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 16, 2021**

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	TGTX	Nasdaq Stock Market LLC

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 April 16, 2021, TG Therapeutics, Inc. (the "Company") issued a press release announcing positive results from the ULTIMATE I & II Phase 3 trials of ublituximab in multiple sclerosis. These data will be previewed today, Friday, April 16, 2021 at 8:30 a.m. on an investor and analyst call and will be presented at American Academy of Neurology 73rd Annual Meeting. 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 16, 2021.

104 Cover Page Interactive Data File (the cover page tags are embedded within the Inline XBRL document).

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: April 16, 2021

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

Exhibit 99.1

TG Therapeutics Announces Positive Results from the ULTIMATE I & II Phase 3 Trials of Ublituximab in Multiple Sclerosis to be Presented at American Academy of Neurology 73rd Annual Meeting

Ublituximab demonstrated superiority versus teriflunomide in reducing annualized relapse rates and MRI brain lesions

Ublituximab was generally well tolerated, with no unexpected safety signals

BLA submission targeted in Q3 2021

Webcast to be held today, Friday, April 16, 2021 at 8:30 AM ET

NEW YORK, April 16, 2021 -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced positive results from two global, active-controlled, Phase 3 studies, called ULTIMATE I & II, evaluating ublituximab, the Company's investigational novel, glycoengineered anti-CD20 monoclonal antibody, compared to teriflunomide, in patients with relapsing forms of multiple sclerosis (RMS). Both studies met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) over a 96-week period ($p<0.005$ in each trial). Key secondary MRI endpoints were also met.

These data will be previewed on a call today and presented at the American Academy of Neurology (AAN) 73rd Annual Meeting, tomorrow April 17, 2021. Details of each event are included below.

Lawrence Steinman, MD, Zimmermann Professor of Neurology & Neurological Sciences, and Pediatrics at Stanford University and Global Study Chair for the ULTIMATE I & II studies commented, "The results of the ULTIMATE I & II studies show that not only did ublituximab effectively reduce relapses in patients with RMS, but had a profound effect on suppressing inflammatory activity, evident by the reduction in both T1 Gd enhancing lesions as well as T2 lesions. Taken together, historically low ARRs, marked reductions in brain lesions and very low rates of confirmed disability progressions resulted in nearly half of the patients treated with ublituximab achieving no evidence of disease activity, a goal we strive for when treating our patients with RMS, which continues to be a challenge to achieve." Dr. Steinman continued, "Today represents an exciting day for RMS patients who continue to need efficacious and convenient treatment options."

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are extremely pleased with the results from the ULTIMATE I & II Phase 3 trials. We believe these data showcase ublituximab to be a highly efficacious treatment option with a generally well tolerated safety profile. If approved, ublituximab will be the only CD20 offered in a convenient one-hour infusion every six months, following the first dose. We look forward to sharing these results during our webcast and at AAN and are targeting a BLA submission for ublituximab to treat patients with RMS in the third quarter of this year."

The ULTIMATE I & II studies investigated the safety and efficacy of a one-hour 450mg infusion of ublituximab every six months, following the Day 1 infusion (150mg over four hours). The studies were conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). Additionally, data from these studies are intended to support a Biologics License Application (BLA) submission for ublituximab in RMS targeted in the third quarter of 2021.

Data highlights from the ULTIMATE I & II Phase III studies in patients with RMS include:

Primary Endpoint: Annualized Relapse Rate (ARR) Results

- In ULTIMATE I, treatment with ublituximab resulted in an ARR of 0.076 compared to 0.188 for teriflunomide, representing a relative reduction of approximately 60% (p<0.0001).
- In ULTIMATE II, treatment with ublituximab resulted in an ARR of 0.091 compared to 0.178 for teriflunomide, representing a relative reduction of approximately 50% (p=0.0022).

MRI Results

- Total number of T1 Gadolinium (Gd) enhancing lesions were reduced as a result of ublituximab treatment by 97% and 96% relative to treatment with teriflunomide in ULTIMATE I & II, respectively (p<0.0001).
- New or enlarging T2 lesions were reduced as a result of ublituximab treatment by 92% and 90% relative to treatment with teriflunomide in ULTIMATE I & II, respectively (p<0.0001).

