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 15, 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)

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 2.02 Results of Operations and Financial Condition.

On November 15, 2018, GT Biopharma, Inc. issued a press release, a copy of which is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

ITEM 9.01 Financial Statements and Exhibits.

99.1 Press release dated November 15, 2018

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 15, 2018

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

Exhibit 99.1

GT
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GT Biopharma Reports Third Quarter 2018 Financial Results and Provides Business Update

– Recent corporate, preclinical, clinical and regulatory advancements expected to position Company for a transformational 2019 –

– FDA clearance of IND to advance first-in-class TriKE, GTB-3550, into first-in-human Phase 1 study for the treatment of AML, MDS and mastocytosis marks significant regulatory milestone –

– Continued progress of Phase 2a study of GTB-1550 with topline results expected in Q1 2019 –

LOS ANGELES, CA (November 15, 2018) – GT Biopharma, Inc. (OTCQB: GTBP and Euronext Paris GTBP.PA) ("GT Biopharma" or the "Company"), an immuno-oncology biotechnology company focused on innovative treatments based on the Company's proprietary NK-engager and Bispecific Antibody Drug Conjugate platforms, announced today its financial results for the third quarter ended September 30, 2018.

The Company also provided an update on its corporate progress, clinical status and anticipated milestones for its pipeline of immuno-oncology products based off the Company's proprietary Tri-specific Killer Engager (TriKE), Tetra-specific Killer Engager (TetraKE) and bi-specific Antibody Drug Conjugate (ADC) technology platforms.

Recent Corporate Highlights:

- Received FDA clearance to commence first-in-human Phase 1 study of first-in-class TriKE, GTB-3550 (OXS-3550), for the treatment of acute myelogenous leukemia, myelodysplatic syndrome and mastocytosis.
- Announced positive preclinical data for two next generation TriKEs in ovarian and head and neck cancers. The studies were conducted by Dr. Daniel Vallera, Director, Section of Molecular Cancer Therapeutics and Dr. Martin Felices, Co-Director of the Translational Therapy Laboratory at the Masonic Cancer Center, University of Minnesota.
- Announced agreement with major pharmaceutical company and initiated preclinical combination trial of GTB-1550 (OXS-1550) and multi-billion dollar oncology drug for testing in several hematologic malignancies.
- Bolstered leadership team with appointments of Dr. Raymond W. Urbanski M.D., Ph.D. as CEO and Chairman of the Board (formerly Chief Medical Officer of the Company); well-respected industry veteran, Dr. John N. Bonfiglio as a new independent Board Member and David Cardino, CPA, as VP, Finance.

"We have made significant progress in building a solid foundation for the Company in what we believe is an important transitional phase for GT Biopharma. The additions and changes to the leadership team and execution of key preclinical, clinical and regulatory milestones are a testament to this progress," commented Raymond Urbanski, M.D., Ph.D., Chief Executive Officer of GT Biopharma. "However, as we navigate through this phase, we certainly face challenges, including ensuring we are properly funded and have the right team in place to propel the Company to our next phase of growth. Successfully completing a financing and bolstering our management team and Board in the near term remains a priority. I, along with our Board, believe GT Biopharma has a first-in-class platform technology and the potential to provide revolutionary advancements in the treatment of various cancers where there remains significant unmet need. We are committed to securing the necessary capital to continue to aggressively execute on our strategy and advance our development programs to drive significant shareholder value. I believe we are taking the necessary steps to position GT Biopharma for a transformational 2019."

Clinical Program Updates

The Company's TriKE product candidates are single-chain, tri-specific scFv recombinant fusion proteins composed of the variable regions of the heavy and light chains (or heavy chain only) of anti-CD16 antibodies, wild-type or a modified form of IL-15 and the variable regions of the heavy and light chains of an antibody designed to precisely target a specific tumor antigen. GT Biopharma utilizes the NK stimulating cytokine human IL-15 as a crosslinker between the two scFvs which is designed to provide a self-sustaining signal leading to the proliferation and activation of NK cells thus enhancing their ability to kill cancer cells mediated by antibody-dependent cell-mediated cytotoxicity (ADCC).

The Company's TetraKE product candidates are single-chain fusion proteins composed of human single-domain anti-CD16 antibody, wild-type IL-15 and the variable regions of the heavy and light chains of two antibodies that are designed to target two specific tumor antigens expressed on specific types of cancer cells.

