

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): **June 18, 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, 9<sup>th</sup> 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.

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**Item 8.01. Other Events.**

On June 18, 2018, TG Therapeutics, Inc. (the “Company”) issued a press release announcing the oral presentation of clinical data from its ongoing Phase 2 study evaluating umbralisib (TGR-1202), the Company’s PI3K delta inhibitor, in patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) who are intolerant to prior BTK or PI3K delta inhibitor therapy, at the 23rd Congress of European Hematology Association (EHA). On June 18, 2018, the Company also announced updated results from its Phase 2 multicenter trial of ublituximab (TG-1101), the Company’s novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS), at the 4th Congress of the European Academy of Neurology (EAN), in Lisbon, Portugal. Copies of the press releases are being filed as Exhibits 99.1 and Exhibits 99.2 and incorporated in this Item by reference.

**Item 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

[99.1](#) Press Release, dated June 18, 2018.

[99.2](#) Press Release, dated June 18, 2018.

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**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: June 18, 2018

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

**TG Therapeutics, Inc. Presents Phase 2 Data Evaluating Umbralisib in CLL Patients Intolerant to Prior BTK or PI3K Delta Inhibitor Therapy at the 23<sup>rd</sup> Congress of the European Hematology Association (EHA)**

NEW YORK NY (June 18, 2018) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced an oral presentation of clinical data from its ongoing Phase 2 study evaluating umbralisib (TGR-1202), the Company's PI3K delta inhibitor, in patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) who are intolerant to prior BTK or PI3K delta inhibitor therapy. Data from this trial were presented over the weekend during an oral session at the 23<sup>rd</sup> Congress of the European Hematology Association (EHA).

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are pleased to present data evaluating umbralisib in patients intolerant to currently approved BTK or PI3K therapies during the EHA annual congress. While there have been great advancements in recent years in the treatment of CLL, this study confirms that there are many patients still in need of an alternative treatment option and that umbralisib can be used safely and effectively in those patients who were not able to tolerate a prior BTK or PI3K therapy. The rate of patients withdrawing from kinase treatment for CLL in real world settings has been estimated to reach upwards of 40%, representing a significant unmet medical need." Mr. Weiss continued, "We are extremely pleased with the data presented at ASCO and EHA this month and we look forward to presenting the topline response rate data from the UNITY- CLL Phase 3 trial by the end of summer 2018."

Highlights from the oral presentation include the following:

***Oral Presentation: A Phase 2 Study to Assess the Safety and Efficacy of Umbralisib (TGR-1202) In Patients with Chronic Lymphocytic Leukemia (CLL) Who Are Intolerant to Prior BTK or PI3K-delta Inhibitor Therapy (Abstract Number S808)***

This presentation includes data from patients with CLL who are intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent umbralisib (TGR-1202). To be eligible for the study patients had to have received prior treatment with a BTK inhibitor (ibrutinib, acalabrutinib) or a PI3K delta inhibitor (idelalisib, duvelisib) and discontinued therapy due to intolerance within 12 months of starting treatment on this study. Forty-seven patients were evaluable for safety of which 46 were evaluable for Progression Free Survival (PFS), (1 patient had a confirmed Richter's Transformation (RT) at enrollment which did not meet eligibility criteria).

Highlights from this presentation include:

- Umbralisib demonstrated a favorable safety profile in patients intolerant to prior BTK or PI3K therapy
- Only 13% discontinued due to an adverse event, of which only one patient discontinued due to a recurrent adverse event (AE) also experienced with prior kinase inhibitor therapy
- Median progression free survival (PFS) and overall survival has not been reached with a median follow-up of 9.5 months
- In this relapsed/refractory CLL population, of which 77% required treatment within 6 months of prior KI discontinuation, 64% had a high-risk molecular / genetic marker and 6% had an ibrutinib resistance mutation, significant clinical activity has been observed

**PRESENTATION DETAILS**

The above referenced presentation is now available on the Publications page, located within the Pipeline section, of the Company's website at [www.tgtherapeutics.com/publications.cfm](http://www.tgtherapeutics.com/publications.cfm).

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## **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**

Some of the statements included in this press release or in the abstracts mentioned in this press release 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 preclinical and clinical trials; the risk that early clinical trial results (both safety and efficacy), that may have supported the acceptance of our data for presentation or influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies or in the final presentations; the risk that the differentiated tolerability profile for umbralisib observed will not be reproduced in full presentations or later larger studies; the risk that the final data from either GENUINE or UNITY-CLL will not support a regulatory filing or approval or that the company will choose not to file a BLA/NDA or seek accelerated approval based on those studies; the risk that the topline overall response rate data from the UNITY-CLL trial is not be statistically significant 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](http://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:**

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**TG Therapeutics, Inc. Announces Updated Results from the Ongoing Phase 2 Study of Ublituximab in Patients with Multiple Sclerosis at the 4<sup>th</sup> Congress of the European Academy of Neurology**

New York, NY, (June 18, 2018) TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated 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 is being presented today at the 4<sup>th</sup> Congress of the European Academy of Neurology in Lisbon, Portugal, via an oral session titled "MS and related Disorders 2", at 17:00 CET.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased to see that the preliminary Week 48 data presented today from this Phase 2 trial supports the Week 24 data presented earlier this year at the AAN meeting. While only an early look at the Week 48 timepoint, the data continue to be impressive and suggestive of a highly efficacious anti-CD20 monoclonal antibody with a manageable safety profile that can be administered in a convenient one-hour infusion. Mr. Weiss continued, "We look forward to presenting the final results from this Phase 2 trial including Week 48 data on up to 48 patients at a major medical meeting later this year."

***Oral Presentation Title: Phase 2 Multicenter Study Results of Ublituximab, a Novel Glycoengineered AntiCD20 Monoclonal Antibody (mAb), in Patients with Relapsing Multiple Sclerosis (RMS)***

This Phase 2 trial is a 48-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 oral presentation includes Week 24 data from 48 patients with relapsing forms of multiple sclerosis (RMS) that were treated with ublituximab across six dosing cohorts, as well as data from the first 14 patients through Week 48.

***Highlights:***

- An Annualized Relapse Rate (ARR) of 0.07, calculated cumulatively, based on 48 subjects with a mean follow-up of approximately 11 months
- 99% median B-cell depletion was observed at week 4 and maintained at Week 24 (n=44)
- Ublituximab completely eliminated all (100%) of T1 Gd-enhancing lesions at Week 24 (n=44) (p=0.003) and at Week 48 (n=14)
- 7.67% Reduction in T2 lesion volume at Week 24 from baseline (n=44) and a 10.5% reduction in T2 lesion volume at Week 48 from baseline (n=14)
- 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 forms 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 by the end of 2018.

**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](http://www.tgtxinc.com/publications.cfm).

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### **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](http://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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