August 14, 2024

# GT Biopharma Reports Second Quarter 2024 Financial Results and Provides Corporate Update

- *GTB-3650 TriKE® Phase 1 trial initiation expected in 2H 2024; initial clinical data expected in 1H 2025*
- *GTB-5550 TriKE® IND submission for treatment of B7H3 positive solid tumors expected in 1H 2025*
- *GTB-5550 Phase 1 dose escalation basket trial initiation expected in 2025 evaluating six solid tumor types, including prostate, breast, head and neck, ovarian, lung, and GI*
- *GTB-7550 TriKE® is in preclinical development for autoimmune indications and targets CD19*
- *Cash of approximately $9.2 million as of June 30, 2024, anticipated to be sufficient to fund operations into 2025*

SAN FRANCISCO, CALIFORNIA, Aug. 14, 2024 (GLOBE NEWSWIRE) -- GT Biopharma, Inc. (the “Company”) (NASDAQ: GTBP), a clinical stage immuno-oncology company focused on developing innovative therapeutics based on the Company's proprietary natural killer (NK) cell engager, TriKE® platform, today announced second quarter 2024 financial results for the period ended June 30, 2024.

“We are thrilled to be in a position to initiate a Phase 1 trial evaluating GTB-3650 in cancer patients in the second half of this year. Initial data from the dose escalation phase of this trial is anticipated in the first half of 2025. We also expect to submit a second IND, for GTB-5550, in the first half of 2025, which has much broader potential in multiple solid tumors and could fuel our future success as a company specializing in NK cell engagers”, said Michael Breen, Executive Chairman and interim Chief Executive Office of GT Biopharma.

The Phase 1 dose escalation study will evaluate GTB-3650 in up to six cohorts (two patients per cohort) in adults with relapsed or refractory (r/r) CD33 expressing hematologic malignancies, including refractory acute myeloid leukemia (AML) and high-risk myelodysplastic syndrome (MDS). GTB-3650 will be dosed in two-week blocks, two weeks on and two weeks off, for up to four months based on clinical benefit. The trial will assess safety, pharmacokinetics, pharmacodynamics, in vivo expansion of endogenous patient NK cells and clinical activity.

“We also remain active in exploring additional opportunities where our TriKE platform technology may have therapeutic utility, especially for autoimmune indications, which are quickly becoming recognized as an intriguing new area for immune-related therapies. Another area of continued interest and work is thoroughly assessing the potential to combine

our engagers with NK cellular therapies," said Michael Breen. "There are compelling reasons to explore combination approaches in this rapidly emerging field, including the potential for synergistic clinical effects. Our patented platform technology can be leveraged across multiple NK cell engager constructs with new targets and for additional diseases, including GTB-7550 which targets CD19 for autoimmune indications. GTB-3650 and GTB-5550 are the frontrunners to further validate our platform, which has already yielded a portfolio of multiple pipeline development candidates. We look forward to advancing all the opportunities in our deep pipeline as the science continues to emerge."

**Second Quarter 2024 Financial Summary**

**Cash Position:** The Company had cash and cash equivalents of approximately $9.2 million as of June 30, 2024, anticipated to be sufficient to fund operations into 2025.

**Research and Development (R&D) Expenses:** R&D expenses for the second quarter ended March 31, 2024 were $1.8 million compared to $2.1 million for the same comparable quarter of 2023, the decrease was primarily due to reduction in raw material costs and partially offset by an increase in scientific research costs. Research and development expenses relate 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 candidates. In late June 2024, we received clearance from the FDA with respect to its IND Application in relation to GTB 3650. We anticipate the direct clinical and preclinical expenses to continue to increase in 2024 as we advance GTB-3650 into the clinic and enroll patients, perform tests for data collection, complete the product development of GTB-5550, and anticipate submission of an 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 (SG&A) Expenses:** SG&A expenses for the second quarter ended June 30, 2024 were $2.1 million compared to $1.5 million for the same comparable quarter of 2023, the increase was primarily due to an increase in legal and professional fees.

**Other Income:** Other income for the second quarter ended June 30, 2024 was $196,000 compared to $1.6 million for the same comparable quarter of 2023, the decrease was primarily due to a $1.3 million reduction in the non-cash change in fair value of warrant liability.

