1,258,279 in fiscal 2023 to \$1,186,972 in fiscal 2024, and average compensation actually paid to our named executive officers other than our PEO decreased from \$862,116 in fiscal 2023 to \$359,710 in fiscal 2024. During fiscal 2022 and 2023, compensation actually paid to our PEO decreased from \$1,498,165 in fiscal 2022 to \$1,258,279 in fiscal 2023, and average compensation actually paid to our named executive officers other than our PEO decreased from \$1,029,311 in fiscal 2022 to \$862,116 in fiscal 2023.

Our net loss during fiscal 2024 will be reported on the Company's 2024 Form 10-K. Our net loss decreased by \$13,287,000 during fiscal 2023 (from a net loss in fiscal 2022 of \$20,884,000 to a net loss in fiscal 2023 of \$7,597,000).

Employment Agreements

The Company is party to employment agreements with both Michael Breen and Alan Urban, each of which are described below. The Company does not currently have employment agreements with any of its other officers and directors.

Michael Breen, Chairman, Interim Chief Executive Officer, and President

On December 31, 2021, the Company entered into a one-year, annually renewable executive services agreement with Mr. Breen, effective November 8, 2021, and amended on June 17, 2022 and February 20, 2023. Under the terms of the amended executive services agreement, Mr. Breen will receive an annual base salary of \$556,200, reimbursement for executive life insurance premiums, a pension contribution equal to 4% of Mr. Breen's gross annual salary, and right to receive any benefit and participate in any benefit plan generally available to the most senior level of employees of the Company. Mr. Breen is eligible to participate in our performance bonus plan or as otherwise determined by our Compensation Committee, with a target annual bonus of 75% of his annual base salary with a minimum guaranteed performance bonus of 25% of base salary.

Upon the termination of Mr. Breen's services for any reason, Mr. Breen will receive his accrued but unpaid salary and vacation pay through the date of termination and any other benefits accrued to him under any benefit plans outstanding at such time, and the reimbursement of documented, unreimbursed expenses incurred prior to such date. Upon our termination of Mr. Breen's services without cause (as defined in the his services agreement) or upon Mr. Breen's termination of his employment for good reason (as defined in his services agreement) prior to the end of the term of his services agreement, Mr. Breen shall also receive (i) a lump sum payment equal to the greater of the amount of his annual base salary (at the then-current rate) that he would have earned through the end of the term of the agreement, and 50% of his annual base salary, plus (ii) a lump sum payment equal to the greater of the bonus paid or payable to Mr. Breen for the immediately preceding year, and the target bonus under our performance bonus plan, if any, in effect during the immediately preceding year, plus (iii) monthly reimbursement for the cost of medical, life and disability insurance coverage at a level equivalent to that provided by our company for a period of the earlier of (a) one year and (b) the time Mr. Breen begins alternative services wherein said insurance coverage is available and offered to Mr. Breen. Mr. Breen will also be designated for election to our Board of Directors during the term of his services agreement.

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Alan Urban, Chief Financial Officer

On June 7, 2024, the Company entered into an Employment Agreement with Mr. Urban (the "Employment Agreement"). The Employment Agreement is effective from June 3, 2024 (the "Effective Date") and shall continue for a period of one year. The Employment Agreement shall automatically renew for successive one year periods unless and until either party provides sixty (60) days' advance written notice prior to applicable renewal term. Pursuant to the Employment Agreement, Mr. Urban will receive an annual base salary of \$375,000 and is eligible to earn an annual discretionary bonus of up to 40% of his annual base salary each calendar year during the term, subject to the achievement of applicable Company and individual performance goals, as determined in the Company's sole discretion. Mr. Urban is eligible to receive a stock award of the Registrant's Common Stock following the three months after the Effective Date. The Employment Agreement further provides that Mr. Urban will be eligible to receive any benefit and participate in any benefit plan generally available to employees of the Company.

The Company may terminate the Employment Agreement without Cause (as such term is defined in the Employment Agreement) at any time and Mr. Urban may terminate his employment for Good Reason (as such term is defined in the Employment Agreement) at any time. Upon a termination of Mr. Urban's employment by the Company without Cause or by Mr. Urban for Good Reason, Mr. Urban will be entitled to receive (i) for a termination or resignation that occurs during the first six months following the Effective Date, a cash severance equal to two (2) months of Mr. Urban's then current Annual Base Salary (as such term is defined in the Employment Agreement) or (ii) for a termination or resignation that occurs any time thereafter, a cash severance equal to five (5) months of Mr. Urban's then current Annual Base Salary, in either case less deductions and withholding required by law, payable in a lump sum within seventy (70) days of the termination of employment (or such shorter period as may allow the severance payment to be exempt from Code Section 409A). Upon a termination of Mr. Urban's employment by the Company for Cause or by Mr. Urban without Good Reason, Mr. Urban will be entitled to the Accrued Amounts (as such term is defined in the Employment Agreement). The Employment Agreement also contains certain non-disclosure covenants that apply during his employment and thereafter.

2022 Omnibus Incentive Plan - Summary

In 2014 we established the 2014 Stock Incentive Plan (the "2014 Plan") and in April 2022 we established the 2022 Omnibus Incentive Plan, collectively (the "Plans"). The Plans were approved by our Board of Directors and stockholders. The purpose of the Plans is to grant stock and options to purchase our common stock, and other incentive awards, to our employees, directors and key consultants. The maximum number of shares of common stock that may be issued pursuant to awards granted under the 2022 Plan is 166,667. Following adoption of the 2022 Plan by our stockholders we only grant incentive awards under the 2022 Plan. The shares of our common stock underlying cancelled and forfeited awards issued under the 2022 Plan may again become available for grant under the 2022 Plan. As of December 31, 2024, there were no shares available for grant under the 2014 Plan. All outstanding incentive stock award grants prior to the adoption of the 2022 Plan were made under the 2014 Plan, and all incentive stock award grants after the adoption of the 2022 Plan have been and will be made under the 2022 Plan. The following table provides information as of December 31, 2024 with respect to the Plans.

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights ⁽¹⁾	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by stockholders (2014 Plan)	—		—
Equity compensation plans approved by stockholders (2022 Plan)	150,535	\$ 32.69	16,132
Total	150,535		16,132

(1) The weighted average exercise price excludes restricted stock awards, which have no exercise price.

Director Compensation

The following table presents information regarding compensation awarded or paid to our non-employee directors for our fiscal year ended December 31, 2024 for the services rendered by them to the Company in all capacities.

Name	Fees earned or paid in cash (\$)	Stock awards (\$)	Option awards (\$)	Total (\$)
Rajesh Shrotriya, M.D.	81,000	—	—	81,000
Bruce Wendel	81,000	—	—	81,000
Charles J. Casamento	65,000	—	—	65,000

During fiscal 2024, our non-employee directors received annual cash compensation in the amount of \$50,000 for service on our Board of Directors, and annual compensation of \$5,000 per committee for service on our Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee. Non-employee members of the Special Committee of our Board of Directors also received a monthly fee of \$8,000 for service on the Special committee for the months of January and February 2024.

Indemnification of Directors and Executive Officers and Limitation of Liability

We have entered into indemnification agreements with each of our current directors and certain key employees. The indemnification agreements, our restated certificate of incorporation and Amended Restated Bylaws require us to indemnify our current and former directors and officers to the fullest extent permitted by Delaware law.

CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Transactions with Officers, Directors and greater than 5% stockholders

Other than listed below, since January 1, 2024, there has not been, nor is there currently proposed, any transaction or series of similar transactions to which we were or will be a party:

- in which the amount involved exceeds the lesser of \$120,000 or one percent of the average of our total assets at year end for the last two completed fiscal years; and
- in which any director, executive officer, stockholder who beneficially owns more than 5% of our common stock or any member of their immediate family had or will have a direct or indirect material interest.

Cytovance

In October 2020, the Company entered into a Master Services Agreement with Cytovance Biologics, Inc. (“Cytovance”), to perform biologic development and manufacturing services, and to produce and test compounds used in the Company’s potential product candidates. The Company subsequently executed numerous Statements of Work (“SOWs”) for the research and development of products for use in clinical trials. On August 24, 2022, the Company entered into a Settlement and Investment Agreement with Cytovance that amended existing SOWs and allowed for future invoices to be settled in in a combination of cash and issuance of the Company’s common stock. The Agreement also set Cytovance’s beneficial ownership limitation at 4.9% of the issued and outstanding shares of the Company’s common stock. On April 25, 2024, the Company entered into an Amendment to the Settlement and Investment Agreement with Cytovance that increased Cytovance’s beneficial ownership limitation to 9.9% of the issued and outstanding shares of the Company’s common stock. On June 30, 2024, Cytovance became a related party as their beneficial ownership exceeded 5% of the issued and outstanding shares of the Company’s common stock.

During the nine months ended September 30, 2024 and 2023, the Company recognized research and development expenses of \$1,365,000 and \$3,691,000, respectively and made cash payments amounting to \$3,432,000 and \$1,710,000, respectively to Cytovance. In addition, the Company issued 127,597 and 57,437 shares of common stock to Cytovance to settle accounts payable valued at approximately \$810,000 and \$1,120,000, respectively. As of September 30, 2024 the Company’s commitments in relation to unbilled and unaccrued SOWs and any related Change Orders from Cytovance for services that have not yet been rendered as of September 30, 2024, amounted to approximately \$1.3 million. As of September 30, 2024 and December 31, 2023, accounts payable to Cytovance amounted to \$638,000 and \$3,515,000, respectively.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information, as of January 9, 2025, with respect to the holdings of (1) each person who is the beneficial owner of more than five percent of our common stock, (2) each of our directors, (3) each named executive officer, and (4) all of our directors and executive officers as a group.