GT Biopharma's TriKEs and TetraKEs are designed to act by binding to a patient's NK cells and a specific tumor antigen enabling an immune synapse between the now IL-15-enhanced NK cell and the targeted cancer cell. The formation of an immune synapse can induce NK cell activation which can lead to the death of the cancer cell. The Company believes the self-sustaining signal caused by its IL-15 cross-linker may enable prolonged and enhanced proliferation and activation of NK cells similar to the increased proliferation of T-cells caused by 41BB-L or CD28 intracellular domains in CAR-T therapy but without the need to enhance the patient's NK cells *ex vivo*.

GTB-1550 (OXS-1550): Most Advanced Bi-specific ADC Candidate

The Company's most advanced bi-specific ADC in development, GTB-1550, targets CD19+ and/or CD22+ hematological malignancies and is currently in the Phase 2 component of a Phase 1/2 Non-Hodgkin's Lymphoma (NHL)/Acute Lymphocytic Leukemia (ALL) trial which is an open-label, investigator-led study.

GTB-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors. When GTB-1550 binds to cancer cells, the cancer cells internalize GTB-1550, and are killed due to the action of drug's cytotoxic diphtheria toxin payload. GTB-1550 has demonstrated success in a Phase 1 human clinical trial in patients with relapsed/refractory B-cell lymphoma or leukemia.

The Company recently assembled a Bi-Specific ADC Advisory Board to collaboratively assess and interpret the GTB-1550 pre-clinical and clinical data, including an interim review of the Phase 1/2 study. Eighteen patients have been enrolled to date, including 12 NHL and six ALL patients. At the time of the interim review, 13 patients met the evaluation criteria, including nine NHL and four ALL patients. More than 50% of patients (seven of 13) exhibited a clinical benefit, defined as stable disease, partial remission or complete remission at Day 29. Of the seven patients, one demonstrated a complete remission (CR), one demonstrated a partial remission (PR) and five demonstrated stable disease (SD).

The efficacy signal was more prominent in ALL patients with 75% (three of four) exhibiting clinical benefit including one CR, one PR and one SD. In the NHL population, four of nine patients exhibited SD. Adverse events were mostly grade 1 and 2 and reversible. One patient had a grade 4 low platelet count, two patients had a grade 3 increase in liver function tests, or LFTs, and one patient had a grade 3 capillary leak. The Company currently expects final data for this trial to be available in the first quarter of 2019.

This work is being conducted by and under the guidance of Dr. Veronika Bachanova, Associate Professor of Medicine, Division of Hematology, Oncology and Transplantation at the University of Minnesota.

GTB-3550 (OXS-3550): TriKE product candidate

GTB-3550 is the Company's first Tri-specific Killer Engager (TriKE) product candidate being initially developed for the treatment acute myelogenous leukemia (AML). GTB-3550 is a single-chain, tri-specific scFv recombinant fusion protein conjugate composed of the variable regions of the heavy and light chains of anti-CD16 and anti-CD33 antibodies and a modified form of IL-15. When the NK stimulating cytokine human IL-15 is used as a crosslinker between the two scFvs, it provides a self-sustaining signal that activates NK cells and enhances their ability to kill.

GT Biopharma recently announced that its Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) is now open and it is authorized to initiate a first-in-human Phase 1 study with GTB-3550, its first-in-class TriKE, for the treatment of AML, myelodysplatic syndrome (MDS) and mastocytosis. The study will be led by Principal Investigator, Sarah A. Cooley, MD, MS, Associate Professor, Division of Hematology, Oncology and Transplantation at Masonic Cancer Center, University of Minnesota.

This single center, first-in-human Phase 1 clinical trial of GTB-3550 will enroll up to 60 subjects with CD33-expressing refractory/relapsed AML, high-risk MDS, or advanced systemic mastocytosis. Subjects will receive a single course of GTB-3550 given as 3 weekly treatment blocks. Each block consists of four consecutive 24-hour continuous infusions of GTB-3550 followed by a 72-hour break after Block #1 and #2. Disease response will be assessed by bone marrow biopsy performed between Day 21 and Day 42 after the start of the 1st infusion. Follow-up for response and survival continues through 6 months from treatment start. The primary objective from the Phase 1 dose finding portion of the study will be to identify the maximum tolerated dose (MTD) of GTB-3550 defined as the dose level that most closely corresponds to a dose limiting toxicity rate (DLT) of 20%. The primary objective from the Phase 2 extended portion of the study will be the potential efficacy of GTB-3550, measured using rates of complete and partial remission. Subjects experiencing clinical benefit and no unacceptable side effects may be considered for a 2nd course of GTB-3550 on a compassionate basis.

