0001493152-24-051873S-1 GT Biopharma, Inc. 2024122320241223172343172344172344 0 0001493152-24-051873 S-1 11 20241223 20241223 GT Biopharma, Inc. 0000109657 2834 941620407 DE 1231 S-1 33 333-284032 241574961 315 MONTGOMERY STREET 10TH FLOOR SAN FRANCISCO CA 94104 (800) 304-9888 315 MONTGOMERY STREET 10TH FLOOR SAN FRANCISCO CA 94104 OXIS INTERNATIONAL INC 19940916 DDI PHARMACEUTICALS INC 19920703 DIAGNOSTIC DATA INC /DE/ 19850312 S-1 1 forms-1.htm Â As filed with the Securities and Exchange Commission on December 23, 2024. Registration No. 333- Â Â Â UNITED STATES SECURITIES AND EXCHANGE COMMISSION WASHINGTON, D.C. 20549 Â Â FORM S-1 REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933 Â Â Â GT BIOPHARMA, INC. (Exact Name of Registrant as Specified in Its Charter) Â Â Â Delaware Â 2834 Â 94-1620407 (State or Other Jurisdiction of Incorporation or Organization) Â (Primary Standard Industrial Classification Code Number) Â (I.R.S. Employer Identification Number) Â 315 Montgomery Street, 10th Floor San Francisco, CA 94104 (415) 919-4040 (Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrantâ€™s Principal Executive Offices) Â Â Â Michael Breen Interim Chief Executive Officer 315 Montgomery Street, 10th Floor San Francisco, CA 94104 Â (415) 919-4040 (Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service) Copies to: Â Â Â Roger W. Bivans Baker & McKenzie LLP 1900 N. Pearl Street, Suite 1500 Dallas, TX 75201, USA (214) 978 3000 Â Charles Phillips Ellenoff Grossman & Schole LLP 1345 Avenue of Americas New York, NY (212) 370 1300 Â Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement. Â 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. â˜’ Â 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. â˜ Â 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. â˜ Â 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. â˜ Â 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 â€œlarge accelerated filer,â€ â€œaccelerated filer,â€ â€œsmaller reporting companyâ€ and â€œemerging growth companyâ€ in Rule 12b-2 of the Exchange Act. Â Large Accelerated filer â˜ Accelerated filer â˜ Â Â Â Â Non-accelerated filer â˜’ Smaller reporting company â˜’ Â Â Â Â Â Â Emerging growth company â˜ Â 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. â˜ Â 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. Â Â Â Â Â Â 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. Â SUBJECT TO COMPLETION DATED DECEMBER 23, 2024 Â PRELIMINARY PROSPECTUS Â Up to Â Â Â Â Â Â Â Â Shares of Common Stock Pre-Funded Warrants to Purchase up to Â Â Â Â Â Â Â Â Shares of Common Stock Common Warrants to Purchase up to Â Â Â Â Â Â Â Â Shares of Common Stock Placement Agent Warrants to Purchase up to Â Â Â Â Â Â Â Â Shares of Common Stock Up to Â Â Â Â Â Â Â Â Shares of Common Stock underlying Pre-Funded Warrants, Common Warrants and Placement Agent Warrants Â Â This is a reasonable best efforts public offering of up to Â Â Â Â Â Â Â Â shares (the â€œsharesâ€) of our common stock, par value $0.001 per share (â€œcommon stockâ€) together with up to Â Â Â Â Â Â Â Â common warrants to purchase up to Â Â Â Â Â Â Â Â shares of common stock at an assumed combined public offering price of $Â Â Â Â Â Â Â Â per share and common warrant (the last reported sale price per share of our common stock on the Nasdaq Capital Market, on Â Â Â Â Â Â Â Â Â Â). 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. This prospectus also covers the shares of common stock issuable from time to time upon the exercise of the common warrants. See â€œDescription of Securities we are Offering â€“ Common Warrants.â€ Â 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 â€œDescription of Securities we are Offering â€“ Pre-Funded Warrants.â€ Â Â Â Â 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 â€œPlan of Distributionâ€ on page 29 of this prospectus for more information regarding these arrangements. This offering will terminate no later than Â Â Â Â Â Â Â Â , 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 (â€œDVPâ€)/receipt versus payment (â€œRVPâ€). 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. Â Our common stock is listed on the Nasdaq Capital Market under the symbol â€œGTBP.â€ On December 20, 2024, the last reported sale price of our common stock on the Nasdaq Capital Market was $1.75 per share. All share, common warrant and pre-funded warrant numbers are based on an assumed combined public offering price of $Â Â Â Â Â Â Â Â 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. Â You should read this prospectus, together with additional information described under the headings â€œIncorporation of Certain Information By Referenceâ€ and â€œWhere You Can Find More Information,â€ carefully before you invest in any of our securities. Â Investing in our securities involves a high degree of risk. See the section entitled â€œRisk Factorsâ€ 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. Â Â Â Â Per Share and Common WarrantÂ Â Â Per Common Pre-Funded Warrant and -Funded WarrantÂ Â Â TotalÂ Public offering priceÂ $Â Â Â Â Â Â Â Â Â Â $Â Â Â Â Â Â Â Â Â Â Â $Â Â Â Â Â Â Â Â Â Â Placement Agent fees(1)Â $Â Â $Â Â Â $Â Â Proceeds to us, before expenses(2)Â $Â Â $Â Â Â $Â Â Â Â (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 Â Â Â Â Â Â Â Â shares of common stock (equal to 6% of the aggregate number of securities sold in this offering, subject to a partial adjustment in the event certain investors participate) at an exercise price of $Â Â Â Â Â Â Â Â 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 â€œplacement agent warrants.â€ See â€œPlan of Distributionâ€ for a complete description of the compensation to be received by the placement agent. Â Â Â (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 $Â Â Â Â Â Â Â Â . Â 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 Â Â Â Â Â Â Â Â , 2025, subject to the satisfaction of customary closing conditions. Â 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. Â Roth Capital Partners Â The date of this prospectus is Â Â Â Â Â Â Â Â , 2024. Â Â Â Â TABLE OF CONTENTS Â Â Page ABOUT THIS PROSPECTUS 1 CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS 2 PROSPECTUS SUMMARY 3 THE OFFERING 8 RISK FACTORS 9 USE OF PROCEEDS 15 CAPITALIZATION 15 DILUTION 16 DESCRIPTION OF CAPITAL STOCK 17 description of securities we are offering 20 MATERIAL TAX CONSIDERATIONS 23 PLAN OF DISTRIBUTION 29 Incorporation of certain information by reference 32 WHERE YOU CAN FIND MORE INFORMATION 33 LEGAL MATTERS 33 EXPERTS 33 Â i Â Â ABOUT THIS PROSPECTUS Â We incorporate by reference important information into this prospectus. You may obtain the information incorporated by reference without charge by following the instructions under â€œWhere You Can Find More Information.â€ You should carefully read this prospectus as well as additional information described under â€œIncorporation of Certain Information by Reference,â€ before deciding to invest in our securities. Â 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. Â 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. Â 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. Â 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 Â® 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 companiesâ€™ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other company. Â 1 Â Â CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS Â Some of the statements in this prospectus are â€œforward-looking statementsâ€ 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 â€œbelieve,â€ â€œexpect,â€ â€œanticipate,â€ â€œintend,â€ â€œplan,â€ â€œforesee,â€ â€œmay,â€ â€œguidance,â€ â€œestimate,â€ â€œpotential,â€ â€œoutlook,â€ â€œtarget,â€ â€œforecast,â€ â€œlikelyâ€ or other similar words or phrases. Similarly, statements that describe our objectives, plans or goals are, or may be, forward-looking statements. Â 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: Â Â â— our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical trials; Â Â Â Â â— our financial condition raises substantial doubt as to our ability to continue as a going concern; Â Â Â Â â— our financial performance and our ability to effectively manage our anticipated growth; Â Â Â Â â— 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; Â Â Â Â â— the impact of laws and regulations; Â Â Â Â â— general economic conditions; Â Â Â Â â— 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; Â Â Â Â â— the timing, scope and likelihood of regulatory filings and approvals; Â Â Â Â â— our continued reliance on third parties to conduct additional clinical trials of our product candidates; Â Â Â Â â— our manufacturing, commercialization, and marketing capabilities and strategy; Â Â Â Â â— 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; Â Â Â Â â— the rate and degree of market acceptance and clinical utility of our product candidates we may develop; Â Â â— our ability to hire additional qualified personnel and attract and retain key employees; and Â Â Â Â â— the result of any future financing efforts; and Â Â Â Â â— our failure to maintain compliance with the Nasdaq Capital Marketâ€™s (â€œNasdaqâ€) continued listing requirements could result in the delisting of our common stock. Â 