Beneficial ownership of our common stock is determined in accordance with the rules of the Securities and Exchange Commission and includes any shares of common stock over which a person exercises sole or shared voting or investment powers, or of which a person has a right to acquire ownership at any time within 60 days of January 9, 2025. Except as otherwise indicated, and subject to applicable community property laws, the persons named in this table have sole voting and investment power with respect to all shares of common stock held by them. The address of each director and officer is 315 Montgomery Street, 10th Floor, San Francisco, California 94104. Applicable percentage ownership in the following table is based on 2,234,328 shares of common stock outstanding as of January 9, 2025 plus, for each person, any securities that person has the right to acquire within 60 days of January 9, 2025.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Outstanding
Five Percent or Greater Stockholders		
Cytovance Biologics, Inc. ⁽¹⁾	219,457	9.8%
Robert A. Marzilli ⁽²⁾	200,000	9.0%
Bristol Investment Fund, Ltd. ⁽³⁾	190,000	7.8%
Executive Officers and Directors:		
Michael Breen ⁽⁴⁾	46,872	2.1%
Alan Urban ⁽⁵⁾	4,537	0.2%
Bruce Wendel ⁽⁶⁾	31,753	1.4%

Rajesh Shrotriya, M.D. ⁽⁷⁾	32,047	1.4%
Charles J. Casamento ⁽⁸⁾	16,666	0.7%
Directors and officers as a group (5 persons) ⁽⁹⁾	131,875	5.7%

- (1) The address for Cytovance Biologics, Inc. is 800 Research Parkway, Suite 200 Oklahoma City, OK 73104.
- (2) The address for Robert A. Marzilli is 457 Sunset Beach Rd., Richmond Hill, Ontario, L4E 3J3, Canada. This information is based on information known to the company through a non-objecting beneficial ownership report (the “NOBO Report”) as of December 31, 2024. Mr. Marzilli has not provided or verified the information appearing on the NOBO Report, and so this information may not be accurate for a number of reasons, including, but not limited to, if Mr. Marzilli has divested such ownership through private contractual or other means not reflected in the NOBO Report, or is the beneficial owner of other shares not disclosed in the NOBO Report.
- (3) The address for Bristol Investment Fund, Ltd. is Citco Trustees (Cayman) Limited, 89 Nexus Way, Camana Bay, PO Box 311063, Grand Cayman KY1-1205, Cayman Islands. Includes shares underlying warrants to purchase 190,000 shares of common stock at \$4.35 per share.
- (4) Includes shares underlying options to purchase 1,666 shares of common stock at \$74.40 per share, and 16,666 shares of common stock at \$25.50 per share.
- (5) Includes shares underlying options to purchase 4,537 shares of common stock at \$2.11 per share.
- (6) Consists of shares underlying options to purchase 3,332 shares of common stock at \$74.40 per share, and 16,666 shares of common stock at \$25.50 per share.
- (7) Consists of shares underlying options to purchase 15,381 shares of common stock at \$74.40 per share, and 16,666 shares of common stock at \$25.50 per share.
- (8) Includes shares underlying options to purchase 16,666 shares of common stock at \$10.50 per share.
- (9) Includes shares underlying options to purchase 91,580 shares of common stock.

DESCRIPTION OF CAPITAL STOCK

The following summary of the rights of our capital stock is not complete and is subject to and qualified in its entirety by reference to our Charter and Bylaws, copies of which are filed as exhibits to our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on March 26, 2024, and the Certificate of Designations and forms of securities, copies of which are filed as exhibits to the registration statement of which this prospectus forms a part, which are incorporated by reference herein.

The following summary describes the material terms of our capital stock. The summary is qualified in its entirety by reference to our certificate of incorporation and our bylaws.

Authorized Shares

Our authorized shares consists of 250,000,000 shares of common stock and 15,000,000 shares of preferred stock, \$0.001 par value per share (the “Preferred Stock”). Our common stock is registered under Section 12(b) of the Exchange Act and is listed on the Nasdaq under the trading symbol “GTBP.”

On February 2, 2024, the Company effectuated a reverse stock-split of its common stock, par value \$0.001 per share, at a ratio of 1 for 30. The Company’s common stock began trading on a reverse stock-split-adjusted basis on The Nasdaq Capital Market on February 5, 2024 under the existing trading symbol “GTBP.”

As a result of the reverse stock-split, every thirty (30) shares of issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share. No fractional shares will be issued in connection with the reverse stock split. Stockholders who otherwise would be entitled to receive fractional shares of common stock will be entitled to receive their pro-rata portion of the net proceeds obtained from the aggregation and sale by the exchange agent of the fractional shares resulting from the reverse stock-split (reduced by any customary brokerage fees, commission and other expenses). The reverse stock split reduced the number of shares of common stock outstanding on the effective date of the reverse stock-split from 41,419,000 shares to 1,380,633 shares, subject to minor adjustments due to the treatment of fractional shares. The number of authorized shares of common stock remains unchanged at 250,000,000 shares.

Proportionate adjustments have been made to the per share exercise price and the number of shares of common stock that may be purchased upon exercise of outstanding stock options and warrants for the Company’s common stock, and to the number of shares of common stock reserved for future issuance pursuant to the Company’s 2022 Omnibus Incentive Plan.

All share and per share information within this report have been adjusted to retroactively reflect the reverse stock-split as of the earliest period presented.

Common Stock

Holders of our common stock are entitled to one vote for each share of common stock held of record for the election of directors and on all matters submitted to a vote of stockholders. Holders of our common stock are entitled to receive dividends ratably, if any, as may be declared by the board 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 currently outstanding or that we may designate and issue in the future. All outstanding shares of our common stock are fully paid and non-assessable. Except as described below in “Anti-Takeover Provisions Under Our Charter and Bylaws and Delaware Law,” holders of a majority of the outstanding shares of stock entitled to vote shall constitute a quorum for the transaction of business, and a vote of the majority of the voting power represented at such meeting at which a quorum is generally required to take action under our certificate of incorporation and bylaws.

Preferred Stock

Our Board is authorized, without action by the stockholders, to designate and issue up to 15,000,000 shares of preferred stock in one or more series. In the past the Board has designated series lettered A through K and issued shares in those series (other than Series K). As of the date of this prospectus, only preferred shares in the series designated C have shares issued and outstanding. Our Board can fix or alter the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions, including dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting a class or series. The issuance of preferred stock could, under certain circumstances, result in one or more of the following adverse effects:

- decreasing the market price of our common stock;
- restricting dividends on our common stock;
- diluting the voting power of our common stock;
- impairing the liquidation rights of our common stock; or

- delaying or preventing a change in control of us without further action by our shareholders.

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

Series C Preferred Stock

For a discussion of the terms of our Series C Preferred Stock, see Note 6 to our audited financial statements, *Stockholders' Equity*, incorporated in this document by reference.

Warrants

Common warrants for the purchase of up to 740,000 shares of common stock (the "2024 Common Warrants") were issued pursuant to a securities purchase agreement between us and certain institutional investors, dated as of May 21, 2024 (the "2024 Purchase Agreement") in registered form and entitle the registered holder to purchase one share of our common stock at a price equal to \$4.35 per share, subject to adjustment as discussed below, terminating at 5:00 p.m., New York City time, on the fifth anniversary of the date of issuance. Also pursuant to the 2024 Purchase Agreement, we had an additional number of outstanding placement agent warrants for the purchase of up to 88,800 shares of common stock at an exercise price of \$5.4375. (the "2024 Placement Agent Warrants," and together with the 2024 Common Warrants, the "2024 Warrants").

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Common warrants to purchase up to an aggregate of 216,667 shares of the Company's common stock (the "2023 Common Warrants"), pre-funded warrants to purchase up to 96,667 shares of the Company's common stock (the "Pre-Funded Warrants"), and placement agent warrants to purchase up to 13,000 of the Company's common stock (the "2023 Placement Agents Warrants," and together with the 2023 Common Warrants and Pre-Funded Warrants, the "2024 Warrants") were issued pursuant to a purchase agreement dated December 30, 2022. The 2023 Common Warrants have an exercise price equal to \$30.00 per share, are exercisable commencing six months following issuance, and have a term of exercise equal to five years following the initial issuance date. The Pre-Funded Warrants had an exercise price of \$0.003 per share, are immediately exercisable and could be exercised at any time after their original issuance until such Pre-Funded Warrants were exercised in full. The 2023 Placement Agents Warrants have an exercise price equal to \$37.50 per share, are exercisable commencing six months following issuance, and have a term of exercise equal to five years following the initial issuance date. The 2023 Shares and 2023 Common Warrants were sold at an offering price of \$30.00 per share and accompanying 2023 Common Warrant and the Pre-Funded Warrants and 2023 Common Warrants were sold at an offering price of \$29.997 per Pre-Funded Warrant and accompanying 2023 Common Warrant.

Holders of 2023 Warrants and 2024 Warrants (together, the "Warrants") may exercise such warrants on a "cashless" basis if an effective registration statement is not available with respect to the offering of shares of common stock upon exercise of such Warrant. In such event, the Holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the Warrants. The exercise price and number of shares of common stock issuable upon exercise of the Warrants may be adjusted in certain circumstances, including in the event of a stock dividend, extraordinary dividend or recapitalization, reorganization, merger or consolidation. The Warrants may be exercised by delivery of a notice of exercise and the aggregate exercise price (assuming no cashless exercise has been elected if an effective registration statement is not available with respect to the offering of shares of common stock upon exercise of such Warrant) to us as specified in such Warrant. Holders of Warrants do not have the rights or privileges of holders of common stock and any voting rights until they exercise their Warrants and receive shares of common stock. After the issuance of shares of common stock upon exercise of the Warrants, each holder will be entitled to one vote for each share held of record on all matters to be voted on by stockholders.

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

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

Amended and Restated Certificate of Incorporation

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

Special Meetings of Stockholders. Our bylaws provide that special meetings of our stockholders may be called only by our Chairman, President or a majority of the entire 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 may determine the number of directors on our board. The inability of stockholders to determine the number of directors or to fill vacancies or newly created seats on our Board makes it more difficult to change the composition of our Board, but these provisions promote a continuity of existing management.

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

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

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

Delaware Anti-takeover Statute

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

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

Transfer Agent and Registrar

Our transfer agent and registrar for our capital stock is Computershare. The transfer agent's address is 8742 Lucent Blvd., Suite 225, Highland Ranch, CO 80129, and its telephone number is (303) 262-0600.

Existing Trading Markets

Our common stock is listed on the Nasdaq Capital Market under the trading symbol "GTBP." The closing sale price of our common stock on the Nasdaq Capital Market on January 23, 2025, was \$2.38 per share.

