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): September 19, 2019

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.)

9350 Wilshire Blvd. Suite 203
Beverly Hills, CA 90212
Phone: (800) 304-9888

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

N/A
(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 1.01. Entry into a Material Definitive Agreement.

On September 19, 2019, GT Biopharma, Inc. (the "Company") entered into an Asset Purchase Agreement (the "Agreement"), pursuant to which the Company sold its rights, titles and interests, including associated patents, to the pharmaceutical product designated by the Company as GTB-004 (the "Product"). Under the Agreement, the Product was purchased by DAS Therapeutics, Inc. who the Company believes is well positioned to take over the clinical development of the Product including obtaining timely approval by the FDA.

The Company received $200,000 at closing. The Company will also participate in the future commercial value of the Product by receiving $6,000,000 upon the achievement of certain sales objectives. In addition, the Company will receive a royalty equal to 1.5% of U.S. sales until such time as the last of the patents associated with the Product expires.

The Product has to do with the treatment of myasthenia gravis.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

No.	Description
99.1	Press Release

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: September 24, 2019

By: /s/ Steven Weldon
Steven Weldon
Chief Financial Officer

Exhibit 99.1

GT BIOPHARMA ANNOUNCES THE SALE OF ITS FIXED DOSE COMBINATION TABLET (GTB-004) FOR MYASTHENIA GRAVIS (CHRONIC AUTOIMMUNE DISEASE) TO DAS THERAPEUTICS

TAMPA, Florida, September 24, 2019 / PRNewswire / -- GT Biopharma, Inc. (OTCQB: GTBP) (GTBP.PA) an immuno-oncology company focused on innovative treatments based on the Company's proprietary NK cell engager (TriKE™) platform and Multi-Target Directed Bispecific Drug Conjugate platform, announced today that it sold the rights to GTB-004 for the treatment of myasthenia gravis to DAS Therapeutics, Inc.

Myasthenia gravis is a chronic autoimmune disease of the neuromuscular junction characterized by muscle weakness. The disease occurs in all ethnic groups and both genders. The prevalence of the disease in the United States is estimated at 14 to 20 per 100,000 population; approximately 36,000 to 60,000 cases in the U.S. (Howard, 2015). Myasthenia gravis most commonly affects adult women (onset between 20 to 40 years) and older men (onset over 60), but it can occur at any age (Myasthenia Gravis Fact Sheet; National Institute of Neurological Disorders and Stroke, 2016).

GTB-004 is a fixed-dose combination tablet for the treatment of the muscle weakness associated with myasthenia gravis. GTB-004 combines pyridostigmine with an antagonist helping to reduce gastrointestinal side effects associated with pyridostigmine therapy.

Under the terms of the Asset Purchase Agreement, DAS Therapeutics acquires all rights, title, clinical data, composition-of-matter and use patents related to GTB-004. GT Biopharma will receive a $200,000 up-front payment, annual royalties of 1.5% of Net Yearly Sales, and a $6 million payment based on achievement of commercial milestone.

Mr. Anthony Cataldo, the Chairman and Chief Executive Officer of GT Biopharma commented “we are pleased that DAS Therapeutics will continue to advance GTB-004 in a Phase II clinical trial and toward product registration via the 505(b)(2) regulatory path.” Mr. Cataldo further stated “we are gratified to have been able to monetize part of our shareholders’ investment from our earlier acquisition of Georgetown Translational Pharmaceuticals, Inc. – a developer of central nervous systems (CNS) targeted therapeutics. We will continue to remain focused on our high value oncology assets, two of which are now in FDA clinical trials.”

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About GTB-3550 Trispecific NK cell Engager (TriKE™)

GTB-3550 (OXS-3550) is the Company's first Tri-specific NK cell Engager (TriKE™) product candidate being initially developed for the treatment 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. The natural killer (NK) cell stimulating cytokine human IL-15 portion of the molecule provides a self-sustaining signal that activates NK cells and enhances their ability to kill. We intend to study GTB-3550 in CD33 positive leukemias such as acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and other CD33+ hematopoietic malignancies.

About GTB-1550 Multi-Target Directed Bispecific Drug Conjugate

GTB-1550 targets cancer cells expressing the CD19 receptor or CD22 receptor or both receptors thereby maximizing cancer cell recognition by binding to CD19+, CD22+ and CD19+/CD22+ cancer cells. 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.

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™) and Multi-Target Directed Bispecific Drug Conjugate technology platforms. Our TriKE platform is designed to harness and enhance the cancer killing abilities of a patient's immune system natural killer cells (NK cells). 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. Our Multi-Target Directed Bispecific Drug Conjugate platform can generate product candidates that are bi-specific, ligand-directed single-chain fusion proteins that, we believe, represent the next generation of targeted therapy.

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, 2018 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 contemplated clinical trials for GTB-3550 or GTB-1550, or 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.

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