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 â€œRisk Factorsâ€ 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. Â 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. Â 2 Â Â Â PROSPECTUS SUMMARY Â 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 â€œRisk Factorsâ€ 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 â€œGTBP,â€ â€œthe Company,â€ â€œwe,â€ â€œusâ€ and â€œourâ€ 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. Â Overview Â 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 (TriKEÂ®), and Tetra-specific Killer Engager (Dual Targeting TriKEÂ®) fusion protein immune cell engager technology platforms. Our TriKEÂ® and Dual Targeting TriKEÂ® platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patientâ€™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 cellâ€™s death. TriKEÂ®s can be designed to target any number of tumor antigens on hematologic malignancies or solid tumors and do not require patient-specific customization. Â We are using our TriKEÂ® 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 TriKEÂ® 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 TriKEÂ®s may have the ability, if approved for marketing, to be used as both monotherapy and in combination with other standard-of-care therapies. Â 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 TriKEÂ® platform and are generating additional intellectual property for specific moieties. Â Product Pipeline Â Our current product candidate pipeline is summarized in the table below Â Â Â 3 Â Â Â GTB-3550 Â GTB-3550 was our first TriKEÂ® product candidate and its clinical development was suspended so that we could focus resources on second-generation TriKEsÂ®. GTB-3550 is a tri-specific killer engager (TriKE) comprised of two single-chain variable fragments (â€œscFvâ€) 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 TriKEÂ® 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. Â GTB-3550 was replaced by a more potent next-generation camelid nanobody TriKEÂ®, 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 TriKEsÂ® 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 TriKEÂ® platform. Â Â Â 4 Â Â Â Second Generation TriKEÂ®s Utilize Camelid Nanobody Technology Â 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 TriKEÂ® product candidates. Â To develop second generation TriKEÂ®s, 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). Â Â 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 IFNÎ³ with the single-domain CD16 TriKEÂ® (cam 16-wt15-33; GTB-3650) compared to the original TriKEÂ® (scFv16-m 15-33; GTB-3550) (see figure below). This data was published by Dr. Felices M et al (2020) in Cancer Immunol Res. Â CD33+ HL60 Targets in Killing Assays Â The purple line represents the GTB-3650 and the blue line represents GTB-3550. Â Â Â 5 Â Â Â GTB-3650 Â GTB-3650 is a TriKEÂ® 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 TriKEÂ® 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 expect to start study enrollment targeting patients with relapsed/refractory AML and high grade MDS early in the first quarter of 2025. This initial study will test 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. The design of the trial has been agreed on with the FDA. Â Â GTB-5550 Â GTB-5550 is a B7-H3 targeted TriKEÂ® which targets B7-H3 on the surface of advanced solid tumors (figure above). GTB-5550 is our first dual camelid TriKEÂ®. 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. Â Â 6 Â Â Â Â GTB-7550 Â GTB-7550 TriKEÂ® is a product candidate in development for the treatment of lupus and other autoimmune disorders. GTB-7550 TriKEÂ® 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. Â Implications of Being a Smaller Reporting Company Â We are a â€œsmaller reporting companyâ€ 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 managementâ€™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 â€œsmaller reporting companyâ€ 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. Â Corporate Information Â Our common stock currently trades on the Nasdaq under the symbol â€œGTBP.â€ 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. Â Â 7 Â Â Â THE OFFERING Â Common Stock to be Offered Â Up to Â Â Â Â Â Â Â Â shares of common stock. Common Warrants to be Offered Â Common warrants to purchase up to Â Â Â Â Â Â Â Â shares of our common stock. Each common warrant has an exercise price of $Â Â Â Â Â Â Â Â per share of common stock. Common warrants will become exercisable immediately after issuance and will expire five years from the date of issuance. Â 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. Â Pre-funded Warrants to be Offered Â 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 purchaserâ€™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. Â Common Stock to be Outstanding Before this Offering Â 2,234,328 shares. Â Â Â Common Stock to be Outstanding Immediately After this Offering Â Â Â Â Â Â Â Â Â shares, (assuming full exercise of the pre-funded warrants and assuming no exercise of the common warrants). Â Â Â Use of Proceeds Â We estimate that the net proceeds from this offering will be approximately $Â Â Â Â Â Â Â Â 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 â€œUse of Proceedsâ€ for additional information. Â Â Â Risk Factors Â An investment in our securities involves a high degree of risk. See â€œRisk Factorsâ€ beginning on page 9 of this prospectus and the other information included and incorporated by reference in Â Â this prospectus for a discussion of the risk factors you should carefully consider before deciding to invest in our securities. Â Â Â Nasdaq Symbol Â Our common stock is listed on the Nasdaq Capital Market under the symbol â€œGTBP.â€ 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. Â 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 Â Â Â Â Â Â Â Â 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 $Â Â Â Â Â Â Â Â 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 â€œNote 7 â€“ Common Stock Warrants and Optionsâ€ to our Third Quarter Report filed on Form 10-Q that is incorporated by reference into this prospectus. Â Â 8 Â Â RISK FACTORS Â 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 â€œRisk Factorsâ€ 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.. Â Risks Related to Our Business Â Risks related to our business risks include, but are not limited to, the following: Â Â â— Our financial condition raises substantial doubt as to our ability to continue as a going concern. Â Â Â Â â— Our business is at an early stage of development and we may not develop therapeutic products that can be commercialized. Â Â Â Â â— 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. Â Â Â Â â— We will need additional capital to conduct our operations and develop our products, and our ability to obtain the necessary funding is uncertain. Â Â Â Â â— Our current and future indebtedness may impose significant operating and financial restrictions on us and affect our ability to access liquidity. Â Â Â Â â— The cost of our research and development programs may be significantly higher than expected, and there is no assurance that they will successful in a timely manner, or at all. Â Â Â Â â— 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. Â Â Â Â â— Claims that we infringe the intellectual property rights of others may prevent or delay our drug discovery and development efforts. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends. Â Â Â Â â— 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. Â Â Â Â â— Clinical drug development is costly, time-consuming and uncertain, and we may suffer setbacks in our clinical development program that could harm our business. Â Â Â Â â— 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. Â Â Â Â â— Obtaining regulatory approval, even after clinical trials that are believed to be successful, is an uncertain process. Â 9 Â Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— Our products may be expensive to manufacture, and they may not be profitable if we are unable to control the costs to manufacture them. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— Our failure to maintain compliance with the Nasdaq Capital Marketâ€™s (â€œNasdaqâ€) continued listing requirements could result in the delisting of our common stock. Â 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. Â Risks Related to our Business Â Our financial condition raises substantial doubt as to our ability to continue as a going concern. Â 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. Â 10 Â Â 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 Companyâ€™s financial condition in relation to its ability to meet its obligations, which has raised substantial doubt about the Companyâ€™s ability to continue as a going concern. While it is very difficult to estimate the Companyâ€™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 Companyâ€™s business prospects, ability to meet long-term liquidity needs and the ability to continue operations. Â Risks Related to this Offering and Our Common Stock Â 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. Â Our common stock is now listed on the Nasdaq Capital Market under the trading symbol â€œGTBPâ€; 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: Â Â â— the number of stockholders; Â Â Â Â â— our operating performance and financial condition; Â Â Â Â â— the market for similar securities; Â Â Â Â â— the extent of coverage of us by securities or industry analysts; and Â Â Â Â â— the interest of securities dealers in making a market in the shares of our common stock. Â 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. Â The volatility of the price of our common stock may also be impacted by the risks discussed under this â€œRisk Factorsâ€ section, in addition to other factors, including: Â Â â— developments in the financial markets and worldwide or regional economies; Â Â Â Â â— announcements of innovations or new products or services by us or our competitors; Â Â Â Â â— announcements by the government relating to regulations that govern our industry; Â Â Â Â â— significant sales of our common stock or other securities in the open market; Â Â Â Â â— variations in interest rates; Â Â Â Â â— changes in the market valuations of other comparable companies; and Â Â Â Â â— changes in accounting principles. Â 11 Â Â Our outstanding warrants and options may affect the market price of our common stock Â 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 stockholdersâ€™ ownership. Â Because our common stock may be deemed a low-priced â€œpennyâ€ stock, an investment in our common stock should be considered high-risk and subject to marketability restrictions. Â 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 brokerâ€“dealers, before effecting transactions in any penny stock, to: Â â— deliver to the customer, and obtain a written receipt for, a disclosure document; Â Â â— disclose certain price information about the stock; Â Â â— disclose the amount of compensation received by the broker-dealer or any associated person of the broker-dealer; Â Â â— send monthly statements to customers with market and price information about the penny stock; and Â Â â— in some circumstances, approve the purchaserâ€™s account under certain standards and deliver written statements to the customer with information specified in rules. Â 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. Â Financial Industry Regulatory Authority (â€œFINRAâ€) sales practice requirements may also limit a stockholderâ€™s ability to buy and sell our common stock, which could depress the price of our common stock. Â In addition to the â€œpenny stockâ€ 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 customerâ€™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. Â 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. Â 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. Â 12 Â Â Anti-takeover provisions may limit the ability of another party to acquire us, which could cause our stock price to decline. Â Delaware law and our restated certificate of incorporation (â€œcertificate of incorporationâ€), our restated bylaws (â€œbylawsâ€) 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. Â We do not currently or for the foreseeable future intend to pay dividends on our common stock. Â 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. Â Purchasers of our common stock in this offering will experience immediate and substantial dilution in the book value of their investment. Â 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 $Â Â Â Â Â Â Â Â 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 â€œDilution.â€ Â Our management will have broad discretion as to the use of the proceeds from this offering, and may not use the proceeds effectively. Â 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 â€œUse of Proceeds.â€ 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. Â We will need additional capital to conduct our operations and develop our products, and our ability to obtain the necessary funding is uncertain. Â 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. Â 13 Â Â 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: Â â— accuracy of the assumptions underlying our estimates for capital needs in 2025 and beyondÍ¾ Â Â â— scientific and clinical progress in our research and development programsÍ¾ Â Â â— 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 marketingÍ¾ Â Â â— our progress with pre-clinical development and clinical trialsÍ¾ Â Â â— the time and costs involved in obtaining regulatory approvalsÍ¾ Â Â â— the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claimsÍ¾ and Â Â â— the number and type of product candidates that we pursue. Â 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. Â 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. Â There is no public market for the common warrants or pre-funded warrants being offered by us in this offering. Â 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. Â 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. Â 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. Â 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. Â 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. Â 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. Â 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 Â Â Â Â Â Â Â Â days from closing of the offering, subject to certain exceptions; and (iii) indemnification for breach of contract. Â Our common stock may be at risk for delisting from the Nasdaq Capital Market in the future if we do not maintain compliance with Nasdaqâ€™s continued listing requirements. Delisting could adversely affect the liquidity of our common stock and the market price of our common stock could decrease. Â 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 stockholdersâ€™ equity above $2,500,000 as set forth in Nasdaq Listing Rule 5550(b)(1). Â On November 21, 2024, the Company received a letter from Nasdaq notifying the Company that its amount of stockholdersâ€™ equity has fallen below the $2,500,000 required minimum for continued listing set forth in Nasdaq Listing Rule 5550(b)(1). Â 14 Â Â Nasdaqâ€™s Letter has no immediate effect on the listing of the Companyâ€™s common stock, and its common stock will continue to trade on The Nasdaq Capital Market under the symbol â€œGTBPâ€ at this time. Under Nasdaq Listing Rules, the Company has until January 6, 2025 to provide Nasdaq with a plan to achieve and sustain compliance. If Nasdaq accepts the Companyâ€™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 Companyâ€™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 Companyâ€™s plan, that the Company will be able to regain compliance with Listing Rule 5550(b)(1) or that the Company will be able meet the continued listing requirements during any compliance period that may be granted by Nasdaq. Â 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 your investment in us. Â USE OF PROCEEDS Â We estimate that the net proceeds from the offering will be approximately $Â Â Â Â Â Â Â Â million, based on the assumed public offering price of $Â Â Â Â Â Â Â Â per share and common warrant, which is the last reported sales price of our common stock on Nasdaq on Â Â Â Â Â Â Â Â Â , 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 $Â Â Â Â Â Â Â 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 agentâ€™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 $Â Â Â Â Â Â Â Â million, $Â Â Â Â Â Â Â Â million, and $Â Â Â Â Â Â Â Â million, respectively, after deducting the estimated placement agent fees and estimated offering expenses payable by us. Â 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. Â CAPITALIZATION Â The following table presents a summary of our cash and cash equivalents and capitalization as of September 30, 2024: Â â— on an actual basis; and Â Â â— 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. Â 15 Â Â 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 Managementâ€™s Discussion and Analysis of Financial Condition and Results of Operations and the historical financial statements and related notes in the Companyâ€™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. Â Â Â As of September 30, 2024Â (in thousands)Â ActualÂ Â As adjustedÂ Cash and cash equivalentsÂ $6,418,000Â Â $Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â Stockholdersâ€™ equity:Â Â Â Â Â Â Â Â Convertible preferred stock, $0.01 par value, 15,000,000 shares authorized Series C, 96,230 shares issued and outstandingÂ $1,000Â $1,000Â Common stock: $0.001 par value; 250,000,000 shares authorized; 2,234,328 shares issued and outstanding, actual; Â Â Â Â Â Â Â Â shares issued and outstanding, pro forma as adjustedÂ $2,000Â Â $Â Â Â Â Â Â Â Â Â Additional paid-in capitalÂ $693,546,000Â Â $Â Â Â Â Â Â Â Â Â Accumulated deficitÂ $(691,452,000)Â $Â Â Â Â Â Â Â Â Â Total stockholdersâ€™ equityÂ $2,097,000Â Â $Â Â Â Â Â Â Â Â Â Â Each $0.25 increase (decrease) in the assumed public offering price of $Â Â Â Â Â Â Â Â per share would increase (decrease) each of cash and cash equivalents, additional paid-in capital and total shareholdersâ€™ equity by approximately $Â Â Â Â Â Â Â Â , 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 shareholdersâ€™ equity by approximately $Â Â Â Â Â Â Â Â , 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. Â 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 Â Â Â Â Â Â Â Â 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 $Â Â Â Â Â Â Â Â 