**Net Loss:** The Company reported a net loss of $3.7 million for the second quarter ended June 30, 2024 compared to a net loss of $2.0 million for the same comparable quarter in 2023. The $1.7 million increase in net loss consisted primarily of a $1.4 million reduction in the non-cash change in fair value of warrant liability and a $600,000 increase in SG&A expenses, partially offset by a $300,000 decrease in R&D expenses (as described above).

**About Camelid Antibodies**

Camelid antibodies are single domain antibodies (sdAbs) from the Camelidae family of mammals that include llamas, camels, and alpacas. These animals produce different types of antibodies compared to those naturally made in humans. Human conventional antibodies have recognition domains made up of heavy chains and light chains. Camelid antibodies have key characteristics, which include high affinity and specificity (equivalent to

conventional antibodies), high thermostability, good solubility and strictly monomeric behavior, small size, relatively low production cost, ease of genetic engineering, format flexibility or modularity, low immunogenicity, and a higher penetration rate into tissues.

**About GT Biopharma, Inc.**

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology therapeutic products based on our proprietary TriKE® NK cell engager platform. Our TriKE® platform is designed to harness and enhance the cancer killing abilities of a patient's immune system's natural killer cells. GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize therapies using TriKE® technology. For more information, please visit gtbiopharma.com.

**Forward-Looking Statements**

Certain statements in this press release may constitute "forward-looking statements" regarding future events and our future results. All statements other than statements of historical facts are statements that could be deemed to be forward-looking statements. These statements are based on current expectations, estimates, forecasts, and projections about the markets in which we operate and the beliefs and assumptions of our management. Words such as "expects," "anticipates," "targets," "goals," "projects", "intends," "plans," "believes," "seeks," "estimates," "endeavors," "strives," "may," or variations of such words, and similar expressions are intended to identify such forward-looking statements. Readers are cautioned that these forward-looking statements are subject to a number of risks, uncertainties and assumptions that are difficult to predict, estimate or verify. Therefore, actual results may differ materially and adversely from those expressed in any forward-looking statements. Such risks and uncertainties include those factors described in our most recent annual report on Form 10-K, as such may be amended or supplemented by subsequent quarterly reports on Form 10-Q, or other reports filed with the Securities and Exchange Commission. Readers are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements are made only as of the date hereof, and we undertake no obligation to publicly release the result of any revisions to these forward-looking statements. For more information, please refer to our filings with the Securities and Exchange Commission.



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**GT BIOPHARMA, INC. AND SUBSIDIARIES**
**Condensed Consolidated Balance Sheets**

| | June 30, 2024 | December 31, 2023 |
|---|---|---|
| | (Unaudited) | |
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 9,249,000 | $ 1,079,000 |
| Short-term investments | — | 12,893,000 |
| Prepaid expenses and other current assets | 18,000 | 84,000 |
| Total Current Assets | 9,267,000 | 14,056,000 |
| Operating lease right-of-use asset | - | 53,000 |
| **TOTAL ASSETS** | $ 9,267,000 | $ 14,109,000 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities | | |
| Accounts payable | $ 1,717,000 | $ 4,328,000 |
| Accrued expenses | 1,765,000 | 1,195,000 |
| Current operating lease liability | — | 58,000 |
| Warrant liability | 277,000 | 1,052,000 |
| **Total Current Liabilities** | 3,759,000 | 6,633,000 |
| Stockholders' Equity | | |
| Convertible Preferred stock, par value $0.01, 15,000,000 shares authorized Series C - 96,230 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively | 1,000 | 1,000 |
| Common stock, par value $0.001, 250,000,000 shares authorized, 2,234,328 and 1,380,633 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively | 2,000 | 1,000 |
| Additional paid in capital | 693,546,000 | 689,539,000 |
| Accumulated deficit | (688,041,000 ) | (682,065,000 ) |
| **Total Stockholders' Equity** | 5,508,000 | 7,476,000 |
| **TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY** | $ 9,267,000 | $ 14,109,000 |

