

TG THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Address	2 GANSEVOORT STREET, 9TH FLOOR NEW YORK, NY, 10014
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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): **February 2, 2018**

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

Delaware
(State or Other Jurisdiction
of Incorporation)

001-32639
(Commission File Number)

36-3898269
(IRS Employer Identification No.)

2 Gansevoort Street, 9th 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.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). 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 February 2, 2018, TG Therapeutics, Inc. (the “Company”) issued a press release announcing results from the Phase 2 multicenter trial of ublituximab (TG-1101), the Company’s novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS) presented during the 3rd Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2018 in San Diego, CA. A copy of the press release is being filed as Exhibits 99.1 and incorporated in this Item by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

[99.1](#) Press Release, dated February 2, 2018.

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: February 2, 2018

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

TG Therapeutics, Inc. Announces Updated Results from the Ongoing Phase 2 Study of Ublituximab (TG-1101) in Patients with Multiple Sclerosis at the Third Annual ACTRIMS Forum 2018

100% reduction of T1 Gd-enhancing lesions at week 24 (n=38)

99% median B-cell depletion was observed at week 4 and maintained at week 24 (n=40)

TG-1101 was well tolerated across all patients including those receiving 1 hour infusions at the Phase 3 dose

New York, NY, (**February 2, 2018**) TG Therapeutics, Inc. (NASDAQ: TGTX), today announced results from the Phase 2 multicenter trial of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS). The data was presented last night during Poster Session 1, from 6:00 PM – 8:00 PM PT, at the 3rd Annual Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2018, in San Diego, California.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are very pleased with the updated Phase 2 data presented last night which now includes 5 cohorts, totaling 40 patients. It's exciting to see that with more patients through 6 months of treatment, the data remain consistent with the earlier results presented at the 2017 ECTRIMS-ACTRIMS meeting. The data continue to demonstrate the positive effects of ublituximab with sustained B-cell depletion through Week 24, complete elimination of T1 Gd-enhancing lesions and 97.5% of subjects without a relapse at Week 24. Importantly, the 1 hour infusion appears to be well tolerated and could represent a more convenient alternative to the currently marketed anti-CD20 monoclonal antibody." Mr. Weiss continued, "We look forward to presenting additional updated Phase 2 data, including data from all 48 patients enrolled in the Phase 2 study through 52 weeks, while we continue to enroll into our global Phase 3 ULTIMATE trials."

This Phase 2 trial is a 52-week randomized, placebo controlled, multi-center study evaluating the safety and efficacy of ublituximab at accelerated infusion times as fast as one hour. Today's poster includes 6 month data from the first 40 patients (of 48 enrolled, 8 too early to evaluate) with RMS that were treated with ublituximab across five dosing cohorts.

Poster Presentation Title: 6 Month Results of a Phase 2a Multicenter Study of Ublituximab, a Novel Glycoengineered Anti-CD20 Monoclonal Antibody, in Relapsing Multiple Sclerosis

Poster Highlights:

- 99% median B-cell depletion was observed at week 4 and maintained at week 24 (6 months) (n=40)
- Ublituximab completely eliminated all (100%) of T1 Gd-enhancing lesions at week 24 (n=38) (p=0.0005)
- 97.5% of subjects (39/40) were relapse free at week 24
 - One confirmed relapse was reported, in Cohort 1. The patient was initially randomized to the placebo arm. The relapse occurred 12 days after the patients' first infusion of 150mg of TG-1101. The patient remains on study and has received the second and third infusions of TG-1101 and to date has remained relapse free.
- Mean EDSS improvement from baseline of 0.3 with 78% of subjects showing improved or stable EDSS
- Ublituximab was well tolerated across all patients including those receiving rapid infusions, as low as a one hour for the 450mg Phase 3 dose

These data presentations support the international Phase 3 ULTIMATE program evaluating ublituximab for the treatment of relapsing form of Multiple Sclerosis (RMS). The Phase 3 trials, entitled ULTIMATE I and ULTIMATE II, are being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) and are being led by Lawrence Steinman, MD, of Stanford University. The ULTIMATE trials are currently enrolling and complete enrollment is expected in the first quarter of 2019.

POSTER

A copy of the above poster can be found on the Publications page, located within the Pipeline section, of the Company's website at www.tgtxinc.com/publications.cfm.

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. Ublituximab (TG-1101) 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 umbralisib (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 ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. 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 and anticipating the timing 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 and Phase 3 trials; 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 data included in any poster presentation will not be reproduced in subsequent data presentations; the risk that the clinical results from the MS Phase 3 program, will not be positive and/or will not support regulatory approval of ublituximab for MS; the risk that ublituximab will not have a differentiated profile from the other drugs in the class and that early signs of best-in-class attributes will not be supported by future results; 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.

CONTACT:

Jenna Bosco
Vice President, Investor Relations
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com