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 â€œNote 7 â€" Common Stock Warrants and Optionsâ€ to our Third Quarter Report filed on Form 10-Q that is incorporated by reference into this prospectus. Â DILUTION Â 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. Â As of September 30, 2024, our net tangible book value was $2,097,000, or $0.94 per share of Common Stock. Â 16 Â Â After giving effect to the foregoing pro forma adjustments and the sale by us of shares of common stock and/or pre-funded warrants at an assumed public offering price of $Â Â Â Â Â Â Â Â 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 $Â Â Â Â Â Â Â Â , or $Â Â Â Â Â Â Â Â per share. This represents an immediate increase in as adjusted net tangible book value of approximately $Â Â Â Â Â Â Â Â per share to our existing stockholders, and an immediate dilution of $Â Â Â Â Â Â Â Â 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. Â Assumed public offering price Â $ Â Â Â Â Â Â Â Â Â Net tangible book value per share as of September 30, 2024 Â $ 0.94 Â Net increase in net tangible book value per share attributable to existing shareholders Â $ Â Â Â Â Â Â Â Â Â As adjusted net tangible book value per share after this offering Â $ Â Â Â Â Â Â Â Â Â Dilution in net tangible book value per share to new investors in the offering Â $ (Â Â Â Â Â Â Â Â) Â 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 Â Â Â Â Â Â Â Â 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 $Â Â Â Â Â Â Â Â 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 â€œNote 7 â€“ Common Stock Warrants and Optionsâ€ to our Third Quarter Report filed on Form 10-Q that is incorporated by reference into this prospectus. Â DESCRIPTION OF CAPITAL STOCK Â 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. Â 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. Â Authorized Shares Â 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 â€œPreferred Stockâ€). Our common stock is registered under Section 12(b) of the Exchange Act and is listed on the Nasdaq under the trading symbol â€œGTBP.â€ Â 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 Companyâ€™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 â€œGTBP.â€ Â 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. Â 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 Companyâ€™s common stock, and to the number of shares of common stock reserved for future issuance pursuant to the Companyâ€™s 2022 Omnibus Incentive Plan. Â 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. Â 17 Â Â Common Stock Â 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 â€œAnti-Takeover Provisions Under Our Charter and Bylaws and Delaware Law,â€ 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. Â Preferred Stock Â 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: Â â—decreasing the market price of our common stock; Â Â â—restricting dividends on our common stock; Â Â â—diluting the voting power of our common stock; Â Â â—impairing the liquidation rights of our common stock; or Â Â â—delaying or preventing a change in control of us without further action by our shareholders. Â 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. Â Series C Preferred Stock Â For a discussion of the terms of our Series C Preferred Stock, see Note 6 to our audited financial statements, Stockholdersâ€™ Equity, incorporated in this document by reference. Â Warrants Â Common warrants for the purchase of up to 740,000 shares of common stock (the â€œ2024 Common Warrantsâ€) were issued pursuant to a securities purchase agreement between us and certain institutional investors, dated as of May 21, 2024 (the â€œ2024 Purchase Agreementâ€) 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 â€œ2024 Placement Agent Warrants,â€ and together with the 2024 Common Warrants, the â€œ2024 Warrantsâ€). Â 18 Â Â Common warrants to purchase up to an aggregate of 216,667 shares of the Companyâ€™s common stock (the â€œ2023 Common Warrantsâ€), pre-funded warrants to purchase up to 96,667 shares of the Companyâ€™s common stock (the â€œPre-Funded Warrantsâ€), and placement agent warrants to purchase up to 13,000 of the Companyâ€™s common stock (the â€œ2023 Placement Agents Warrants,â€ and together with the 2023 Common Warrants and Pre-Funded Warrants, the â€œ2024 Warrantsâ€) 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. Â Holders of 2023 Warrants and 2024 Warrants (together, the â€œWarrantsâ€) may exercise such warrants on a â€œcashlessâ€ 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 on 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. Â Anti-Takeover Provisions Under Our Charter and Bylaws and Delaware Law Â 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. Â Amended and Restated Certificate of Incorporation Â 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. Â 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. Â 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. Â 19 Â Â 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. Â 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. Â 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. Â Delaware Anti-takeover Statute Â We are subject to Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a â€œbusiness combinationâ€ with an â€œinterested stockholderâ€ 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 â€œbusiness combinationâ€ 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 â€œinterested stockholderâ€ is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporationâ€™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. Â 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. Â Transfer Agent and Registrar Â Our transfer agent and registrar for our capital stock is Computershare. The transfer agentâ€™s address is 8742 Lucent Blvd., Suite 225, Highland Ranch, CO 80129, and its telephone number is (303) 262-0600. Â Existing Trading Markets Â Our common stock is listed on the Nasdaq Capital Market under the trading symbol â€œGTBP.â€ The closing sale price of our common stock on the Nasdaq Capital Market on December 20, 2024, was $1.75 per share. Â Listing on the Nasdaq Capital Market Â Our common stock is listed on the Nasdaq Capital Market under the symbol â€œGTBP.â€ Â DESCRIPTION OF SECURITIES WE ARE OFFERING Â We are offering up to Â Â Â Â Â Â Â Â shares of our common stock (or pre-funded warrants in lieu of) and up to common warrants to purchase up to Â Â Â Â Â Â Â Â 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. Â

Â Â Common Stock Â The material terms and provisions of our common stock are described under the caption â€œDescription of Capital Stockâ€ in this prospectus and are incorporated herein by reference. Â Common Warrants Â General Â 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. Â Duration, Exercise Price and Form Â Each common warrant offered hereby has an initial exercise price per share equal to $Â Â Â Â Â Â Â Â . 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. Â Exercisability Â 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 holderâ€™s common warrants to the extent that the holder would own more than 4.99% (or 9.99%, at the holderâ€™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 holderâ€™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. Â Cashless Exercise Â 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. Â

Â Â Fundamental Transactions Â 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. Â Transferability Â 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. Â Exchange Listing Â 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. Â Right as a Stockholder Â Except as otherwise provided in the common warrants or by virtue of such holderâ€™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. Â Pre-Funded Warrants Â General Â 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. Â Duration, Exercise Price and Form Â 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. Â Exercisability Â 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 holderâ€™s pre-funded warrants to the extent that the holder would own more than 4.99% (or 9.99%, at the holderâ€™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 holderâ€™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. Â Cashless Exercise Â 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. Â Fundamental Transactions Â 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. Â TransferabilityÂ Â 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. Â Exchange Listing Â 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. Â Right as a Stockholder Â Except as otherwise provided in the pre-funded warrants or by virtue of such holderâ€™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. Â Placement Agent Warrants Â 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. Â The placement agent warrants are substantially similar to the common warrants, except that each placement agent warrant will have an exercise price of $Â Â Â Â Â Â Â Â 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 the commencement of sales of the offering. Â 22 Â Â MATERIAL TAX CONSIDERATIONS Â 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 â€œcapital assetsâ€ within the meaning of Section 1221 of the U.S. Internal Revenue Code of 1986, as amended (the â€œCodeâ€). 