March 2, 2026

GT Biopharma Reports Full Year 2025 Financial Results

Phase 1 trial evaluating GTB-3650 TriKE® continues to actively enroll, with the next update anticipated in Q3 2026 following completion of enrollment in dose Cohort 5

Phase 1 basket trial evaluating GTB-5550 TriKE® in multiple solid tumor types known to express B7-H3 remains on track to initiate mid-2026

Unaudited proforma cash balance as of January 31, 2026 of approximately $9 million anticipated to provide sufficient cash runway through Q4 2026

SAN FRANCISCO, CALIFORNIA, March 02, 2026 (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 full year 2025 financial results for the period ended December 31, 2025.

"2026 looks to bring more significant milestones for the company, as we plan to initiate the first clinical trial with GTB-5550," said Michael Breen, Executive Chairman and Chief Executive Officer. "Advancing our third TriKE candidate into the clinic underscores the continued momentum of our pipeline. GTB-3650 has shown an excellent safety profile thus far, and the higher dose cohorts will be more reflective of surpassing a potential efficacy threshold. With sufficient cash runway through Q4 2026, we look forward to providing the next update in the third quarter of 2026."

GTB-3650 TriKE for CD33 positive leukemias

The ongoing Phase 1 dose escalation study is evaluating GTB-3650 for relapsed or refractory (r/r) CD33 expressing hematologic malignancies, including refractory acute myeloid leukemia and high-risk myelodysplastic syndrome. Enrollment in Cohort 4 (10 µg/kg/day) is ongoing, and the Company expects to initiate dosing in Cohort 5 (25 µg/kg/day) in Q2 2026. The Company anticipates providing the next update in the third quarter of 2026, which would include longer term follow-up on the six patients in Cohort 1 through 3 as well as initial observations from patients in Cohort 4 and Cohort 5. Dose escalation may continue up to Cohort 7 as necessary with the potential to evaluate GTB-3650 in a total of 14 patients (two patients per cohort). GTB-3650 is dosed in two-week blocks, two weeks on and two weeks off, for up to four months based on clinical benefit. The trial aims to assess the safety, pharmacokinetics, pharmacodynamics, in vivo expansion of endogenous patient NK cells and clinical activity.

GTB-5550 TriKE for B7H3 positive solid tumor cancers

The Phase 1 basket trial with GTB-5550 will be the first dual nanobody TriKE® tested with more patient-friendly subcutaneous dosing. The Phase 1a dose escalation portion of the trial will test up to 6 dose levels to identify the maximum tolerated dose (MTD). After the dose escalation phase, the Phase 2 expansion component of the trial will then confirm the MTD identified in the Phase 1a trial in up to seven different possible metastatic disease cohorts (castration-resistant prostate cancer, ovarian cancer, breast cancer, head and neck cancer, non-small cell lung cancer, pancreatic cancer, and bladder cancer) and further evaluate its safety, tolerability and preliminary anti-tumor activity. The Company remains well on track to initiate the trial in mid-2026.

GTB-5550 will be administered by subcutaneous (SQ) injection in the abdominal area for 5 consecutive days during Week 1 and Week 2 followed by 2 weeks of no treatment. One treatment cycle is 4 weeks in duration. A minimum of 2 cycles is planned, and patient-appropriate disease reassessment is performed after 2 cycles and every 8-12 weeks thereafter. Treatment may continue until disease progression, unacceptable toxicity, patient refusal, or treatment is no longer in the best interest of the patient. Patients are followed for 12 months to determine progression free survival (PFS) and overall survival (OS).

Year Ended December 31, 2025 Financial Summary

Cash Position: The Company had cash and cash equivalents of approximately $7 million as of December 31, 2025, and an unaudited proforma cash balance as of January 31, 2026 of approximately $9 million, which is anticipated to be sufficient to fund the Company's operations through the fourth quarter of 2026.

Research and Development (R&D) Expenses: R&D expenses for the year ended December 31, 2025 were approximately $3.5 million compared to $5.8 million for the prior year. The $2.3 million decrease was primarily due to a reduction in production and material costs. R&D expenses primarily relate to the Company's continued licensing, development and production of its most advanced TriKE® product candidates GTB-3650 and GTB-5550 along with the progression on other promising product candidates. In late June 2024, the Company received clearance from the Food and Drug Administration with respect to its Investigational New Drug ("IND") application in relation to its next generation GTB-3650 camelid nanobody product. Study enrollment began in early 2025 and the Company has advanced into the clinic, enrolling patients, and performing tests for data collection throughout the year. In late January 2026, the Company received clearance from the FDA with respect to its IND Application in relation to GTB-5550, with a Phase 1 dose escalation basket trial expected to initiate mid-2026.

Selling, General and Administrative (SG&A) Expenses (Excluding Stock Compensation): SG&A expenses for the year ended December 31, 2025 were relatively flat compared to the prior year, amounting to approximately $8.5 million compared to $8.3 million, respectively.

Loss from Operations: The Company reported a loss from operations of approximately $12.4 million for the year ended December 31, 2025, compared to $14.4 million for the prior year. The $2 million decrease consisted primarily of significant decreases in R&D expenses (as described above).

Net Loss: The Company reported a net loss of approximately $28.4 million for the year ended December 31, 2025, compared to $13.2 million for the prior year. The $15.2 million increase consisted almost entirely of a non-cash expense resulting from the change in fair value of additional investment rights connected to the Company's Series L Preferred Stock during the year.

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 "aims," "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 the use of 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 (i) the Company's ability to continue as a going concern; (ii) the risk that if the Company experiences delays or difficulties in the enrollment of patients in clinical trials, those clinical trials could take longer than expected to complete and the Company's receipt of necessary regulatory approvals could be delayed or prevented; (iii) the risk that the Company will need additional capital to conduct its operations and develop its products, and the Company's ability to obtain the necessary funding is uncertain; (iv) the risk that the Company's common stock may be delisted in the future if the Company is unable to maintain compliance with continued listing requirements; (v) the risk that the Company's products may fail to achieve necessary safety and efficacy endpoints during clinical trials, which may limit the company's ability to general revenues from therapeutic products and (vi) those other 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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Source: GT Biopharma, Inc.