TG THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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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): **April 28, 2017**

TG Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-32639**	**36-3898269**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2 Gansevoort Street, 9 th Floor
New York, New York 10014
(Address of Principal Executive Offices)

(212) 554-4484
(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 the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act.
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Item 8.01. Other Events.

On April 28, 2017, TG Therapeutics, Inc. (the "Company") issued a press release announcing preliminary results from its ongoing Phase 2 study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in patients with relapsing forms of multiple sclerosis (RMS). The data was presented at the 69 th American Academy of Neurology (AAN) annual meeting, taking place in Boston, MA. A copy of the press release is being filed as Exhibit 99.1 and incorporated in this Item by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

99.1 Press Release, dated April 28, 2017.

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.

TG Therapeutics, Inc.
(Registrant)

Date: May 1, 2017

By: /s/ Sean A. Power
Sean A. Power
Chief Financial Officer

INDEX TO EXHIBITS

Exhibit Number	Description
99.1.	Press Release, dated April 28, 2017

TG Therapeutics Announces Preliminary Results from Ongoing Phase 2 Study of TG-1101 (ublituximab) in Patients with Multiple Sclerosis at the American Academy of Neurology 69th Annual Meeting

MS patients treated with TG-1101 exhibited median B-cell depletion of 99% at week 4

TG-1101 was well tolerated with no grade 3/4 adverse events reported, with median time on study of 5 months

NEW YORK, April 28, 2017 -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced preliminary results from its ongoing Phase 2 study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in patients with relapsing forms of multiple sclerosis (RMS). The data is being presented today at the 69 th American Academy of Neurology (AAN) annual meeting, taking place in Boston, MA. The poster is available for viewing during poster session 6, from 8:30 AM – 5:30 PM ET.

The poster, entitled "Preliminary results of Phase 2 Multicenter Study of Ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of Multiple Sclerosis (RMS) demonstrates rapid and robust B cell depletion" (Abstract Number: 3113; Poster number 6.348), includes data from 24 patients with RMS treated with TG-1101. Three dosing cohorts of up to 8 patients each were evaluated to assess the safety and tolerability of TG-1101 at accelerated infusion.

Highlights from the poster include:

- TG-1101 was well tolerated with no Grade 3/4 adverse events observed and the most commonly report AE being infusion related reactions, with median time on study of 5 months
- All scheduled doses were fully delivered to all subjects to date
- The independent DSMB reviewed safety data for each cohort periodically and approved continuation of the study at each review based on acceptable safety measures
- All patients met the primary end-point of >95% B-cell depletion by 4 weeks
- The median B-cell depletion at week 4 was 99% after two infusions (Day 1 and 15) with a cumulative dose of 600mg, which compares favorably with other anti-CD20 monoclonal antibodies

"We are highly encouraged by the data presented today demonstrating that TG-1101 is a potent and effective B-cell depleting agent. With the recent approval of ocrelizumab, B-cell depletion therapy is now recognized as a highly efficacious treatment option for patients with MS. We look forward to following these patients and reporting on established MS efficacy endpoints later this year, which require longer-term follow-up," stated Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer. Mr. Weiss continued, "We believe TG-1101 represents an exciting option in the treatment of MS and believe this Phase 2 trial sets the stage for our Phase 3 program that we expect to commence in the coming months."

"Information gained from this Phase 2 ublituximab trial has helped guide the development of the Phase 3 program, and will further the process of gaining a new innovative treatment option for patients with MS. The investigators in the clinical trial are pleased with the results thus far, and look forward to the full data set in the future," stated Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX, and the Principal Investigator for this Phase 2 study.

"The preliminary analysis of the immune profiles demonstrate efficient B-cell depletion occurs with ublituximab therapy. We are excited by the potential of ublituximab to provide patients with another treatment option and look forward to further exploring the immune profiling data to perhaps shed light on how B-cell depletion ameliorates MS progression. Understanding how B-cell depletion alters the immune response may also help us understand mechanisms that underlie the pathology of MS, also an area that is not fully understood," stated Amy Lovett-Racke, PhD, Professor of the Department of Microbial Infection and Immunity at the Ohio State University Medical Center in Columbus, OH.

POSTER PRESENTATION DETAILS

A copy of the poster presentation is available on the Company's website at www.tgtherapeutics.com , located on the Publications Page, within the Pipeline section.

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the company is developing two therapies targeting hematological malignancies and autoimmune diseases. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. TG Therapeutics is also developing TGR-1202, an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies, with TG-1101 recently entering clinical development for autoimmune disorders. The Company also has preclinical programs to develop IRAK4 inhibitors, BET inhibitors, and anti-PD-L1 and anti-GITR antibodies. TG Therapeutics is headquartered in New York City.

Cautionary Statement

Statements included in this press release, particularly those with respect to anticipating the benefit of the early data seen in the Phase 2 MS trial, as well as anticipating the timing of the release of additional data from our Phase 2 MS trial and commencement of our MS Phase 3 program may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Among the factors that could cause our actual results to differ materially are the following: our ability to successfully and cost-effectively complete the MS Phase 2 trial; the risk that early clinical results that supported our decision to move forward will not be reproduced in additional patients in expansion cohorts or in the MS Phase 3 program; the risk that the clinical results from the MS Phase 3 program, if conducted, will be not positive and/or will not support regulatory approval of TG-1101 for MS;the risk that TG-1101 will not have a differentiated profile from the other drugs in the class;the risk that trials will take longer to enroll than expected; our ability to achieve the milestones we project over the next year; our ability to manage our cash in line with our projections, and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at www.tgtherapeutics.com . The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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