The Company believes that GTB-3550 could serve as a relatively safe, cost-effective, and easy-to-use therapy for refractory/relapsed AML, high-risk MDS and advanced systemic mastocytosis and could also be combined with chemotherapy and/or other agents as frontline therapy thus targeting a much larger patient population.

GT Biopharma's initial and ongoing work is being conducted in collaboration with the Masonic Cancer Center at the University of Minnesota under research agreements led by Dr. Jeffrey Miller, the Deputy Director and Dr. Daniel Vallera, Director, Section of Molecular Cancer Therapeutics.

GT Biopharma has an exclusive worldwide license agreement with the University of Minnesota to further develop and commercialize cancer therapies using proprietary TriKE technology developed by researchers at the university to target NK cells to cancer.

Upcoming Milestones Expected to Drive Value

- Initiate Phase 1 first-in-human clinical trial of GTB-3550 for the treatment of Relapse/Refractory AML, High Risk MDS, and Advanced Systemic Mastocytosis in the first half of 2019;
- Announce topline results from Phase 2a trial of GTB-1550 in Q1 2019;
- Conduct end of Phase 2a (EOP2a) meeting for GTB-1550 with U.S. FDA in the first half of 2019;
- Advance ongoing GTB-C3550 IND-enabling studies & TetraKE pre-clinical program to target the larger solid tumor population and are working towards beginning clinical trials in 2019;
- Bolster executive management team and board with key expertise to continue to transform the Company;
- Participate in key scientific conferences;
- Make progress in advancing potential corporate and business development opportunities; and
- Uplist to a National Exchange.

Summary of Financial Results for Third Quarter 2018

For the quarter ended September 30, 2018, the Company reported a net loss of approximately $235,783,000 or a net loss per diluted share of $4.70, compared to a net loss of $130,625,000 or a net loss per diluted share of $8.15 for the same quarter 2017. For the nine months ended September 30, 2018, GT Biopharma reported a net loss of approximately $254,955,000 or a net loss per diluted share of $5.09, compared to $138,146,000 or a net loss per diluted share of $24.54 for the same period 2017.

At September 30, 2018, the Company has an accumulated deficit of $524,453,000 and cash of $1,232,000.

About GT Biopharma, Inc.

GT Biopharma, Inc. is a clinical stage biopharmaceutical company focused on the development and commercialization of immuno-oncology products based off our proprietary Tri-specific Killer Engager (TriKE), Tetra-specific Killer Engager (TetraKE) and bi-specific Antibody Drug Conjugate (ADC) technology platforms. Our TriKE and TetraKE platforms generate proprietary moieties designed to harness and enhance the cancer killing abilities of a patient's own natural killer, or NK, cells. Once bound to a NK cell, our moieties are designed to enhance the NK cell and precisely direct it to one or more specifically-targeted proteins (tumor antigens) expressed on a specific type of cancer, ultimately resulting in the cancer cell's death. TriKEs and TetraKEs are made up of recombinant fusion proteins, can be designed to target certain tumor antigens on hematologic malignancies, sarcomas or solid tumors and do not require patient-specific customization. They are designed to be dosed in a common outpatient setting similar to modern antibody therapeutics and are expected to have reasonably low cost of goods. Our ADC platform can generate product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of ADCs.

For more information, please visit www.gtbiopharma.com.

GT
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GT Biopharma, Inc. and Subsidiaries
Consolidated Balance Sheets
(Unaudited)
(In thousands, except par value and share data)

