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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended: December 31, 2023
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: 001-40023

GT BIOPHARMA, INC.
(Exact name of Registrant as specified in its charter)

Delaware	94-1620407
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

8000 Marina Blvd.
Suite 100
Brisbane, CA 94005
(Address of principal executive offices) (Zip code)

(415) 919-4040
(Registrant's telephone number including area code)
Securities registered pursuant to Section 12(b) of the Act:

Title of Securities	Trading Symbol(s)	Exchanges on which Registered
Common Stock, $0.001 Par Value	GTBP	Nasdaq Capital Market

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the registrant's common stock, $0.001 par value per share, held by non-affiliates on June 30, 2023 was approximately $11.5 million. As of March 26, 2024, there were 1,380,633 shares of the registrant's common stock, $0.001 par value, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

In Part III, portions of the registrant's 2024 Proxy Statement to be filed with the Securities and Exchange Commission within 120 days of the Registrant's fiscal year end.

Table of Contents

SUMMARY RISK FACTORS

Our business involves significant risks. Below is a summary of the material risks that our business faces, which makes an investment in our securities speculative and risky. This summary does not address all these risks. These risks are more fully described below under the heading "Risk Factors" in Part I, Item 1A of this annual report on Form 10-K. Before making investment decisions regarding our securities, you should carefully consider these risks. The occurrence of any of the events or developments described below could have a material adverse effect on our business, results of operations, financial condition, prospects and stock price. In such event, the market price of our securities could decline, and you could lose all or part of your investment. In addition, there are also additional risks not described below that are either not presently known to us or that we currently deem immaterial, and these additional risks could also materially impair our business, operations or market price of our common stock.

- Our business is at an early stage of development and we may not develop therapeutic products that can be commercialized.
- We have a history of operating losses and we expect to continue to incur losses for the foreseeable future and we may never generate revenue or achieve profitability.
- If we fail to meet our obligations under our license agreements, we may lose our rights to key technologies on which our business depends.
- Our reliance on the activities of our non-employee consultants, research institutions and scientific contractors, whose activities are not wholly within our control, may lead to delays in development of our proposed products.
- We have limited clinical testing and regulatory capabilities, and human clinical trials are subject to extensive regulatory requirements, very expensive, time-consuming and difficult to design and implement. Our products may fail to achieve necessary safety and efficacy endpoints during clinical trials, which may limit our ability to generate revenues from therapeutic products.
- We are subject to extensive regulation, which can be costly and time consuming and can subject us to unanticipated delays. Even if we obtain regulatory approval for some of our products, those products may still face regulatory difficulties.
- Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- We currently lack manufacturing capabilities to produce our therapeutic product candidates at commercial-scale quantities and do not have an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the product.
- We rely on third parties to conduct preclinical and clinical trials of our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- Epidemic or pandemic outbreaks such as COVID-19 (coronavirus), natural disasters, whether or not caused by climate change, unusual weather conditions, terrorist acts and political events, could disrupt business and result in halting our clinical trials and otherwise adversely affect our financial performance.
- There has been a limited public market for our common stock, and we do not know whether one will develop to provide 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.
- Because our common stock may be deemed a "penny" stock, an investment in our common stock should be considered high-risk and subject to marketability restrictions.

PART I

CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, including any documents which may be incorporated by reference into this Annual Report, contains "Forward-Looking Statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are "Forward-Looking Statements" for purposes of these provisions, including our plans of operation, any projections of revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or services, any statements regarding future economic conditions or performance, and any statements of assumptions underlying any of the foregoing. All Forward-Looking Statements included in this document are made as of the date hereof and are based on information available to us as of such date. We assume no obligation to update any Forward-Looking Statement. In some cases, Forward-Looking Statements can be identified by the use of terminology such as "may," "will," "expects," "plans," "anticipates," "intends," "believes," "estimates," "potential," or "continue," or the negative thereof or other comparable terminology. Although we believe that the expectations reflected in the Forward-Looking Statements contained herein are reasonable, there can be no assurance that such expectations or any of the Forward-Looking Statements will prove to be correct, and actual results could differ materially from those projected or assumed in the Forward-Looking Statements. Future financial condition and results of operations, as well as any Forward-Looking Statements are subject to inherent risks and uncertainties, including any other factors referred to in our press releases and reports filed with the Securities and Exchange Commission. All subsequent Forward-Looking Statements attributable to the company or persons acting on its behalf are expressly qualified in their entirety by these cautionary statements. Additional factors that may have a direct bearing on our operating results are described under "Risk Factors" and elsewhere in this Annual Report on Form 10-K.

Introductory Comment

Throughout this Annual Report on Form 10-K, the terms "GT Biopharma," "GTBP," "we," "us," "our," "the company" and "our company" refer to GT Biopharma, Inc., a Delaware corporation formerly known as DDI Pharmaceuticals, Inc., Diagnostic Data, Inc. and OXIS International, Inc., together with our subsidiaries.

ITEM 1. BUSINESS

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based on our proprietary Tri-specific Killer Engager (TriKE®) fusion protein immune cell engager technology platform. Our TriKE® platform generates proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically targeted proteins expressed on a specific type of cancer cell or virus infected cell, resulting in the targeted cell's death. TriKE®s can be designed to target any number of tumor antigens on hematologic malignancies or solid tumors and do not require patient-specific customization.

We are using our TriKE® platform with the intent to bring to market immuno-oncology products that can treat a range of hematologic malignancies, and solid tumors. The platform is scalable, and we are putting processes in place to be able to produce investigational new drug (IND) ready moieties in a timely manner after a specific TriKE® conceptual design. Specific drug candidates can then be advanced into the clinic on our own or through potential collaborations with partnering companies. We believe our TriKE®s may have the ability, if approved for marketing, to be used as both monotherapy and in combination with other standard-of-care therapies.

We are also using our TriKE® platform to develop therapeutics useful for the treatment of infectious disease such as for the treatment of patients infected by the human immunodeficiency virus (HIV). While the use of anti-retroviral drugs has substantially improved the health and increased the longevity of individuals infected with HIV, these drugs are designed to suppress virus replication to help modulate progression to acquired immunodeficiency syndrome (AIDS) and to limit further transmission of the virus. Despite the use of anti-retroviral drugs, infected individuals retain reservoirs of latent HIV-infected cells that, upon cessation of anti-retroviral drug therapy, can reactivate and re-establish an active HIV infection. For a curative therapy, destruction of these latent HIV infected cells must take place. The HIV-TriKE® contains the antigen binding fragment (Fab) from a broadly neutralizing antibody targeting the HIV-Env protein or a protein that binds infected CD4+ T cells. The HIV-TriKE® is designed to target HIV while redirecting NK cell killing specifically to actively replicating HIV infected cells. The HIV-TriKE® induced NK cell proliferation and demonstrated the ability in vitro to reactivate and kill HIV-infected T-cells. These findings indicate a potential role for the HIV-TriKE® in the reactivation and elimination of the latently infected HIV reservoir cells by harnessing the NK cell's ability to mediate the antibody-directed cellular cytotoxicity (ADCC).

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

Immuno-Oncology Platform

Tri-specific Killer Engagers (TriKE®s)

The generation of chimeric antigen receptor, or CAR, expressing T cells from monoclonal antibodies has represented an important step forward in cancer therapy. These therapies involve the genetic engineering of T cells to express either CARs, or T cell receptors, or TCRs, and are designed such that the modified T cells can recognize and destroy cancer cells. While a great deal of interest has recently been placed upon chimeric antigen receptor T, or CAR-T, therapy, it has certain limitations for broad potential applicability because it can require an individual approach that is expensive, time consuming, and may be difficult to apply on a large scale. NK cells represent an important immunotherapeutic target as they are involved in tumor immune-surveillance, can mediate antibody-dependent cell-mediated cytotoxicity (ADCC), contain pre-made granules with perforin and granzyme B and can quickly secrete inflammatory cytokines, and unlike T cells they do not require antigen priming and can kill cells in the absence of major histocompatibility complex (MHC) presentation of antigens. Unlike full-length antibodies, TriKE® constructs are composed of a single-chain fusion protein that binds the CD16 receptor of NK cells directly producing a potent and lasting cytotoxic killing response, interleukin 15 (IL-15) to promote NK cell activation, persistence and proliferation, and a cancer cell targeting moiety. An additional benefit of TriKE® may have been its attractive biodistribution, as a consequence of their smaller size, which we expect to be important in the treatment of solid tumors. In addition to these advantages, TriKE® is designed to be non-immunogenic, have appropriate clearance properties, and can be engineered to target a variety of tumor antigens.

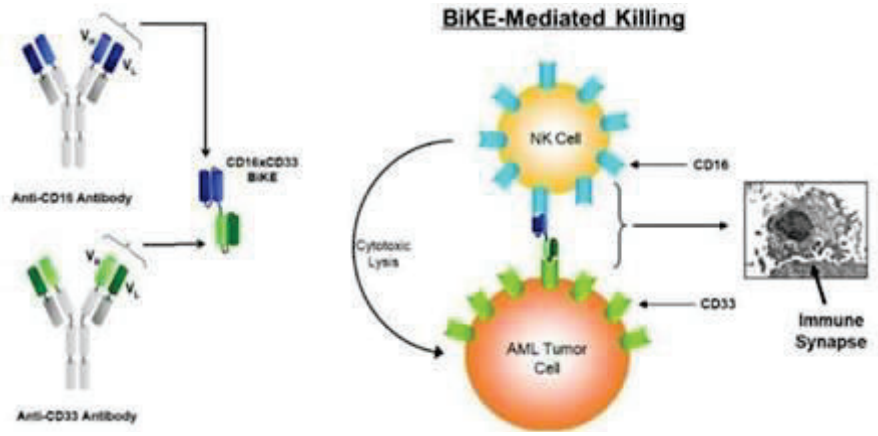
We believe there is a continued unmet medical need for targeted immuno-oncology therapies that can have the potential to be dosed in a patient-friendly outpatient setting, can be used on a stand-alone basis, augment the current monoclonal antibody therapeutics, or be used in conjunction with more traditional cancer therapy. We believe our TriKE® constructs have this potential and therefore we have generated, and intend to continue to generate, a pipeline of product candidates to be advanced into the clinic on our own or through potential collaborations with larger companies.

GTB-3550 TriKE® and Phase 1 Acute Myeloid Leukemia/Myelodysplastic Syndrome (AML/MDS) Phase 1 Clinical Trial

GTB-3550 was the Company's first-generation TriKE® product candidate which was a single-chain, tri-specific recombinant fusion protein construct composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15, all connected by small peptide linkers. The GTB-3550 Phase 1 clinical trial for treatment of patients with CD33-expressing, high risk myelodysplastic syndromes and refractory/relapsed acute myeloid leukemia opened for patient enrollment in September 2019 and completed enrollment in September 2021. The clinical trial was conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick and Dr. Mark Juckett.

Background and Select Non-Clinical Data

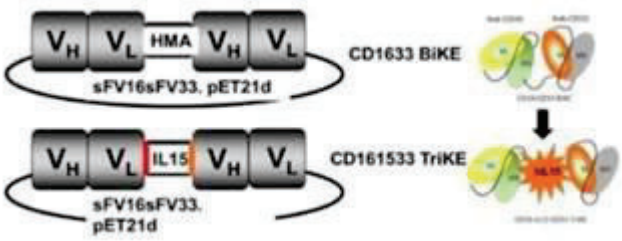
In conjunction with our research agreement with the Masonic Cancer Center at the University of Minnesota, the exploration of targeting NK cells to a variety of tumors initially focused on novel bi-specific killer engagers, or BiKEs, composed of the variable portions of antibodies targeting the CD16 activating receptor on NK cells and CD33 (AML and MDS; see figure below), B7H3 (solid tumors – breast, lung, colon, prostate), Her2 (Breast, Gastric), or CD19/CD22 (B cell lymphomas) on the tumor cells.



Subsequently, a tri-specific (TriKE®) construct that replaced the linker molecule between the CD16 scFv and the CD33 scFv with a modified IL-15 molecule, containing flanking sequences, was generated, and tested. Data indicates that the CD16 x IL-15 x CD33 potently induce proliferation of healthy donor NK cells, possibly greater than that induced by exogenous IL-15, which is absent in the BiKE platform. Targeted delivery of the IL-15 through the TriKE® also resulted in specific expansion of the NK cells without inducing T cell expansion on post-transplant patient samples.

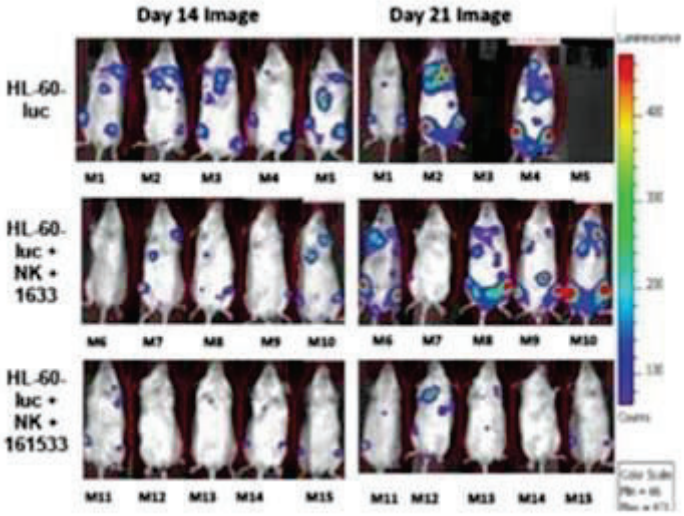
When compared to the CD16 x CD33 BiKE, the CD16 x IL-15 x CD33 TriKE® is also capable of potently restoring killing capacity of post-transplant NK cells against CD33-expressing HL-60 targets and primary AML blasts. These results demonstrated the ability to functionally incorporate an IL-15 cytokine into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

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



The CD33 targeting TriKE® constructs was tested against three separate human tumor cell lines to evaluate specificity: CD33+ HL-60 (promyelocitic leukemia) cells, CD33, Raji (Burkitt's lymphoma), and CD33- HT29 (colorectal adenocarcinoma). TriKE® (GTB-3550) activity was only seen against the CD33+ HL-60 cells containing a Luc reporter to allow for in vivo imaging of the tumors, were used to show in vivo efficacy of BiKE (1633) and TriKE® (GTB-3550) against relevant human tumor targets (HL-60-luc) over an extended period of time. The system consisted of initial conditioning of NSG mice using radiation (250-275 cGy), followed by injection of the tumor cells (I.V. for HL-60-luc, a three-day growth phase, injection of human NK cells, and repeated injection of the drugs of interest, BiKE and TriKE® (three to five times a week). Imaging was carried out at Day 7, 14, and 21, and extended as needed. Subsequent studies were also carried out to evaluate other TriKEs expressing targeting arms against other tumor antigens (B7H3 and HER2 for instance).

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



Based on these results, and others, the IND for GTB-3550 was filed in June 2017 by the University of Minnesota. The FDA requested that additional preclinical toxicology, additional information and clarifications on manufacturing, and clinical development plans. The requested additional information and clarifications were completed and incorporated into the IND in eCTD format. We filed the IND amendment in June 2018 and announced on November 1, 2018, that the FDA granted approval of the IND and the Company was authorized to initiate a first-in-human Phase 1 study with GTB-3550 in AML, MDS, and systemic mastocytosis. The Phase 1 clinical trial was initiated in September 2019 and closed in September 2021.

Targeting Solid Tumors and Other Potentially Attractive Characteristics

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

Examples of our earlier stage solid tumor targeting product candidates are focused on CD33, B7-H3, Her2, CD19, CLEC12A, CD22, and CD133 alone and in combination. We believe these constructs have the potential to target prostate, breast, colon, ovarian, liver, and head and neck cancers. Depending on the availability of drug supply, we hope to initiate human clinical testing for certain of our solid tumor product candidates in the first half of 2025.

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

We are using our TriKE® platform with the intent to bring to market multiple immuno-oncology products that can treat a range of hematologic malignancies and solid tumors. The platforms are scalable, and we are currently working with a third-party product manufacturer investigating the optimal GMP production expression system for TriKE® constructs.

We believe TriKE®s will have the ability, if approved for marketing, to be used as both monotherapy and in combination with standard-of-care therapies.

Immuno-Oncology Product Candidates

GTB-3550

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

GTB-3550 was replaced by a more potent next-generation camelid nanobody TriKE®, GTB-3650, both targeting CD33 on relapsed/refractory Acute Myeloid Leukemia (AML) and high-risk Myelodysplastic Syndromes (MDS). The pivot from GTB-3550 to GTB-3650 in our clinical development was based on a solid preclinical foundation that showed markedly enhanced potency of the camelid modification of the first-generation TriKE. 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 2nd generation TriKE platform.

About High-Risk Myelodysplastic Syndromes

Myelodysplastic Syndromes is a rare form of bone marrow-related cancer caused by irregular blood cell production within the bone marrow. As a result of this irregular production, MDS patients do not have sufficient normal red blood cells, white blood cells and/or platelets in circulation. High-risk MDS is associated with poor prognosis, diminished quality of life, and a higher chance of transformation to acute myeloid leukemia. The goals of therapy are to reduce disease associated symptoms and the risk of disease progression and death, thereby improving both quality and quantity of life. United States incidence of MDS is estimated to be 10,000 cases per year, although the condition is thought to be under diagnosed. The prevalence has been estimated to be from 60,000 to 170,000 in the United States. Approximately 40% of patients with High-Risk MDS transform to AML, another aggressive cancer with poor outcomes.