No Evidence of Disease Activity (NEDA) Results

- In ULTIMATE I, 44.6% of ublituximab treated patients achieved NEDA representing a 198% improvement over teriflunomide (p <0.0001).
- In ULTIMATE II, 43% of ublituximab treated patients achieved NEDA representing a 277% improvement over teriflunomide (p<0.0001).

Prespecified Pooled Disability Results

- A very low rate of disability progression was observed across all treatment groups. Only 5.2% of ublituximab treated patients showed a 12-week Confirmed Disability Progression (CDP), compared to 5.9% with teriflunomide, and only 3.3% of ublituximab treated patients showeda 24-week CDP, compared to 4.8% with teriflunomide; neither was statistically different.
- Ublituximab treatment increased the proportion of patients with 12-week Confirmed Disability Improvement (CDI) and 24-week CDI, demonstrating a 100% improvement in 12-week CDI (12% v. 6%; p=0.0003), and an 88% improvement in 24-week CDI (9.6% v. 5.1%; p=0.0026) compared to teriflunomide.

Ublituximab was generally well tolerated with no unexpected safety signals. Overall, the proportion of patients in the ublituximab group with adverse events was similar to the teriflunomide group in a pooled analysis of both studies (approximately 88% in each treatment group); the most common adverse event associated with ublituximab was infusion related reactions (47.7% of patients who received ublituximab experienced at least one infusion-related reaction vs. 12.2 percent for the teriflunomide group).

ULTIMATE I & II PHASE 3 INVESTOR & ANALYST WEBCAST DETAILS

- Date & Time: Friday April 16, 2021 at 8:30 AM ET
- Key Opinion Leader Participants:
  - Lawrence Steinman, MD, of Stanford University and the Global Study Chair for the ULTIMATE I & II Phase 3 trials
  - Edward J. Fox, MD, PhD, of Central Texas Neurology Consultants and Chair for the ublituximab Phase 2 trial
  - Enrique Alvarez, MD, PhD, of University of Colorado Medicine
- Live Webcast: http://ir.tgtherapeutics.com/events (also archived for future review)

AAN ANNUAL MEETING POSTER PRESENTATION DETAILS
Title: Efficacy and safety of ublituximab versus teriflunomide in relapsing multiple sclerosis: Results of the Phase 3 ULTIMATE I and II trials

- Date & Time: Available for viewing beginning Saturday April 17, 2021 at 8:00 AM ET
- Abstract Number: 4494
- Lead Author: Lawrence Steinman, MD, Zimmermann Professor of Neurology & Neurological Sciences, and Pediatrics at Stanford University

ABOUT THE ULTIMATE I & II TRIALS
ULTIMATE I and ULTIMATE II are two independent Phase 3, randomized, double-blinded, active-controlled, global, multi-center studies evaluating the efficacy and safety/tolerability of ublituximab (450mg dose administered by one-hour intravenous infusion every 6 months, following a Day 1 infusion of 150mg over four hours and a Day 15 infusion of 450mg over one hour) versus teriflunomide (14mg oral tablets taken once daily) in subjects with relapsing forms of Multiple Sclerosis (RMS). The ULTIMATE I & II trials enrolled a total of 1,094 patients with RMS across 10 countries. These trials were led by Lawrence Steinman, MD, Zimmermann Professor of Neurology & Neurological Sciences, and Pediatrics at Stanford University and were conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). Both studies have met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) over a 96-week period ($p<0.005$ in each trial). Ublituximab treatment resulted in an ARR of <0.10 in each of ULTIMATE I & II, with a relative reduction in ARR of approximately 60% and 50%, respectively, over teriflunomide. Key secondary MRI endpoints have also been met. Data from these studies are intended to support a Biologics License Application (BLA) submission for ublituximab in RMS targeted Q3 2021. Additional information on these clinical trials can be found at www.clinicaltrials.gov (NCT03277261; NCT03277248).