Listing on the Nasdaq Capital Market

Our common stock is listed on the Nasdaq Capital Market under the symbol "GTBP."

DESCRIPTION OF SECURITIES WE ARE OFFERING

We are offering up to 3,361,344 shares of our common stock (or pre-funded warrants in lieu of) and up to common warrants to purchase up to 3,361,344 shares of common stock. Each share of common stock is being offered together with one common warrant to purchase one share of common stock. We are also offering pre-funded warrants to those purchasers whose purchase of shares of common stock in this offering would result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding shares of common stock following the consummation of this offering in lieu of the shares of common stock that would result in such excess ownership. Each pre-funded warrant will be exercisable for one share of common stock. Each pre-funded warrant is being offered together with one common warrant to purchase one share of common stock. No warrant for fractional shares of common stock will be issued, rather warrants will be issued only for whole shares of common stock. We are also registering the shares of common stock issuable from time to time upon exercise of the pre-funded warrants and common warrants offered hereby.

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Common Stock

The material terms and provisions of our common stock are described under the caption '*Description of Capital Stock*' in this prospectus and are incorporated herein by reference.

Common Warrants

General

The following is a summary of certain terms and provisions of the common warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the common warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of common warrant for a complete description of the terms and conditions of the common warrants.

Duration, Exercise Price and Form

Each common warrant offered hereby has an initial exercise price per share equal to \$. Each common warrant is exercisable for one share of common stock. The common warrants are exercisable immediately following issuance, and have a term of exercise equal to five years following the initial exercise date. The exercise price and number of shares issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The common warrants will be issued in certificated form only.

Exercisability

The common warrants are exercisable immediately after issuance, at the option of each holder, in whole or in part, by delivering to us a duly-executed exercise notice accompanied by payment in full for the number of shares purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of such holder's common warrants to the extent that the holder would own more than 4.99% (or 9.99%, at the holder's election) of our outstanding common stock immediately after exercise, except that upon notice from the holder to us, the holder may decrease or increase the limitation of ownership of outstanding stock after exercising the holder's common warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants, provided that any increase in such limitation shall not be effective until 61 days following notice to us. No fractional shares will be issued in connection with the exercise of a common warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Cashless Exercise

If, at the time a holder exercises its common warrants, a registration statement registering the issuance of the shares of common stock underlying the common warrants under the Securities Act, is not then effective or available for the resale of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the common warrant.

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Fundamental Transactions

In the event of any fundamental transaction, as described in the common warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our shares of common stock, then upon any subsequent exercise of a common warrant, the holder will have the right to receive as alternative consideration, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of common stock for which the common warrant is exercisable immediately prior to such event. In addition, upon a fundamental transaction, the holder will have the right to require us to repurchase its common

warrant at its fair value using the Black Scholes option pricing formula in the common warrants; provided, however, that, if the fundamental transaction is not within our control, including not approved by our board of directors, then the holder shall only be entitled to receive the same type or form of consideration (and in the same proportion), at the Black Scholes value of the unexercised portion of the common warrant, that is being offered and paid to the holders of our common stock in connection with the fundamental transaction.

Transferability

Subject to applicable laws, a common warrant may be transferred at the option of the holder upon surrender of the common warrant to us together with the appropriate instruments of transfer.

Exchange Listing

There is no trading market available for the common warrants on any securities exchange or nationally recognized trading system. We do not intend to list the common warrants on any securities exchange or nationally recognized trading system. Without an active market, the liquidity of the common warrants will be limited.

Right as a Stockholder

Except as otherwise provided in the common warrants or by virtue of such holder's ownership of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

Pre-Funded Warrants

General

The following is a summary of certain terms and provisions of the pre-funded warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the pre-funded warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of pre-funded warrant for a complete description of the terms and conditions of the pre-funded warrants.

Duration, Exercise Price and Form

Each pre-funded warrant offered hereby has an initial exercise price per share equal to \$0.0001. Each pre-funded warrant is exercisable for one share of common stock. The pre-funded warrants are exercisable immediately, and will be exercisable until exercised in full. The exercise price and number of shares issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price. The pre-funded warrants will be issued in certificated form only.

Exercisability

The pre-funded warrants are exercisable immediately, at the option of each holder, in whole or in part, by delivering to us a duly-executed exercise notice accompanied by payment in full for the number of shares purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of such holder's pre-funded warrants to the extent that the holder would own more than 4.99% (or 9.99%, at the holder's election) of our outstanding common stock immediately after exercise, except that upon notice from the holder to us, the holder may decrease or increase the limitation of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants, provided that any increase in such limitation shall not be effective until 61 days following notice to us. No fractional shares will be issued in connection with the exercise of a pre-funded warrant. In lieu of fractional shares, we will either pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price or round up to the next whole share.

Cashless Exercise

A holder, in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrant.

Fundamental Transactions

In the event of any fundamental transaction, as described in the pre-funded warrants and generally including any merger with or into another entity, sale of all or substantially all of our assets, tender offer or exchange offer, or reclassification of our shares of common stock, then upon any subsequent exercise of a pre-funded warrant, the holder will have the right to receive as alternative consideration, for each share of common stock that would have been issuable upon such exercise immediately prior to the occurrence of such fundamental transaction, the number of shares of common stock of the successor or acquiring corporation or of our company, if it is the surviving corporation, and any additional consideration receivable upon or as a result of such transaction by a holder of the number of shares of common stock for which the pre-funded warrant is exercisable immediately prior to such event.

Transferability

Subject to applicable laws, a pre-funded warrant may be transferred at the option of the holder upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

Exchange Listing

There is no trading market available for the pre-funded warrants on any securities exchange or nationally recognized trading system. We do not intend to list the pre-funded warrants on any securities exchange or nationally recognized trading system. Without an active market, the liquidity of the pre-funded warrants will be limited.

Right as a Stockholder

Except as otherwise provided in the pre-funded warrants or by virtue of such holder's ownership of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Placement Agent Warrants

The following is a summary of certain terms and provisions of the placement agent warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the placement agent warrant, the form of which will be filed as an exhibit to the registration statement of which this prospectus forms a part. Prospective investors should carefully review the terms and provisions of the form of placement agent warrant for a complete description of the terms and conditions of the placement agent warrants.

The placement agent warrants are substantially similar to the common warrants, except that each placement agent warrant will have an exercise price of \$ _____ per share (which represents 125% of the public offering price per share of common stock and accompanying common warrants sold in this offering) and will expire five years from

MATERIAL TAX CONSIDERATIONS

The following is a discussion of material U.S. federal income tax consequences generally applicable to the acquisition, ownership, and disposition of common stock, common warrants, and pre-funded warrants issued pursuant to this offering. This discussion does not address tax consequences other than those pertaining to U.S. federal income taxation. For example, this discussion does not address any consequences relating to estate or gift taxation, the alternative minimum tax, or the Medicare tax on investment income. Nor does this discussion address any aspects of U.S. state or local or non-U.S. taxation. This discussion applies only to holders that hold our common stock, common warrants, and pre-funded warrants as “capital assets” within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended (the “Code”). This discussion does not address all aspects of U.S. federal income taxation that may be relevant to holders in light of their particular circumstances or status, including:

- financial institutions or financial services entities;
- broker-dealers;
- S corporations;
- partnerships (including entities or arrangements treated as partnerships for U.S. federal income tax purposes);
- taxpayers that are subject to the mark-to-market accounting rules;
- tax-exempt entities;
- governments or agencies or instrumentalities thereof;
- insurance companies;
- regulated investment companies or real estate investment trusts;
- expatriates or former long-term residents or citizens of the United States;
- persons for whom our common stock or pre-funded warrants constitute “qualified small business stock” within the meaning of Section 1202 of the Code;
- persons that hold our securities as part of a straddle, constructive sale, hedging, conversion or other integrated or similar transaction;
- persons subject to the alternative minimum tax;
- U.S. persons whose functional currency is not the U.S. dollar;
- controlled foreign corporations;
- accrual method taxpayers that file applicable financial statements as described in Section 451(b) of the Code; or
- passive foreign investment companies.

If a partnership (or any entity or arrangement treated as a partnership for U.S. federal income tax purposes) holds common stock, common warrants, or pre-funded warrants, the tax treatment of such partnership and a person treated as a partner of such partnership will generally depend on the status of the partner and the activities of the partnership. Partnerships holding any common stock, common warrants, or pre-funded warrants, and persons that are treated as partners of such partnerships, should consult their tax advisors.

This discussion is based on the Code, Treasury Regulations promulgated under the Code, and judicial and administrative interpretations thereof, all as of the date hereof. U.S. tax law is subject to change, which change could apply retroactively and could affect the tax considerations described herein. We have not and do not intend to seek any ruling from the U.S. Internal Revenue Service (the “IRS”) regarding any U.S. federal income tax considerations described herein. There can be no assurance that the IRS will not take positions inconsistent with the considerations discussed below or that any such positions would not be sustained by a court.

EACH PROSPECTIVE INVESTOR SHOULD CONSULT ITS TAX ADVISOR WITH RESPECT TO THE PARTICULAR TAX CONSEQUENCES TO SUCH PROSPECTIVE INVESTOR OF THE ACQUISITION, OWNERSHIP, AND DISPOSITION OF COMMON STOCK, COMMON WARRANTS, AND PRE-FUNDED WARRANTS, INCLUDING THE EFFECTS OF U.S. FEDERAL, STATE AND LOCAL, AND NON-U.S. TAX LAWS.

CHARACTERIZATION OF COMMON STOCK, COMMON WARRANTS, AND PRE-FUNDED WARRANTS

Allocation of Purchase Price Between Common Stock, Common Warrants, and Pre-Funded Warrants

For U.S. federal income tax purposes, each holder that acquires common stock (or pre-funded warrants) and common warrants pursuant to this offering should allocate the purchase price paid by such holder between the underlying common stock or pre-funded warrant (as applicable) and common warrant based on their relative fair market values at the time of issuance. The amount of purchase price allocated to each share of common stock or pre-funded warrant (as applicable) and each common warrant should establish the applicable holder’s initial tax basis in such share of common stock or pre-funded warrant (as applicable) and such common warrant. We do not intend to advise holders with respect to the relative fair market values of common stock, common warrants, and pre-funded warrants. Each holder is accordingly urged to consult its tax advisor with respect to the allocation of purchase price between common stock, common warrants, and pre-funded warrants.