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: Â â—financial institutions or financial services entities; Â Â Â â—broker-dealers; Â Â Â â—S corporations; Â Â Â â—partnerships (including entities or arrangements treated as partnerships for U.S. federal income tax purposes); Â Â Â â—taxpayers that are subject to the mark-to-market accounting rules; Â Â Â â—tax-exempt entities; Â Â Â â—governments or agencies or instrumentalities thereof; Â Â Â â—insurance companies; Â Â Â â—regulated investment companies or real estate investment trusts; Â Â Â â—expatriates or former long-term residents or citizens of the United States; Â Â Â â—persons for whom our common stock or pre-funded warrants constitute â€œqualified small business stockâ€ within the meaning of Section 1202 of the Code; Â Â Â â—persons that hold our securities as part of a straddle, constructive sale, hedging, conversion or other integrated or similar transaction; Â Â Â â—persons subject to the alternative minimum tax; Â Â Â â—U.S. persons whose functional currency is not the U.S. dollar; Â Â Â â—controlled foreign corporations; Â Â Â â—accrual method taxpayers that file applicable financial statements as described in SectionÂ 451(b) of the Code; or Â Â Â â—passive foreign investment companies. Â 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. Â 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 â€œIRSâ€) 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. Â 23 Â Â 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, ANDÂ NON-U.S. TAX LAWS. Â CHARACTERIZATION OF COMMON STOCK, COMMON WARRANTS, AND PRE-FUNDED WARRANTS Â Allocation of Purchase Price Between Common Stock, Common Warrants, and Pre-Funded Warrants Â 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 holderâ€™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. Â Characterization of Pre-Funded Warrants Â Although the characterization of theÂ pre-fundedÂ 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 eachÂ pre-fundedÂ 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. Â U.S. HOLDERS Â As used herein, a â€œU.S. Holderâ€ 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: Â â—an individual citizen or resident of the United States, Â Â Â â—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, Â Â Â â—an estate whose income is subject to U.S. federal income tax regardless of its source, or Â Â Â â—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. Â Distributions on Our Common Stock Â 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 â€œqualified dividend incomeâ€ 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. Holderâ€™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 â€œâ€”U.S. Holdersâ€”Sale, Exchange, or Other Taxable Disposition of Our Common Stock, Pre-Funded Warrants, or Common Warrants.â€ Â 24 Â Â Sale, Exchange, or Other Taxable Disposition of Our Common Stock, Pre-Funded Warrants, or Common Warrants Â 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. Holderâ€™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. Holderâ€™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. Â Exercise of a Pre-Funded Warrant Â As described in â€œâ€”Characterization of Common Stock, Common Warrants, and Pre-Funded Warrantsâ€”Characterization of Pre-Funded Warrantsâ€ 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. Holderâ€™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. Holderâ€™s tax basis in the pre-funded warrant and the nominal exercise price of such pre-funded warrant. The U.S. Holderâ€™s holding period in the share of our common stock received upon exercise of the pre-funded warrant should include the U.S. Holderâ€™s holding period for the pre-funded warrant. Â Exercise or Lapse of a Common Warrant Â 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. Holderâ€™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. Holderâ€™s tax basis in the common warrant and the exercise price of such common warrant. It is unclear whether a U.S. Holderâ€™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. Holderâ€™s tax basis in the common warrant. The deductibility of capital losses is subject to limitations. Â 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. Â 25 Â Â Possible Constructive Distributions Â 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. Holderâ€™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 â€œâ€”U.S. Holdersâ€”Distributions on Our Common Stock.â€ 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. Â Information Reporting and Backup Withholding Â 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. Holderâ€™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. Â NON-U.S. HOLDERS Â As used herein, a â€œnon-U.S. Holderâ€ 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. Â Distributions on Our Common Stock Â 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. Holderâ€™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. Holderâ€™s adjusted tax basis in our common stock and then, to the extent such distribution exceeds the non-U.S. Holderâ€™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 â€œâ€”Non-U.S. Holdersâ€”Sale, Exchange or Other Taxable Disposition of Our Common Stock, Pre-Funded Warrants, or Common Warrants.â€ Â Dividends paid by us to a non-U.S. Holder that are effectively connected with such non-U.S. Holderâ€™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 â€œbranch profits taxâ€ at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty). Â 26 Â Â Sale, Exchange, or Other Taxable Disposition of Our Common Stock, Pre-Funded Warrants, or Common Warrants Â 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: Â (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; Â Â Â (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 â€œbranch profits taxâ€ at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty); or Â Â Â (iii)subject to certain exceptions discussed below, we are or have been a U.S. real property holding corporation (a â€œUSRPHCâ€) at any time during the shorter of the five-year period preceding such disposition and such non-U.S. Holderâ€™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. Â For purposes of item (iii) immediately above, we will generally be classified as a USRPHC if the fair market value of our â€œUnited States real property interestsâ€ 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 anticipating 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. Holderâ€™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. Â Exercise of a Pre-Funded Warrant Â The U.S. federal income tax treatment of a non-U.S. Holderâ€™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 â€œâ€”U.S. Holdersâ€”Exercise of a Pre-Funded Warrant.â€ Â Exercise or Lapse of a Common Warrant Â The U.S. federal income tax treatment of a non-U.S. Holderâ€™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 â€œâ€”U.S. Holdersâ€”Exercise or Lapse of a Common Warrant.â€ 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. Holderâ€™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. Holderâ€™s U.S. federal income tax liability unless the loss is effectively connected with the non-U.S. Holderâ€™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. Â 27 Â Â 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. Â Possible Constructive Distributions Â As described above under â€œâ€”U.S. Holdersâ€”Possible Constructive Distributions,â€ 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 â€œâ€”Non-U.S. Holdersâ€”Distributions on Our Common Stock.â€ Â Information Reporting and Backup Withholding Â 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. Holderâ€™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. Â Foreign Account Tax Compliance Act Â Sections 1471 through 1474 of the Code and the Treasury Regulations and administrative guidance promulgated thereunder (commonly referred as the â€œForeign Account Tax Compliance Actâ€ or â€œFATCAâ€) 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 â€œsubstantial United States ownersâ€ or (ii) provides certain information regarding the entityâ€™s â€œsubstantial United States owners,â€ 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. Â 28 Â Â PLAN OF DISTRIBUTION Â We engaged Roth Capital Partners, LLC (â€œRothâ€ or the â€œplacement agentâ€), 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 Â Â Â Â Â Â Â Â , 2024. 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 â€œreasonable best effortsâ€ 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 terminateâ€¯no later than Â Â Â Â Â Â Â Â , 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. Â 29 Â Â We will enter into a securities purchase agreement directly with the institutional investors, at the investorâ€™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. Â Placement Agent Fees and Expenses Â 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. Â Â Â Â Per Share and Common Warrant Â Â Per Pre-Funded Warrant and Common Warrant Â Â Total Â Public offering price Â Â $ Â Â Â Â Â Â Â Â Â Â Â $ Â Â Â Â Â Â Â Â Â Â Â $ Â Â Â Â Â Â Â Â Â Â Â Placement Agent fees(1) Â Â $ Â Â Â $ Â Â $ Â Â Proceeds to us, before expenses(2) Â Â $ Â Â Â $ Â Â $ Â Â Â Â (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 Â Â Â Â Â Â Â Â shares of common stock (equal to 6% of the aggregate number of securities sold in this offering, subject to a partial adjustment in the event certain investors participate) at an exercise price of $Â Â Â Â Â Â Â Â 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 â€œplacement agent warrants.