About Acute Myeloid Leukemia

Acute myeloid leukemia is a type of cancer in which the bone marrow makes abnormal myeloblasts (a type of white blood cell), red blood cells, or platelets. The median age at the time of diagnosis is 65–69 years. AML is an aggressive disease and is fatal without anti-leukemic treatment. Among patients treated with chemotherapy, 65% to 80% achieve complete remission. Despite a plethora of novel agents that have been approved by the U.S. Food and Drug Administration since 2017 for treatment of AML, once complete remission (CR) is achieved, approximately 50% of patients age < 60 years of age and up to 90% of patients ≥ 60 years of age will relapse, despite consolidation strategies. Furthermore, while 10–40% of younger AML patients are primarily refractory to AML induction therapy, the number is considerably higher for patients above 60 years (40–60%). The vast majority of fit AML patients will undergo hematopoietic stem cell transplantation (HSCT) after achieving a CR. However, 40% of these patients relapse after HSCT. Thus, refractory or relapsed (r/r) AML is a very common scenario in AML and despite recent advances and new targeted therapies, the management of AML remains a challenge, particularly in older adults ineligible for intensive therapies. According to the National Cancer Institute (NCI), the five-year survival rate is about 35% in people under 60 years old, and 10% in people over 60 years old. Older people whose health is too poor for intensive chemotherapy have a typical survival of five to ten months. AML accounts for approximately 1.8% of cancer deaths in the United States.

About GTB-3550 TriKE® Clinical Trial

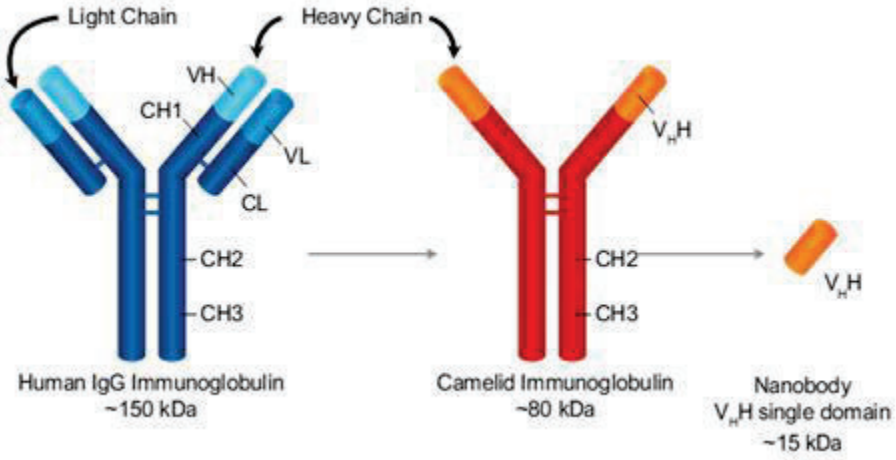
We opened our GTB-3550 Phase 1 clinical trial in September 2019 and enrolled our first patient in January 2020. Patients with CD33+ malignancies (primary induction failure or relapsed AML with failure of one reinduction attempt or high-risk MDS progressed on two lines of therapy) age 18 and older were eligible (ClinicalTrials.gov Identifier NCT03214666). The primary endpoint is to identify the maximum tolerated dose (MTD) of GTB-3550 TriKE®. Correlative objectives include the number, phenotype, activation status and function of NK cells and T cells. From January, 2020 until September, 2021 twelve patients received escalating doses of GTB-3550 in the Phase 1 trial. The results of this trial were presented at several conferences in 2021 and 2022. To summarize, the therapy was overall well tolerated and safe. There were no serious cases of cytokine release syndrome observed. Four of twelve patients had transient reductions in bone marrow leukemic blast cells. Correlative studies showed activation, proliferation, and persistence of functionally active endogenous NK cells. The results of our first generation GTB-3550 Phase 1 clinical trial support our plans to advance the next generation camelid nanobody into the clinic.

The Next Generation of Camelid Nanobody TriKE®s

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 and consist of two heavy chains. These nanobodies have the potential to have greater affinity to target antigens, potentially resulting in greater potency. GT Biopharma is utilizing this camelid antibody structure for all its new TriKE® product candidates.

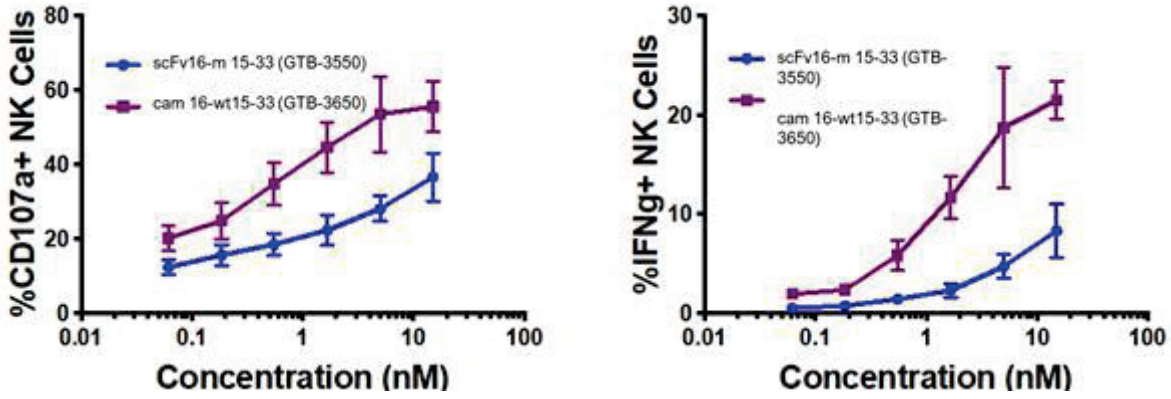
Generation of humanized single-domain antibody targeting CD16 for incorporation into the TriKE® platform

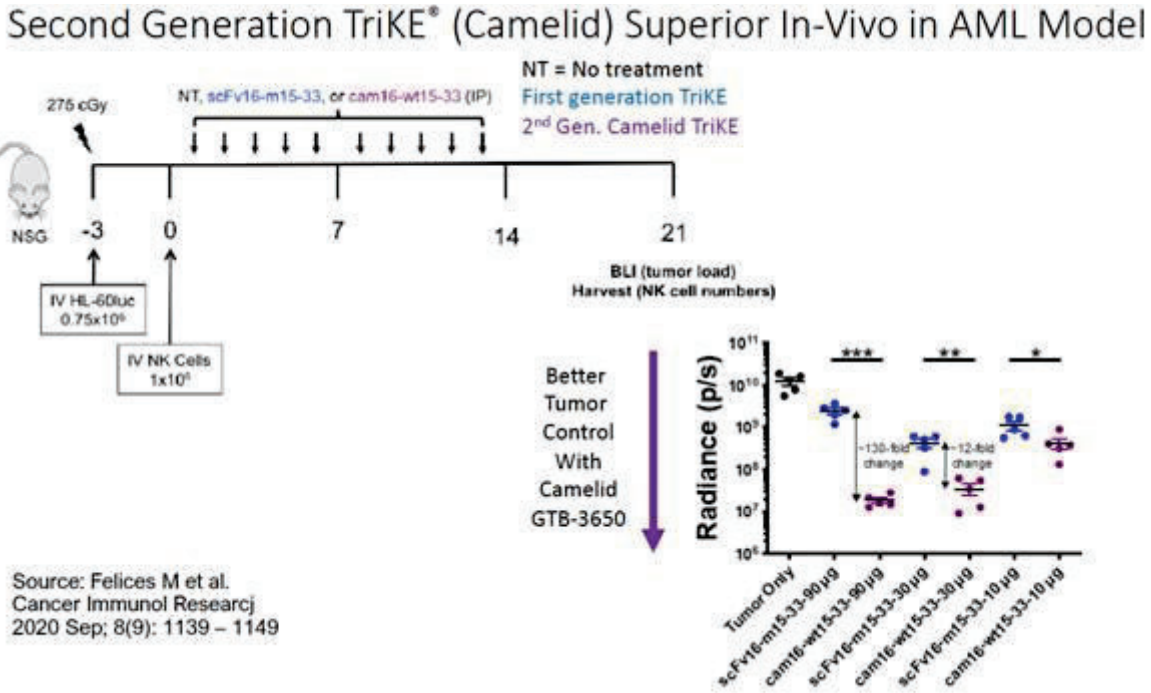
To develop second generation TriKE®s, we designed a new humanized CD16 engager derived from a single-domain antibody. While scFvs consist of a heavy and a light variable chain joined by a linker, single-domain antibodies consist of a single variable heavy chain capable of engaging without the need of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



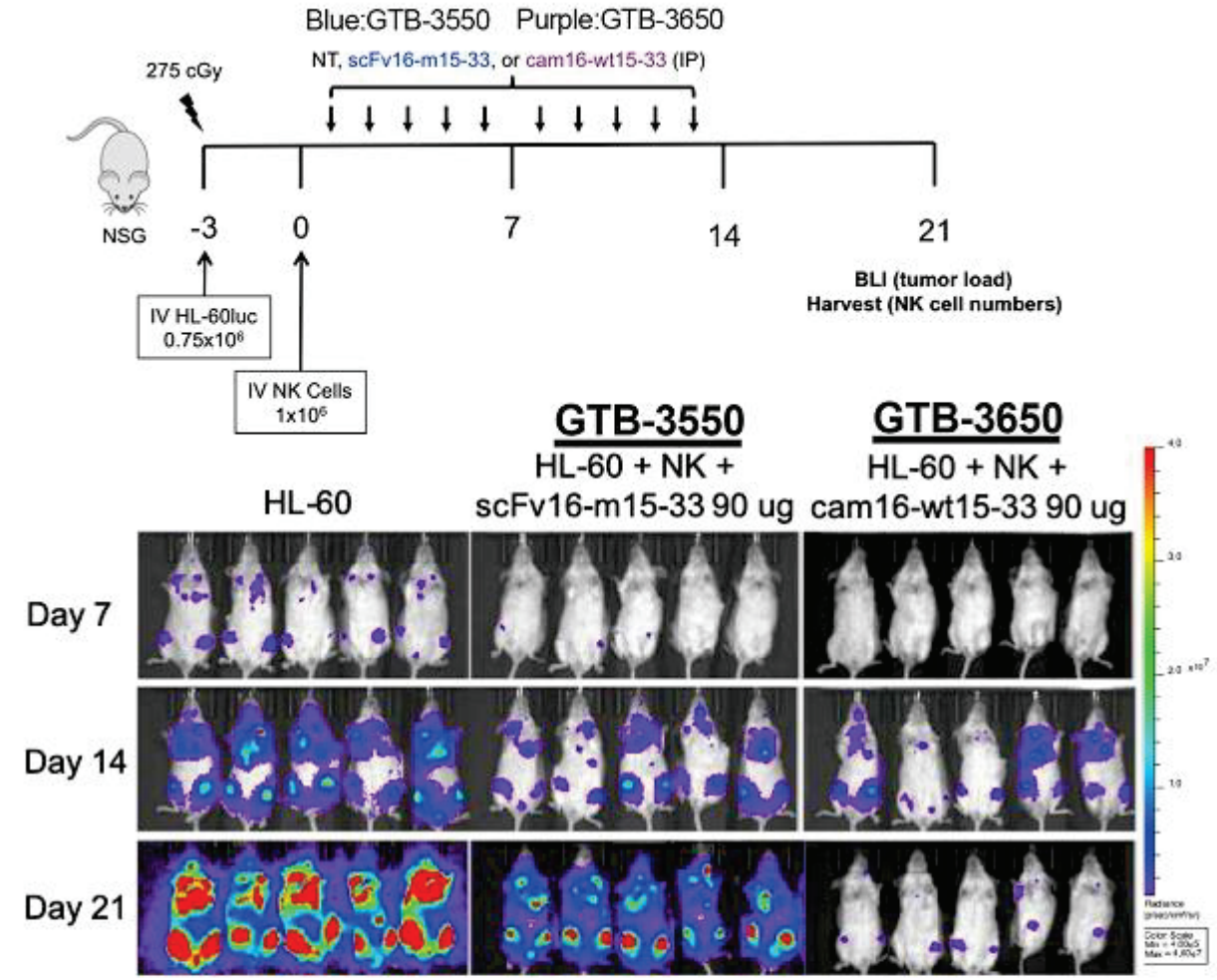
These single-domain antibodies are thought to have certain attractive features for antibody engineering, including physical stability, ability to bind deep grooves, and increased production yields, amongst others. Pre-clinical studies demonstrated increased NK cell activation against CD33+ targets including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

CD33+ HL60 Targets in Killing Assays
(Purple line represents the GTB-3650 and Blue line represents GTB-3550)





Source: Felices M et al.
Cancer Immunol Researcj
2020 Sep; 8(9): 1139 – 1149


Blue:GTB-3550 Purple:GTB-3650
NT, scFv16-m15-33, or cam16-wt15-33 (IP)
275 cGy
NSG
-3
0
7
14
21
BLI (tumor load)
Harvest (NK cell numbers)
IV HL-60luc
0.75x10^6
IV NK Cells
1x10^6
GTB-3550
HL-60 + NK +
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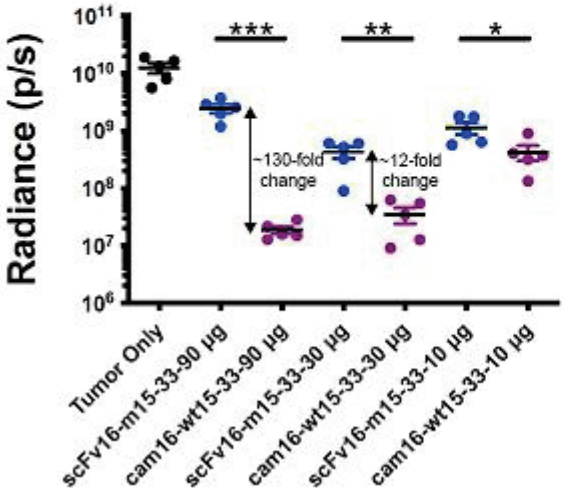
HL-60
Day 7
Day 14
Day 21


Radiance (p/s)
***
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*
~130-fold change
~12-fold change
Tumor Only
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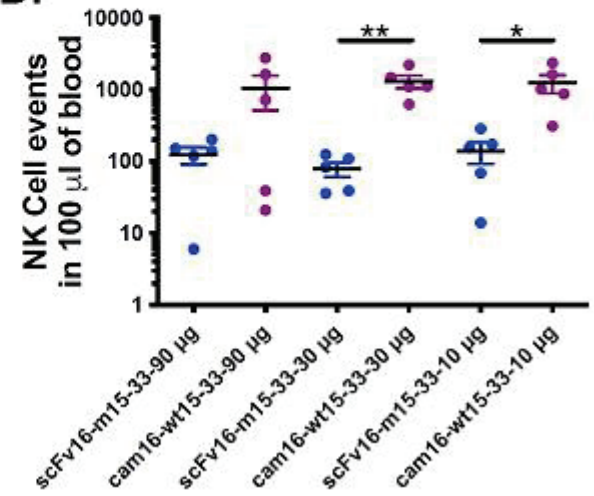
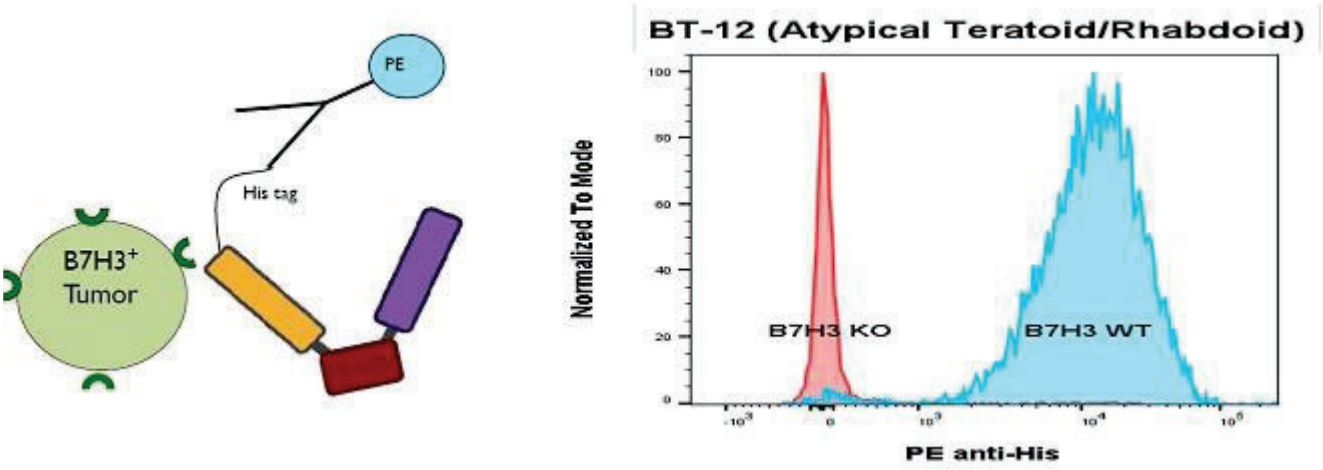
scFv16-m15-33-10 µg
cam16-wt15-33-10 µg

D.