Characterization of Pre-Funded Warrants

Although the characterization of the pre-funded warrants for U.S. federal income tax purposes is not entirely clear, we intend to take the position that each pre-funded warrant is treated for U.S. federal income tax purposes as a share of our common stock. This is because the exercise price of each pre-funded warrant is a nominal amount equal to \$0.0001. The remainder of this discussion assumes that the characterization of pre-funded warrants described above will be respected for U.S. federal income tax purposes.

U.S. HOLDERS

As used herein, a “U.S. Holder” is a beneficial owner of our common stock, pre-funded warrant, or common warrant (as applicable) that is, for U.S. federal income tax purposes:

- an individual citizen or resident of the United States,
- a corporation (or other entity that is treated as a corporation for U.S. federal income tax purposes) that is created or organized (or treated as created or organized) in or under the laws of the United States or any state thereof or the District of Columbia,
- an estate whose income is subject to U.S. federal income tax regardless of its source, or
- a trust if (1) a U.S. court can exercise primary supervision over the administration of such trust and one or more U.S. persons have the authority to control all substantial decisions of the trust or (2) it has a valid election in place to be treated as a U.S. person.

Distributions on Our Common Stock

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. If we do make distributions with respect to our common stock, a U.S. Holder generally should be required to include in gross income as a dividend the amount of any cash distribution or the fair market value of any other property distributed with respect to shares of our common stock, to the extent the distribution is paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts treated as a dividend that we pay to a U.S. Holder that is a taxable corporation may qualify for a dividends received deduction, provided certain holding period and other requirements are satisfied. Amounts treated as a dividend that we pay to a non-corporate U.S. Holder may be taxed as “qualified dividend income” at preferential tax rates accorded to long-term capital gains, subject to certain exceptions and provided certain holding period and other requirements are satisfied. Distributions in excess of current and accumulated earnings and profits should generally constitute a return of capital that is applied against and that reduces (not below zero) the U.S. Holder’s adjusted tax basis in its shares of our common stock. Any remaining excess should generally be treated as gain realized on the sale or other disposition of our common stock and should generally be treated as described below under “—U.S. Holders—Sale, Exchange, or Other Taxable Disposition of Our Common Stock, Pre-Funded Warrants, or Common Warrants”

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Sale, Exchange, or Other Taxable Disposition of Our Common Stock, Pre-Funded Warrants, or Common Warrants

Upon a sale, exchange, or other taxable disposition of our common stock, pre-funded warrants, or common warrants, a U.S. Holder generally should recognize capital gain or loss equal to the difference between the amount realized on such sale, exchange, or other taxable disposition and the U.S. Holder’s adjusted tax basis in the applicable shares of our common stock, pre-funded warrants, or common warrants. Any such capital gain or loss generally should be long-term capital gain or loss if the U.S. Holder’s holding period for the shares of our common stock, pre-funded warrants, or common warrants so disposed of exceeds one year. Long-term capital gains recognized by non-corporate U.S. Holders may be eligible to be taxed at reduced rates. The deductibility of capital losses is subject to limitations.

Exercise of a Pre-Funded Warrant

As described in “—Characterization of Common Stock, Common Warrants, and Pre-Funded Warrants—Characterization of Pre-Funded Warrants” above, we intend to take the position that each pre-funded warrant is treated for U.S. federal income tax purposes as a share of our common stock. Based on this characterization, a U.S. Holder generally should not recognize taxable gain or loss as a result of the acquisition of shares of our common stock upon exercise of a pre-funded warrant for its nominal exercise price. The U.S. Holder’s tax basis in the share of our common stock received upon exercise of the pre-funded warrant should be an amount equal to the sum of the U.S. Holder’s tax basis in the pre-funded warrant and the nominal exercise price of such pre-funded warrant. The U.S. Holder’s holding period in the share of our common stock received upon exercise of the pre-funded warrant should include the U.S. Holder’s holding period for the pre-funded warrant.

Exercise or Lapse of a Common Warrant

A U.S. Holder generally should not recognize taxable gain or loss as a result of the acquisition of shares of our common stock upon exercise of a common warrant for cash in the amount of its exercise price. The U.S. Holder’s tax basis in the share of our common stock received upon exercise of the common warrant generally should be an amount equal to the sum of the U.S. Holder’s tax basis in the common warrant and the exercise price of such common warrant. It is unclear whether a U.S. Holder’s holding period for the shares of our common stock received upon exercise of the common warrant will commence on the date of exercise of the common warrant or the day following the date of exercise of the common warrant. In either case, the holding period should not include the period during which the U.S. Holder held the common warrant. If a common warrant is allowed to lapse unexercised, a U.S. Holder generally should recognize a capital loss equal to such U.S. Holder’s tax basis in the common warrant. The deductibility of capital losses is subject to limitations.

The U.S. federal income tax treatment of a cashless exercise of common warrants is unclear under current law and could differ from the treatment described above. A cashless exercise could be considered a taxable event. U.S. Holders are urged to consult their own tax advisors regarding the cashless exercise of a common warrant and the U.S. federal income tax treatment thereof.

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Possible Constructive Distributions

The terms of each common warrant provide in certain circumstances for an adjustment to the exercise price of the common warrant or an increase in the shares of our common stock issuable upon exercise. An adjustment made pursuant to a bona fide, reasonable, adjustment formula which has the effect of preventing dilution generally is not taxable. The U.S. Holders of the common warrant would, however, be treated as receiving a constructive distribution from us if, for example, the adjustment increases the U.S. Holder’s proportionate interest in our assets or earnings and profits (e.g., through a decrease to the exercise price or an increase in the number of shares of our common stock that would be obtained upon exercise) as a result of a distribution of cash or other property with respect to shares of our common stock. Such a constructive distribution to a U.S. Holder of common warrant would generally be treated as if such U.S. Holder had received a cash distribution from us in an amount equal to the fair market value of such increased interest, taxed under principles similar to those described in “—U.S. Holders—Distributions on Our Common Stock.” The rules governing constructive distributions as a result of certain adjustments with respect to a common warrant are complex. U.S. Holders are urged to consult their tax advisors on the potential existence and tax consequences of any such constructive distribution with respect to a common warrant.

Information Reporting and Backup Withholding

U.S. backup withholding and information reporting requirements may apply to distributions on our common stock, constructive distributions on common warrants, and the receipt of proceeds from the sale, exchange, or other disposition of our common stock, pre-funded warrants, or common warrants. Backup withholding generally should not apply, however, to a U.S. Holder who furnishes a correct taxpayer identification number and makes other required certifications, or who is otherwise exempt from backup withholding and establishes such exempt status. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a U.S. Holder’s U.S. federal income tax liability, and a U.S. Holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the

appropriate claim for refund with the IRS and furnishing any required information.

NON-U.S. HOLDERS

As used herein, a “non-U.S. Holder” is a beneficial owner of our common stock, pre-funded warrant, or common warrant (as applicable) that, for U.S. federal income tax purposes, is or is treated as an individual, corporation, estate or trust that is not a U.S. Holder.

Distributions on Our Common Stock

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. If we do make distributions with respect to our common stock, any such distribution made to a non-U.S. Holder with respect to our common stock should generally constitute a dividend for U.S. federal income tax purposes to the extent paid out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Provided that any such dividend is not effectively connected with such non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base maintained by such non-U.S. Holder), and subject to the discussion below regarding backup withholding and FATCA (defined below), such dividend should generally be subject to withholding tax from the gross amount of the dividend at a rate of 30%, unless such non-U.S. Holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E, as applicable). Any distribution not constituting a dividend should generally be treated first as reducing (not below zero) the non-U.S. Holder’s adjusted tax basis in our common stock and then, to the extent such distribution exceeds the non-U.S. Holder’s adjusted tax basis, as gain realized from the sale or other disposition of our common stock, which should generally be treated as described below under “—Non-U.S. Holders—Sale, Exchange or Other Taxable Disposition of Our Common Stock, Pre-Funded Warrants, or Common Warrants.”

Dividends paid by us to a non-U.S. Holder that are effectively connected with such non-U.S. Holder’s conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base maintained by such non-U.S. Holder) should generally not be subject to U.S. withholding tax, provided such non-U.S. Holder complies with certain certification and disclosure requirements (usually by providing an IRS Form W-8ECI). Instead, such dividends should generally be subject to U.S. federal income tax, net of certain deductions, at the same graduated individual or corporate rates applicable to U.S. Holders. If the non-U.S. Holder is a corporation, dividends that are effectively connected income may also be subject to a “branch profits tax” at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

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Sale, Exchange, or Other Taxable Disposition of Our Common Stock, Pre-Funded Warrants, or Common Warrants

Subject to the discussion below regarding backup withholding and FATCA, a non-U.S. Holder generally should not be subject to U.S. federal income tax on gain realized from a sale, exchange, or other disposition of our common stock, pre-funded warrants, or common warrants unless:

- (i) such non-U.S. Holder is an individual who was present in the United States for 183 days or more in the taxable year of such disposition and certain other requirements are met, in which case any gain realized will generally be subject to a flat 30% U.S. federal income tax;
- (ii) the gain is effectively connected with a trade or business of such non-U.S. Holder in the United States (and, if required by an applicable income tax treaty, attributable to a U.S. permanent establishment or fixed base maintained by such non-U.S. Holder), in which case such gain will be subject to U.S. federal income tax, net of certain deductions, at the same graduated individual or corporate rates applicable to U.S. Holders, and any such gain of a non-U.S. Holder that is a corporation may be subject to an additional “branch profits tax” at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty); or
- (iii) subject to certain exceptions discussed below, we are or have been a U.S. real property holding corporation (a “USRPHC”) at any time during the shorter of the five-year period preceding such disposition and such non-U.S. Holder’s holding period, in which case (a) gain recognized by such non-U.S. holder on the sale, exchange, or other disposition of our common stock, pre-funded warrants, or common warrants should generally be subject to tax at generally applicable U.S. federal income tax rates and (b) a buyer of our common stock, pre-funded warrants, or common warrants from such non-U.S. Holder may be required to withhold U.S. federal income tax at a rate of 15% of the amount realized upon such disposition.