	September 30, 2018	December 31, 2017
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 1,232	$ 576
Prepaid expenses	15	-
Total Current Assets	1,247	576
Intangible assets	25,263	253,777
Deposits	21	9
Fixed assets, net	5	6
Total Other Assets	25,289	253,792
TOTAL ASSETS	$ 26,536	$ 254,368
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 2,251	$ 2,546
Accrued expenses	344	102
Line of credit	31	31
Convertible debentures, net of discount of $488	10,597	-
Total Current Liabilities	13,223	2,679
Total liabilities	13,223	2,679
Stockholders' Equity:		
Convertible preferred stock - $0.001 par value; 15,000,000 shares authorized:		
Series C - 96,230 and 96,230 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1	1
Series J – 1,163,548 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	1	1
Common stock - $0.001 par value; 750,000,000 shares authorized; and 50,227,978 and 50,117,977 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively	50	50
Additional paid-in capital	537,883	521,305
Accumulated deficit	(524,453)	(269,499)
Noncontrolling interest	(169)	(169)
Total Stockholders' Equity	13,313	251,689
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 26,536	$ 254,368

GT
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GT BIOPHARMA, INC. AND SUBSIDIARIES
Consolidated Statements of Operations
(Unaudited)
(In thousands, except per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2018	2017	2018	2017
Operating expenses:				
Research and development	1,111	526	7,835	911
Selling, general and administrative expenses	5,035	126,330	10,628	128,768
Loss on impairment	228,514	-	228,514	-
Total operating expenses	234,660	126,856	246,977	129,679
Loss from operations	(234,660)	(126,856)	(246,977)	(129,679)
Other income (expense):				
Interest expense	(1,123)	(3,769)	(7,978)	(8,467)
Total other income (expense)	(1,123)	(3,769)	(7,978)	(8,467)
Loss before provision for income taxes	(235,783)	(130,625)	(254,955)	(138,146)
Provision for income tax	-	-	-	-
Net loss	(235,783)	(130,625)	(254,955)	(138,146)
Net loss per common share – basic and diluted	$ (4.70)	$ (8.15)	$ (5.09)	$ (24.54)
Weighted average common shares outstanding – basic and diluted	50,154,516	16,027,687	50,130,202	5,628,529

The accompanying condensed notes are an integral part of these consolidated financial statements.

Forward-Looking Statements

This press release contains certain forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, including statements regarding the potential acquisition, the likelihood of closing the potential transaction, our clinical focus, and our current and proposed trials. Words and expressions reflecting optimism, satisfaction or disappointment with current prospects, as well as words such as “believes,” “hopes,” “intends,” “estimates,” “expects,” “projects,” “plans,” “anticipates” and variations thereof, or the use of future tense, identify forward-looking statements, but their absence does not mean that a statement is not forward-looking. Our forward-looking statements are not guarantees of performance and actual results could differ materially from those contained in or expressed by such statements. In evaluating all such statements, we urge you to specifically consider the various risk factors identified in our Form 10-K for the fiscal year ended December 31, 2017 in the section titled “Risk Factors” in Part I, Item 1A and in our subsequent filings with the Securities and Exchange Commission, any of which could cause actual results to differ materially from those indicated by our forward-looking statements.

Our forward-looking statements reflect our current views with respect to future events and are based on currently available financial, economic, scientific, and competitive data and information on current business plans. You should not place undue reliance on our forward-looking statements, which are subject to risks and uncertainties relating to, among other things: (i) the sufficiency of our cash position and our ongoing ability to raise additional capital to fund our operations, (ii) our ability to complete our Phase 1 study of TriKe, GTB-3550 and or our Phase 2 trial of CTB-1550 and to meet the FDA's requirements with respect to safety and efficacy, (iii) our ability to identify patients to enroll in our clinical trials in a timely fashion, (iv) our ability to achieve approval of a marketable product, (v) design, implementation and conduct of clinical trials, (vii) the results of our clinical trials, including the possibility of unfavorable clinical trial results, (vii) the market for, and marketability of, any product that is approved, (viii) the existence or development of treatments that are viewed by medical professionals or patients as superior to our products, (ix) regulatory initiatives, compliance with governmental regulations and the regulatory approval process, and social conditions, and (x) various other matters, many of which are beyond our control. Should one or more of these risks or uncertainties develop, or should underlying assumptions prove to be incorrect, actual results may vary materially and adversely from those anticipated, believed, estimated, or otherwise indicated by our forward-looking statements.

We intend that all forward-looking statements made in this press release will be subject to the safe harbor protection of the federal securities laws pursuant to Section 27A of the Securities Act, to the extent applicable. Except as required by law, we do not undertake any responsibility to update these forward-looking statements to take into account events or circumstances that occur after the date of this press release. Additionally, we do not undertake any responsibility to update you on the occurrence of any unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

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