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

## GT BIOPHARMA, INC. AND SUBSIDIARIES
## Condensed Consolidated Statements of Operations

| | For The Three Months Ended June 30, | | For the Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| | (Unaudited) | (Unaudited) | (Unaudited) | (Unaudited) |
| **Operating Expenses:** | | | | |
| Research and development | $ 1,784,000 | $ 2,095,000 | $ 2,561,000 | $ 3,745,000 |
| Selling, general and administrative (including $120,000 and $398,000 from stock compensation granted to officers, directors, and employees during the three months ended June 30, 2024 and 2023, respectively, and $222,000 and $905,000 for the six months ended June 30, 2024 and 2023, respectively) | 2,122,000 | 1,526,000 | 4,436,000 | 3,541,000 |
| Loss from Operations | (3,906,000) | (3,621,000) | (6,997,000) | (7,286,000) |
| **Other Income (Expense)** | | | | |
| Interest income | 105,000 | 220,000 | 247,000 | 384,000 |
| Interest expense | — | (1,000) | — | (213,000) |
| Change in fair value of warrant liability | 117,000 | 1,387,000 | 775,000 | 4,311,000 |
| Gain on extinguishment of debt | — | 14,000 | — | 547,000 |
| Unrealized gain (loss) on marketable securities | 1,000 | 9,000 | (1,000) | 38,000 |
| Other | (27,000) | — | — | — |
| **Total Other Income** | 196,000 | 1,629,000 | 1,021,000 | 5,067,000 |
| **Net Loss** | $ (3,710,000) | $ (1,992,000) | $ (5,976,000) | $ (2,219,000) |
| **Net Loss Per Share - Basic and Diluted** | $ (2.17) | $ (1.49) | $ (3.86) | $ (1.68) |
| **Weighted average common shares outstanding - basic and diluted** | 1,711,955 | 1,339,087 | 1,546,294 | 1,321,069 |

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

## GT BIOPHARMA, INC. AND SUBSIDIARIES
## Condensed Consolidated Statements of Cash Flows

| | For The Six Months Ended June 30, | |
|---|---|---|
| | 2024 | 2023 |
| | (Unaudited) | (Unaudited) |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net loss | $ (5,976,000) | $ (2,219,000) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock based compensation - services | - | 315,000 |
| Stock based compensation - officers, directors, and employees | 222,000 | 905,000 |
| Change in fair value of warrant liability | (775,000) | (4,311,000) |
| Gain on extinguishment of share settled debt | - | (547,000) |
| Change in operating lease right-of-use assets | 53,000 | 51,000 |
| Unrealized loss (gain) on marketable securities | (1,000) | (38,000) |
| Changes in operating assets and liabilities: | | |
| Decrease in prepaid expenses | 67,000 | 5,000 |
| Increase (Decrease) in accounts payable and accrued expenses | (1,231,000) | 1,052,000 |
| (Decrease) in operating lease liability | (58,000) | (54,000) |
| Net Cash Used in Operating Activities | (7,699,000) | (4,841,000) |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Sale (purchase) of investments | 12,893,000 | (4,332,000) |
| Net Cash Provided by (Used in) Investing Activities | 12,893,000 | (4,332,000) |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Proceeds from issuance of common stock and warrants, net | 2,976,000 | 6,268,000 |
| Net Cash Provided by Financing Activities | 2,976,000 | 6,268,000 |
| Net Increase (Decrease) in Cash and Cash Equivalents | 8,170,000 | (2,905,000) |
| Cash at Beginning of Period | 1,079,000 | 5,672,000 |
| Cash at End of Period | $ 9,249,000 | $ 2,767,000 |
| SUPPLEMENTAL DISCLOSURES OF CASH FLOW INFORMATION: | | |
| Cash paid during the year for: | | |
| Interest | $ - | $ - |
| Income taxes | $ - | $ - |
| SUPPLEMENTAL DISCLOSURES OF NON-CASH INVESTING AND FINANCING ACTIVITIES | | |
| Initial recognition of fair value of warrant liability | $ - | $ 5,831,000 |
| Fair value of common stock issued to a vendor to settle accounts payable | $ 810,000 | $ 591,000 |

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

Source: GT Biopharma, Inc.