ABOUT UBLITUXIMAB
Ublituximab is an investigational glycoengineered monoclonal antibody that targets a unique epitope on CD20-expressing B-cells. When ublituximab binds to the B-cell it triggers a series of immunological reactions, including antibody-dependent cellular cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC), leading to destruction of the cell. Additionally, ublituximab is uniquely designed, to lack certain sugar molecules normally expressed on the antibody. Removal of these sugar molecules, a process called glycoengineering, has been shown to enhance the potency of ublituximab, especially the ADCC activity. Targeting CD20 using monoclonal antibodies has proven to be an important therapeutic approach for the management of B-cell malignancies and autoimmune disorders, both diseases driven by the abnormal growth or function of B-cells.

ABOUT MULTIPLE SCLEROSIS
Relapsing multiple sclerosis (RMS) is a chronic demyelinating disease of the central nervous system (CNS) and includes people with relapsing-remitting multiple sclerosis (RRMS) and people with secondary progressive multiple sclerosis (SPMS) who continue to experience relapses. RRMS is the most common form of multiple sclerosis (MS) and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. It is estimated that nearly 1 million people are living with MS in the United States and approximately 85% are initially diagnosed with RRMS.[1,2] The majority of people who are diagnosed with RRMS will eventually transition to SPMS, in which they experience steadily worsening disability over time. Worldwide, more than 2.3 million people have a diagnosis of MS.[1]

ABOUT TG THERAPEUTICS, INC.
TG Therapeutics is a fully-integrated, commercial stage biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. In addition to an active research pipeline including five investigational medicines

1. MS Prevalence. National Multiple Sclerosis Society website. https://www.nationalmssociety.org/About-the-Society/MS-Prevalence. Accessed October 26, 2020.

2. Multiple Sclerosis International Federation, 2013 via Datamonitor p. 236.

across these therapeutic areas, TG has received accelerated approval from the U.S. FDA for UKONIQ™ (umbralisib), for the treatment of adult patients with relapsed/refractory marginal zone lymphoma who have received at least one prior anti-CD20-based regimen and relapsed/refractory follicular lymphoma who have received at least three prior lines of systemic therapies. Currently, the Company has two programs in Phase 3 development for the treatment of patients with relapsing forms of multiple sclerosis (RMS) and patients with chronic lymphocytic leukemia (CLL) and several investigational medicines in Phase 1 clinical development. For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and Linkedin.

UKONIQ™ is a trademark of TG Therapeutics, Inc.

Cautionary Statement
This press release contains 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. Such forward looking statements include but are not limited to statements regarding the results of the ULTIMATE I & II studies and the Company's plans and timelines for submission of a Biologics License Application (BLA) for ublituximab for the treatment of relapsing forms of Multiple Sclerosis (RMS).

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release. In addition to the risk factors identified from time to time in our reports filed with the U.S. Securities and Exchange Commission (SEC), factors that could cause our actual results to differ materially include the following: the risk that the data from the ULTIMATE I & II trials that we announce or publish may change, or the perceived product profile may be impacted, as more data or additional endpoints (including efficacy and safety) are analyzed; the risk that safety issues will emerge despite our belief that there were no unexpected safety signals identified in the ULTIMATE I & II trials ; our ability to complete the BLA submission for ublituximab in RMS within the timeline projected and the risk that FDA will not accept the submission; the risk that the clinical results from the ULTIMATE I & II trials will not support regulatory approval of ublituximab to treat RMS for efficacy, safety or other issues or, if approved, that we will not receive regulatory approval within the timeline projected; the risk that if approved, ublituximab will not be commercially successful; our ability to expand our commercial infrastructure, and successfully launch, market and sell ublituximab in RMS if approved; the Company's reliance on third parties for manufacturing, distribution and supply, and a range of other support functions for our commercial and clinical products, including ublituximab; the uncertainties inherent in research and development; and the risk that the ongoing COVID-19 pandemic and associated government control measures have an adverse impact on our research and development plans or commercialization efforts. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and in our other filings with the SEC. 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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