For purposes of item (iii) immediately above, we will generally be classified as a USRPHC if the fair market value of our “United States real property interests” equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests and our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes. Although there can be no assurance, we believe that we are not currently a USRPHC and we do not anticipate becoming a USRPHC. Even if we are or become a USRPHC, a non-US Holder should generally not be subject to U.S. federal income tax under the rules discussed in item (iii) with respect to gain realized on a sale or other disposition of our common stock if (A) our common stock is considered to be regularly traded on an established securities market and (B) such non-U.S. Holder has not owned and is not deemed to have owned more than 5% of our common stock at any time during the shorter of the five-year period preceding such disposition and such non-U.S. Holder’s holding period. There can be no assurance that shares of our common stock qualify as regularly traded on an established securities market for purposes of these rules.

Exercise of a Pre-Funded Warrant

The U.S. federal income tax treatment of a non-U.S. Holder’s exercise of a pre-funded warrant generally should correspond to the U.S. federal income tax treatment of the exercise of a pre-funded warrant held by a U.S. Holder, as described above under “—U.S. Holders—Exercise of a Pre-Funded Warrant.”

Exercise or Lapse of a Common Warrant

The U.S. federal income tax treatment of a non-U.S. Holder’s exercise of a common warrant generally should correspond to the U.S. federal income tax treatment of the exercise of a common warrant held by a U.S. Holder, as described above under “—U.S. Holders—Exercise or Lapse of a Common Warrant.” If a common warrant is allowed to lapse unexercised, a non-U.S. Holder generally should recognize a loss equal to such non-U.S. Holder’s tax basis in the common warrant. However, subject to additional conditions and restrictions, a non-U.S. Holder generally cannot utilize a loss recognized upon expiration of a common warrant to reduce the non-U.S. Holder’s U.S. federal income tax liability unless the loss is effectively connected with the non-U.S. Holder’s conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a U.S. permanent establishment or fixed base maintained by the non-U.S. Holder) or if the loss is treated as U.S.-source and incurred by a non-U.S. Holder that is an individual during a taxable year in which the non-U.S. Holder is present in the United States for at least 183 days.

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The U.S. federal income tax treatment of a cashless exercise of common warrants is unclear under current law and could differ from the considerations described above. A cashless exercise could be considered a taxable event. Non-U.S. Holders are urged to consult their own tax advisors regarding any cashless exercise of a common warrant and the U.S. federal income tax treatment thereof.

Possible Constructive Distributions

As described above under “—U.S. Holders—Possible Constructive Distributions,” certain adjustments with respect to the common warrants may give rise to a constructive distribution, the consequences of which to a non-U.S. Holder would be similar to those described above under “—Non-U.S. Holders—Distributions on Our Common Stock.”

Information Reporting and Backup Withholding

U.S. backup withholding and information reporting requirements may apply to distributions on our common stock, constructive distributions on common warrants, and the receipt of proceeds from the sale or disposition of our common stock, pre-funded warrants, or common warrants. A non-U.S. Holder may have to comply with certification procedures to establish that it is not a U.S. person for U.S. federal income tax purposes, to otherwise establish an exemption from information reporting and backup withholding requirements, or to claim a reduced rate of withholding under an applicable income tax treaty. Backup withholding is not an additional tax. Amounts withheld as backup withholding may be credited against a non-U.S. Holder’s U.S. federal income tax liability, and a non-U.S. Holder generally may obtain a refund of any excess amounts withheld under the backup withholding rules by timely filing the appropriate claim for refund with the IRS and furnishing any required information.

Foreign Account Tax Compliance Act

Sections 1471 through 1474 of the Code and the Treasury Regulations and administrative guidance promulgated thereunder (commonly referred to as the “Foreign Account Tax Compliance Act” or “FATCA”) generally impose withholding at a rate of 30% in certain circumstances on dividends in respect of securities (including our common stock), and (subject to the proposed Treasury Regulations discussed below) the gross proceeds derived from the sale or other disposition of our common stock, which are held by or through certain foreign financial institutions (including investment funds), unless any such institution (i) enters into, and complies with, an agreement with the IRS to, among other things, comply with specified due diligence, report, on an annual basis, information with respect to interests in, and accounts maintained by, the institution that are owned by certain U.S. persons and by certain non-U.S. entities that are wholly or partially owned by U.S. persons and to withhold on certain payments, or (ii) if allowed under an intergovernmental agreement between the United States and an applicable foreign country, reports such information to its local tax authority, which may exchange such information with the U.S. authorities. An intergovernmental agreement between the United States and an applicable foreign country may modify these requirements. Accordingly, the disclosure of the ownership of the entity through which our securities (including our common stock, pre-funded warrants, and common warrants) is held will affect the determination of whether such withholding and reporting is required. Withholding agents may, however, rely on proposed U.S. Treasury Regulations that would no longer require FATCA withholding on payments of gross proceeds. A withholding agent, and not GT BIOPHARMA, INC., will determine whether or not to implement gross proceeds FATCA withholding. Similarly, dividends in respect of our common stock held by an investor that is a non-financial non-U.S. entity that does not qualify under certain exceptions will generally be subject to withholding at a rate of 30%, unless such entity either (i) certifies to the applicable withholding agent that such entity does not have any “substantial United States owners” or (ii) provides certain information regarding the entity’s “substantial United States owners,” which may in turn be provided to the U.S. Department of Treasury. All holders should consult their tax advisors regarding the possible implications of FATCA on their investment in our common stock, pre-funded warrants, and common warrants.

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PLAN OF DISTRIBUTION

We engaged Roth Capital Partners, LLC (“Roth” or the “placement agent”), to act as our exclusive placement agent to solicit offers to purchase the securities offered by this prospectus on a reasonable best efforts basis subject to the terms and conditions of the placement agency agreement dated _____, 2025. Roth is not purchasing or selling any securities, nor are they required to arrange for the purchase and sale of any specific number or dollar amount of securities, other than to use their “reasonable best efforts” to arrange for the sale of the securities by us. Therefore, we may not sell the entire amount of securities being offered. There is no minimum amount of proceeds that is a condition to closing of this offering. The placement agent does not guarantee that it will be able to raise new capital in this offering. The terms of this offering were subject to market conditions and negotiations between us and prospective investors in consultation with the placement agent. The placement agent will have no authority to bind us. This offering will terminate no later than February 28, 2025, unless we decide to terminate the offering (which we may do at any time in our discretion) prior to that date. We will have one closing for all the securities purchased in this offering. The combined public offering price per share (or pre-funded warrant) and accompanying common warrant will be fixed for the duration of this offering. Roth may engage one or more sub-placement agents or selected dealers to assist with the offering.

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We will enter into a securities purchase agreement directly with the institutional investors, at the investor’s option, who purchase our securities in this offering. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering.

Placement Agent Fees and Expenses

The following table shows the per share and accompanying common warrants, and per pre-funded warrant and accompanying common warrants, and total placement agent fees we will pay in connection with the sale of the securities in this offering.

	Per Share and Common Warrant	Per Pre-Funded Warrant and Common Warrant	Total
Public offering price	\$	\$	\$
Placement Agent fees ⁽¹⁾	\$	\$	\$
Proceeds to us, before expenses ⁽²⁾	\$	\$	\$

(1) Includes a cash fee up to 6% of the gross proceeds raised in this offering; provided, however, the cash fee shall equal 3% of the gross proceeds raised in this offering for securities purchased by certain excluded investors, to be paid to the placement agent. We have also agreed to reimburse the placement agent for certain of its offering-related expenses in an aggregate amount up to \$100,000. In addition, we have agreed to issue the placement agent or its designees warrants to purchase up to _____ shares of common stock (equal to 6% of the aggregate number of shares of common stock and pre-funded warrants sold in this offering, subject to a partial adjustment in the event certain investors participate) at an exercise price of \$ _____ per share, which represents 125% of the public offering price per share of common stock and common warrants. We refer to these warrants in this prospectus as the “placement agent warrants.”

(2) Because there is no minimum number of securities or amount of proceeds required as a condition to closing in this offering, the actual public offering amount, placement agent fees, and proceeds to us, if any, are not presently determinable and may be substantially less than the total maximum offering amounts set forth above.

We estimate that the total expenses of the offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding placement agent fees, will be approximately \$390,531, all of which are payable by us. This figure includes the placement agent’s accountable expenses, including, but not limited to, legal fees for placement agent’s legal counsel, that we have agreed to pay at the closing of the offering up to an aggregate expense reimbursement of \$100,000.

Placement Agent Warrants

In addition, we have agreed to issue to the placement agent, or its designees, warrants to purchase up to 201,680 shares of common stock (equal to 6% of the aggregate number of shares of common stock and pre-funded warrants sold in this offering, subject to a partial adjustment in the event certain investors participate) at an exercise price of \$ _____ per share, which represents 125% of the public offering price per share of common stock and accompanying common warrant, and exercisable for five years from the date of the commencement of sales in this offering. We refer to these warrants in this prospectus as the “placement agent warrants.” The placement agent warrants are in substantially similar form to the common warrants being issued to investors as part of this offering other than as described herein. The placement agent warrants and underlying shares of common stock are registered on the registration statement of which this prospectus is a part. The form of the placement agent warrant will be included as an exhibit to this registration statement of which this prospectus forms a part.

Other Relationships

The placement agent may, from time to time, engage in transactions with or perform services for us in the ordinary course of its business and may continue to receive compensation from us for such services.

Determination of Offering Price

The combined public offering price per share and common warrant and the combined public offering price per pre-funded warrant and common warrant we are offering and the exercise prices and other terms of the warrants were negotiated between us and the investors, in consultation with the placement agent based on the trading of our common stock prior to this offering, among other things. Other factors considered in determining the public offering prices of the securities we are offering and the exercise prices and other terms of the warrants include the history and prospects of our company, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, an assessment of our management, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

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Transfer Agent and Registrar

Our transfer agent and registrar for our capital stock is Computershare. The transfer agent’s address is 8742 Lucent Blvd., Suite 225, Highland Ranch, CO 80129, and its telephone number is (303) 262-0600.