NK Cell events in 100 µl of blood
**
*
scFv16-m15-33-90 µg
cam16-wt15-33-90 µg
scFv16-m15-33-30 µg
cam16-wt15-33-30 µg
scFv16-m15-33-10 µg
cam16-wt15-33-10 µg

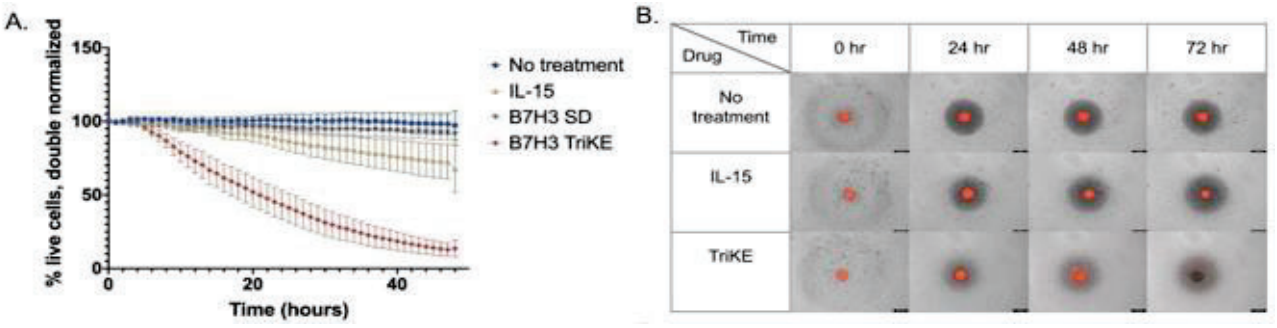
GTB-3650

As seen in the figure above, AML control in vivo was superior with GTB-3650 (purple dots) compared to the first-generation TriKE (blue dots). GTB-3650 is a CD33 targeted TriKE® which targets CD33 on the surface of myeloid leukemias. We are advancing GTB-3650 through preclinical studies and have filed an Investigational New Drug (IND) application with the FDA in December, 2023. The Company continues to be in a productive dialogue with the FDA with respect to its IND Application in relation to GTB 3650. We further anticipate approval to start study enrollment targeting patients with relapsed/refractory AML and high grade MDS by the second half of 2024. 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.



GTB-5550

GTB-5550 is a B7-H3 targeted TriKE® which targets B7-H3 on the surface of advanced solid tumors (figure above). B7-H3 is an exciting target as it displays specific expression 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 tumor settings, 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 have initiated a GMP manufacturing campaign in anticipation of filing an IND in the late second half of 2024. 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 to the FDA was regarding pre-clinical toxicology and a pivot to subcutaneous dosing. The initial trial 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). This is dependent on manufacturing of clinical materials. We expect a study targeting patients with B7-H3 positive solid tumors in the first half of 2025.



Oncology Markets

Acute Myeloid Leukemia and Myelodysplastic Syndromes

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

B7-H3 Positive Solid Tumors

The B7-H3 protein, which functions as a checkpoint inhibitor, has been identified in many of the most common solid tumor cancers, including but not limited to bladder, breast, cervical, colorectal, endometrial, esophageal, gastric, glioma, kidney, liver, lung, pancreatic, prostate, head and neck cancer, and melanoma. In recent studies, B7-H3 has been identified as a critical promoter of tumor cell proliferation, migration, invasion, epithelial-to-mesenchymal transition, cancer stemness and drug resistance. Because this protein does not seem to be expressed in normal cells, this makes it an attractive target for therapeutic intervention.

Manufacturing

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

Patents and Trademarks

Immuno-oncology platform

TriKE® Patents

On August 24, 2021, two patents were issued by the US Patent Office covering our pipeline of clinical and non-clinical product candidates consisting of tri-specific killer engagers, or TriKE®s, designed to target natural killer, or NK, cells and tumor or virus infected cells forming an immune synapse between the NK cell and the tumor cell thereby inducing NK cell activation at that site. The patents broadly include TriKE®s that target the CD16 receptor, which includes the more potent camelid nanobody sequence, an IL-15 activating domain, and any targeting domain.

University of Minnesota License Agreements

2016 Exclusive Patent License Agreement

We are party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, ("UofMN") to further develop and commercialize cancer therapies using TriKE® technology developed by researchers at the UofMN to target NK cells to cancer. Under the terms of the 2016 agreement, we received exclusive rights to conduct research and to develop, make, use, sell, and import TriKE® technology worldwide for the treatment of any disease, state or condition in humans. We are responsible for obtaining all permits, licenses, authorizations, registrations and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as the TriKE® technology, including without limitation the FDA and the European Agency for the Evaluation of Medicinal Products in the European Union. Under the agreement, the University of Minnesota received an upfront payment of $200,000, annual license maintenance fees of $100,000 beginning in 2021, 4% royalty fees (not to exceed 6% under subsequent license agreements or amendments to this agreement), upon sale of a licensed product or a minimum annual royalty payment ranging from $250,000 to $5.0 million. The agreement also includes certain milestone payments totaling $3.1 million, and one-time sales milestone payments of $1.0 million upon reaching $250 million in gross sales and $5.0 million upon reaching $500 million in cumulative gross sales of licensed products.

2021 Exclusive License Agreement

On March 26, 2021, we entered into an agreement with the UofMN specific to the B7H3 targeted TriKE®. Under the agreement, the UofMN received an upfront license fee of $20,000, and will receive annual license maintenance fees of $5,000 beginning in 2022, 2.5% to 5% royalty fees or minimum annual royalty payments of $250,000 beginning in the first year after the first commercial sale of licensed product, and $2.0 million beginning in the fifth year after the first commercial sale of licensed product. The agreement also includes certain milestone payments totaling $3.1 million and one-time sales milestone payments of $1.0 million upon reaching $250 million in gross sales, and $5.0 million upon reaching $500 million in cumulative gross sales of licensed products. There is no double payment intended; if one of the milestone payments has been paid under the 2016 agreement, no further payment is due for the corresponding milestone above.

Reverse Stock Split

On February 1, 2024, the Company announced a reverse stock-split of its common stock, par value $0.001 per share, at a ratio of 1 for 30. The reverse stock-split became effective on February 2, 2024. The Company's common stock began trading on a reverse stock-split-adjusted basis on The Nasdaq Capital Market on February 5, 2024, under our existing trading symbol "GTBP."

As a result of the reverse stock-split, every thirty (30) shares of issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share. No fractional shares were 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).

Proportionate adjustments were 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 for the Company's common stock and to the number of shares of common stock reserved for future issuance pursuant to the GT Biopharma, Inc. 2022 Omnibus Incentive Plan.

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

Employees and Human Capital Resources

At the date of this Annual Report, we have 2 full-time employees and eight consultants to carry on our operations. Many of our activities are outsourced to consultants who provide services to us on a project basis. As business activities require and capital resources permit, we will hire additional employees to fulfill our Company's needs.

Form and Year of Organization

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

Available Information

We post our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act, free of charge, on the Investors section of our public website (www.gtbiopharma.com) as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC . In addition, you can read our SEC filings over the Internet at the SEC's website at www.sec.gov. The contents of these websites are not incorporated into this annual report on Form 10-K. Further, our references to the URLs for these websites are intended to be inactive textual references only.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below in addition to the other information contained in this Annual Report on Form 10-K before deciding whether to invest in shares of our common stock. If any of the following risks actually occur, our business, financial condition or operating results could be harmed. In that case, the trading price of our common stock could decline and you may lose part or all of your investment. In the opinion of management, the risks discussed below represent the material risks known to the company. Additional risks and uncertainties not currently known to us or that we currently deem immaterial may also impair our business, financial condition and operating results and adversely affect the market price of our common stock.

Risks Related to Our Business

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

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

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

During the year ended December 31, 2023, the Company reported a net loss of $7.6 million and as of December 31, 2023 and had an accumulated deficit of $682.1 million. We have not generated any revenue to date and are not profitable, and have incurred losses in each year since our inception. We do not expect to generate any product sales or royalty revenues for the foreseeable future. We expect to incur significant additional operating losses for the foreseeable future as we expand research and development and clinical trial efforts.

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

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

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

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

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

- the accuracy of the assumptions underlying our estimates for capital needs in 2023 and beyond;
- scientific and clinical progress in our research and development programs;
- the magnitude and scope of our research and development programs and our ability to establish, enforce and maintain strategic arrangements for research, development, clinical testing, manufacturing and marketing;
- our progress with pre-clinical development and clinical trials;
- the time and costs involved in obtaining regulatory approvals;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims; and
- the number and type of product candidates that we pursue.

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

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

Our research and development costs could exceed our projections requiring us to significantly modify our planned operations.

Our currently projected expenditures for 2024 include approximately $3.0 million for research and development. The actual cost of our programs could differ significantly from our current projections if we change our planned development process. In the event that actual costs of our clinical program, or any of our other ongoing research activities, are significantly higher than our current estimates, we may be required to significantly modify our planned level of operations.

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

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

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

As defined in Regulation 12b-2 under the Securities Exchange Act of 1934, or the Exchange Act, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim consolidated financial statements will not be prevented, or detected on a timely basis.

We have taken measures to mitigate potential issues and have implemented a functional system of internal controls over financial reporting. However, such controls may become inadequate due to changes in conditions, or the degree of compliance with such policies or procedures may deteriorate, which could result in the discovery of material weaknesses and deficiencies. In any event, the process of determining whether our existing internal control over financial reporting is compliant with Section 404 of the Sarbanes-Oxley Act, or Section 404, and sufficiently effective requires the investment of substantial time and resources, including by certain members of our senior management.

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

Our intellectual property may be compromised.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We will have to hire additional employees to carry on our business operations. If we are unable to hire qualified personnel, we may not be able to implement our business strategy.

We currently have two full-time employees and eight consultants to carry on our operations. Our interim Chief Executive Officer and Executive Chairman of the Board provides his services through a consulting arrangement. The loss of the services of any of our employees or consultants could delay our product development programs and our research and development efforts. In order to develop our business in accordance with our business strategy, we will have to hire additional qualified personnel, including in the areas of manufacturing, clinical trials management, regulatory affairs, finance, discovery biology, and business development. We will need to raise sufficient funds to hire and retain the necessary employees and consultants.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- discovery of safety or tolerability concerns, such as serious or unexpected toxicities or side effects or exposure to otherwise unacceptable health risks, with respect to study participants;

- lack of effectiveness of any product candidate during clinical trials or the failure of our product candidates to meet specified endpoints;

- delays in subject recruitment and enrollment in clinical trials or inability to enroll a sufficient number of patients in clinical trials to ensure adequate statistical ability to detect statistically significant treatment effects;
- difficulty in retaining subjects and volunteers in clinical trials;
- difficulty in obtaining the IRB's approval for studies to be conducted at each clinical trial site;
- inadequacy of or changes in our manufacturing process or the product formulation or method of delivery;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective Contract Research Organizations, ("CROs"), clinical trial sites and other third-party contractors;
- inability to add a sufficient number of clinical trial sites;
- uncertainty regarding proper formulation and dosing;
- failure by us, our employees, our CROs or their employees or other third-party contractors to comply with contractual and applicable regulatory requirements or to perform their services in a timely or acceptable manner;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols;
- inability or unwillingness of medical investigators to follow our clinical protocols;
- difficulty in maintaining contact with subjects during or after treatment, which may result in incomplete data; or
- changes in applicable laws, regulations and regulatory policies.

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

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

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

- the severity of the disease under investigation;
- the frequency of the molecular alteration we are seeking to target in the applicable trial;
- the eligibility criteria for the study in question;
- the perceived risks and benefits of the product candidate under study;
- the extent of the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;

- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

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

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

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

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

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

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

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

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

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

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

- the product candidates require significant clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be filed with the FDA and other regulatory authorities;

- data obtained from pre-clinical and nonclinical animal testing and clinical trials can be interpreted in different ways, and regulatory authorities may not agree with our respective interpretations or may require us to conduct additional testing;

- negative or inconclusive results or the occurrence of serious or unexpected adverse events during a clinical trial could cause us to delay or terminate development efforts for a product candidate; and/or

- FDA and other regulatory authorities may require expansion of the size and scope of the clinical trials.

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

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

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

- we may not be able to demonstrate to the FDA's satisfaction that our product candidates are safe and effective for any indication;

- the results of clinical trials may not meet the level of statistical significance or clinical significance required by the FDA for approval;

- the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials;

- the FDA may not find the data from pre-clinical studies and clinical trials sufficient to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;

- the FDA may disagree with our interpretation of data from pre-clinical studies or clinical trials, or may not accept data generated at our clinical trial sites;

- the data collected from pre-clinical studies and clinical trials of our product candidates may not be sufficient to support the submission of applications for regulatory approval;

- the FDA may have difficulties scheduling an advisory committee meeting in a timely manner, or the advisory committee may recommend against approval of our application or may recommend that the FDA require, as a condition of approval, additional pre-clinical studies or clinical trials, limitations on approved labeling, or distribution and use restrictions;

- the FDA may require development of a risk evaluation and mitigation strategy as a condition of approval;

- the FDA may identify deficiencies in the manufacturing processes or facilities of third-party manufacturers with which we enter into agreements for clinical and commercial supplies;

- the FDA may change their approval policies or adopt new regulations that adversely affect our applications for pre-market approval; and

- the FDA may require simultaneous approval for both adults and for children and adolescents delaying needed approvals, or we may have successful clinical trial results for adults but not children and adolescents, or vice versa.

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

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

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

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

- warning letters or other actions requiring changes in product manufacturing processes or restrictions on product marketing or distribution;

- product recalls or seizures or the temporary or permanent withdrawal of a product from the market;

- suspending any ongoing clinical trials;

- temporary or permanent injunctions against our production operations;

- refusal of our applications for pre-market approval or an investigational new drug application; and

- fines, restitution or disgorgement of profits or revenue, the imposition of civil penalties or criminal prosecution.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- our establishment and demonstration to the medical community of the clinical efficacy and safety of our proposed products;

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

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

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

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

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

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

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

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

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

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

Our therapeutic immuno-oncology (IO) development programs face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery activities or funding, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates. According to Global Data, Thematic Research: Immuno-Oncology (March 2021), as of December 2020, there are 4,822 industry-sponsored clinical trials for immuno-oncology with 422 drugs in development. Phase 2 trials constitute the majority of the IO pipeline, followed by early-stage molecules in Phase 1/2 and Phase 1. For late-stage pipeline products, 484 clinical trials are ongoing in Phase 3, and 51 are in Phase 2/3 development. There are currently 22 marketed immuno-oncology agents. Cancer vaccine products lead the category with 9 products followed by checkpoint modulators with 8 approved drugs. The indications with the most marketed IO agents in the United States are metastatic melanoma and non-small cell lung cancer, with 6 approved products each. The market value of bispecific antibodies, cancer vaccines, checkpoint modulators, cell therapies, and oncolytic viruses globally has increased sharply in the past 10 years with nearly $29 billion in 2019 compared to $370 million in 2010 .

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We face risks associated with security breaches or cyber-attacks.

We face risks associated with security breaches or cyber-attacks of our computer systems or those of our third-party representatives, vendors, and service providers. Armed conflicts in the Middle East and between Russia and Ukraine, and tensions with countries such as Iran and North Korea and resulting geopolitical uncertainties also could result in an increase in cyberattacks that could either directly or indirectly impact our operations. Although we have implemented security procedures and controls to address these threats, such as firewalls, encryption, access controls, and employee training programs, cybersecurity threats are dynamic and evolving and our systems may still be vulnerable to theft, loss or misuse of data, including proprietary or confidential information, relating to our business, products, employees, suppliers and customers; disruption due to computer viruses and programming errors; attacks by third parties including destruction of data or demanding ransom to return control of our systems and services; or similar disruptive problems.

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

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

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

The occurrence of one or more natural disasters, such as tornadoes, hurricanes, fires, floods and earthquakes, unusual weather conditions, epidemic outbreaks, terrorist attacks or disruptive political events in certain regions where our operations are located could adversely affect our business. Epidemic or pandemic outbreaks, such as COVID-19 (coronavirus) could impact our management and our ability to conduct clinical trials. This also may affect the market conditions that would limit our ability to raise additional capital. This could have a sustained material adverse effect on our business, financial condition and results of operations.

Risks Related to Our Common Stock

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

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

- the number of stockholders;

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

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

Other factors may also contribute to volatility of the price of our common stock and could subject our common stock to wide fluctuations. These include, but are not limited to:

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

We may not be able to maintain compliance with the continued listing requirements of The Nasdaq Capital Market.

Our common stock is listed on The Nasdaq Capital Market. In order to maintain that listing, we must satisfy minimum financial and other requirements including, without limitation, a requirement that our closing bid price be at least $1.00 per share. On February 22, 2023, we received a deficiency letter from The Nasdaq Listing Qualifications Department (the "Staff") of the Nasdaq Stock Market LLC ("Nasdaq") notifying us that, for the last 30 consecutive business days, the closing bid price for our common stock had been below the minimum $1.00 per share required for continued listing on The Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(a)(2) ("Rule 5550(a)(2)"). We are currently in compliance with Nasdaq listing requirements. If we fail to continue to meet all applicable continued listing requirements for The Nasdaq Capital Market in the future and Nasdaq determines to delist our common stock, the delisting could adversely affect the market liquidity of our common stock, and our ability to obtain financing to repay debt and fund our operations.

