November 16, 2026

GT Biopharma Reports Third Quarter 2026 Financial Results

Phase 1 trial evaluating GTB-3650 TriKE® remains ongoing, with an update anticipated in Q4 2026

Phase 1 basket trial evaluating GTB-5550 TriKE® in multiple solid tumor types known to express B7-H3 remains ongoing, with an update anticipated in Q4 2026

FDA clearance of a new IND for GTB-5550 in multiple myeloma under an investigator sponsored trial protocol; Phase 1 trial initiation contingent upon timing and receipt of non-dilutive grant funding

Oral presentation at the SITC 2026 Annual Meeting on November 6, 2026 showcased new preclinical data demonstrating an enhanced effect of combining GTB-5550 with a KRAS inhibitor (KRASi), which was shown to sensitize pancreatic tumor cells to NK cell cytotoxicity

Cash balance as of September 30, 2026 of approximately $10 million anticipated to provide sufficient cash runway into Q3 2027

SAN FRANCISCO, CALIFORNIA, Nov. 16, 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 third quarter 2026 financial results for the period ended September 30, 2026.

"This quarter we broadened the potential reach of GTB-5550 with FDA clearance of a new IND in multiple myeloma, while continuing to enroll patients in both of our ongoing Phase 1 trials," said Michael Breen, Executive Chairman and Chief Executive Officer. "This expansion reflects the versatility of our TriKE® platform, and our growing use of AI-based tools is helping us identify additional development candidates for 2027. With cash runway into Q3 2027, we are well positioned and look forward to providing updates on both Phase 1 programs in the fourth quarter."

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 is ongoing, with Cohort 4 complete and enrollment of Cohort 5 in progress. The Company expects to provide an update in Q4 2026.

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 ongoing Phase 1 trial with GTB-5550 is the first nanobody TriKE® tested with more patient-friendly subcutaneous dosing. The Phase 1a dose escalation portion of the trial is focused primarily on enrolling prostate cancer patients and will evaluate up to 6 dose levels to identify the maximum tolerated dose (MTD). Enrollment in Cohort 1 and Cohort 2 is complete and enrollment in Cohort 3 is in progress. The Company expects to provide an update in Q4 2026.

After the dose escalation phase, the Phase 1b expansion component will enroll patients with up to 7 different tumor types (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.

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. Subsequent cycles receive treatment three times weekly for 2 weeks followed by 2 weeks of no treatment. 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). More details can be found on clinicaltrials.gov with the identifier: NCT07541573.

GTB-5550 TriKE for multiple myeloma

In September 2026, the Company announced FDA clearance of a new IND for GTB-5550 in multiple myeloma (MM) under an investigator sponsored trial protocol. Initiation of the Phase 1 trial in MM patients is contingent upon timing and receipt of non-dilutive grant funding. The Phase 1a/1b trial would be the first-in-human trial of a B7-H3-targeted TriKE® in MM and will use subcutaneous administration intended to extend the half-life relative to prior intravenous TriKE® formulations. The Phase 1a dose escalation portion will enroll 4th line and later patients with MM and evaluate up to 6 dose cohorts to identify the MTD. Following dose escalation, the Phase 1b expansion cohort will enroll a total of 25 patients treated at the MTD and further evaluate safety, tolerability and preliminary anti-tumor activity.

GTB-5550 will be administered by subcutaneous (SQ) injection in the abdominal area on 3 non-consecutive days per week during Week 1 and Week 2, followed by 2 weeks of no treatment. One treatment cycle is 4 weeks in duration, and this dosing schedule is repeated for each subsequent cycle. A minimum of 2 cycles is planned, and disease reassessment (monoclonal protein and free light chain analysis) is performed on Day 28 of each cycle. Patients with stable disease may continue for up to 4 cycles total, and those with a partial response or better may continue for up to 1 year. Patients are followed for 12 months from

the first dose of GTB-5550 to determine progression-free survival (PFS) and overall survival (OS).

Third Quarter Ended September 30, 2026 Financial Summary

Cash Position: The Company had cash and cash equivalents of approximately $10 million as of September 30, 2026, which is anticipated to be sufficient to fund the Company's operations into the third quarter of 2027.

Research and Development (R&D) Expenses: R&D expenses for the third quarter of 2026 were approximately $1.7 million compared to $0.6 million for the same comparable quarter of 2025. The $1.1 million increase was primarily due to an increase in material costs. R&D expenses primarily relate to the Company's continued licensing, development, production, and clinical trials 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 with the first 4 cohorts now enrolled. 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 with the first patient dosed in May 2026.

Selling, General and Administrative (SG&A) Expenses (Excluding Stock Compensation): SG&A expenses for the third quarter of 2026 were approximately $1.8 million compared to $2.4 million for the same comparable quarter of 2025. The $0.6 million decrease was primarily due to a decrease in consulting fees, and to a lesser extent, marketing expenses.

Loss from Operations: The Company reported a loss from operations for the third quarter of 2026 of approximately $3.5 million compared to $3.4 million for the same comparable quarter of 2025. As described above, the $0.1 million increase was primarily due to a $1.1 million increase in R&D expenses, offset by a $0.6 million decrease in SG&A expenses and a $0.4 decrease in non-cash stock compensation expense.

Net Loss: The Company reported a net loss of approximately $3.5 million for the third quarter of 2026, compared to net income of $8.3 million for the same comparable quarter of 2025. The $11.8 million increase in net loss consisted primarily of $11.4 million of non-cash other income from the change in fair value of Greenshoe Rights liability which occurred in the same comparable quarter of 2025 and did not occur in the current quarter.

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," "will," "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.

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

Investor Relations Contact:

LifeSci Advisors
Corey Davis, Ph.D.
cdavis@lifesciadvisors.com
212-915-2577

LinkedIn |Facebook |X |Instagram | YouTube

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Source: GT Biopharma, Inc.