The Nasdaq Capital Market Listing

Our common stock is currently listed on the Nasdaq Stock Market LLC under the symbol “GTBP.” On January 23, 2025, the reported closing price per share of our common stock was \$2.38. The final public offering price will be determined between us, the placement agent and the investors in the offering, and may be at a discount to the current market price of our common stock. Therefore, the assumed public offering price used throughout this prospectus may not be indicative of the final public offering price. There is no established public trading market for the common warrants or pre-funded warrants, and we do not expect such markets to develop. In addition, we do not intend to apply for a listing of the common warrants or pre-funded warrants on any national securities exchange or other nationally recognized trading system.

Indemnification

We have agreed to indemnify the placement agent against certain liabilities, including certain liabilities arising under the Securities Act, or to contribute to payments that the placement agent may be required to make for these liabilities.

Lock-up Restrictions

We have agreed for a period of sixty days following the closing of this offering not to issue, enter into an agreement to issue or announce the issuance or proposed issuance of shares of our common stock or any other securities convertible into, or exercisable or exchangeable for, shares of common stock or file any registration statement or amendment or supplement thereto, subject to limited exceptions. This agreement does not apply to, in addition to certain customary exceptions, the issuance by us of equity or debt securities pursuant to acquisitions or strategic transactions approved by a majority of our disinterested directors, where not for the purpose of raising capital, provided that, in each case, such securities are issued as “restricted securities” (as defined in Rule 144 under the Securities Act), and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the sixty day lock-up period.

We have also agreed for a period of one year following the closing date of this offering not to (i) issue or agree to issue equity or debt securities convertible into, or exercisable or exchangeable for, shares at a conversion price, exercise price or exchange price which floats with the trading price of our shares or which may be adjusted after issuance upon the occurrence of certain events or (ii) enter into any agreement, including an equity line of credit, whereby we may issue securities at a future-determined price, subject to certain conditions and exceptions.

Our directors, executive officers and certain stockholders have also entered into customary lock-up agreements. Under these agreements, these individuals have agreed, subject to specified exceptions, not to sell or transfer any shares of common stock or securities convertible, exchangeable or exercisable into, shares of our common stock during a period ending sixty days after the closing of this offering.

The placement agent may waive these prohibitions in its sole discretion and without notice.

Regulation M

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The placement agent will be required to comply with the requirements of the Securities Act and the Exchange Act of 1934, as amended (the “Exchange Act”), including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the placement agent. Under these rules and regulations, the placement agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

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Electronic Distribution

A prospectus in electronic format may be made available on a website maintained by the placement agent and the placement agent may distribute prospectuses electronically. Other than the prospectus in electronic format, the information on these websites is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the placement agent and should not be relied upon by investors.

The SEC allows us to “incorporate by reference” the information we file with it, which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus. The information incorporated by reference is considered to be part of this prospectus, and because we are a smaller reporting company, later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings (including those made after the initial filing of the registration statement of which this prospectus is a part and prior to the effectiveness of such registration statement) we will make with the SEC under Sections 13(a), 13(c), 14, or 15(d) of the Exchange Act until the termination of the offering of the shares covered by this prospectus (other than information furnished under Item 2.02 or Item 7.01 of Form 8-K):

- our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on [March 26, 2024](#);
- our Quarterly Report on Form 10-Q for the quarter ended March 31, June 30 and September 30, 2024, filed with the SEC on [May 15, 2024](#), [August 14, 2024](#), and [November 14, 2024](#), respectively;
- our definitive proxy statement on Schedule 14A, filed with the SEC on [April 29, 2024](#);
- our Current Reports on Form 8-K filed with the SEC on [February 1, 2024](#), [April 30, 2024](#), [May 23, 2024](#), [June 7, 2024](#), [June 26, 2024](#), [June 27, 2024](#); [September 16, 2024](#), [November 21, 2024](#), [November 27, 2024](#), and [January 27, 2025](#); and
- the description of our common stock contained in [Exhibit 4.3](#) to our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 26, 2024, including any amendment or report filed for the purpose of updating such description.

All documents the Company subsequently filed with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, except as to any portion of any report or documents that is not deemed filed under such provisions, (1) on or after the date of filing of the registration statement containing this prospectus and prior to the effectiveness of the registration statement and (2) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold or the registration statement of which this prospectus is a part has been withdrawn, shall be deemed incorporated by reference in this prospectus and to be a part of this prospectus from the date of filing of those documents and will be automatically updated and, to the extent described above, supersede information contained or incorporated by reference in this prospectus and previously filed documents that are incorporated by reference in this prospectus. Any statements contained in a previously filed document incorporated by reference into this prospectus is deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus, or in a subsequently filed document also incorporated by reference herein, modifies or supersedes that statement.

Nothing in this prospectus shall be deemed to incorporate information furnished but not filed with the SEC pursuant to Item 2.02, 7.01 or 9.01 of Form 8-K.

Upon written or oral request, we will provide without charge to each person to whom a copy of the prospectus is delivered a copy of the documents incorporated by reference herein (other than exhibits to such documents, unless such exhibits are specifically incorporated by reference herein). You may request a copy of these filings, at no cost, by contacting GT Biopharma, Inc.

We maintain a website at <https://ir.gtbiopharma.com>. You may access our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and other reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act with the SEC free of charge at our website as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC.

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There have been no material changes to the Company’s affairs that have occurred since December 31, 2023 that have not been described in a Form 10-Q or Form 8-K filed under the Exchange Act.

WHERE YOU CAN FIND MORE INFORMATION

We have filed a registration statement on Form S-1 under the Securities Act with the SEC with respect to this offering. This prospectus was filed as a part of that registration statement but does not contain all of the information contained in the registration statement and exhibits. Reference is thus made to the omitted information. Statements made in this prospectus are summaries of the material terms of contracts, agreements and documents and are not necessarily complete; however, all information we considered material has been disclosed. Reference is made to each exhibit for a more complete description of the matters involved and these statements are qualified in their entirety by the reference. You can find, copy and inspect information we file at the SEC’s public reference room, which is located at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the SEC’s public reference room. The SEC also maintains a web site (<http://www.sec.gov>) that contains this filed registration statement, reports and other information regarding us that we have filed electronically with the SEC. For more information pertaining to our company and this offering, reference is made to the registration statement.

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by Baker & McKenzie LLP, Dallas, Texas. The placement agent is being represented by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The financial statements of GT Biopharma, Inc. at December 31, 2023, and for the year in the period ending December 31, 2023, incorporated by reference into this prospectus, have been audited by Weinberg & Company, P.A., an independent registered public accounting firm, and the financial statements of GT Biopharma, Inc. at December 31, 2023, and for the year in the period ending December 31, 2023, incorporated by reference into this prospectus, have been audited by Weinberg & Company, P.A., each as set forth in their report thereon incorporated by reference herein, and are included in reliance upon such reports given on the authority of such firms as experts in accounting and auditing.

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Up to 3,361,344 Shares of Common Stock

Up to 3,361,344 Pre-Funded Warrants to Purchase up to 3,361,344 Shares of Common Stock

Up to 3,361,344 Common Warrants to Purchase up to 3,361,344 Shares of Common Stock

Up to 201,680 Placement Agent Warrants to Purchase up to 201,680 Shares of Common Stock

Up to 6,924,368 Shares of Common Stock underlying up to 3,361,344 Pre-Funded Warrants,

up to 3,361,344 Common Warrants and up to 201,680 Placement Agent Warrants



PRELIMINARY PROSPECTUS

Roth Capital Partners

The date of this prospectus is _____, 2025.

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PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distributions

The following table indicates the expenses to be incurred in connection with the offering described in this registration statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimated except the Securities and Exchange Commission registration fee.

SEC registration fee	\$	2,541
FINRA filing fee	\$	2,990
Accounting fees and expenses	\$	35,000
Legal fees and expenses	\$	350,000
Miscellaneous	\$	*
Total	\$	<u>390,531</u>

Item 14. Indemnification of Directors and Officers

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

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

Item 15. Recent Sales of Unregistered Securities

Since December 2021, the Company made the following issuances of its unregistered securities pursuant exemptions contained in Section 4(a)(2) or 3(a)(9) of the Securities Act and/or Rule 506 of Regulation D promulgated thereunder:

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- On August 24, 2022, the Company entered into a revised agreement with this third-party manufacturer and issued 40,742 shares of common stock with a fair value of approximately \$3.2 million as part of a payment arrangement.
- During the year ended December 31, 2022, the Company issued 11,257 shares of common stock upon conversion of notes payable.
- During the year ended December 31, 2022, the Company issued 23,654 shares of common stock to officers, employees, and board of directors with a fair value of approximate \$2.5 million. This included 12,602 shares with a fair value of \$938,000 that were granted during the year.
- During the year ended December 31, 2022, the Company issued 17,562 shares of common stock to consultants with a fair value of approximately \$2.1 million.
- During the year ended December 31, 2022, the Company issued 57,437 shares of common stock to settle approximately \$700,000 of vendor payables.
- During the year ended December 31, 2023, the Company issued 14,237 shares of common stock to officers, employees, and board of directors with a fair value of approximate \$267,000. This included 13,333 shares with a fair value of \$115,000 that were granted during the year.
- During the year ended December 31, 2023, the Company issued 1,545 shares of common stock to consultants with a fair value of approximately \$162,000.
- On January 4, 2023, the Company entered into a purchase agreement signed on December 30, 2022, between the Company and an institutional investor for the issuance and sale, in a registered direct offering of 120,000 shares of the Company's common stock, pre-funded warrants to purchase up to 96,667 shares of the Company's common stock, warrants to purchase up to an aggregate of 216,667 shares of the Company's common stock and placement agent warrants to purchase up to 13,000 of the Company's common stock. The Company raised \$6.5 million from the offering.
- On April 30, 2024, the Company issued 36,018 shares of common stock to settle \$278,500 of vendor accounts payable. The shares were valued at the month-end closing price of the Company's common stock for the months for which services were provided by the vendor.
- On May 23, 2024, the Company issued 740,000 common warrants, each to purchase one share of common stock at an exercise price equal to \$4.35 and are exercisable immediately upon issuance and will expire on the date that is five years following the date of issuance.