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

As of December 31, 2023, we had 1,380,633 shares of common stock issued and outstanding and warrants outstanding for the purchase of up to 304,962 additional shares of common stock at an average exercise price of $63.30 per share, all of which are exercisable as of the date of this Annual Report (subject to certain beneficial ownership limitations). The amount of common stock reserved for issuance may have an adverse impact on our ability to raise capital and may affect the price and liquidity of our common stock in the public market. In addition, the issuance of these shares of common stock will have a dilutive effect on current stockholders' ownership.

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

Historically, the trading price of our common stock has been $5.00 per share or lower, and deemed a penny stock, as defined in Rule 3a51-1 under the Exchange Act, and subject to the penny stock rules of the Exchange Act specified in rules 15g-1 through 15g-10. Those rules require broker–dealers, before effecting transactions in any penny stock, to:

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

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

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

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

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

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We currently have research coverage by one securities analyst, and we may never obtain research coverage by additional analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our common stock may be negatively affected. In the event that we receive additional securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

[Cybersecurity is an important aspect of our business operations, and we are committed to protecting our systems, data, and the information of our clients and stakeholders. We recognize that cybersecurity threats are constantly evolving and that maintaining robust security measures is an ongoing process. Below is an overview of our cybersecurity risk management and the measures we have in place:

- ***Governance and Oversight***: Our Board of Directors and senior management are actively involved in overseeing our cybersecurity policies and practices and managing those responsible for coordinating and implementing cybersecurity initiatives across the organization.

- ***Risk Assessment and Management***: We conduct risk assessments to identify potential cybersecurity threats and vulnerabilities. This includes evaluating the likelihood and potential impact of various threats, such as data breaches, malware attacks, and insider threats. Based on these risk assessments, we develop and implement risk management strategies to mitigate identified risks.

- ***Information Security Policies and Procedures***: We have established information security policies and procedures that govern the use, protection, and handling of sensitive information. These policies cover areas such as data encryption, access controls, password management, incident response, and employee training.

- ***Network and Infrastructure Security***: We employ a range of technical measures to secure our network and infrastructure, including firewalls, intrusion detection and prevention systems, and vulnerability assessments. We also use encryption to protect data both in transit and at rest.

- ***Employee Training and Awareness***: We provide cybersecurity training to employees to raise awareness of the latest threats and best practices for protecting sensitive information. This includes training on how to recognize phishing attempts, handling secure data, and reporting security incidents.

- ***Third-Party Risk Management***: We assess the cybersecurity practices of our third-party vendors and service providers, including conducting due diligence on vendors before engaging their services and monitoring their compliance with our security requirements.

- ***Compliance and Reporting***: We comply with all applicable laws and regulations related to cybersecurity, including data protection and privacy laws.

While we believe that our current cybersecurity measures are robust, we recognize that the cybersecurity landscape is constantly evolving, and we remain vigilant in monitoring and adapting our practices to address emerging threats. We are committed to maintaining the confidentiality, integrity, and availability of our systems and data and to protecting the interests of our clients and stakeholders.]

ITEM 2. PROPERTIES

At the date of the issuance of this Annual Report, we sublease offices comprising of 4,500 rentable square feet at 8000 Marina Blvd, Suite 100, Brisbane, CA 94005 under a sublease that expires on June 30, 2024.

ITEM 3. LEGAL PROCEEDINGS

On May 24, 2023, TWF Global, LLC ("TWF") filed a Complaint in the California Superior Court for the County of Los Angeles naming the Company as defendant. The Complaint alleges that TWF is the holder of two Convertible Promissory Notes ("Notes") and that the Company did not deliver shares of common stock due on conversion in February 2021. TWF was seeking per diem liquidated damages based on the terms of alleged Notes. On July 14, 2023, the Company filed a motion to dismiss for improper forum because the terms of the Notes, as alleged, require disputes to be filed in New York state and federal courts. TWF voluntarily dismissed its Complaint before the California Superior Court of Los Angeles without prejudice. The Company subsequently filed a Summons and Complaint for Interpleader against TWF and Z One LLC before the Supreme Court of the State of New York County of New York, asking the Supreme Court to determine if the Company's shares of common stock are properly registered to TWF or Z One LLC, as both of these entities have made conflicting demands for registration of the shares of common stock. On February 5, 2024, the Company filed a motion for entry of default against TWF, seeking an order directing the Company to register the shares of common stock in the name of Z-One and that the Company be released from all associated liability and claims. The Court has not yet ruled on the Company's motion. The Company believes that any claims related to the Notes are without merit and will continue to defend vigorously against these claims.

On May 11, 2023, our former interim Chief Executive Officer, Dr. Greg Berk, filed a complaint with the Occupational Safety and Health Administration alleging retaliation against him during his tenure at the Company for raising concerns related to the public disclosure of certain product timelines. The Company is vigorously defending this matter and believe it to be without merit. At this early stage in the proceedings, the Company is not able to determine the probability of the outcome of this matter or a range of reasonably expected losses, if any.

On May 13, 2022, the Company made an arbitration demand upon Michael Handelman, its former Chief Financial Officer, asserting that he breached his fiduciary duty by misappropriating Company funds and shares of common stock, among other things. The Company seeks among other relief, monetary damages estimated at $470,000; the return of 13,903 shares of our common stock received without authorization; and an award of the Company's attorneys' fees and any forum and arbitration fees. As a component of Mr. Handelman's contract with the Company, disputes shall be fully addressed and finally resolved by binding arbitration conducted by the American Arbitration Association (AAA). In connection with any such arbitration, the Company shall bear all costs not otherwise borne by a plaintiff in a court proceeding.

On March 20, 2024, the Arbitrator issued an interim award in favor of the Company in the amount of $409,000 and directed Mr. Handelman to return the disputed 13,903 shares of common stock. The Arbitrator also awarded the Company its attorney fees and forum costs in an amount to be determined at the time of the final award.

On August 28, 2019, a complaint was filed in the Superior Court of California, County of Los Angeles, West Judicial District, Santa Monica Courthouse, Unlimited Civil Division by Jeffrey Lion and by Daniel Vallera, as individuals. The complaint was filed against GT Biopharma, Inc. and its subsidiary OXIS Biotech, Inc. The Plaintiffs allege breach of a license agreement between the Plaintiffs and the Company entered into on or about September 3, 2015. The Company filed an answer to the complaint denying many allegations and asserting affirmative defenses. The Company reached a settlement of the case and paid on March 4, 2022, $425,000 in full and final settlement of the claims.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Our common stock is traded on the Nasdaq Capital Market under the trading symbol "GTBP." Until May 2009, our common stock was traded on the OTC Bulletin Board ("OTCBB") under the symbol "OXIS." From May 20, 2009 until March 11, 2010, our common stock was traded on Pink OTC Markets Inc. trading platform under the symbol "OXIS." From January 2015 to August 2017, our common stock was quoted on the OTCQB under the "OXIS" trading symbol. From August 2017 to February 11, 2021, our common stock was quoted on the OTCQB under the "GTBP" trading symbol.

Our common stock is also quoted on several European based exchanges including Berlin (GTBP.BE), Frankfurt (GTBP.DE), the Euronext (GTBP.NX) and Paris, (GTBP.PA). The foregoing trading prices exclude trading on these foreign stock markets.

Stockholders

As of March 26, 2024, there were 30 stockholders of record, which does not include stockholders who hold their shares in "street name." The transfer agent for our common stock is ComputerShare Limited, whose address is 8742 Lucent Blvd., Suite 225, Highland Ranch, CO 80129.

Dividends

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

Equity Compensation Plan Information

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Recent Issuances of Unregistered Securities

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 during the year ended December 31, 2023:

- The Company issued 15,782 shares of common stock to consultants in accordance with various consulting agreements.
- The Company issued 120,000 shares of common stock in a public offering and 96,667 shares of common stock for exercise of prefunded warrants.
- The Company issued 57,437 shares of common stock in the settlement of vendors payables.

Issuer Purchases of Equity Securities

We did not repurchase any shares during the fourth quarter of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Some of the statements in this Annual Report on Form 10-K are "forward-looking statements" within the meaning of the safe harbor from liability established by the Private Securities Litigation Reform Act of 1995. Forward-looking statements include statements regarding our current beliefs, goals and expectations about matters such as our expected financial position and operating results, our business strategy and our financing plans. The forward-looking statements in this report are not based on historical facts, but rather reflect the current expectations of our management concerning future results and events. The forward-looking statements generally can be identified by the use of terms such as "believe," "expect," "anticipate," "intend," "plan," "foresee," "may," "guidance," "estimate," "potential," "outlook," "target," "forecast," "likely" or other similar words or phrases. Similarly, statements that describe our objectives, plans or goals are, or may be, forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be different from any future results, performance and achievements expressed or implied by these statements. We cannot guarantee that our forward-looking statements will turn out to be correct or that our beliefs and goals will not change. Our actual results could be very different from and worse than our expectations for various reasons. You should carefully review all information, including the discussion of risk factors under "Part I. Item 1A: Risk Factors" and elsewhere in this annual report. Any forward-looking statements in the Form 10-K 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 Form 10-K to reflect subsequent events or circumstances.

Overview

We are a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE®) technology platform. Our TriKE® platform generates proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells, or NK cells. Once bound to an NK cell, our moieties are designed to enhance the NK cell, and precisely direct it to one or more specifically-targeted proteins expressed on a specific type of cancer cell or virus infected cell, ultimately resulting in the targeted cell's death. TriKE® is composed of recombinant fusion proteins and interleukin 15 (IL-15), can be designed to target any number of tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization.

As shown in the accompanying consolidated financial statements, the Company has an accumulated deficit of $682.1 million as of December 31, 2023. On a consolidated basis, the Company had cash and cash equivalents of $1.1 million and short-term investments of $12.9 million at December 31, 2023. We anticipate we will have to raise additional capital to fund our selling, general and administrative, and research and development expenses until we have a marketable product. There are no assurances that we will be able to raise the funds necessary to maintain our operations or to implement our business plan. The consolidated financial statements included in this Annual Report on Form 10-K do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts and classification of liabilities that might be necessary in the event we cannot continue our operations.

COVID-19

In March 2020, the World Health Organization declared coronavirus COVID-19 a global pandemic. This contagious disease outbreak, which has continued to spread, has adversely affected workforces, customers, economies, and financial markets globally. It has also disrupted the normal operations of many businesses. This outbreak could decrease spending, adversely affect demand for the Company's products, and harm the Company's business and results of operations.

During the year ended December 31, 2023, the Company believes the COVID-19 pandemic did impact its operating results. However, the Company has not observed any impairments of its assets or a significant change in the fair value of its assets due to the COVID-19 pandemic. At this time, it is not possible for the Company to predict the duration or magnitude of the adverse results of the outbreak and its effects on the Company's business or results of operations, financial condition, or liquidity.

The Company has been following the recommendations of health authorities to minimize exposure risk for its team members, including the temporary closure of its corporate office and having team members work remotely. Most vendors have transitioned to electronic submission of invoices and payments.

Corporate Developments

On May 1, 2023, Charles Casamento joined as a member of the Company's Board of Directors.

Reverse Stock Split

On February 1, 2024, the Company announced a reverse stock-split of its common stock, par value $0.001 per share, at a ratio of 1 for 30. The reverse stock-split became effective on February 2, 2024. The Company's common stock began trading on a reverse stock-split-adjusted basis on The Nasdaq Capital Market on February 5, 2024, under our existing trading symbol "GTBP."

As a result of the reverse stock-split, every thirty (30) shares of issued and outstanding common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share. No fractional shares were 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).

Proportionate adjustments were 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 for the Company's common stock and to the number of shares of common stock reserved for future issuance pursuant to the GT Biopharma, Inc. 2022 Omnibus Incentive Plan.

All share and per share information has been adjusted to retroactively reflect the reverse stock-split as of the earlies period presented.

Private Placement of Common Stock

On January 4, 2023, GT Biopharma received gross proceeds of $6.5 million, before deducting placement agent fees and other offering expenses of $232,000 in relation to a purchase agreement (the "Purchase Agreement") signed on December 30, 2022, between the Company and an institutional investor (the "Purchaser") for the issuance and sale, in a registered direct offering (the "Offering"), of 120,000 shares of the Company's common stock, par value $0.001 per share (the "Shares"), pre-funded warrants to purchase up to 96,667 shares of the Company's common stock (the "Pre-Funded Warrants"), warrants to purchase up to an aggregate of 216,667 shares of the Company's common stock (the "Common Warrants") and placement agent warrants to purchase up to 13,000 of the Company's common stock (the "Placement Agents Warrants"). The Common Warrants have an exercise price equal to $30.00, became exercisable commencing six months following issuance, and shall have a term of exercise equal to five years following the initial exercise date. The Pre-Funded Warrants had an exercise price of $0.003 per Share, were immediately exercisable and could be exercised at any time after their original issuance until such Pre-Funded Warrants were exercised in full. The Placement Agents Warrants have an exercise price equal to $37.50, became exercisable commencing six months following issuance, and shall have a term of exercise equal to five years following the initial exercise date. The Shares and Common Warrants were sold at an offering price of $30.00 per Share and accompanying Common Warrant and the Pre-Funded Warrants and Common Warrants were sold at an offering price of $29.997 per Pre-Funded Warrant and accompanying Common Warrant.

Issuance of Common Stock in Public Offering

On February 16, 2021, the Company completed a public offering of 164,834 shares of common stock to investors for net proceeds of $24.7 million, after deducting underwriting discounts, commissions and other direct offering expenses. As part of the offering, the Company also granted to these investors, warrants to purchase 173,075 shares of common stock. The warrants are fully vested, exercisable at $165.00 per share and will expire in five years.

As a result of the completion of the public offering and the successful listing of the Company's shares of common stock on the Nasdaq Capital Market, convertible notes and accrued interest totaling $38.8 million, were mandatorily converted into 380,444 shares of the Company's common stock at its stated conversion rate of $102.00 per share. The Company issued 369,534 shares of common stock to the note holders while the remaining 10,910 common shares, valued at $1.1 million, were issuable at December 31, 2021.

During the year ended December 31, 2022, the Company issued the remaining 10,910 common shares. In addition, the Company also issued an additional 347 shares of commons stock with a fair value of $35,000 as settlement to a noteholder.

Significant Agreements

TriKE® Agreement

In June 2017, we entered into a co-development partnership agreement with Altor BioScience Corporation in which we agreed to collaborate exclusively in the clinical development of a novel 161533 (GTB-3550) TriKE® fusion protein for cancer therapies using our TriKE® technology. The GTB-3550 Phase 1 clinical trial for treatment of patients with CD33-expressing, high risk myelodysplastic syndromes and refractory/relapsed acute myeloid leukemia opened for patient enrollment in September 2019 and completed enrollment in September 2021. The results of our first generation GTB-3550 Phase 1 clinical trial support our plans to advance the next generation camelid nanobody into the clinic, and as such, no further clinical development will ensue with GTB-3550.

University of Minnesota Scientific Research Agreement

We are a party to a scientific research agreement with the Regents of the University of Minnesota ("UofMN"), effective June 16, 2021. This scientific research agreement aims to work with the Company with three major goals in mind: (1) support the Company's TriKE® product development and GMP manufacturing efforts; (2) TriKE® pharmacokinetics optimization in humans; and (3) investigation of the patient's native NK cell population based on insights obtained from the analysis of the human data generated during our GTB-3550 clinical trial. The major deliverables proposed here are: (1) creation of IND enabling data for TriKE® constructs in support of our product development and GMP manufacturing efforts; (2) TriKE® platform drug delivery changes to allow transition to alternative drug delivery means and extended PK in humans; and (3) gain an increased understanding of changes in the patient's native NK cell population as a result of TriKE® therapy. Most studies will use TriKE® DNA/amino acid sequences created by us under current UMN/GTB licensing terms. This agreement expired on June 30, 2023. The Company and UofMN are negotiating the terms of a new scientific research agreement and expect to finalize it in the first half of 2024.

For the years ended December 31, 2023 and 2022, we recorded an expense of $383,000 and $766,000 pursuant to the scientific research agreement for each respective period. We have recorded an expense in the aggregate of $2.1 million as of December 31, 2023 pursuant to this agreement.

Subcontract Manufacturing Agreement

On October 5, 2020, we entered into a Master Services Agreement with a third-party product manufacturer to perform biologic development and manufacturing services on behalf of the Company. Associated with this, we have subsequently signed five Statements of Work ("SOWs") for the research and development of products for use in clinical trials. On August 24, 2022, we entered into a revised agreement with this third-party manufacturer and issued 40,743 shares of common stock with a fair value of $3.2 million as part of a payment arrangement. The shares were valued at $79.80 per share based on the closing price of the Company's common stock on the date of the agreement. As part of the revised agreement, we paid to this third-party manufacturer $3.3 million in cash on specified dates. In addition, the Company and the third-party manufacturer agreed that services to be rendered in future periods, as specified in the agreement, will be paid or settled at the Company's discretion, in a combination of cash and issuance of the Company's common stock. The agreement also amended certain agreements executed in prior years which eliminated future financial commitments of the Company.

The SOWs agreements totaled approximately $13.0 million, of which $7.5 million was incurred at that date and an additional $5.5 million is in process. The Company was indebted $3.5 million to this third- party manufacturer as of December 31, 2023.

