

March 26, 2024



Biopharma, Inc.

GT Biopharma Reports Fourth Quarter and Full-Year 2023 Financial Results

- *Remain in active dialogue with the FDA regarding IND clearance for GTB-3650, a 2nd generation nanobody TriKE[®] for treatment of CD33+ leukemia*
- *Phase 1 trial with GTB-3650 anticipated to start in 2H 2024*
- *Anticipate submitting an IND for GTB-5550 targeting B7H3 for multiple solid tumors, including prostate and breast, in Q4 2024*
- *Cash of approximately \$14 million as of December 31, 2023, provides sufficient runway to fund operations into 2025*

BRISBANE, CALIFORNIA, March 26, 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 fourth quarter and full-year 2023 results for the period ended December 31, 2023.

"We continue to make good progress with the FDA regarding IND clearance for GTB-3650, and eagerly anticipate the start of Phase 1 this year," said Michael Breen, Executive Chairman and Interim Chief Executive Office of GT Biopharma. "We are also anticipating an IND submission for our 2nd asset, GTB-5550, for multiple solid tumors, including breast and prostate cancers, in Q4 of this year. We have sufficient cash runway into 2025 and anticipate having initial data from our Phase 1 trial with GTB-3650 by the end of 2024/early 2025."

Fourth Quarter and Year End 2023 Financial Summary

Cash Position: The Company had cash, cash equivalents and short-term investments of \$13.97 million as of December 31, 2023 compared to \$16.51 million as of December 31, 2022. This is anticipated to provide sufficient runway to fund operations into 2025.

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2023 were \$1.36 million compared to \$2.84 million for the same quarter of 2022. R&D expenses for the year ended December 31, 2023 were \$6.47 million compared to \$8.81 million for the year ended December 31, 2022. The \$2.34 million reduction in R&D for the year ended December 31, 2023 over 2022 was primarily due to a \$3.59 million reduction in licensing and administrative costs, offset by an increase of \$1.25 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 of other promising product candidates. The reduction of \$3.59 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.

General and Administrative (G&A) Expenses: G&A expenses for the fourth quarter of 2023 were \$1.81 million compared to \$2.94 million for the same quarter in 2022. G&A expenses for the year ended December 31, 2023 was \$7.11 million compared to \$12.45 million for the year ended December 31, 2022. The decrease in G&A of \$5.34 million for the year ended December 31, 2023 as compared to 2022 was primarily attributable to a reduction of \$1.68 million in stock compensation expenses for officers, employees and board of directors and \$1.92 million for outside consultants, a reduction of \$1.31 million in consulting board advisory board fees, and a reduction of \$0.50 million in patents and insurance costs. 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

Other income net of other expenses, for the fourth quarter ended December 31, 2023 was \$0.21 million compared to \$0.19 million for the same quarter ended December 31, 2022. Other income, net of other expenses for the year ended December 31, 2023 was \$5.98 million compared to \$0.37 million for the year ended December 31, 2022. Other income and expenses consisted of interest income, interest expense, change in the fair value of warrant liability, gain on extinguishment of debt, and unrealized gain and loss on marketable securities. The increase in other income net of expenses for the year ended December 31, 2023 was primarily due to the change in fair value of warrant liability as a result of fair value remeasurement which resulted in a gain of \$4.8 million and \$0.12 million for the years ended December 31, 2023 and 2022, respectively.

Net Loss: The Company reported a net loss of \$2.96 million for the fourth quarter ended December 31, 2023 compared to a loss of \$5.58 million for the same quarter in 2022. The Company reported a loss of \$7.60 million for the year ended December 31, 2023, compared to a net loss of \$20.88 million for the year ended December 31, 2022.

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 two main types of antibodies. One type of antibody camelids produce is the conventional antibody that is made up of two heavy chains and two light chains. They also produce another type of antibody that is made up of only two heavy chains and no light chain. This is known as heavy chain IgG (hcIgG). While these antibodies do not contain the CH1 region, they retain an antigen binding domain called the VHH region. VHH antibodies, also known as single domain antibodies, contain only the VHH region from the camelid antibody. 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. Examples of forward-looking statements in this press release include statements regarding our IND applications, Phase 1 trials and operating expenses and cash runway. 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.

TriKE[®] is a registered trademark owned by GT Biopharma, Inc.

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