

March 28, 2022



Biopharma, Inc.

GT Biopharma Reports Fourth Quarter and Full-Year 2021 Financial Results and Provides Corporate Update

- Presented novel TriKE[®] pre-clinical data driving NK cell immunotherapy against non-small cell lung cancer (NSCLC) in the hypoxic solid tumor microenvironment at ESMO TAT Congress.
- Demonstrated novel B7-H3 targeting dual camelid nanobody TriKE[®] and GTB-5550 induce NK cell activation against broad spectrum of tumors at ESMO IO Congress 2021.
- GT Biopharma to participate in poster-presentation sessions at the following upcoming EBMT and AACR medical conferences.
- \$32.0 million in cash, cash equivalents and short-term investments as of December 31, 2021, is expected to provide ample runway to fund operations into 2023, including Phase 1 clinical development of its lead products GTB-3650 and GTB-5550.

BRISBANE, Calif., March 28, 2022 /PRNewswire/ -- 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 2021 results for the period ended December 31, 2021.



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"We're excited for GTB-3650's prospects in the new year as we advance the Company's second-generation Tri-specific NK cell engager (TriKE[®]) technology into an IND-enabling study. The development of GTB-3650, our lead-asset second generation nanobody TriKE[®] has been significantly de-risked, propelled by GTB-3550 predecessor data published in 2021 including: positive first-in-human Phase 1 data; and in-vivo animal model data, conducted in combination with a bispecific killer cell engager asset," said Michael Breen, Executive Chairman and Interim Chief Executive Officer. "Our optimism continues to rise as these proof-of-concept data demonstrate a well-tolerated safety profile and strong NK cell activation against a broad range of tumors. In total, the Company's TriKE[®] nanobody platform, a rich platform technology, has demonstrated broad utility. We are confident in our ability to develop these assets as a monotherapy, as a combination therapy with conventional chemotherapy, or in combination with other potential joint commercialization technologies."

Quarterly Highlights

- The Company presented pre-clinical TriKE[®] data in an oral poster-presentation both virtually and in-person at [ESMO Targeted Anticancer Therapies \(TAT\) Congress](#), March 7–8, 2022.
 - The pre-clinical evidence suggests, despite the difference in circulating immune cells of Stage IVB NSCLC patients, mesothelin-targeted TriKE[®] can work alongside current standard of care and provide benefit even in the hypoxic environment of a solid tumor.
- Dr. Jeffrey Miller, GT Biopharma consultant Chief Scientific Officer, also participated in an oral poster-presentation session at the [European Society for Medical Oncology Immuno-Oncology \(ESMO IO\) Congress](#), December 8–11, 2021.
 - The presentation highlighted the broad activity of GTB-5550, which harbors wild-type IL-15 in combination with TriKE[®] against B7-H3-expressing tumors.

Upcoming Conference Participation

- GT Biopharma will participate in poster-presentation sessions at the following upcoming medical conferences:
 - EBMT Abstract AS_EBMT-2022-00508, "A Tri-specific Killer Engager (TriKE[®]) against B7-H3 enhances NK cell mediated killing of multiple myeloma"
 - AACR Abstract 3435, "GTB-5550 (cam16-IL15-camB7H3) Tri-specific Killer Engager (TriKE[®]) drives natural killer cell activation and antibody dependent cellular cytotoxicity against head and neck squamous cell carcinomas"

Fourth Quarter and Year End 2021 Financial Summary

Cash Position: The Company had total cash, cash equivalents and short-term investments of \$32.0 million as of December 31, 2021, compared to \$5.3 million as of December 30, 2020. This is expected to provide ample runway to fund operations into 2023 including Phase 1 clinical development of its lead products GTB-3650 and GTB-5550.

Research and Development (R&D) Expenses: R&D expenses for the fourth quarter of 2021 were \$6.3 million compared to \$233,000 in the same quarter a year ago. R&D

expenses for the year-ending December 31, 2021, were \$9.6 million compared to \$485,000 in the year ended December 31, 2020. Research and development expenses increased primarily due to the admittance of additional patients into the Phase 1 GTB-3550 clinical trial and the continued development and production of our most advanced TriKE® product candidates GTB-3650 and GTB-5550.

General and Administrative (G&A) Expenses: G&A expenses for the fourth quarter of 2021 were \$11.8 million compared to \$2.0 million in the same quarter a year-ago. G&A expenses for the year ending December 31, 2021, were \$47.9 million compared to \$6.3 million for the year ending December 31, 2020. The increase in general and administrative expenses was primarily attributable to the increase in stock-based compensation and expenses incurred in support of our planned growth and new public company compliance initiatives. For the year ended December 31, 2021, we incurred \$33.9 million of stock-based compensation expense as compared to \$269,000 in stock-based compensation expense for the year ended December 31, 2020.

Net Loss: For the fourth quarter of 2021, the Company reported a net loss of \$18.0 million, compared to a net loss of \$6.3 million in the same quarter a year ago. For the year ended December 31, 2021, the Company reported a net loss of \$58.0 million compared to a net loss of \$28.3 million for the year ending December 31, 2020.

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 (hclgG). 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. 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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