- On May 23, 2024, the Company issued placement agent warrants to the placement agent to purchase up to 88,800 shares of common stock as part of the compensation payable to the placement agent in connection with such offering at an exercise price of \$5.4375 per share and will expire five years from the commencement of sales of the offering.
- On June 30, 2024, the Company issued 91,579 shares of common stock to settle \$531,300 of vendor accounts payable. The shares were valued at the month-end closing price of the Company's common stock for the months for which services were provided by the vendor.
- Since December 2021, we have issued 29,935 shares of common stock with a fair value of approximately \$1,053,000 in connection with compensation of the Company's officers and directors.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

Exhibit Index

Exhibit Number	Exhibit Description	Form	Date	Number	File No.	Filed Herewith
3.1	Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002	10-KSB	04/01/02	3.A		
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., dated February 9, 2011	10-K	03/31/2011	3.2		
3.3	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of July 19, 2017	8-K/A	03/15/2018	3.1		
3.4	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of February 10, 2021	8-K	02/11/2021	3.1		
3.5	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective June 13, 2022	10-K	03/30/2023	3.5		
3.6	Amended and Restated Bylaws of GT Biopharma, Inc., effective November 3, 2022	8-K	11/09/2022	3.1		
3.7	Certificate of Amendment of Restated Certificate of Incorporation of GT Biopharma, Inc., effective February 1, 2024	8-K	02/01/2024	3.1		
4.1	Certificate of Designation of Preferences, Rights and Limitations of Series J-1 Preferred Stock of GT Biopharma, Inc., dated April 3, 2019	8-K	04/04/2019	3.1		
4.2	Certificate of Designation of Preferences, Rights and Limitations of Series K Preferred Stock of GT Biopharma, Inc., dated February 22, 2021	10-K	04/16/2021	4.2		
4.3	Description of the Registrant's Securities Registered pursuant to Section 12 of the Securities Exchange Act of 1934, as Amended	10-K	03/30/2023	4.3		
4.4	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/2017	10.2		
4.5	Form of Common Stock Purchase Warrant (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/2017	10.3		
4.6	Registration Rights Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	01/23/2018	10.2		
4.7	Form of Senior Convertible Note (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	01/23/2018	10.3		
4.8	Form of Warrant to Purchase Common Stock (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	01/23/2018	10.4		
4.9	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated August 2, 2018)	8-K	08/03/2018	4.1		
4.10	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 7, 2018)	8-K	09/07/2018	4.1		
4.11	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 24, 2018)	8-K	09/28/2018	4.1		

Exhibit Number	Exhibit Description	Form	Date	Number	File No.	Filed Herewith
4.12	Form of Secured Convertible Note (related to Securities Purchase Agreement, dated February 4, 2019)	8-K	02/06/2019	4.1		
4.13	Registration Rights Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/2019	10.2		
4.14	Form of Convertible Note (related to Securities Purchase Agreement, dated August 20, 2019)	8-K	05/24/2019	4.1		
4.15	Registration Rights Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/20/2019	10.2		
4.16	Form of Convertible Note (related to Securities Purchase Agreement, dated May 22, 2019)	8-K	05/24/2019	4.1		
4.17	Registration Rights Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/2020	10.2		
4.18	Registration Rights Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/2020	10.2		
4.19	Form of Convertible Note (related to Securities Purchase Agreement, dated January 30, 2020)	10-Q	05/15/2020	10.3		
4.20	Form of Registration Rights Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/2020	10.5		

4.21	Form of Convertible Note (related to Securities Purchase Agreement executed in April/May 2020)	10-Q	05/15/2020	10.6	
4.22	Registration Rights Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/2020	10.3	
4.23	Form of Convertible Note (related to Securities Purchase Agreement, dated July 7, 2020)	8-K	07/09/2020	4.1	
4.24	Form of Convertible Note, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020).	8-K	06/19/2020	10.2	
4.25	Form of Pre-Funded Warrant to Purchase Common Stock, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020).	8-K	06/19/2020	10.3	
4.26	Form of Convertible Note (related to Securities Purchase Agreement, dated September 16, 2020)	8-K	09/22/2020	4.1	
4.27	Form of Secured Convertible Note	8-K	11/09/2020	4.1	
4.28	Form of Settlement Note, dated November 9, 2020.	10-Q	11/13/2020	10.20	
4.29	Settlement Note, dated December 22, 2020, by GT Biopharma Inc. payable to Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B.	8-K	12/28/2020	10.2	
4.30	Form of Amendment to Convertible Note, dated January 31, 2021	8-K	02/01/2020	10.2	
4.31	Form of Common Warrant	8-K	01/03/2023	4.1	
4.32	Form of Pre-Funded Warrant	8-K	01/03/2023	4.2	
4.33	Form of Placement Agent Warrant	8-K	01/03/2023	4.3	
4.34	Form of Common Warrant	8-K	05/23/2024	4.1	
4.35	Form of Common Warrant	S-1/A	01/27/2025	4.35	
4.36	Form of Pre-Funded Warrant	S-1/A	01/27/2025	4.36	
4.37	Form of Placement Agent Warrant	S-1/A	01/27/2025	4.37	
4.38	GT Biopharma, Inc. 2022 Omnibus Incentive Plan	DEF 14A	04/29/2022		
5.1	Opinion of Baker & McKenzie LLP	S-1		5.1	X
10.1	Exclusive License Agreement, dated July 18, 2016, between the Regents of the University of Minnesota and Oxis Biotech, Inc.	10-Q	08/11/2017	10.3	
10.2	License Agreement, dated September 3, 2015, among Daniel A. Vallera, Jeffrey Lion and Oxis Biotech, Inc.	10-Q	08/11/2017	10.4	
10.3	Clinical Trial Agreement, dated September 2019, between the Regents of the University of Minnesota and GT Biopharma, Inc.	10-Q	05/15/2020	10.7	

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Exhibit Number	Exhibit Description	Form	Date	Number	File No.	Filed Herewith
10.4	Securities Purchase Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/2020	10.1		
10.5	Form Securities Purchase Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/2020	10.4		
10.6	Securities Purchase Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/2020	10.1		
10.7	Form of Standstill and Forbearance Agreement, dated June 23, 2020, between the Company and certain holders of convertible notes and debentures	8-K	06/23/2020	10.1		
10.8	Settlement Agreement, dated June 19, 2020, among GT Biopharma, Inc., Empery Asset Master Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, Anthony Cataldo and Paul Kessler.	8-K	06/19/2020	10.1		
10.9	Executive Employment Agreement, dated October 19, 2018, among GT Biopharma, Inc. and Raymond W. Urbanski	10-Q	11/14/2018	10.17		
10.10	Consultant Agreement, dated February 14, 2018, among GT Biopharma, Inc., Georgetown Translational Pharmaceuticals, Inc. and Anthony J. Cataldo	8-K	02/21/2018	10.3		
10.11	Employment agreement with Anthony Cataldo	10-Q	08/14/2020	10.11		
10.12	Employment agreement with Steven Weldon	10-Q	08/14/2020	10.12		
10.13	Securities Purchase Agreement, dated September 16, 2020, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/22/2020	10.1		
10.14	Master Services Agreement, dated October 5, 2020, between Gt Biopharma, Inc. and Cytovance Biologics, Inc.	8-K	10/06/2020	10.1		
10.15	Form of First Amendment and Extension of Standstill and Forbearance Agreement	8-K	11/04/2020	10.1		
10.16	Securities Purchase Agreement	8-K	11/09/2020	10.1		
10.17	Settlement Agreement, dated as of November 9, 2020, by and among Adam Kasower, East Ventures, Inc., A British Virgin Islands company, SV Booth Investments III, LLC, a Delaware limited liability company and Theorem Group, LLC, a California LLC and GT Biopharma Inc., a Delaware corporation.	10-Q	11/13/2020	10.21		
10.18	Steve Weldon Letter of Resignation, dated November 11, 2020	10-Q	11/13/2020	10.22		
10.19	Board Service Agreement with Bruce Wendel, dated November 11, 2020	10-Q	11/13/2020	10.23		
10.20	Board Service Agreement with Greg Berk, dated November 11, 2020	10-Q	11/13/2020	10.24		
10.21	Consultant Agreement with Michael Handelman, dated November 13, 2020	10-Q	11/13/2020	10.1		
10.22	Form of Amendment to Convertible Note & Standstill Agreement	8-K	12/23/2020	10.1		
10.23	Settlement Agreement, dated as of December 22, 2020, by and among Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B, Anthony Cataldo, Paul Kessler and GT Biopharma Inc., a Delaware corporation.	8-K	12/28/2020	10.1		
10.24	Form of Second Amendment and Extension of Standstill and Forbearance Agreement.	8-K	02/01/2020	10.1		
10.25	Board Service Agreement with Rajesh Shrotriya, dated January 12, 2021.	S-1/A	02/08/2021	10.69		

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Exhibit Number	Exhibit Description	Form	Date	Number	File No.	Filed Herewith
10.26	Board Service Agreement with Michael Breen, dated January 12, 2021.	S-1/A	02/08/2021	10.70		

