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): **August 1, 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, 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 August 1, 2017, TG Therapeutics, Inc. (the "Company") issued a press release announcing it has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of two Phase 3 clinical trials for TG-1101 (ublituximab), the Company's glycoengineered anti-CD20 monoclonal antibody, for the treatment of relapsing forms of Multiple Sclerosis (RMS). A copy of the press release is being filed as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

99.1 Press Release, dated August 1, 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: August 1, 2017

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated August 1, 2017.

TG Therapeutics Announces Special Protocol Assessment (SPA) Agreement with the FDA for a Phase 3 Program of TG-1101 (ublituximab) for Patients with Multiple Sclerosis (MS)

Global Phase 3 Program Expected to Commence Before End of Q3 2017

International Phase 3 Trials Entitled "ULTIMATE I" and "ULTIMATE II" to be Led by Lawrence Steinman, MD, of Stanford University

NEW YORK, August 1, 2017– TG Therapeutics, Inc. (Nasdaq: TGTX) announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of two Phase 3 clinical trials for TG-1101 (ublituximab), the Company's glycoengineered anti-CD20 monoclonal antibody, for the treatment of relapsing forms of Multiple Sclerosis (RMS). The SPA provides agreement that the two Phase 3 trial designs adequately address objectives that, if met, would support the regulatory submission for approval of TG-1101.

The RMS Phase 3 program consists of two trials, called the ULTIMATE I and ULTIMATE II trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing TG-1101 (ublituximab) to teriflunomide in subjects with RMS. The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment. Each trial will enroll approximately 440 subjects, randomized in a 1:1 ratio, with approximately 880 patients to be enrolled across both trials.

Lawrence Steinman, MD, George A. Zimmermann Professor and Professor of Pediatrics, Neurology and Neurological Sciences at Stanford University, and global study chair for both ULTIMATE I and ULTIMATE II trials commented, "B-cell targeted therapy with anti-CD20 monoclonal antibodies has been shown to be very active in the treatment of multiple sclerosis, and with the recent approval of ocrelizumab, we have entered a new era of B-cell targeted therapy for MS. The Phase 2 data recently presented for ublituximab demonstrates an encouraging safety and efficacy profile in the treatment of MS with this novel glycoengineered anti-CD20 monoclonal antibody. We are excited to lead this global Phase 3 program, and believe the unique attributes of ublituximab, in particular the rapid infusion times and potential pricing advantages, may provide added convenience and enhance patient care and access over currently available therapies."

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics, stated "Reaching agreement with the FDA on the design of our Phase 3 program for TG-1101 in RMS has been a priority for us and we would like to thank the FDA for its invaluable guidance throughout this process. We have long believed the potential of TG-1101 is beyond oncology and believe this significant Phase 3 program will establish TG-1101 as an important new drug in the treatment of MS. The early data from our Phase 2 clinical trial, the highly successful pivotal results for the anti-CD20 monoclonal antibody ocrelizumab in MS, and the substantial safety data generated in our oncology program, gives us a high level of confidence in the potential for a successful outcome." Mr. Weiss continued, "Our team in concert with our CRO has been hard at work on the logistics and the launch of these Phase 3 trials on a global basis, and we look forward to enrolling our first patient before the end of the summer."

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 also in 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.

About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application.

Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessment, please visit: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080571.pdf.

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 the timing of the first patient enrolled into 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, 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 some of the perceived attributes of TG-1101, in particular the infusion times and potential pricing advantages may not be incorporated into future plans 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.

TGTX - G

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