Clinical Trial Agreement

In September 2019, we executed clinical trial agreement with the Regents of the University of Minnesota, to commence enrollment in its first-in-human GTB-3550 TriKE® (CD16/IL-15/CD33) Phase 1, open-label, dose escalation clinical trial for the treatment of CD33-expressing, high risk myelodysplastic syndromes, refractory/relapsed acute myeloid leukemia or advanced systemic mastocytosis. The clinical trial was conducted at the University of Minnesota's Masonic Cancer Center in Minneapolis, Minnesota under the direction of Dr. Erica Warlick and Dr. Mark Juckett. The primary objective of the trial was to determine safety and tolerability as well as the maximum tolerated dose of GTB-3550 TriKE®. The hypothesis was that GTB-3550 TriKE® would induce natural killer cell function by targeting malignant cells as well as CD33+ myeloid derived suppressor cells (MDSC) which contribute to tumor induced immunosuppression. Because CD16 is a potent activating receptor on NK cells, this single agent GTB-3550 investigational agent may induce a targeted anti-CD33+ tumor response. The phase 1 trial was completed in September 2021.

License Agreements

See discussion of Patents and Licenses above under Item 1: Business

Results of Operations

Comparison of the Years Ended December 31, 2023 and 2022

Research and Development Expenses

During the years ended December 31, 2023 and 2022, we incurred $6.5 million and $8.8 million of research and development expenses (R&D), respectively. The $2.3 million reduction in R&D was primarily due to a $3.6 million reduction in licensing and administrative costs, offset by an increase of $1.3 million in R&D costs related to our continued development and production of our most advanced TriKE® product candidates GTB-3650 and GTB-5550 along with the progression on other promising product candidates. The reduction of $3.6 million in licensing and administrative costs over the previous year was primarily due to better management of R&D expenses with consultants and reduction in stock compensation to employees. We anticipate our direct clinical and preclinical expenses to continue to increase in 2024 as we plan to advance our next generation GTB-3650 camelid nanobody product into the clinic and enroll patients, perform tests for data collection, complete the product development of GTB 5550 and anticipate submission of IND application for GTB 5550 in the fourth quarter of 2024. We do not, however, anticipate an increase in related R&D licensing and administrative costs.

Selling, General and Administrative Expenses

During the years ended December 31, 2023 and 2022, we incurred $7.1 million and $12.4 million of selling, general and administrative expenses (S,G&A), respectively. The decrease in S,G&A of $5.3 million as compared to 2022 was primarily attributable to a reduction of $1.7 million in stock compensation expenses for officers, employees and Board of Directors and $1.9 million for outside consultants, reduction of $1.3 million in consulting advisory board fees, and reduction of $500,000 in patents and insurance costs for the year ended December 31, 2023. S,G&A decreased due to better managing and use of consultants and advisors, and overall reductions in other general and administrative expenses in 2023.

Other Income/Expense

Other income net of other expenses, was $6.0 million and $373,000 for the years ended December 31, 2023 and 2022, respectively. Other income and expenses consisted of interest income, interest expense, change in the fair value of warrant lability, gain on extinguishment of debt, and unrealized gain and loss on marketable securities.

We recorded interest income of $780,000 and $292,000 for the years ended December 31, 2023 and 2022, respectively. Interest income increased primarily due to the interest earned on short-term investments due to higher interest rates during the year 2023.

We recorded interest expense of $213,000 and $8,000 for the years ended December 31, 2023 and 2022, respectively. The increase in interest expense was due to the financing costs incurred associated with the issuance of warrants accounted as warrant liability during 2023, with no such comparable costs in 2022.

The change in fair value of warrant liability was due to fair value remeasurement which resulted in a gain of $4.8 million and $119,000 for the years ended December 31, 2023 and 2022, respectively.

We recorded a gain on extinguishment of debt of $547,000 and $0 for the years ended December 31, 2023 and 2022, respectively. The gain resulted due to share settlement of a greater amount of vendor accounts payable than the fair value of the shares on the date of settlement.

We recorded $48,000 of unrealized gain on marketable securities for the year ended December 31, 2023 as compared to unrealized loss on marketable securities for the year ended December 31, 2022 as a result of fair value remeasurement of our marketable securities.

We recorded other income of $20,000 related to subletting our premises during the year ended December 31, 2023 compared to $0 for the year ended December 31, 2022.

Liquidity and Capital Resources

The Company's current operations have focused on business planning, raising capital, establishing an intellectual property portfolio, hiring, and conducting preclinical studies and clinical trials. The Company does not have any product candidates approved for sale and has not generated any revenue from product sales. The Company has sustained operating losses since inception and expects such losses to continue over the foreseeable future. On January 4, 2023, the Company raised $6.5 million from an institutional investor by selling 120,000 shares of common stock, and pre-funded warrants to purchase up to 96,667 shares of common stock. During 2021, the Company had raised $24.7 million through issuance of common stock, had raised $16.4 million through the exercise of warrants and raised $1.2 million from a series of issuances of convertible notes. The Company reported $14.0 million of cash and short-term investments at December 31, 2023. We anticipate that we will need cash of approximately $10.0 million for the next twelve months for research and development and selling, general and administrative expenses. We expect the cash and short-term investments totaling $14.0 million will be sufficient to fund operations for the following 12 months, and anticipate raising additional funds as needed to fund our continued clinical trials.

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

The Company has incurred substantial losses since inception to December 31, 2023. The Company anticipates incurring additional losses until such time, it can generate significant sales or revenue from out-licensing of its products currently in development. Substantial additional financing will be needed by the Company to fund its operations and to commercially develop its product candidates.

Management is currently evaluating different strategies to obtain the required funding for future operations. These strategies may include but are not limited to public offerings of equity and/or debt securities; and payments from potential strategic research and development, licensing and/or marketing arrangements with other pharmaceutical companies.

Critical Accounting Policies

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

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America. The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, OXIS Biotech, Inc. and Georgetown Translational Pharmaceuticals, Inc. Intercompany transactions and balances have been eliminated in consolidation.

Accounting Estimates

The preparation of consolidated financial statements in conformity with Generally Accepted Accounting Principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates include accruals for potential liabilities, assumptions used in deriving the fair value of derivative liabilities, share-based compensation and valuation of deferred tax assets. Actual results could differ from those estimates.

Stock-Based Compensation

The Company accounts for share-based awards to employees and nonemployees and consultants in accordance with the provisions of Accounting Standards Codification 718, *Compensation-Stock Compensation*. Stock-based compensation cost is measured at fair value on the grant date and that fair value is recognized as expense over the requisite service, or vesting period.

The Company values its equity awards using the Black-Scholes option pricing model, and accounts for forfeitures when they occur. Use of the Black-Scholes option pricing model requires the input of subjective assumptions including expected volatility, expected term, and a risk-free interest rate. The Company estimates volatility using its own historical stock price volatility. The expected term of the instrument is estimated by using the simplified method to estimate expected term. The risk-free interest rate is estimated using comparable published federal funds rates.

Inflation

We believe that inflation has not had a material adverse impact on our business or operating results during the periods presented.

Off-balance Sheet Arrangements

We have no off-balance sheet arrangements as of December 31, 2023.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

This company qualifies as a smaller reporting company, as defined in 17 C.F.R. §229.10(f) (1) and is not required to provide information by this Item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Please see the consolidated financial statements beginning on page F-1 located in Part IV of this Annual Report on Form 10-K.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Our principal executive officer and principal financial officer evaluated the effectiveness of our "disclosure controls and procedures" (as such term is defined in Rules 13a-15(e) and 15d-15(e) of the United States Securities Exchange Act of 1934, as amended), as of December 31, 2023. Based on that evaluation, we have concluded that our disclosure controls and procedures were effective as of December 31, 2023.

Management's Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934, as amended, as a process designed by, or under the supervision of, a company's principal executive and principal accounting officers and effected by a company's board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company

- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and

- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the company's assets that could have a material effect on the consolidated financial statements.

All internal control systems, no matter how well designed, have inherent limitations and can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

As of December 31, 2023, our management, including our interim Chief Executive Officer and Chief Financial Officer conducted an assessment of the effectiveness of the Company's internal control over financial reporting. In making this assessment, we used the criteria set forth by the COSO framework. Based upon our evaluation, we concluded that our internal controls over financial reporting were operating effectively with a significant level of precision as of December 31, 2023.

Attestation Report on Internal Control over Financial Reporting.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm, due to an exemption under the JOBS Act for small reporting companies.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the period covered by this Annual Report on Form 10-K that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Although we have altered some work routines due to the COVID-19 pandemic, the changes in our work environment, including remote work arrangements, have not materially impacted our internal controls over financial reporting and have not adversely affected the Company's ability to maintain operations.

ITEM 9B. OTHER INFORMATION

Insider Trading Arrangements

During the fiscal year ended December 31, 2023, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

Information responsive to this item is incorporated herein by reference to our definitive proxy statement with respect to our 2024 Annual Meeting of Stockholders to be filed with the SEC within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

The Company's consolidated financial statements and related notes thereto are listed and included in this Annual Report beginning on page F-1. The following documents are furnished as exhibits to this Annual Report on Form 10-K.

EXHIBIT INDEX

		Incorporated by Reference			
Exhibit Number	**Exhibit Description**	**Form**	**Date**	**Number**	**Filed Herewith**
3.1	Restated Certificate of Incorporation as filed in Delaware September 10, 1996 and as thereafter amended through March 1, 2002	10-KSB	04/01/2002	3.A	
3.2	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., dated February 9, 2011	10-K	03/31/2011	3.2	
3.3	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of July 19, 2017	8-K/A	03/15/2018	3.1	
3.4	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective as of February 10, 2021	8-K	02/11/2021	3.1	
3.5	Certificate of Amendment to the Restated Certificate of Incorporation of GT Biopharma, Inc., effective June 13, 2022	10-K	03/30/2023	3.5	
3.6	Amended and Restated Bylaws of GT Biopharma, Inc., effective November 3, 2022	8-K	11/09/2022	3.1	
3.7	Certificate of Amendment of Restated Certificate of Incorporation of GT Biopharma, Inc., effective February 1, 2024	8-K	02/01/2024	3.1	
4.1	Certificate of Designation of Preferences, Rights and Limitations of Series J-1 Preferred Stock of GT Biopharma, Inc., dated April 3, 2019	8-K	04/04/2019	3.1	
4.2	Certificate of Designation of Preferences, Rights and Limitations of Series K Preferred Stock of GT Biopharma, Inc., dated April 3, 2019	10-K	04/16/2021	4.2	
4.3	Description of the Registrant's Securities Registered pursuant to Section 12 of the Securities Exchange Act of 1934, as Amended	10-K	03/30/2023	4.3	
10.1	Exclusive License Agreement, dated July 18, 2016, between the Regents of the University of Minnesota and Oxis Biotech, Inc.	10-Q	08/11/2017	10.3	
10.2	License Agreement, dated September 3, 2015, among Daniel A. Vallera, Jeffrey Lion and Oxis Biotech, Inc.	10-Q	08/11/2017	10.4	
10.3	Clinical Trial Agreement, dated September 2019, between the Regents of the University of Minnesota and GT Biopharma, Inc.	10-Q	5/15/2020	10.7	
10.4	Note Conversion Agreement, dated as of August 29, 2017, among GT Biopharma, Inc. and the holders of the convertible notes and debentures named therein	10-Q	11/14/2017	10.5	
10.5	Amendment Agreement related to Note Conversion Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the holders of the convertible notes and debentures named therein	10-Q	11/14/2017	10.8	
10.6	Warrant Exercise Agreement, dated August 29, 2017, among GT Biopharma, Inc. and the warrant holders named therein	10-Q	11/14/2017	10.6	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.7	Amendment Agreement related to Warrant Exercise Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the warrant holders named therein	10-Q	11/14/2017	10.9	
10.8	Preferred Stock Exchange Agreement, dated as of August 29, 2017, among GT Biopharma, Inc. and the holders of preferred stock named therein	10-Q	11/14/2017	10.7	
10.9	Amendment Agreement related to Preferred Stock Exchange Agreement, dated October 10, 2017, among GT Biopharma, Inc. and the holders of preferred stock named therein	10-Q	11/14/2017	10.10	
10.10	Securities Purchase Agreement, dated January 9, 2017, among OXIS International, Inc. and the purchasers named therein	8-K	01/13/2017	10.1	
10.11	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/2017	10.2	
10.12	Form of Common Stock Purchase Warrant (related to Securities Purchase Agreement, dated January 9, 2017)	8-K	01/13/2017	10.3	
10.13	Securities Purchase Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	01/23/2018	10.1	
10.14	Registration Rights Agreement, dated January 22, 2018, among GT Biopharma, Inc. and the buyers named therein	8-K	01/23/2018	10.2	
10.15	Form of Senior Convertible Note (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	01/23/2018	10.3	
10.16	Form of Warrant to Purchase Common Stock (related to Securities Purchase Agreement, dated January 22, 2018)	8-K	01/23/2018	10.4	
10.17	Securities Purchase Agreement, dated August 2, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/03/2018	10.1	
10.18	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated August 2, 2018)	8-K	08/03/2018	4.1	
10.19	Stock Pledge Agreement, dated August 2, 2018, by the Pledgors named therein for the benefit of Grushko & Mittman, P.C.	10-Q	08/14/2018	10.10	
10.20	Security Purchase Agreement, dated September 7, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/07/2018	10.1	
10.21	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 7, 2018)	8-K	09/07/2018	4.1	
10.22	Security Purchase Agreement, dated September 24, 2018, among GT Biopharma, Inc. and the purchasers named therein	8-K	09/28/2018	10.1	
10.23	Form of 10% Senior Convertible Debenture (related to Securities Purchase Agreement, dated September 24, 2018)	8-K	09/28/2018	4.1	
10.24	Securities Purchase Agreement, dated February 4, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	02/06/2019	10.1	
10.25	Registration Rights Agreement, dated February 4, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	02/06/2019	10.3	
10.26	Form of Secured Convertible Note (related to Securities Purchase Agreement, dated February 4, 2019)	8-K	02/06/2019	4.1	
10.27	Security Agreement, dated February 4, 2019, among GT Biopharma, Inc. and Alpha Capital Anstalt, as collateral agent	8-K	02/06/2019	10.2	
10.28	Securities Purchase Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/2019	10.1	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.29	Registration Rights Agreement, dated May 22, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	05/24/2019	10.2	
10.30	Form of Convertible Note (related to Securities Purchase Agreement, dated May 22, 2019)	8-K	05/24/2019	4.1	
10.31	Securities Purchase Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/20/2019	10.1	
10.32	Registration Rights Agreement, dated August 20, 2019, among GT Biopharma, Inc. and the purchasers named therein	8-K	08/20/2019	10.2	
10.33	Form of Convertible Note (related to Securities Purchase Agreement, dated August 20, 2019)	8-K	08/20/2019	4.1	
10.34	Securities Purchase Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/2020	10.1	
10.35	Registration Rights Agreement, dated January 30, 2020, among GT Biopharma, Inc. and the purchaser named therein	10-Q	05/15/2020	10.2	
10.36	Form of Convertible Note (related to Securities Purchase Agreement, dated January 30, 2020)	10-Q	05/15/2020	10.3	
10.37	Form Securities Purchase Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/2020	10.4	
10.38	Form of Registration Rights Agreement among GT Biopharma, Inc. and the purchaser named therein (executed in April/May 2020)	10-Q	05/15/2020	10.5	
10.39	Form of Convertible Note (related to Securities Purchase Agreement executed in April/May 2020)	10-Q	05/15/2020	10.6	
10.40	Securities Purchase Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/2020	10.1	
10.41	Registration Rights Agreement, dated July 7, 2020, among GT Biopharma, Inc. and the purchaser named therein	8-K	07/09/2020	10.3	
10.42	Form of Convertible Note (related to Securities Purchase Agreement, dated July 7, 2020)	8-K	07/09/2020	4.1	
10.43	Form of Standstill and Forbearance Agreement, dated June 23, 2020, between the Company and certain holders of convertible notes and debentures	8-K	06/23/2020	10.1	
10.44	Settlement Agreement, dated June 19, 2020, among GT Biopharma, Inc., Empery Asset Master Ltd., Empery Tax Efficient, LP and Empery Tax Efficient II, LP, Anthony Cataldo and Paul Kessler.	8-K	06/19/2020	10.1	
10.45	Form of Convertible Note, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020)	8-K	06/19/2020	10.1	
10.46	Form of Pre-Funded Warrant to Purchase Common Stock, dated June 19, 2020 (related to Settlement Agreement, dated June 19, 2020)	8-K	06/19/2020	10.1	
10.47	Consultant Agreement, dated February 14, 2018, among GT Biopharma, Inc., Georgetown Translational Pharmaceuticals, Inc. and Anthony J. Cataldo	8-K	2/21/2018	10.3	
10.48	Employment agreement with Anthony Cataldo++	10-Q	8/14/2020	10.11	
10.49	Form of Convertible Note (related to Securities Purchase Agreement, dated September 16, 2020)	8-K	9/22/2020	4.1	
10.50	Securities Purchase Agreement, dated September 16, 2020, among GT Biopharma, Inc. and the purchasers named therein	8-K	9/22/2020	10.1	
10.51	Master Services Agreement, dated October 5, 2020, between GT Biopharma, Inc. and Cytovance Biologics, Inc.	8-K	10/6/2020	10.1	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.52	Form of First Amendment and Extension of Standstill and Forbearance Agreement	8-K	11/4/2020	10.1	
10.53	Form of Secured Convertible Note	8-K	11/9/2020	4.1	
10.54	Securities Purchase Agreement	8-K	11/9/2020	10.1	
10.55	Settlement Agreement, dated as of November 9, 2020, by and among Adam Kasower, East Ventures, Inc., A British Virgin Islands company, SV Booth Investments III, LLC, a Delaware limited liability company and Theorem Group, LLC, a California LLC and GT Biopharma Inc., a Delaware corporation.	10-Q	11/13/2020	10.19	
10.56	Form of Settlement Note, dated November 9, 2020.	10-Q	11/13/2020	10.20	
10.57	Board Service Agreement with Bruce Wendel, dated November 11, 2020++	10-Q	11/13/2020	10.22	
10.58	Board Service Agreement with Greg Berk, dated November 11, 2020++	10-Q	11/13/2020	10.23	
10.59	Consultant Agreement with Michael Handelman, dated November 13, 2020++	10-Q	11/13/2020	10.24	
10.60	Form of Amendment to Convertible Note & Standstill Agreement	8-K	12/23/2020	10.1	
10.61	Settlement Agreement, dated as of December 22, 2020, by and among Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B, Anthony Cataldo, Paul Kessler and GT Biopharma Inc., a Delaware corporation.	8-K	12/28/2020	10.1	
10.62	Settlement Note, dated December 22, 2020, by GT Biopharma Inc. payable to Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B.	8-K	12/28/2020	10.2	
10.63	Form of Second Amendment and Extension of Standstill and Forbearance Agreement.	8-K	02/1/2020	10.1	
10.64	Form of Amendment to Convertible Note, dated January 31, 2021	8-K	02/1/2020	10.2	
10.65	Board Service Agreement with Rajesh Shrotriya, dated January 12, 2021.++	S-1/A	02/08/2021	10.69	
10.66	Board Service Agreement with Michael Breen, dated January 12, 2021. ++	S-1/A	02/08/2021	10.70	
10.67	Amendment to Settlement Note with Alto Opportunity Master Fund, SPC - Segregated Master Portfolio B.	S-1/A	02/08/2021	10.71	
10.68	Form of Securities Purchase Agreement - December 2020 / January 2021 Notes	S-1/A	02/08/2021	10.72	
10.69	Form of December 2020 / January 2021 Note	S-1/A	02/08/2021	10.73	
10.70	Amended and Restated Employment Agreement with Anthony Cataldo, dated April 23, 2021.++	10-Q	5/17/2021	10.1	
10.71	Amended and Restated Employment Agreement with Michael Handelman, dated April 23, 2021.++	10-Q	5/17/2021	10.2	
10.72	Amended and Restated Employment Agreement with Dr. Gregory Berk, dated April 23, 2021.++	10-Q	5/17/2021	10.3	
10.73	Exclusive License Agreement with Regents of the University of Minnesota, dated March 26, 2021.	10-K	03/28/2022	10.73	
10.74	Research Agreement with Regents of the University of Minnesota, dated June 16, 2021.	10-K	03/28/2022	10.74	
10.75	Sublease Agreement dated November, 2021, between Aimmune Therapeutics, Inc. (Sublandlord) and GT Biopharma, Inc. (Subtenant)	10-K	03/28/2022	10.75	
10.76	Employment Agreement with Michael Breen, entered into as of December 31, 2021 with an effective date of November 8, 2021. ++	10-K	03/28/2022	10.76	