â€ Â (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. Â 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 $Â Â Â Â Â Â Â Â , all of which are payable by us. This figure includes the placement agentâ€™s accountable expenses, including, but not limited to, legal fees for placement agentâ€™s legal counsel, that we have agreed to pay at the closing of the offering up to an aggregate expense reimbursement of $100,000. Â Placement Agent Warrants Â In addition, we have agreed to issue to the placement agent, or its designees, warrants to purchase up to Â Â Â Â Â Â Â Â shares of common stock (equal to 6% of the aggregate number of securities sold in this offering, subject to a partial adjustment in the event certain investors participate) at an exercise price of $Â Â Â Â Â Â Â Â 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 â€œplacement agent warrants.â€ 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. Â Other Relationships Â 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. Â Determination of Offering Price Â 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. Â 30 Â Â Transfer Agent and Registrar Â Our transfer agent and registrar for our capital stock is Computershare. The transfer agentâ€™s address is 8742 Lucent Blvd., Suite 225, Highland Ranch, CO 80129, and its telephone number is (303) 262-0600. Â The Nasdaq Capital Market Listing Â Our common stock is currently listed on the Nasdaq Stock Market LLC under the symbol â€œGTBP.â€ On December 20, 2024, the reported closing price per share of our common stock was $1.75. 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. Â Indemnification Â 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. Â Lock-up Restrictions Â We have agreed for a period of Â Â Â Â Â Â Â Â 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 â€œrestricted securitiesâ€ (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 Â Â Â Â Â Â Â Â -day lock-up period. Â We have also agreed for a period of Â Â Â Â Â Â Â Â 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. Â Our directors and executive officers 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 Â Â Â Â Â Â Â Â days after the date of this prospectus. Â The placement agent may waive these prohibitions in its sole discretion and without notice. Â Regulation M Â 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 â€œExchange Actâ€), 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. Â 31 Â Â Electronic Distribution Â 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. Â INCORPORATION OF CERTAIN INFORMATION BY REFERENCE Â The SEC allows us to â€œincorporate by referenceâ€ 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): Â Â â— our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on March 26, 2024; Â â— 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; Â â— our definitive proxy statement on Schedule 14A, filed with the SEC on April 29, 2024; Â â— 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 and November 27, 2024; and Â â— 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. Â 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. Â 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. Â 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. Â 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. Â 32 Â Â There have been no material changes to the Companyâ€™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. Â WHERE YOU CAN FIND MORE INFORMATION Â 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 SECâ€™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 SECâ€™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. Â LEGAL MATTERS Â 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. Â EXPERTS Â 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. Â 33 Â Â Up to Â Â Â Â Â Â Â Â Shares of Common Stock Â Pre-Funded Warrants to Purchase up to Â Â Â Â Â Â Â Â Shares of Common Stock Â Common Warrants to Purchase up to Â Â Â Â Â Â Â Â Shares of Common Stock Â Placement Agent Warrants to Purchase up to Â Â Â Â Â Â Â Â Shares of Common Stock Â Up to Â Â Â Â Â Â Â Â Shares of Common Stock underlying Pre-Funded Warrants, Common Warrants and Placement Agent Warrants Â Â PRELIMINARY PROSPECTUS Â Roth Capital Partners Â The date of this prospectus is Â Â Â Â Â Â Â Â , 2024. Â 34 Â Â PART II Â INFORMATION NOT REQUIRED IN PROSPECTUS Â Item 13. Other Expenses of Issuance and Distributions Â 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. Â SEC registration feeÂ $1,975Â FINRA filing feeÂ $2,435Â Accounting fees and expensesÂ $35,000Â Legal fees and expensesÂ $200,000Â MiscellaneousÂ $* TotalÂ $239,410Â Â Item 14. Indemnification of Directors and Officers Â Section 145 of the DGCL provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneysâ€™ 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. Â 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 directorâ€™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. Â Item 15. Recent Sales of Unregistered Securities Â 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: Â 35 Â Â Â â— 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. Â Â Â Â â— During the year ended December 31, 2022, the Company issued 11,257 shares of common stock upon conversion of notes payable. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— During the year ended December 31, 2022, the Company issued 57,437 shares of common stock to settle approximately $700,000 of vendor payables. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— 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 Companyâ€™s common stock, pre-funded warrants to purchase up to 96,667 shares of the Companyâ€™s common stock, warrants to purchase up to an aggregate of 216,667 shares of the Companyâ€™s common stock and placement agent warrants to purchase up to 13,000 of the Companyâ€™s common stock. The Company raised $6.5 million from the offering. Â Â Â Â â— 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 Companyâ€™s common stock for the months for which services were provided by the vendor. Â Â Â Â â— 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. Â Â Â Â â— 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. Â Â Â Â â— 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 Companyâ€™s common stock for the months for which services were provided by the vendor. Â Â Â Â â— 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 Companyâ€™s officers and directors. Â 36 Â Â Item 16. Exhibits and Financial Statement Schedules Â (a)Exhibits Â Exhibit Index Â Exhibit Number Â Exhibit Description Â Form Â Date Â Number Â File No. Â Filed Herewith 3.1 Â Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002 Â 10-KSB Â 04/01/02 Â 3.A Â Â Â Â 3.2 Â Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., dated February 9, 2011 Â 10-K Â 03/31/2011 Â 3.2 Â Â Â Â 3.3 Â Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of July 19, 2017 Â 8-K/A Â 03/15/2018 Â 3.1 Â Â Â Â 3.4 Â Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of February 10, 2021 Â 8-K Â 02/11/2021 Â 3.1 Â Â Â Â 3.5 Â Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective June 13, 2022 Â 10-K Â 03/30/2023 Â 3.5 Â Â Â Â 3.6 Â Amended and Restated Bylaws of GT Biopharma, Inc., effective November 3, 2022 Â 8-K Â 11/09/2022 Â 3.1 Â Â Â Â 3.7 Â Certificate of Amendment of Restated Certificate of Incorporation of GT Biopharma, Inc., effective February 1, 2024 Â 8-K Â 02/01/2024 Â 3.1 Â Â Â Â 4.1 Â Certificate of Designation of Preferences, Rights and Limitations of Series J-1 Preferred Stock of GT Biopharma, Inc., dated April 3, 2019 Â 8-K Â 04/04/2019 Â 3.1 Â Â Â Â 4.2 Â Certificate of Designation of Preferences, Rights and Limitations of Series K Preferred Stock of GT Biopharma, Inc., dated February 22, 2021 Â 10-K Â 04/16/2021 Â 4.2 Â Â Â Â 4.3 Â Description of the Registrantâ€™s Securities Registered pursuant to Section 12 of the Securities Exchange Act of 1934, as Amended Â 10-K Â 03/30/2023 Â 4.3 Â Â Â Â 4.4** Â Form of Common Warrant Â Â Â Â Â Â Â Â Â Â 4.5** Â Form of Pre-Funded Warrant Â Â Â Â Â Â Â Â Â Â 4.6** Â Form of Placement Agent Warrant Â Â Â Â Â Â Â Â Â Â 4.9 Â Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated January 9, 2017) Â 8-K Â 01/13/2017 Â 10.2 Â Â Â Â 4.10 Â Form of Common Stock Purchase Warrant (related to Securities Purchase Agreement, dated January 9, 2017) Â 8-K Â 01/13/2017 Â 10.3 Â Â Â Â 4.11 Â Registration Rights Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein Â 8-K Â 01/23/2018 Â 10.2 Â Â Â Â 4.12 Â Form of Senior Convertible Note (related to Securities Purchase Agreement, dated January 22, 2018) Â 8-K Â 01/23/2018 Â 10.3 Â Â Â Â 4.13 Â Form of Warrant to Purchase Common Stock (related to Securities Purchase Agreement, dated January 22, 2018) Â 8-K Â 01/23/2018 Â 10.4 Â Â Â Â 4.14 Â Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated August 2, 2018) Â 8-K Â 08/03/2018 Â 4.1 Â Â Â Â 4.15 Â Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 