10.27	Amendment to Settlement Note with Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B.	S-1/A	02/08/2021	10.71	
10.28	Form of Securities Purchase Agreement - December 2020 / January 2021 Notes	S-1/A	02/08/2021	10.72	
10.29	Form of December 2020 / January 2021 Note	S-1/A	02/08/2021	10.73	
10.30	Amended and Restated Employment Agreement with Anthony Cataldo, dated April 23, 2021.	10-Q	05/17/2021	10.1	
10.31	Amended and Restated Employment Agreement with Michael Handelman, dated April 23, 2021.	10-Q	05/17/2021	10.2	
10.32	Amended and Restated Employment Agreement with Dr. Gregory Berk, dated April 23, 2021	10-Q	05/17/2021	10.3	
10.33	Exclusive License Agreement with Regents of the University of Minnesota, dated March 26, 2021	10-K	03/28/2022	10.73	
10.34	Research Agreement with Regents of the University of Minnesota, dated June 16, 2021.	10-K	03/28/2022	10.74	
10.35	Sublease Agreement dated November, 2021, between Aimmune Therapeutics, Inc. (Sublandlord) and GT Biopharma, Inc. (Subtenant)	10-K	03/28/2022	10.75	
10.36	Employment Agreement with Michael Breen, entered into as of December 31, 2021 with an effective date of November 8, 2021	10-K	03/28/2022	10.76	
10.37	Amendment No. 1 to Employment Agreement with Michael Breen, dated as of June 17, 2022.	10-K	03/26/2024	10.77	
10.38	Amendment No. 2 to Services Agreement with Michael Breen, dated as of February 20, 2023.	10-K	03/26/2024	10.78	
10.39	Board Service Agreement with Michael Breen dated November 11, 2020	10-Q	05/16/2022	10.1	
10.40	Employment Agreement with Manu Ohri dated May 15, 2022	10-Q	05/16/2022	10.2	
10.41	Amendment No. 1 to Employment Agreement with Manu Ohri, dated as of February 17, 2023	10-K	03/26/2024	10.81	
10.42	Settlement and Investment Agreement dated August 24, 2022, by and between GT Biopharma, Inc. and Cytovance Biologics, Inc.	10-Q	10/31/2022	10.1	
10.43	Form of Securities Purchase Agreement, dated December 2022, by and between GT Biopharma, Inc. and the purchasers named therein.	8-K	01/03/2023	10.1	
10.44	Amendment No. 1 to Settlement and Investment Agreement, dated as of April 25, 2024, by and between GT Biopharma, Inc. and Cytovance Biologics, Inc.	8-K	04/30/2024	10.1	
10.45	Amended and Restated Exclusive Patent License Agreement with the Regents of the University of Minnesota, dated May 13, 2024	10-Q	04/30/2024	10.2	
10.46	Sponsored Research Agreement with the Regents of the University of Minnesota dated May 20, 2024	10-Q	04/30/2024	10.3	
10.47	Form of Securities Purchase Agreement	8-K	05/23/2024	10.1	
10.48	Form of Placement Agency Agreement	8-K	05/23/2024	10.2	
10.49	Code of Ethics	10-K	03/31/2015	14.1	
10.50	Investigator Initiated Clinical Trial Agreement	8-K	11/18/2024	10.1	
10.51	Form of Securities Purchase Agreement	S-1/A	01/27/2025	10.51	
10.52	Form of Placement Agency Agreement	S-1/A	01/27/2025	10.52	
10.53	Employment Agreement between the Company and Alan Urban, dated as of June 7, 2024	8-K	06/07/2024	10.1	
21.1	Subsidiaries of GT Biopharma, Inc.	10-K	03/31/2015	21.1	
23.1	Consent of Weinberg & Company				X

Exhibit Number	Exhibit Description	Form	Date	Number	File No.	Filed Herewith
23.2	Consent of Baker McKenzie LLP (incl. in Exhibit 5.1)					X
24.1	Power of Attorney (included on signature page of the initial filing).	S-1	12/23/2024	24.1		
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X
107	Filing Fee Table	S-1	01/27/2025	107		

† Confidential treatment granted from the Securities and Exchange Commission as to certain portions, which portions have been omitted and filed separately with the Securities and Exchange Commission.

+ Schedules have been omitted pursuant to Item 601(b)(2) of Regulation S-K. GT Biopharma, Inc. will furnish copies of any such schedules to the Securities and Exchange Commission upon request.

** To be filed by amendment.

Item 17. Undertakings

(1) The undersigned registrant hereby undertakes:

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

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

ii. To reflect in the prospectus any facts or events arising after the effective date of 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 SEC pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

- iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement; provided, however, that paragraphs (1)(i), (1)(ii) and (1)(iii) above do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

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- b. That, for the purpose of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.
- c. 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.
- d. That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.
- e. That, for the purpose of determining liability of the registrant under the Securities Act to any purchaser in the initial distribution of the securities, the undersigned registrant hereby 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 (§ 230.424 of this chapter);A
 - 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.
- (2) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to Section 13(a) or Section 15(d) of the Exchange Act (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Exchange Act) that is incorporated by reference in the registration statement 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.

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- (3) The undersigned registrant hereby undertakes that:
- a. 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 on Rule 430A and contained in a form of prospectus filed by the undersigned 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; and
 - b. 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.
- (4) Insofar as indemnification for liabilities arising under the Securities Act 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 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 and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Los Angeles, State of California, on February 7, 2025.

GT Biopharma Inc.

Date: February 7, 2025

By: /s/ Michael Breen*
Michael Breen
Interim Chief Executive Officer

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 dates indicated below.

/s/ Michael Breen *
Michael Breen, Executive Chairman of the Board and
Interim Chief Executive Officer
February 7, 2025

/s/ Alan Urban
Alan Urban, Chief Financial Officer
February 7, 2025

/s/ Bruce Wendel*
Bruce Wendel, Vice Chairman of the Board
February 7, 2025

/s/ Rajesh Shrotriva*
Rajesh Shrotriva, Director
February 7, 2025

/s/ Charles J. Casamento*
Charles J. Casamento, Director
February 7, 2025

*By /s/ Alan Urban
Alan Urban,
Attorney-in-fact


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 Washington, DC
 * Associated Firm

** In cooperation with Trench, Rossi e Watanabe Advo

February 7, 2025

GT Biopharma, Inc.
 315 Montgomery Street, 10th Floor
 San Francisco, CA 94104

Ladies and Gentlemen:

We have acted as counsel to GT Biopharma, Inc., a Delaware corporation (the “Company”), in connection with its filing with the Securities and Exchange Commission (the “SEC”) of a registration statement on Form S-1 (File Number 333-284032) (the “Registration Statement”) under the Securities Act of 1933, as amended (the “Securities Act”) including a related prospectus filed with the Registration Statement (the “Prospectus”), with respect to the offering and resale by the Company of (i) up to 3,361,344 shares of common stock, par value \$0.001 (the “Common Stock”) per share (the “Shares”), (ii) up to 3,361,344 pre-funded warrants exercisable for one share of common stock at an exercise price of \$0.0001 per share (the “Pre-Funded Warrants”), with each Pre-Funded Warrant to be sold reducing the number of Shares to be sold on a one-for-one basis, (iii) up to 3,361,344 common warrants to purchase 3,361,344 shares of the Company’s common stock (the “Common Warrants”), (iv) up to 201,680 warrants to Roth Capital Partners, LLC as placement agent (the “Placement Agent”) to purchase up to 201,680 shares of common stock at an exercise price equal to 125% of the public offering price of the Shares for a five-year term (the “Placement Agents Warrants,” and together with the Pre-Funded Warrants and the Common Warrants, the “Warrants”), and (v) up to 6,924,368 shares of Common Stock issuable from time to time upon the exercise of the Warrants (the “Warrant Shares”).

In connection therewith, we have examined originals or copies certified or otherwise identified to our satisfaction of (i) the Registration Statement, (ii) the Prospectus, (iii) the form of securities purchase agreement filed as exhibit 10.51 to the Registration Statement, (iv) the form of placement agent agreement filed as exhibit 10.52 to the Registration Statement, (v) the Restated Certificate of Incorporation of the Company, as amended and supplemented to date, (vi) the restated Bylaws of the Company, as amended to date, (vii) the form of Common Warrant, form of Pre-Funded Warrant and form of Placement Agent Warrant filed as exhibits 4.35, 4.36 and 4.37, respectively, to the Registration Statement (viii) such other corporate records, agreements, documents and instruments and certificates or comparable documents of public officials and officers and representatives of the Company as we have deemed necessary or appropriate for the expression of the opinions contained herein. As to any facts material to our opinion, we have made no independent investigation of such facts and have relied, to the extent that we deem such reliance proper, upon certificates of public officials and officers or other representatives of the Company.

In rendering the opinions contained herein, we have assumed (i) the truthfulness of all information contained in all of the documents reviewed by us, (ii) the genuineness of all signatures on all documents examined by us, (iii) the legal capacity of all natural persons signing such documents, (iv) the due authority of all parties signing such documents, (v) the authenticity of all documents submitted to us as originals, and (vi) the conformity to the originals of all documents submitted to us as copies.

Based upon and subject to the foregoing, we are of the opinion that:

1. The Shares have been duly and validly authorized and, when sold in accordance with the Registration Statement and the Prospectus, will be validly issued, fully paid and non-assessable.
2. The Warrants have been duly authorized and, when the Warrants have been duly executed and delivered by the Company, and when paid for by the purchasers in accordance with the terms of the Prospectus and the securities purchase agreement, will constitute the legal, valid and binding obligations of the Company, enforceable against the Company in accordance with their terms.
3. With respect to the Warrant Shares that may be issued from time to time upon the exercise of the Warrants, when issued and paid for upon the exercise of the Warrants in accordance with their respective terms, such Warrant Shares will be duly and validly authorized and will be validly issued, fully paid and non-assessable.



The opinions expressed above are limited to the General Corporation Law of the State of Delaware and the federal laws of the United States of America. We do not purport to cover herein the application of the securities or "Blue Sky" laws of the various states.

This opinion letter is limited to the matters stated herein, and no opinion is implied or may be inferred beyond the matters expressly stated. We hereby consent to the use of our opinion as herein set forth as an exhibit to the Registration Statement and to the use of our name under the caption "Legal Matters" in the prospectus forming a part of the Registration Statement. In giving this consent, we do not hereby admit that we come within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the SEC promulgated thereunder or Item 509 of Regulation S-K.

Very truly yours,

/s/ Baker & McKenzie LLP
BAKER & MCKENZIE LLP

Consent of Independent Registered Public Accounting Firm

We hereby consent to the incorporation by reference in the foregoing Amendment No. 2 to the Registration Statement on Form S-1 (File No. 333-284032) of our report dated March 26, 2024, relating to the consolidated financial statements of GT Biopharma, Inc. and Subsidiaries as of December 31, 2023 and 2022 which appear in GT Biopharma, Inc.'s Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the Securities and Exchange Commission on March 26, 2024. We also consent to the reference to our firm under the caption "Experts" in such Registration Statement and related Prospectus.

/s/ Weinberg & Company, P.A.

Los Angeles, California
February 7, 2025
