UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 OR 15(d) of The Securities Exchange Act of 1934

Date of Report:
(Date of earliest event reported)

June 27, 2024

GT Biopharma, Inc.
(Exact name of registrant as specified in its charter)

Delaware
(State or other Jurisdiction of Incorporation)

1-40023	**94-1620407**
(Commission File Number)	(IRS Employer Identification No.)

8000 Marina Blvd., Suite 100
Brisbane, CA 94005
(Address of Principal Executive Offices and zip code)

(800) 304-9888
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12(b))

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each Class	Trading Symbol(s)	Name of each Exchange on which registered
Common stock, $0.001 par value	GTBP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 8.01. Other Events.

FDA Clearance of IND Application

On June 27, 2024, GT Biopharma, Inc. (the "Company") issued a press release announcing U.S. Food and Drug Administration (FDA) clearance of its Investigational New Drug (IND) application for GTB-3650, allowing the Company to proceed with a Phase 1 clinical trial.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Fully Remote Company

Effective as of July 1, 2024, the Company will become a fully remote company. Accordingly, it will not maintain a principal executive office. For purposes of compliance with applicable requirements of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended, any stockholder communication required to be sent to the Company's principal executive offices may be directed to 315 Montgomery Street, 10th Floor, San Francisco, California 94104, or by email to auditcommittee@gtbiopharma.com.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release issued June 27, 2024, entitled "GT Biopharma Announces FDA Clearance of Investigational New Drug (IND) Application for GTB-3650, an NK Cell Engager for Treatment of CD33+ Leukemia".
104	Cover Page Interactive Data File (embedded as Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GT BIOPHARMA, INC.

Date: June 27, 2024

By: */s/ Alan Urban*
Alan Urban
Chief Financial Officer

Exhibit 99.1

GT Biopharma Announces FDA Clearance of Investigational New Drug (IND) Application for GTB-3650, an NK Cell Engager for Treatment of CD33+ Leukemia

- *GTB-3650 Phase 1 trial initiation expected in H2 2024; initial clinical data expected in H1 2025*
- *GTB-5550 TriKE® IND submission for treatment of B7H3 positive solid tumors expected in Q1 2025*
- *GTB-5550 Phase 1 dose escalation basket trial initiation expected in 2025 evaluating GTB-5550 in six solid tumor cancers, including prostate, breast, head and neck, ovarian, lung, and GI*
- *Cash runway anticipated to be sufficient to fund operations into 2025*

SAN FRANCISCO, CALIFORNIA, June 27, 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 FDA clearance of its IND application for GTB-3650, allowing the company to proceed with a Phase 1 clinical trial, which is anticipated to start in second half of 2024.

"FDA clearance for GTB-3650 is a tremendous accomplishment and we look forward to submitting our next IND in the first quarter of 2025 for GTB-5550, which will target multiple solid tumors", said Michael Breen, Executive Chairman and Interim Chief Executive Officer of GT Biopharma. "As we ramp up our clinical activities, we plan to start the Phase 1 trial with GTB-3650 in the coming months followed by multiple data readouts in 2025. We also expect to start a basket trial with GTB-5550 for multiple solid tumors in 2025 and remain very enthusiastic in our pursuit of additional opportunities for various autoimmune indications where our TriKE's may have therapeutic utility."

The Phase 1 dose escalation study will evaluate GTB-3650 in up to six cohorts of adult patients with relapsed or refractory (r/r) CD33 expressing hematologic malignancies, including 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.

"GTB-3650 is designed to target NK cells within the immune system to potentially overcome many of the limitations of current AML chemotherapies," said Michael Breen. "Our trial design should give us an early read on safety and potential therapeutic activity and also provide valuable learnings that we can translate into our clinical development plans for follow-on TriKE molecules, including GTB-5550."

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 tri-specific killer engager (TriKE®) platform, which is designed to harness and enhance the cancer killing abilities of a patient's own natural killer (NK) cells. Each TriKE construct consist of three parts: 1) an arm that engages with CD16, an activating receptor of NK cells, 2) an interleukin (IL)-15 moiety that is essential for NK cell survival, proliferation, priming and motility, and 3) an arm that binds to tumor-specific antigens. 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 release include statements regarding initiating clinical trials, expected clinical data, expected IND application submissions, expected dose escalation basket trial initiation 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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