7, 2018) Â 8-K Â 09/07/2018 Â 4.1 Â Â Â Â 4.16 Â Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 24, 2018) Â 8-K Â 09/28/2018 Â 4.1 Â Â Â Â Â 37 Â Â Exhibit Number Â Exhibit Description Â Form Â Date Â Number Â File No. Â Filed Herewith 4.17 Â Form of Secured Convertible Note (related to Securities Purchase Agreement, dated February 4, 2019) Â 8-K Â 02/06/2019 Â 4.1 Â Â Â Â 4.18 Â Registration Rights Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein Â 8-K Â 05/24/2019 Â 10.2 Â Â Â Â 4.19 Â Form of Convertible Note (related to Securities Purchase Agreement, dated August 20, 2019) Â 8-K Â 05/24/2019 Â 4.1 Â Â Â Â 4.20 Â Registration Rights Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein Â 8-K Â 08/20/2019 Â 10.2 Â Â Â Â 4.21 Â Form of Convertible Note (related to Securities Purchase Agreement, dated May 22, 2019) Â 8-K Â 05/24/2019 Â 4.1 Â Â Â Â 4.22 Â Registration Rights Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein Â 10-Q Â 05/15/2020 Â 10.2 Â Â Â Â 4.23 Â Registration Rights Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein Â 10-Q Â 05/15/2020 Â 10.2 Â Â Â Â 4.24 Â Form of Convertible Note (related to Securities Purchase Agreement, dated January 30, 2020) Â 10-Q Â 05/15/2020 Â 10.3 Â Â Â Â 4.25 Â Form of Registration Rights Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020) Â 10-Q Â 05/15/2020 Â 10.5 Â Â Â Â 4.26 Â Form of Convertible Note (related to Securities Purchase Agreement executed in April/May 2020) Â 10-Q Â 05/15/2020 Â 10.6 Â Â Â Â 4.27 Â Registration Rights Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein Â 8-K Â 07/09/2020 Â 10.3 Â Â Â Â 4.28 Â Form of Convertible Note (related to Securities Purchase Agreement, dated July 7, 2020) Â 8-K Â 07/09/2020 Â 4.1 Â Â Â Â 4.29 Â Form of Convertible Note, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020). Â 8-K Â 06/19/2020 Â 10.2 Â Â Â Â 4.30 Â Form of Pre-Funded Warrant to Purchase Common Stock, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020). Â 8-K Â 06/19/2020 Â 10.3 Â Â Â Â 4.31 Â Form of Convertible Note (related to Securities Purchase Agreement, dated September 16, 2020) Â 8-K Â 09/22/2020 Â 4.1 Â Â Â Â 4.32 Â Form of Secured Convertible Note Â 8-K Â 11/09/2020 Â 4.1 Â Â Â Â 4.33 Â Form of Settlement Note, dated November 9, 2020. Â 10-Q Â 11/13/2020 Â 10.20 Â Â Â Â 4.34 Â Settlement Note, dated December 22, 2020, by GT Biopharma Inc. payable to Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B. Â 8-K Â 12/28/2020 Â 10.2 Â Â Â Â 4.35 Â Form of Amendment to Convertible Note, dated January 31, 2021 Â 8-K Â 02/01/2020 Â 10.2 Â Â Â Â 4.36 Â Form of Common Warrant Â 8-K Â 01/03/2023 Â 4.1 Â Â Â Â 4.37 Â Form of Pre-Funded Warrant Â 8-K Â 01/03/2023 Â 4.2 Â Â Â Â 4.38 Â Form of Placement Agent Warrant Â 8-K Â 01/03/2023 Â 4.3 Â Â Â Â 4.39 Â Form of Common Warrant Â 8-K Â 05/23/2024 Â 4.1 Â Â Â Â 4.40 Â GT Biopharma, Inc. 2022 Omnibus Incentive Plan Â DEF 14A Â 04/29/2022 Â Â Â Â Â Â 5.1** Â Opinion of Baker & McKenzie LLP Â S-1 Â Â Â 5.1 Â Â Â Â 10.1 Â Exclusive License Agreement, dated July 18, 2016, between the Regents of the University of Minnesota and Oxis Biotech, Inc. Â 10-Q Â 08/11/2017 Â 10.3 Â Â Â Â 10.2 Â License Agreement, dated September 3, 2015, among Daniel A. Vallera, Jeffrey Lion and Oxis Biotech, Inc. Â 10-Q Â 08/11/2017 Â 10.4 Â Â Â Â 10.3 Â Clinical Trial Agreement, dated September 2019, between the Regents of the University of Minnesota and GT Biopharma, Inc. Â 10-Q Â 05/15/2020 Â 10.7 Â Â Â Â Â 38 Â Â Exhibit Number Â Exhibit Description Â Form Â Date Â Number Â File No. Â Filed Herewith 10.4 Â Securities Purchase Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein Â 10-Q Â 05/15/2020 Â 10.1 Â Â Â Â 10.5 Â Form Securities Purchase Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020) Â 10-Q Â 05/15/2020 Â 10.4 Â Â Â Â 10.6 Â Securities Purchase Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein Â 8-K Â 07/09/2020 Â 10.1 Â Â Â Â 10.7 Â Form of Standstill and Forbearance Agreement, dated June 23, 2020, between the Company and certain holders of convertible notes and debentures Â 8-K Â 06/23/2020 Â 10.1 Â Â Â Â 10.8 Â 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. Â 8-K Â 06/19/2020 Â 10.1 Â Â Â Â 10.9 Â Executive Employment Agreement, dated October 19, 2018, among GT Biopharma, Inc. and Raymond W. Urbanski Â 10-Q Â 11/14/2018 Â 10.17 Â Â Â Â 10.10 Â Consultant Agreement, dated February 14, 2018, among GT Biopharma, Inc., Georgetown Translational Pharmaceuticals, Inc. and Anthony J. Cataldo Â 8-K Â 02/21/2018 Â 10.3 Â Â Â Â 10.11 Â Employment agreement with Anthony Cataldo Â 10-Q Â 08/14/2020 Â 10.11 Â Â Â Â 10.12 Â Employment agreement with Steven Weldon Â 10-Q Â 08/14/2020 Â 10.12 Â Â Â Â 10.13 Â Securities Purchase Agreement, dated September 16, 2020, among GT Biopharma, Inc. and the purchasers named therein Â 8-K Â 09/22/2020 Â 10.1 Â Â Â Â 10.14 Â Master Services Agreement, dated October 5, 2020, between Gt Biopharma, Inc. and Cytovance Biologics, Inc. Â 8-K Â 10/06/2020 Â 10.1 Â Â Â Â 10.15 Â Form of First Amendment and Extension of Standstill and Forbearance Agreement Â 8-K Â 11/04/2020 Â 10.1 Â Â Â Â 10.16 Â Securities Purchase Agreement Â 8-K Â 11/09/2020 Â 10.1 Â Â Â Â 10.17 Â 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. Â 10-Q Â 11/13/2020 Â 10.19 Â Â Â Â 10.18 Â Steve Weldon Letter of Resignation, dated November 11, 2020 Â 10-Q Â 11/13/2020 Â 10.21 Â Â Â Â 10.19 Â Board Service Agreement with Bruce Wendel, dated November 11, 2020 Â 10-Q Â 11/13/2020 Â 10.22 Â Â Â Â 10.20 Â Board Service Agreement with Greg Berk, dated November 11, 2020 Â 10-Q Â 11/13/2020 Â 10.23 Â Â Â Â 10.21 Â Consultant Agreement with Michael Handelman, dated November 13, 2020 Â 10-Q Â 11/13/2020 Â 10.24 Â Â Â Â 10.22 Â Form of Amendment to Convertible Note & Standstill Agreement Â 8-K Â 12/23/2020 Â 10.1 Â Â Â Â 10.23 Â 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. Â 8-K Â 12/28/2020 Â 10.1 Â Â Â Â 10.24 Â Form of Second Amendment and Extension of Standstill and Forbearance Agreement. Â 8-K Â 02/01/2020 Â 10.1 Â Â Â Â 10.25 Â Board Service Agreement with Rajesh Shrotriya, dated January 12, 2021. Â S-1/A Â 02/08/2021 Â 10.69 Â Â Â Â Â 39 Â Â Exhibit Number Â Exhibit Description Â Form Â Date Â Number Â File No. Â Filed Herewith 10.26 Â Board Service Agreement with Michael Breen, dated January 12, 2021. Â S-1/A Â 02/08/2021 Â 10.70 Â Â Â Â 10.27 Â Amendment to Settlement Note with Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B. Â S-1/A Â 02/08/2021 Â 10.71 Â Â Â Â 10.28 Â Form of Securities Purchase Agreement - December 2020 / January 2021 Notes Â S-1/A Â 02/08/2021 Â 10.72 Â Â Â Â 10.29 Â Form of December 2020 / January 2021 Note Â S-1/A Â 02/08/2021 Â 10.73 Â Â Â Â 10.30 Â Amended and Restated Employment Agreement with Anthony Cataldo, dated April 23, 2021. Â 10-Q Â 05/17/2021 Â 10.1 Â Â Â Â 10.31 Â Amended and Restated Employment Agreement with Michael Handelman, dated April 23, 2021. Â 10-Q Â 05/17/2021 Â 10.2 Â Â Â Â 10.32 Â Amended and Restated Employment Agreement with Dr. Gregory Berk, dated April 23, 2021 Â 10-Q Â 05/17/2021 Â 10.3 Â Â Â Â 10.33 Â Exclusive License Agreement with Regents of the University of Minnesota, dated March 26, 2021 Â 10-K Â 03/28/2022 Â 10.73 Â Â Â Â 10.34 Â Research Agreement with Regents of the University of Minnesota, dated June 16, 2021. Â 10-K Â 03/28/2022 Â 10.74 Â Â Â Â 10.35 Â Sublease Agreement dated November, 2021, between Aimmune Therapeutics, Inc. (Sublandlord) and GT Biopharma, Inc. (Subtenant) Â 10-K Â 03/28/2022 Â 10.75 Â Â Â Â 10.36 Â Employment Agreement with Michael Breen, entered into as of December 31, 2021 with an effective date of November 8, 2021 Â 10-K Â 03/28/2022 Â 10.76 Â Â Â Â 10.37 Â Amendment No. 1 to Employment Agreement with Michael Breen, dated as of June 17, 2022. Â 10-K Â 03/26/2024 Â 10.77 Â Â Â Â 10.38 Â Amendment No. 2 to Services Agreement with Michael Breen, dated as of February 20, 2023. Â 10-K Â 03/26/2024 Â 10.78 Â Â Â Â 10.39 Â Board Service Agreement with Michael Breen dated November 11, 2020 Â 10-Q Â 05/16/2022 Â 10.1 Â Â Â Â 10.40 Â Employment Agreement with Manu Ohri dated May 15, 2022 Â 10-Q Â 05/16/2022 Â 10.2 Â Â Â Â 10.41 Â Amendment No. 1 to Employment Agreement with Manu Ohri, dated as of February 17, 2023 Â 10-K Â 03/26/2024 Â 10.81 Â Â Â Â 10.42 Â Settlement and Investment Agreement dated August 24, 2022, by and between GT Biopharma, Inc. and Cytovance Biologics, Inc. Â 10-Q Â 10/31/2022 Â 10.1 Â Â Â Â 10.43 Â Form of Securities Purchase Agreement, dated December 2022, by and between GT Biopharma, Inc. and the purchasers named therein. Â 8-K Â 01/03/2023 Â 10.1 Â Â Â Â 10.44 Â Amendment No. 1 to Settlement and Investment Agreement, dated as of April 25, 2024, by and between GT Biopharma, Inc. and Cytovance Biologics, Inc. Â 8-K Â 04/30/2024 Â 10.1 Â Â Â Â 10.45 Â Amended and Restated Exclusive Patent License Agreement with the Regents of the University of Minnesota, dated May 13, 2024 Â 10-Q Â 04/30/2024 Â 10.2 Â Â Â Â 10.46 Â Sponsored Research Agreement with the Regents of the University of Minnesota dated May 20, 2024 Â 10-Q Â 04/30/2024 Â 10.3 Â Â Â Â 10.47 Â Form of Securities Purchase Agreement Â 8-K Â 05/23/2024 Â 10.1 Â Â Â Â 