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): November 1, 2018

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

Delaware	**000-08092**	**94-1620407**
(State or other Jurisdiction of Incorporation or organization)	(Commission File Number)	(IRS Employer I.D. No.)

310 N. Westlake Blvd
Suite 206
Westlake Village, CA 91362
Phone: (800) 304-9888
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

(Former name, former address and former fiscal year, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

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

☐ Soliciting material pursuant to Rule l 4a- l 2 under the Exchange Act (17 CFR 240. l 4a- l 2)

☐ Pre-commencement communications pursuant to Rule l 4d-2(b) under the Exchange Act (17 CFR 240. l 4d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240. l 3e-4(c))

ITEM 8.01 Other Events

On November 1, 2018, GT Biopharma announced that in reference to the Investigational New Drug Application submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for GTB-3550 (OXS-3550), the Food and Drug Administration has completed its review and concluded that the clinical investigation of protocol HM2015-39: "CD16/IL-15/CD33 (161533) Tri-Specific Killer Engagers (TriKEs) for the Treatment of High Risk Myelodysplastic Syndromes, Refractory/Relapsed Acute Myeloid Leukemia and Advanced Systemic Mastocytosis" may be initiated.

ITEM 9.01 Exhibits.

10.1 Letter from Food and Drug Administration indicating authorization to initiate clinical investigation

SIGNATURE PAGE

Pursuant to the requirement of the Securities and 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.

Dated: November 1, 2018

By: /s/ Raymond W. Urbanski
Raymond W. Urbanski
Chairman and Chief Executive Officer

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

IND 136205

REMOVE FULL CLINICAL HOLD

GT Biopharma
Attention: Raymond W. Urbanski, MD, PhD
Chief Medical Officer
26950Alsace Drive
Calabasas, CA 91302

Dear Dr. Urbanski:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for OXS-3550.

We also refer to your amendment dated October 17, 2018, which provides a complete response to our September 28, 2018, letter which cited the reasons for continuing the full clinical hold on this IND and the information needed to resolve the clinical hold issues.

We have completed the review of your submission, and have concluded that the clinical investigation of protocol HM2015-39: "*CD16/IL-15/CD33 (161533) Tri-Specific Killer Engagers (TriKEs) for the Treatment of High Risk Myelodysplastic Syndromes, Refractory/Relapsed Acute Myeloid Leukemia and Advanced Systemic Mastocytosis*" may be initiated.

ADDITIONAL IND RESPONSIBILITIES

As sponsor of this IND, you are responsible for compliance with the FDCA (21 U.S.C. §§ 301 et. seq.) as well as the implementing regulations [Title 21 of the Code of Federal Regulations (CFR)]. A searchable version of these regulations is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm. Your responsibilities include:

- Reporting any unexpected fatal or life-threatening suspected adverse reactions to this Division no later than 7 calendar days after initial receipt of the information [21 CFR 312.32(c)(2)].

- Reporting any (1) serious, unexpected suspected adverse reactions, (2) findings from other clinical, animal, or in-vitro studies that suggest significant human risk, and (3) a clinically important increase in the rate of a serious suspected adverse reaction to this Division and to all investigators no later than 15 calendar days after determining that the information qualifies for reporting [21 CFR 312.32(c)(1)]. Submit 15-day reports to FDA electronically in eCTD format via the ESG; and

- Submitting annual progress reports within 60 days of the anniversary of the date that the IND became active (the date clinical studies were permitted to begin) [21 CFR 312.33].

If you have any questions, call Jennifer Lee, Regulatory Project Manager, at (240) 402-4622.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, MD
Director
Division of Hematology Products
Office of Hematology and Oncology Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

ALBERT B DEISSEROTH
10/26/2018

Reference ID: 4341425