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)
December 4, 2023

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 under the Exchange Act (17 CFR 240.14a-12)

☐ 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.

On December 4, 2023, GT Biopharma, Inc. issued a press release announcing the submission of an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) for the development of GTB-3650, a 2nd generation nanobody TriKE® for the treatment of patients with CD33+ leukemia.

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

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	**Description**
99.1	Press Release issued December 4, 2023 entitled "GT Biopharma Announces IND Submission for GTB-3650 for Treatment of CD33+ Leukemia."
104	Cover Page Interactive Data File (embedded as Inline XBRL document).

SIGNATURE

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: December 4, 2023

By: */s/ Manu Ohri*
Manu Ohri
Chief Financial Officer

Exhibit 99.1

GT Biopharma Announces IND Submission
for GTB-3650 for Treatment of CD33+ Leukemia

BRISBANE, CALIFORNIA, December 5, 2023 — GT Biopharma, Inc. (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 the submission of an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) for the development of GTB-3650, a 2nd generation nanobody TriKE® for the treatment of patients with CD33+ leukemia, including relapsed/refractory acute myelogenous leukemia (AML) and high-risk myelodysplastic syndrome (MDS).

"Today's announcement is an important milestone for GT Biopharma, and we look forward to advancing GTB-3650 for treatment of CD33+ leukemia. We are excited to expeditiously move this molecule into the clinic as we execute on our clinical objectives in 2024," stated Michael Breen, GT Biopharma's Executive Chairman, Board of Directors and Interim Chief Executive Officer.

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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