Exhibit Number	Exhibit Description	Incorporated by Reference			Filed Herewith
		Form	Date	Number	
10.77	Amendment No. 1 to Employment Agreement with Michael Breen, dated as of June 17, 2022. ++				X
10.78	Amendment No. 2 to Services Agreement with Michael Breen, dated as of February 20, 2023. ++				X
10.79	Board Service Agreement with Michael Breen dated November 11, 2020++	10-Q	05/16/2022	10.1	
10.80	Employment Agreement with Manu Ohri dated May 15, 2022++	10-Q	05/16/2022	10.2	
10.81	Amendment No. 1 to Employment Agreement with Manu Ohri, dated as of February 17, 2023++				X
10.82	Settlement and Investment Agreement dated August 24, 2022, by and between GT Biopharma, Inc. and Cytovance Biologics, Inc.**	10-Q	10/31/2022	10.1	
10.83	Form of Securities Purchase Agreement, dated December 2022, by and between GT Biopharma, Inc. and the purchasers named therein.	8-K	01/03/2023	10.1	
10.84	Form of Common Warrant	8-K	01/03/2023	4.1	
10.85	Form of Pre-Funded Warrant	8-K	01/03/2023	4.2	
10.86	Form of Placement Agent Warrant	8-K	01/03/2023	4.3	
14.1	Code of Ethics	10-K	03/31/2015	14.1	
21.1	Subsidiaries of GT Biopharma, Inc.	10-K	03/31/2015	21.1	
23.1	Consent of Weinberg & Company, P.A.				X
24.1	Power of Attorney (included on signature page)				
31.1	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *				X
32.2	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *				X
101.INS	Inline XBRL Instance Document.				X
101.SCH	Inline XBRL Taxonomy Extension Schema Document.				X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.				X
104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				

++ Indicates management contract or compensatory plan.
* This certification shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that Section, nor shall it be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act.
**The Registrant has omitted portions of this exhibit that are both not material and the type of information that the Registrant treats as private or confidential.

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GT Biopharma, Inc.

Dated: March 26, 2024

By: */s/ Manu Ohri*
Manu Ohri, Chief Financial Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Michael Breen and Manu Ohri, and each of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution for him, and in his name in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, and any of them or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Position	Date
/s/ Michael Breen Michael Breen	Executive Chairman of the Board and Interim Chief Executive Officer (Principal Executive Officer)	March 26, 2024
/s/ Manu Ohri Manu Ohri	Chief Financial Officer (Principal Financial and Accounting Officer)	March 26, 2024
/s/ Bruce Wendel Bruce Wendel	Vice Chairman of the Board	March 26, 2024
/s/ Rajesh Shrotriya Rajesh Shrotriya, M.D.	Director	March 26, 2024
/s/ Charles Casamento Charles Casamento	Director	March 26, 2024

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

INDEX TO FINANCIAL STATEMENTS

Financial Statements of GT Biopharma, Inc.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Stockholders and Board of Directors of GT Biopharma, Inc.
Brisbane, California

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of GT Biopharma, Inc. (the "Company") as of December 31, 2023 and 2022 and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matter Description

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that (1) relates to accounts or disclosures that are material to the financial statements and (2) involved especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

Valuation of Warrant Liability

Description of the Matter

As described in Note 5 to the financial statements, during the year ended December 31, 2023, the Company issued certain warrants to acquire its common stock and such warrants contained provisions and terms that resulted in the warrants requiring recognition as fair value liabilities. The warrant liabilities are required to be measured at fair value initially at issuance, and subsequently thereafter at each reporting date including December 31, 2023.

We identified auditing the valuation of the warrant liabilities as a critical audit matter due to the complexity of the accounting for the transaction and the significant judgements used by the Company in determining the fair value of the warrant liabilities. This required a high degree of auditor judgment and increased auditor effort in auditing the determination and valuation of the warrant liabilities.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- We obtained and examined the warrant liability agreement, including assessing the reasonableness of its presentation as a liability in the financial statements.
- We evaluated the appropriateness of the model used to value the warrant liability and tested the reasonableness of the assumptions used by the Company in determining the fair value of the warrant liability.
- We developed an independent expectation of the warrant liability and compared our independent expectation to the Company calculated value.

Liquidity Assessment

Description of the Matter

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As disclosed in Note 2 to the financial statements, for the year ended December 31, 2023 the Company had cash and short-term investments of $14.0 million, working capital of $7.4 million and stockholders' equity $7.5 million as of December 31, 2023. Management evaluated the Company's liquidity within one year after the date of issuance of the consolidated financial statements to determine if there is substantial doubt about the Company's ability to continue as a going concern. Management has concluded that, based on its current plans and projections, the Company will be able to satisfy its liquidity requirements for more than one year from when these financial statements were issued. In the preparation of the liquidity assessment, management applied judgment to estimate the projected cash flows of the Company.

We identified management's evaluation of the Company's ability to continue as a going concern and related disclosures as a critical audit matter due to the significant judgments and assumptions used by management in preparing the Company's forecasted cash flows and the risk of bias in management's judgments and assumptions in estimating these cash flows. Auditing these judgments and assumptions required a high degree of auditor judgment and increased auditor effort required to address these matters.

How We Addressed the Matter in Our Audit

The primary procedures we performed to address this critical audit matter included:

- We obtained management's cash flow forecasts covering the going concern assessment period and evaluated the reasonableness of the cash flow forecast by comparing it to historical operating results.
- We evaluated Managements assumptions in the preparing these forecasts and examined the underlying evidence.
- We performed sensitivity analyses on the projected research and development and general and administrative expenses used in the Company's cash flow projections to evaluate the impact on the conclusions reached by management.
- We evaluated the adequacy of management's disclosure in the financial statements regarding the Company's liquidity by comparing to other audit evidence obtained to determine whether such information is consistent with the Company's liquidity disclosure

Weinberg & Company, P.A.
Los Angeles, California
March 26, 2024

GT BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Balance Sheets
(In Thousands, Except Par Value and Share Data)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,079	$ 5,672
Short-term investments	12,893	10,836
Prepaid expenses and other current assets	84	54
Total Current Assets	14,056	16,562
Operating lease right-of-use asset	53	165
Deposits	-	9
TOTAL ASSETS	$ 14,109	$ 16,736
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 4,328	$ 3,140
Accrued expenses	1,195	1,669
Current operating lease liability	58	110
Warrant liability	1,052	19
Total Current Liabilities	6,633	4,938
Non-current operating lease liability	-	64
Total Liabilities	$ 6,633	$ 5,002
Stockholders' Equity		
Convertible Preferred stock, par value $0.01, 15,000,000 shares authorized, Series C - 96,230 shares issued and outstanding at December 31, 2023 and 2022, respectively	1	1
Common stock, par value $0.001, 250,000,000 shares authorized, 1,380,633 shares and 1,090,748 shares issued and outstanding at December 31, 2023 and 2022, respectively	1	33
Additional paid in capital	689,539	686,168
Accumulated deficit	(682,065)	(674,468)
Total Stockholders' Equity	7,476	11,734
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 14,109	$ 16,736

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(In Thousands, Except Share Data)

	For the Year Ended December 31,	
	2023	**2022**
Revenues	$ -	$ -
Operating Expenses:		
Research and development (including $0 and $718 of stock compensation to officers, directors and employees during the years ended December 31, 2023 and 2022, respectively)	6,466	8,811
Selling, general and administrative (including $2,200 and $3,903 of stock compensation to officers, directors and employees during the years ended December 31, 2023 and 2022, respectively)	7,110	12,446
Total Operating Expenses	13,576	21,257
Loss from Operations	(13,576)	(21,257)
Other (Income) Expense		
Interest income	(780)	(292)
Interest expense	213	8
Change in fair value of warrant liability	(4,797)	(119)
Gain on extinguishment of debt	(547)	-
Unrealized (gain) loss-on marketable securities	(48)	30
Other	(20)	-
Total Other (Income) Expense	(5,979)	(373)
Net Loss	$ (7,597)	$ (20,884)
Net Loss Per Share - Basic and Diluted	$ (5.64)	$ (19.66)
Weighted average common shares outstanding - basic and diluted	1,347,713	1,062,267

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Stockholders' Equity
(In Thousands)

	Preferred Shares		Common Shares		Common Shares Issuable		Additional Paid in	Accumulated	
	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, December 31, 2021	96	$ 1	1,069	$ 1	11	$ 1,113	$ 674,379	$ (653,584)	$ 21,910
Cancellation of common stock previously issued for services	-	-	(10)	-	-	-	-	-	-
Cancellation of common stock previously issued to prior CEO	-	-	(62)	-	-	-	(224)	-	(224)
Common stock issued upon conversion of notes payable	-	-	11	-	(11)	(1,113)	1,148	-	35
Issuance of common stock as equity compensation to officers, employees, and board of directors	-	-	24	-	-	-	2,522	-	2,522
Issuance of common stock as equity compensation to consultants	-	-	18	-	-	-	2,092	-	2,092
Fair value of vested stock options	-	-	-	-	-	-	3,032	-	3,032
Issuance of common stock in settlement of vendor payable	-	-	41	-	-	-	3,251	-	3,251
Net loss	-	-	-	-	-	-	-	(20,884)	(20,884)
Balance, December 31, 2022	96	1	1,091	1	-	-	686,200	(674,468)	11,734
Private placement of common stock	-	-	120	-	-	-	6,268	-	6,268
Initial recognition of fair value of warrant liability	-	-	-	-	-	-	(5,831)	-	(5,831)
Issuance of common stock as equity compensation to officers, employees, and board of directors	-	-	14	-	-	-	267	-	267
Issuance of common stock as equity compensation to consultants	-	-	2	-	-	-	163	-	163
Issuance of common stock for exercise of Prefunded Warrants	-	-	97	-	-	-	-	-	-
Fair value of vested stock options	-	-	-		-	-	1,770	-	1,770
Issuance of common shares in settlement of debt	-	-	57	-	-	-	702	-	702
Net loss	-	-	-	-	-	-	-	(7,597)	(7,597)
Balance, December 31, 2023	**96**	**$ 1**	**1,381**	**$ 1**	**-**	**$ -**	**$ 689,539**	**$ (682,065)**	**$ 7,476**

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

GT BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Cash Flows
(In Thousands)

	For the Year Ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (7,597)	$ (20,884)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation - consultants and research and development	163	2,522
Stock based compensation - officers, employees and board of directors	267	2,092
Stock based compensation - vested stock options	1,770	3,032
Fair value of common stock issued to a noteholder as settlement	-	35
Change in fair value of warrant liability	(4,797)	(119)
Change in operating lease right-of-use assets	112	95
Gain from extinguishment of debt	(547)	(31)
Unrealized (gain) loss on marketable securities	(48)	30
Changes in operating assets and liabilities:		
(Increase) decrease in prepaid expenses and other current assets	(30)	136
(Increase) decrease in deposits	9	(9)
Increase (decrease) in accounts payable and accrued expenses	1,962	(2,030)
Decrease in operating lease liability	(116)	(86)
Net Cash Used in Operating Activities	(8,852)	(15,217)
CASH FLOWS FROM INVESTING ACTIVITIES		
(Purchase) sale of investments	(2,009)	12,145
Net Cash Used in Investing Activities	(2,009)	12,145
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock	6,268	-
Cancellation of common stock upon settlement with former officer	-	(224)
Net Cash Provided by (Used in) Financing Activities	6,268	(224)
Net Decrease in Cash	(4,593)	(3,296)
Cash at Beginning of Period	5,672	8,968
Cash at End of Period	$ 1,079	$ 5,672
SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION:		
Cash paid during the year for:		
Interest	$ 213	$ -
Income taxes	$ -	$ -
SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES		
Right-of-use assets exchanged for lease liabilities	$ -	$ 260
Initial recognition of fair value of warrant liability	$ 5,831	$ -
Common stock issued upon settlement of debt	$ 702	$ 3,251

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

Note 1 – Organization and Operations

The corporate predecessor of GT Biopharma, Inc, Diagnostic Data, Inc., was incorporated in the state of California in 1965. Diagnostic Data, Inc. changed its incorporation to the state of Delaware on December 21, 1972 and changed its name to DDI Pharmaceuticals, Inc. on March 11, 1985. On September 7, 1994, DDI Pharmaceuticals, Inc. merged with International BioClinical, Inc. and Bioxytech S.A. and changed its name to OXIS International, Inc. On July 17, 2017, OXIS International, Inc. changed its name to GT Biopharma, Inc. (the "Company").

The Company is a clinical stage biopharmaceutical company focused on the development and commercialization of novel immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE®), and Tetra-specific Killer Engager (Dual Targeting TriKE®) platforms. The Company's TriKE® and Dual Targeting TriKE® platforms generate proprietary therapeutics designed to harness and enhance the cancer killing abilities of a patient's own natural killer cells (NK cells).

Reverse Stock Split

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

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

Proportionate adjustments will be 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 for the Company's common stock and to the number of shares of common stock reserved for future issuance pursuant to the GT Biopharma, Inc. 2022 Omnibus Incentive Plan.

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

Note 2 – Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying consolidated financial statements have been prepared in accordance with the accounting principles generally accepted in the United States of America. The consolidated financial statements include the accounts of the Company, and its wholly-owned subsidiaries, OXIS Biotech, Inc. and Georgetown Translational Pharmaceuticals, Inc. All intercompany transactions and balances have been eliminated in consolidation.

Liquidity

The accompanying consolidated financial statements have been prepared under the assumption that the Company will continue as a going concern. Such assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The Company has no recurring source of revenue and has recorded a net loss of $7.6 million and used cash in operations of $8.9 million for the year ended December 31, 2023. The Company had a cash and short-term investments balance of $14.0 million at December 31, 2023. We anticipate that we will need cash of approximately $10.0 million for the next twelve months for research and development and selling, general and administrative expenses. We expect the cash and short-term investments totaling $14.0 million will be sufficient to fund operations for the following 12 months, and anticipate raising additional funds as needed to fund our continued clinical trials. Management anticipates that the $14.0 million of cash and cash equivalents and short-term investments available are adequate to satisfy the liquidity needs of the Company for at least one year from the date the Company's 2023 consolidated financial statements are issued.