10.48 Â Form of Placement Agency Agreement Â 8-K Â 05/23/2024 Â 10.2 Â Â Â Â 10.49 Â Code of Ethics Â 10-K Â 03/31/2015 Â 14.1 Â Â Â Â 10.50 Â Investigator Initiated Clinical Trial Agreement Â 8-K Â 11/18/2024 Â 10.1 Â Â Â Â 10.51** Â Form of Securities Purchase Agreement Â Â Â Â Â Â Â Â Â Â 10.52** Â Form of Placement Agency Agreement Â Â Â Â Â Â Â Â Â Â 10.53 Â Employment Agreement between the Company and Alan Urban, dated as of June 7, 2024 Â 8-K Â 6/7/2024 Â 10.1 Â Â Â Â 21.1 Â Subsidiaries of GT Biopharma, Inc. Â 10-K Â 03/31/2015 Â 21.1 Â Â Â Â 23.1 Â Consent of Weinberg & Company Â Â Â Â Â Â Â Â Â X Â 40 Â Â Exhibit Number Â Exhibit Description Â Form Â Date Â Number Â File No. Â Filed Herewith 23.2** Â Consent of Baker McKenzie LLP (incl. in Exhibit 5.1) Â Â Â Â Â Â Â Â Â X 24.1 Â Power of Attorney Â S-1 Â 06/20/2024 Â 24.1 Â Â Â Â 101.INS Â XBRL Instance Document Â Â Â Â Â Â Â Â Â X 101.SCH Â XBRL Taxonomy Extension Schema Document Â Â Â Â Â Â Â Â Â X 101.CAL Â XBRL Taxonomy Extension Calculation Linkbase Document Â Â Â Â Â Â Â Â Â X 101.DEF Â XBRL Taxonomy Extension Definition Linkbase Document Â Â Â Â Â Â Â Â Â X 101.LAB Â XBRL Taxonomy Extension Label Linkbase Document Â Â Â Â Â Â Â Â Â X 101.PRE Â XBRL Taxonomy Extension Presentation Linkbase Document Â Â Â Â Â Â Â Â Â X 107 Â Filing Fee Table Â S-1 Â Â Â 107 Â Â Â X Â â€ 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. Â Â ** To be filed by amendment. Â Item 17. Undertakings Â (1) The undersigned registrant hereby undertakes: Â Â a. To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement: Â Â i. To include any prospectus required by Section 10(a)(3) of the Securities Act; Â Â Â Â 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 â€œCalculation of Registration Feeâ€ table in the effective registration statement; and Â Â Â Â 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. Â 41 Â Â Â 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. Â Â Â Â 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. Â Â Â Â 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. Â Â Â Â 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: Â Â i. Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424 (Â§ 230.424 of this chapter);Â Â Â Â 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; Â Â Â Â 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 Â Â Â Â iv. Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser. Â (2) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrantâ€™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 planâ€™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. 42 Â Â (3) The undersigned registrant hereby undertakes that: Â Â 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 Â Â 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. Â (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. Â 43 Â Â SIGNATURES Â Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Los Angeles, State of California, on December 23, 2024. Â Â GT Biopharma Inc. Â Â Â Date: December 23, 2024 By: /s/ Michael Breen Â Â Michael Breen Â Â Interim Chief Executive Officer Â POWER OF ATTORNEY Â Each person whose signature appears below hereby constitutes and appoints each of Michael Breen and Alan Urban is true and lawful attorney-in-fact and agent with full power of substitution and re-substitution, for him and in his name, place, and stead, in any and all capacities, to sign any amendments to this registration statement, and to sign any registration statement for the same offering covered by this registration statement, including post-effective amendments or registration statements filed pursuant to Rule 462(b) under the Securities Act of 1933, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming that each of said such attorneys-in-fact and agents or his or her substitute or substitutes, may do or cause to be done by virtue hereof. Â 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. Â /s/ Michael Breen Â Michael Breen, Executive Chairman of the Board and Â Interim Chief Executive Officer Â December 23, 2024 Â Â Â /s/ Alan Urban Â Alan Urban, Chief Financial Officer Â December 23, 2024 Â Â Â /s/ Bruce Wendel Â Bruce Wendel, Vice Chairman of the Board Â December 23, 2024 Â Â Â /s/ Rajesh Shrotriva Â Rajesh Shrotriva, Director Â December 23, 2024 Â Â Â /s/ Charles J. Casamento Â Charles J. Casamento, Director Â December 23, 2024 Â Â 44 Â EX-23.1 2 ex23-1.htm Â Exhibit 23.1 Â Consent of Independent Registered Public Accounting Firm Â We hereby consent to the incorporation by reference in the foregoing Registration Statement on Form S-1 (File No. 333-________) 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.â€™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 â€œExpertsâ€ in such Registration Statement and related Prospectus. Â /s/ Weinberg & Company, P.A. Â Â Â Los Angeles, California Â December 23, 2024 Â Â Â Â EX-FILING FEES 3 ex107.htm Â Exhibit 107 Â Calculation of Filing Fee Tables Â Form S-1 (Form Type) Â GT Biopharma, Inc. (Exact Name of Registrant as Specified in its Charter) Â Table 1: Newly Registered Securities Â Â Â Security TypeÂ Security Class TitleÂ Fee Calculation or Carry Forward RuleÂ Amount RegisteredÂ Â Proposed Maximum Offering Price Per UnitÂ Â Maximum Aggregate Offering Price(1)Â Â Fee RateÂ Â Amount of Registration FeeÂ Fees to Be PaidÂ EquityÂ Common stock, par value $0.0001 per share(2)Â 457(o)Â Â â€"Â Â Â â€"Â Â $6,000,000.00Â Â Â 0.0001531Â Â $918.60Â Fees to Be PaidÂ EquityÂ Pre-funded warrants to purchase common stock, $0.0001 par value per share(3)(5)(6)Â 457(g)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Fees to Be PaidÂ EquityÂ Common stock, $0.0001 par value per share, underlying the pre-funded warrants(5)(6)Â 457(o)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Fees to Be PaidÂ EquityÂ Common warrants to purchase common stock(3)Â 457(g)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Fees to Be PaidÂ EquityÂ Common stock, par value $0.0001 per share, underlying common warrants(4)Â 457(o)Â Â â€"Â Â Â â€"Â Â $6,000,000.00Â Â Â 0.0001531Â Â $918.60Â Fees to Be PaidÂ EquityÂ Placement Agent Warrants to purchase common stock(3) stock (2)Â 457(g)Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â â€"Â Â Â Â Â Fees to Be PaidÂ EquityÂ Common stock, par value $0.0001 per share, underlying placement agent warrants(7)Â 457(o)Â Â â€"Â Â Â â€"Â Â $900,000.00Â Â Â 0.0001531Â Â $137.79Â Â Â Total Offering AmountsÂ Â Â Â Â Â $12,900,000.00Â Â Â Â Â Â $1,974.99Â Â Â Total Fees Previously PaidÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â â€"Â Â Â Total Fee OffsetsÂ Â Â Â Â Â Â Â Â Â Â Â Â Â Â â€"Â Â Â Net Fee DueÂ Â Â Â Â Â Â Â Â Â Â Â Â Â $1,974.99Â Â (1)Estimated solely for the purpose of computing the registration fee in pursuant to Rule 457(o) under the Securities Act of 1933, as amended. Â Â (2)Pursuant to Rule 416(a) under the Securities Act, this registration statement shall also cover an indeterminate number of shares that may be issued and resold resulting from stock splits, stock dividends or similar transactions. Â Â (3)Pursuant to Rule 457(g) of the Securities Act, no separate registration fees are payable with respect to the common warrants, pre-funded warrants or placement agent warrants to purchase shares of common stock, $0.0001 par value per share, offered hereby since the offering of shares of common stock underlying the warrants, pre-funded warrants and placement agent warrants are being registered hereby. Â Â (4)In addition to the common stock set forth in this table, pursuant to Rule 416 under the Securities Act, this registration statement also registers such indeterminate number of common stock as may become issuable upon exercise of the pre-funded warrants and common warrants. Â Â (5)The proposed maximum aggregate offering price of the common stock proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the offering price of any pre-funded warrants offered and sold in the offering, and as such the proposed maximum offering price of the common stock and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants) if any, is $6,000,000. Â Â (6)The registrant may issue pre-funded warrants to purchase common stock in the offering. The purchase price of each pre-funded warrant will equal the price per share at which shares of common stock are being sold to the public in this offering, minus $0.0001, which constitutes the pre-funded portion of the exercise price, and the remaining unpaid exercise price of the pre-funded warrant will equal $0.0001 per share (subject to adjustment as provided for therein). Â Â (7)The registrant has agreed to issue upon the closing of this offering, warrants (the â€œplacement agent warrantsâ€) to the placement agent entitling it to purchase up to 6% of the number of securities sold in this offering. The exercise price of the placement agent warrants is equal to 125% of the public offering price of the securities offered hereby. As estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act, the proposed maximum aggregate offering price of the placement agent warrants is $900,000, which is equal to 125% of $720,000 (6% of $12,000,000). Â Â Â GRAPHIC 4 forms-1_001.jpg

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