Historically, the Company has financed its operations through public and private sales of common stock, issuance of preferred stock, issuance of convertible debt instruments, and strategic collaborations. There can be no assurances that the Company will be able to secure additional financing on acceptable terms. In the event that the Company does not generate sufficient cash flows from investing and financing activities, the Company will be forced to delay, reduce, or eliminate some or all of its discretionary spendings, which could adversely affect the Company's business prospects, ability to meet long-term liquidity needs or ability to continue operations.

Accounting Estimates

The preparation of consolidated financial statements in conformity with Generally Accepted Accounting Principles ("GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include accruals for potential liabilities, assumptions used in deriving the fair value of warrant liabilities, share-based compensation and valuation of deferred tax assets. Actual results could differ from those estimates.

Cash Equivalents and Short-Term Investments

The Company considers highly liquid investments with maturities of three months or less at the date of acquisition as cash equivalents in the accompanying consolidated financial statements. As of December 31, 2023, total cash and cash equivalents which consist of cash and money market funds, amounted to approximately $1.1 million.

The Company also invested its excess cash in commercial paper and corporate notes and bonds. Management generally determines the appropriate classification of its investments at the time of purchase. We classify these investments as short-term investments as part of current assets, based upon our ability and intent to use any and all of these investments as necessary to satisfy liquidity requirements that may arise from our businesses. Investments are carried at fair value with the unrealized holding gains and losses reported in the accompanying consolidated statements of operations. As of December 31, 2023, total short-term investments amounted to approximately $12.9 million.

Fair Value of Financial Instruments

Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") ASC 820-10 requires entities to disclose the fair value of financial instruments, both assets and liabilities recognized and not recognized on the balance sheet for which it is practicable to estimate fair value. ASC 820-10 defines the fair value of a financial instrument as the amount at which the instrument could be exchanged in a current transaction between willing parties.

The three levels of the fair value hierarchy are as follows:

Level 1 Valuations based on unadjusted quoted prices in active markets for identical assets or liabilities that the entity has the ability to access.

Level 2 Valuations based on quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable data for substantially the full term of the assets or liabilities.

Level 3 Valuations based on inputs that are unobservable, supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

The carrying amount of the Company's warrant liability of $1.1 million at December 31, 2023 and $19,000 at December 31, 2022 was based on Level 2 measurements.

The carrying amounts of the Company's other financial assets and liabilities, such as cash and cash equivalents, short term investments, prepaid expenses and other current assets, accounts payable, accrued expenses, approximate their fair values because of the short maturity of these instruments.

Warrant Liability

The Company evaluates its financial instruments to determine if such instruments are derivatives or contain features that qualify as embedded derivatives in accordance with ASC Topic 815, "*Derivatives and Hedging*" ("ASC 815"). For derivative financial instruments that are accounted for as liabilities, the derivative instrument is initially recorded at its fair value and is then re-valued at each reporting date, with changes in the fair value reported in the statements of operations.

The Company's use of derivative financial instruments is generally limited to warrants issued by the Company that do not meet the criteria for equity treatment and are recorded as liabilities. We do not use financial instruments or derivatives for any trading purposes.

Stock-Based Compensation

The Company periodically issues stock-based compensation to officers, directors, employees and consultants for services rendered. Such issuances vest and expire according to terms established at the issuance date.

Stock-based payments to officers, directors, employees and consultants for acquiring goods and services from non-employees, which include grants of employee stock options, are recognized in the financial statements based on their grant date fair values in accordance with ASC 718, *Compensation-Stock Compensation*. Stock based payments to officers, directors, employees and consultants, which are generally time vested, are measured at the grant date fair value and depending on the conditions associated with the vesting of the award, compensation cost is recognized on a straight-line or graded basis over the vesting period. Recognition of compensation expense for non-employees is in the same period and manner as if the Company had paid cash for the services. The fair value of stock options granted is estimated using the Black-Scholes option-pricing model, which uses certain assumptions related to risk-free interest rates, expected volatility, expected life, and future dividends. The assumptions used in the Black-Scholes option pricing model could materially affect compensation expense recorded in future periods.

Research and Development Costs

Costs incurred for research and development are expensed as incurred. The salaries, benefits, and overhead costs of personnel conducting research and development of the Company's products comprise research and development expenses. Purchased materials that do not have an alternative future use are also expensed.

Leases

The Company accounts for its lease in accordance with the guidance of ASC 842, *Leases*. The Company determines whether a contract is, or contains, a lease at inception. Right-of-use assets represent the Company's right to use an underlying asset during the lease term, and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Right-of-use assets and lease liabilities are recognized at lease commencement based upon the estimated present value of unpaid lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at lease commencement in determining the present value of unpaid lease payments.

Net Loss Per Share

Basic earnings (loss) per share is computed using the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed using the weighted-average number of common shares and the dilutive effect of contingent shares outstanding during the period. Potentially dilutive contingent shares, which primarily consist of stock issuable upon exercise of stock options and warrants have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

The following shares were excluded in the computation of the diluted net loss per share because their effect is anti-dilutive:

	December 31,	
	2023	2022
Warrants to purchase common stock	304,962	77,909
Options to purchase common stock	126,265	54,348
Total anti-dilutive securities	431,227	132,257

Concentration

Cash is deposited in one financial institution. The balances held at this financial institution at times may be in excess of Federal Deposit Insurance Corporation ("FDIC") insurance limits of up to $250,000. Management believes that the financial institutions that hold the Company's cash are financially sound and, accordingly, minimal credit risk exists.

The Company has a significant concentration of expenses incurred and accounts payable from a single vendor (Note 4).

Segments

The Company determined its reporting units in accordance with "*Segment Reporting*" ("ASC 280"). Management evaluates a reporting unit by first identifying its operating segments under ASC 280. The Company then evaluates each operating segment to determine if it includes one or more components that constitute a business. If there are components within an operating segment that meet the definition of a business, the Company evaluates those components to determine if they must be aggregated into one or more reporting units. If applicable, when determining if it is appropriate to aggregate different operating segments, the Company determines if the segments are economically similar and, if so, the operating segments are aggregated.

Management has determined that the Company has one consolidated operating segment. The Company's reporting segment reflects the manner in which its chief operating decision maker reviews results and allocates resources. The Company's reporting segment meets the definition of an operating segment and does not include the aggregation of multiple operating segments.

Recently Issued Accounting Pronouncements

The Company's management has evaluated all the recently issued, but not yet effective, accounting standards and guidance that have been issued or proposed by the FASB or other standards-setting bodies through the filing date of these financial statements and does not believe the future adoption of any such pronouncements will have a material effect on the Company's financial position and results of operations.

Note 3 – Fair Value of Financial Instruments

The estimated fair values of financial instruments outstanding were (in thousands):

	December 31, 2023			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments	$ 12,845	$ 48	$ —	$ 12,893
Total	$ 12,845	$ 48	$ —	$ 12,893

	December 31, 2022			
	Cost	Unrealized Gains	Unrealized Losses	Fair Value
Short-term investments	$ 10,866	$ —	$ (30)	$ 10,836
Total	$ 10,866	$ —	$ (30)	$ 10,836

The following table represents the Company's fair value hierarchy for its financial assets (cash equivalents and short-term investments, in thousands):

	December 31, 2023			
	Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 443	$ 443	$ —	$ —
Corporate notes and commercial paper	12,893	—	12,893	—
Total financial assets	$ 13,336	$ 443	$ 12,893	$ —

	December 31, 2022			
	Fair Value	Level 1	Level 2	Level 3
Money market funds	$ 5,505	$ 5,505	$ —	$ —
Corporate notes and commercial paper	10,836	—	10,836	—
Total financial assets	$ 16,341	$ 5,505	$ 10,836	$ —

As of December 31, 2023 and 2022, the fair value of the warrant liability amounted to $1.1 million and $19,000, respectively. (Note 5 – Warrant Liability).

Note 4 – Accounts Payable

Accounts payable consisted of the following (in thousands):

	December 31, 2023	December 31, 2022
Accounts payable to a third-party manufacturer	$ 3,515	$ 2,283
Other accounts payable	813	857
Total accounts payable	$ 4,328	$ 3,140

The Company relies on a third-party contract manufacturing operation to produce and/or test our compounds used in our potential product candidates.

On October 5, 2020, the Company entered into a Master Services Agreement with a third-party product manufacturer to perform biologic development and manufacturing services on behalf of the Company. Associated with this, the Company has subsequently signed five Statements of Work ("SOWs") for the research and development of products for use in clinical trials. The Company's commitments in relation to these SOWs and any related Change Orders totaled approximately $15.6 million.

On August 24, 2022, the Company entered into a payment agreement with this third-party manufacturer and issued 40,743 shares of common stock with a fair value of $3.2 million as part of that agreement. The shares were valued at $79.80 per share based on the closing price of the Company's common stock on the date of the agreement. As part of the agreement, the Company also paid this third-party manufacturer $1.3 million on September 1, 2022, $1.0 million on October 3, 2022, and $1.0 million in November 2022. In addition, the Company and the third-party manufacturer agreed that services to be rendered in future periods, as specified in the agreement, will be paid or settled at the Company's discretion, in a combination of cash and issuance of the Company's common stock. The agreement also amended certain agreements executed in prior years which eliminated future financial commitments of the Company.

During the year ended December 31, 2022, the Company recorded research and development expenses in the aggregate of $3.6 million for services rendered by this third-party product manufacturer and made additional payments of $900,000. As of December 31, 2022, the outstanding balance due to this third-party product manufacturer amounted to $2.3 million.

During the year ended December 31, 2023, the Company recorded research and development expenses in the aggregate of $4.6 million for services rendered by this third-party product manufacturer, made additional payments of $2.2 million, issued 57,436 additional shares of stock in settlement of $1.2 million of accounts payable with a fair value of $1.1 million, which resulted in a gain of $547,000 on that settlement. The common stock issued were valued at the respective date of their issuance. As of December 31, 2023, the outstanding balance due to this third-party product manufacturer amounted to $3.5 million.

Note 5 – Warrant Liability

The details of warrant liability transactions for the years ended December 31, 2023 and 2022 are as follows (in thousands):

	Year Ending	
	December 31, 2023	December 31, 2022
Beginning balance	$ 19	$ 138
Fair value upon issuance of warrants	5,830	—
Change in fair value	(4,797)	(119)
Ending balance	$ 1,052	$ 19

2023 Warrants

On January 4, 2023, as part of the private placement offering, the Company issued common stock, warrants to purchase up to an aggregate of 216,667 shares of the Company's common stock (the "Common Warrants"), and placement agent warrants to purchase up to 13,000 shares of the Company's common stock (the "Placement Agents Warrants" see Note 6 – Stockholders' Equity).

The Purchase Warrant provides for a value calculation for the Purchase Warrant using the Black Scholes model in the event of certain fundamental transactions. The fair value calculation provides for a floor on the volatility amount utilized in the value calculation at 100% or greater. The Company has determined this provision introduces leverage to the holders of the Purchase Warrant that could result in a value that would be greater than the settlement amount of a fixed-for-fixed option on the Company's own equity shares. Therefore, pursuant to ASC 815, the Company has classified the Purchase Warrant as a liability in its consolidated balance sheet. The classification of the Purchase Warrant, including whether the Purchase Warrant should be recorded as liability or as equity, is evaluated at the end of each reporting period with changes in the fair value reported in other income (expense) in the consolidated statements of operations and comprehensive loss. The Purchase Warrant was initially recorded at a fair value at $5.8 million at the grant date and is re-valued at each reporting date. Upon the closing of placement, the fair value of the Purchase Warrant liability was recorded as a cost of capital.

During 2023, the Company recognized change in fair value of the warrant liability of $4.7 million. As of December 31, 2023, the fair value of the warrant liability was $1.1 million.

All changes in the fair value of the warrant liabilities are recognized as a change in fair value of warrant liability in the Company's consolidated statements of operations until they are either exercised or expire.

The warrant liabilities for the Common Warrants and the Placement Agents Warrants were valued using a Binomial pricing model with the following weighted average assumptions:

	December 31, 2023	At Inception
Stock price	$ 7.80	$ 36.00
Risk-free interest rate	4.26%	3.60%
Expected volatility	115.2%	121.5%
Expected life (in years)	4.0 – 4.5	5.0
Expected dividend yield	-	-
Fair value of warrants (in thousands)	$ 1,050	$ 5,830

2020 Warrants

During the year ended December 31, 2020, the Company issued certain warrants that contained a fundamental transaction provision that could give rise to an obligation to pay cash to the warrant holder upon occurrence of certain change in control type events. In accordance with ASC 480, the fair value of these warrants is classified as a liability in the Consolidated Balance Sheets and will be re-measured at the end of every reporting period with the change in value reported in the statement of operations. The warrant liabilities were valued using a Binomial pricing model with an estimated fair value of $138,000 as of December 31, 2021.

During 2022, the Company recognized change in fair value of the derivative liability of $119,000. As of December 31, 2022, the fair value of the warrant liability was $19,000.

During 2023, the Company recognized change in fair value of the derivative liability of $17,000. As of December 31, 2023, the fair value of the warrant liability was $2,000.

The warrant liabilities were valued using a Binomial pricing model with the following average assumptions:

	December 31, 2023	December 31, 2022
Stock price	$ 7.80	$ 36.00
Risk-free interest rate	4.54%	4.22%
Expected volatility	89%	109%
Expected life (in years)	1.6	2.6
Expected dividend yield	-	-
Fair value of warrants	$ 2,000	$ 19,000

The risk-free interest rate was based on rates established by the Federal Reserve Bank. The Company uses the historical volatility of its common stock to estimate the future volatility for its common stock. The expected life of the derivative securities was determined by the remaining contractual life of the derivative instrument. The expected dividend yield was based on the fact that the Company has not paid dividends to its common stockholders in the past and does not expect to pay dividends to its common stockholders in the future.

Note 6 – Stockholders' Equity

The Company is authorized to issue 250,000,000 shares of common stock at a par value of $0.001, and 15,000,000 shares of preferred stock at par value $0.01 per share as of December 31, 2023.

Common Stock

Private Placement of Common Stock

On January 4, 2023, GT Biopharma received gross proceeds of $6.5 million, before deducting placement agent fees and other offering expenses of $232,000 in relation to a purchase agreement (the "Purchase Agreement") signed on December 30, 2022, between the Company and an institutional investor (the "Purchaser") for the issuance and sale, in a registered direct offering (the "Offering"), of 120,000 shares of the Company's common stock, par value $0.001 per share (the "Shares"), pre-funded warrants to purchase up to 96,667 shares of the Company's common stock (the "Pre-Funded Warrants"), warrants to purchase up to an aggregate of 216,667 shares of the Company's common stock (the "Common Warrants") and placement agent warrants to purchase up to 13,000 of the Company's common stock (the "Placement Agents Warrants"). The Common Warrants have an exercise price equal to $30.00, became exercisable commencing six months following issuance, and shall have a term of exercise equal to five years following the initial exercise date. The Pre-Funded Warrants had an exercise price of $0.003 per Share, were immediately exercisable and could be exercised at any time after their original issuance until such Pre-Funded Warrants were exercised in full. The Placement Agents Warrants have an exercise price equal to $37.50, became exercisable commencing six months following issuance, and shall have a term of exercise equal to five years following the initial exercise date. The Shares and Common Warrants were sold at an offering price of $30.00 per Share and accompanying Common Warrant and the Pre-Funded Warrants and Common Warrants were sold at an offering price of $29.997 per Pre-Funded Warrant and accompanying Common Warrant.

The Common Warrants and the Placement Agents Warrants contained a clause not considered to be within the Company's control. The Company determined that the provision represented a variable that is not an input to the fair value of a "fixed-for-fixed" option as defined under ASC 815-40, and thus the Common Warrants and the Placement Agent Warrants are not considered indexed to the Company's own stock and not eligible for an exception from derivative accounting. Accordingly, the Common Warrants and the Placement Agent Warrants were classified as a warrant liability, and $5.8 million of the initial common stock offering was classified as a warrant liability (Note 5 – Warrant Liability).

In May 2023, the 96,667 Pre-Funded Warrants were exercised.

Common Stock Issuable

As a result of the completion of a public offering on February 16, 2021 and listing of the Company's shares of common stock on the Nasdaq Capital Market, convertible notes payable and accrued interest totaling $38.8 million were mandatorily converted into 380,444 shares of the Company's common stock. As of December 31, 2021, 10,909 shares of common stock were still unissued to the corresponding noteholders with a total notes payable and accrued interest of $1.1 million and was accounted as common stock issuable in the accompanying consolidated statements of stockholders' equity.

During the year ended December 31, 2022, the Company issued the remaining 10,909 common shares issuable valued at $1.1 million. In addition, the Company also issued an additional 347 shares of commons stock with a fair value of $35,000 as settlement with a noteholder.

Cancellation of Common Stock Previously Issued for Services

The Company cancelled 9,700 previously issued shares of common stock during the year ended December 31, 2022.

Issuance of Common Stock as Equity Compensation to Officers, Employees and Board of Directors

During the year ended December 31, 2023, the Company issued 14,237 shares of common stock and recognized stock compensation expense of $267,000 to account for the fair value of common stock that vested. This included 13,333 shares with a fair value of $115,000 that were granted during the year.

During the year ended December 31, 2022, the Company issued 23,654 shares of common stock and recognized stock compensation expense of $2.5 million to account for the fair value of common stock that vested. This included 12,602 shares with a fair value of $938,000 that were granted during the year.

As of December 31, 2023 and 2022, there were no unvested shares granted to officers, employees and directors.

Equity Compensation to Consultants

During the year ended December 31, 2023, the Company issued 1,545 shares of common stock and recognized stock compensation expense of $162,000 to account for the fair value of common stock that vested.

During the year ended December 31, 2022, the Company issued 17,562 shares of common stock and recognized stock compensation expense of $2.1 million to account for the fair value of common stock that vested.

As of December 31, 2023, there were no unvested shares of common stock issued to consultants.

Cancellation of Common Stock Upon Settlement with a Former Officer

On April 29, 2022, the Company entered into a settlement agreement with its former Chief Executive Officer ("Officer") and received 61,500 shares of its previously issued common stock in full and final settlement of all its claims against the Officer. The common stock was subsequently cancelled and returned to treasury. In addition, the Company incurred legal and professional expenses of $224,000. The legal and professional fees incurred were accounted as costs of the acquisition of the common stock and recorded as a reduction to additional paid in capital. Both the Company and the Officer released each other from claims under the settlement agreement.

Preferred Stock

Series C Preferred Stock

At December 31, 2023 and 2022, there were 96,230 shares of Series C Preferred Stock, par value $0.01 per share (the "Series C Preferred Stock") issued and outstanding.

As a result of reverse stock-splits in previous years and the agreement terms for adjusting the rights of the related shares, the 96,230 shares of Series C Preferred Stock are not convertible to common stock, have no voting rights, and in the event of liquidation, the holders of the Series C Preferred Stock would not participate in any distribution of the assets or surplus funds of the Company. The holders of Series C Preferred Stock also are not currently entitled to any dividends if and when declared by the Company's board of directors (the "Board"). No dividends to holders of the Series C Preferred Stock were declared or unpaid as of and for the period ended December 31, 2023.

Series K Preferred Stock

On February 16, 2021, the Board designated 115,000 shares of Series K preferred stock, par value $.01. (the "Series K Preferred Stock").

Shares of the Series K Preferred Stock are convertible at any time, at the option of the holders, into shares of the Company's common stock at an effective conversion rate of 100 shares of common stock for each share of Series K Preferred Stock. Shares of the Series K Preferred Stock have the same voting rights a shares of the Company's common stock, with the holders of the Series K Preferred Stock entitled to vote on an as-converted-to-common stock basis, subject to the beneficial ownership limitation, together with the holders of the Company's common stock on all matters presented to the Company's stockholders. The Series K Preferred Stock are not entitled to any dividends (unless specifically declared by the Board), but will participate on an as-converted-to-common-stock basis in any dividends to the holders of the Company's common stock. In the event of the Company's dissolution, liquidation or winding up, the holders of the Series K Preferred Stock will be on parity with the holders of the Company's common stock and will participate, on a on an as-converted-to-common stock basis, in any distribution to holders of the Company's common stock.

As of December 31, 2023 and 2022, there were no Series K Preferred stock issued and outstanding.

Warrants and Options

Common Stock Warrants

Stock warrant transactions for the years ended December 31, 2023 and 2022, were as follows:

	Number of Warrants	Weighted-Average Exercise Price
Warrants outstanding at December 31, 2021	77,909	$ 159.00
Granted	-	-
Forfeited/canceled	-	-
Exercised	-	-
Warrants outstanding at December 31, 2022	77.909	159.00
Granted	326,333	21.30
Forfeited/canceled	(2,613)	102.00
Exercised	(96,667)	0.003
Warrants outstanding at December 31, 2023	304,962	$ 63.30
Warrants exercisable at December 31, 2023	304,962	$ 63.30

As of December 31, 2023 and 2022, all issued and outstanding warrants were fully vested. There was no intrinsic value of the outstanding warrants as of December 31, 2023 and 2022, as the exercise price of these warrants was equal to or greater than the market price.

Common Stock Options

Stock option transactions for the years ended December 31, 2023 and 2022 were as follows:

	Number of Options	Weighted-Average Exercise Price
Options outstanding at December 31, 2021	10,083	$ 91.50
Granted	51,098	74.40
Forfeited/canceled	(6,833)	74.40
Exercised	-	-
Options outstanding at December 31, 2022	54,348	77.10
Granted	83,333	22.50
Forfeited/canceled	(11,416)	84.30
Exercised	-	-
Options outstanding at December 31, 2023	126,265	$ 39.60
Options exercisable at December 31, 2023	117,980	$ 42.00

Year Ended December 31, 2023

On January 27, 2023, the Company granted stock options to employees and members of its board of directors to purchase an aggregate of 66,667 shares of common stock at an exercise price of $25.50 per share. The stock options expire in 10 years, vest over twelve months and had a fair value of $1.4 million at the date of grant determined using the Black-Scholes Option Pricing model with the weighted average assumptions below.

On May 15, 2023, the Company granted stock options to a member of its board of directors to purchase 16,666 shares of common stock at an exercise price of $10.50 per share. The stock options expire in 10 years, vest over twelve months and had a fair value of $175,000 on at the date of grant determined using the Black-Scholes Option Pricing model.

Due to the departure of certain employees during the year end December 31, 2023, 11,416 stock option were forfeited or expired unexercised.

The Company used the following weighted average assumptions in the Black-Scholes Option Pricing model to compute the fair value of the stock options granted during the year ended December 31, 2023.

Stock price	$10.50 - $25.50
Risk-free interest rate	3.62% - 3.99%
Expected volatility	120.81% - 123.61%
Expected life (in years)	5.3
Expected dividend yield	-

During the year ended December 31, 2023, the Company recognized stock compensation expense relating to the vesting of options granted in 2023 totaling $1.8 million to account the fair value of stock options that vested in fiscal 2023.

There was no intrinsic value of the outstanding options as of December 31, 2023 as the exercise price of these options was greater than the market price.

As of December 31, 2023, unamortized fair value of the 8,085 unvested stock options amounted to $186,000 which will be recognized in future periods.

Year Ended December 31, 2022

On July 15, 2022, the Company granted certain consultants, employees, officers and directors stock options to purchase an aggregate of 51,098 shares of common stock. The stock options are exercisable at $74.40 per share and will expire in 10 years. A portion of the options vested immediately with the remaining portion vesting over a period of 5 months up to 36 months. The fair value of the options amounted to $3.4 million or an average of $66.60 per share and were calculated using the Black Scholes Option pricing model.

The Company used the following weighted average assumptions in the Black-Scholes Option Pricing model to compute the fair value of the stock options granted during the year ended December 31, 2022.

Stock price	$	74.40
Risk-free interest rate		3.03%
Expected volatility		125.53%
Expected life (in years)		6.2
Expected dividend yield		-

The Company recorded forfeitures of 6,833 options to purchase common stock during 2022 due to the resignation of two employees. The forfeitures were related to shares that had not yet been vested.

During the year ended December 31, 2022, the Company recorded total stock compensation of $3.0 million to account the fair value of stock options that vested in fiscal 2022.

Note 7 – Commitments and Contingencies

Litigation

The Company is involved in certain legal proceedings that arise from time to time in the ordinary course of our business. Except for income tax contingencies, the Company records accruals for contingencies to the extent that our management concludes that the occurrence is probable and that the related amounts of loss can be reasonably estimated. Legal expenses associated with the contingency are expensed as incurred. There is no current or pending litigation of any significance with the exception of the matters that have arisen under, and are being handled in, the normal course of business.

A. On May 11, 2023, our former interim Chief Executive Officer, Dr. Greg Berk, filed a complaint with the Occupational Safety and Health Administration alleging retaliation against him during his tenure at the Company for raising concerns related to the public disclosure of certain product timelines. The Company is vigorously defending this matter and believe it to be without merit. At this early stage in the proceedings, the Company is not able to determine the probability of the outcome of this matter or a range of reasonably expected losses, if any.

B. On May 13, 2022, the Company made an arbitration demand upon Michael Handelman, its former Chief Financial Officer, asserting that he breached his fiduciary duty by misappropriating Company funds and shares of common stock, among other things. The Company seeks among other relief, monetary damages estimated at $470,000; the return of 13,903 shares of our common stock received without authorization; and an award of the Company's attorneys' fees and any forum and arbitration fees.

   As a component of Mr. Handelman's contract with the Company, disputes shall be fully addressed and finally resolved by binding arbitration conducted by the American Arbitration Association (AAA). In connection with any such arbitration, the Company shall bear all costs not otherwise borne by a plaintiff in a court proceeding.

   On March 20, 2024, the Arbitrator issued an interim award in favor of the Company in the amount of $409,000 and directed Mr. Handelman to return the disputed 13,903 shares of common stock . The Arbitrator also awarded the Company its attorney fees and forum costs in an amount to be determined at the time of the final award.

C. On May 24, 2023, TWF Global, LLC ("TWF") filed a Complaint in the California Superior Court for the County of Los Angeles naming the Company as defendant. The Complaint alleges that TWF is the holder of two Convertible Promissory Notes ("Notes") and that the Company did not deliver shares of common stock due on conversion in February 2021. TWF was seeking per diem liquidated damages based on the terms of alleged Notes. On July 14, 2023, the Company filed a motion to dismiss for improper forum because the terms of the Notes, as alleged, require disputes to be filed in New York state and federal courts. TWF voluntarily dismissed its Complaint before the California Superior Court of Los Angeles without prejudice. The Company subsequently filed a Summons and Complaint for Interpleader against TWF and Z One LLC before the Supreme Court of the State of New York County of New York, asking the Supreme Court to determine if the Company's shares of common stock are properly registered to TWF or Z One LLC, as both of these entities have made conflicting demands for registration of the shares of common stock. On February 5, 2024, the Company filed a motion for entry of default against TWF, seeking an order directing the Company to register the shares of common stock in the name of Z-One and that the Company be released from all associated liability and claims. The Court has not yet ruled on the Company's motion. The Company believes that any claims related to the Notes are without merit and will continue to defend vigorously against these claims.

Significant Agreements

Research and Development Agreements

The Company is a party to a scientific research agreement with the Regents of the University of Minnesota ("UofMN"), effective June 16, 2021. This scientific research agreement aims to work with the Company with three major goals in mind: (1) support the Company's TriKE® product development and GMP manufacturing efforts; (2) TriKE® pharmacokinetics optimization in humans; and (3) investigation of the patient's native NK cell population based on insights obtained from the analysis of the human data generated during our GTB-3550 clinical trial. The major deliverables proposed here are: (1) creation of IND enabling data for TriKE® constructs in support of our product development and GMP manufacturing efforts; (2) TriKE® platform drug delivery changes to allow transition to alternative drug delivery means and extended PK in humans; and (3) gain an increased understanding of changes in the patient's native NK cell population as a result of TriKE® therapy. Most studies will use TriKE® DNA/amino acid sequences created by us under current UMN/GTB licensing terms. This agreement expired on June 30, 2023. The Company and UofMN are negotiating the terms of a new scientific research agreement and expect to finalize it in the first half of 2024.

For the years ended December 31, 2023 and 2022, the Company recorded an expense of $383,000 and $766,000 pursuant to the scientific research agreement for each respective period. The Company has recorded expense in the aggregate of $2.1 million as of December 31, 2023 pursuant to this agreement.

Patent and License Agreements

2016 Exclusive Patent License Agreement

The Company is party to an exclusive worldwide license agreement with the Regents of the University of Minnesota, ("UofMN"), to further develop and commercialize cancer therapies using TriKE® technology developed by researchers at the UofMN to target NK cells to cancer. Under the terms of the 2016 agreement, the Company receives exclusive rights to conduct research and to develop, make, use, sell, and import TriKE® technology worldwide for the treatment of any disease, state, or condition in humans. The Company is responsible for obtaining all permits, licenses, authorizations, registrations, and regulatory approvals required or granted by any governmental authority anywhere in the world that is responsible for the regulation of products such as the TriKE® technology, including without limitation the FDA and the European Agency for the Evaluation of Medicinal Products in the European Union. Under the agreement, the UofMN received an upfront payment of $200,000, and an annual License Maintenance fee of $100,000 beginning in 2021. The agreement also includes 4% royalty fees, (not to exceed 6% under subsequence license agreements or amendments to this agreement or minimum annual royalty payments ranging from $250,000 to $5.0 million. The agreement also includes certain performance milestone payments totaling $3.1 million, and one-time sales milestone payments of $1.0 million upon reaching $250 million in gross sales, and $5.0 million upon reaching $500 million dollars in cumulative gross sales of Licensed Products.

The Company did not incur any research and development expense relating to the 2016 Exclusive Patent License Agreement for the year ended December 31, 2023.

2021 Patent License Agreement

On March 26, 2021, the Company signed an agreement specific to the B7H3 targeted TriKE®. Under the agreement, the UofMN received an upfront license fee of $20,000, and will receive an annual License Maintenance fee of $5,000 beginning in 2022, 2.5% to 5% royalty fees, or minimum annual royalty payments of $250,000 beginning in the year after the first commercial sales of Licensed Product, and $2.0 million beginning in the fifth year after the first commercial sale of such Licensed Product. The agreement also includes certain performance milestone payments totaling $3.1 million, and one-time sales milestone payments of $1.0 million upon reaching $250 million in gross sales, and $5.0 million upon reaching $500 million dollars in cumulative gross sales of Licensed Products. There is no double payment intended; if one of the milestone payments has been paid under the 2016 agreement no further payment is due for the corresponding milestone above.

The Company did not incur any research and development expense relating to the 2021 Patent License Agreement for the years ended December 31, 2023 and 2022, respectively.

Employee Compensation

The following table summarizes the Company's future financial commitment to certain employees pursuant to their respective employment agreements (in thousands):

Year ending	Amount
2024	$ 1,015
2025	53
Total	$ 1,068

Note 8 – Operating Leases

Leases with an initial term of 12 months or less are not recorded on the balance sheet. The Company accounts for the lease and non-lease components of its leases as a single lease component. Rent expense is recognized on a straight-line basis over the lease term. Operating lease Right-of-Use ("ROU") assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Generally, the implicit rate of interest in arrangements is not readily determinable and the Company utilizes its incremental borrowing rate in determining the present value of lease payments. The Company's incremental borrowing rate is a hypothetical collateralized borrowing rate based on its understanding of what its credit rating would be. The operating lease ROU asset includes any lease payments made and excludes lease incentives.

On November 19, 2021, the Company entered into a sublease with a third party for 4,500 square feet of office space located in Brisbane, California, with a commencement date of January 1, 2022, and maturing on June 30, 2024. As a result of this agreement, the Company recognized ROU asset and liability of $247,294 pursuant to ASC 842*, Leases.*

On February 8, 2022, the Company entered into a copier lease which would end on February 7, 2025. As a result, the Company recognized an additional ROU asset and liability of $13,000. In October 2023, this lease was cancelled and the remaining ROU asset of $6,000 was written off against the cancelled lease liability.

Other information related to leases and future minimum lease payments under non-cancellable operating leases were as follows:

	December 31, 2023	December 31, 2022
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 118,000	$ 109,000
Right-of-use assets obtained in exchange for lease liabilities:		
Operating leases	$ 53,000	$ 165,000
Weighted-average remaining lease term (in years):		
Operating leases	0.5	1.75
Weighted-average discount rate:		
Operating leases	10%	10%

Future minimum lease payments under non-cancellable operating leases were as follows:

	December 31, 2023 (Unaudited)
Within one year	$ 60,000
Thereafter	-
Total future minimum lease payments	60,000
Less – discount	(2,000)
Lease liability	$ 58,000

Note 9 – Income Tax

The Company did not record any income tax provision for the years ended December 31, 2023 and 2022, respectively, due to the Company's net losses. The Company files income tax returns in the United States ("Federal") and California, Minnesota and Massachusetts ("State") jurisdictions. The Company is subject to Federal and State income tax examinations by tax authorities for all years since its inception. At December 31, 2023, the Company had Federal and State net operating loss carry forwards available to offset future taxable income of approximately $238 million. These carry forwards will begin to expire in the year ending December 31, 2030, subject to IRS limitations, including change in ownership. The Company periodically evaluates the likelihood of the realization of deferred tax assets, and adjusts the carrying amount of the deferred tax assets by a valuation allowance to the extent the future realization of the deferred tax assets is not judged to be more likely than not. The Company considers many factors when assessing the likelihood of future realization of our deferred tax assets, including recent cumulative earnings experience by taxing jurisdiction, expectations of future taxable income or loss, the carry-forward periods available to us for tax reporting purposes, and other relevant factors.

Based on the weight of available evidence, including cumulative losses in recent years and expectations of future taxable income, the Company has determined that it was more likely than not that its deferred tax assets would not be realized at December 31, 2023 and 2022, respectively. Accordingly, the Company has recorded a valuation allowance for 100% of its cumulative deferred tax assets.

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

	December 31,	
	2023	2022
Deferred tax assets:		
Federal net operating loss carryforward	$ 66,679	$ 66,741
Stock based compensation and other items	3,216	4,674
Intellectual property	37,219	41,572
Section 14 research and development	2,578	-
Deferred tax assets before valuation	109,692	112,987
Valuation allowance	(109,692)	(112,987)
Net deferred income tax assets	$ -	$ -

A reconciliation of the federal statutory income tax rate and the effective income tax rate as a percentage of income before income tax provision is as follows for the year ended:

	December 31,	
	2023	2022
Federal statutory income tax rate	21%	21%
State tax, net of federal benefit	8%	8%
Change in valuation allowance on net operating loss carryforwards	(29)%	(29)%
Effective income tax rate	0%	0%