

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): **December 3, 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 December 3, 2018, TG Therapeutics, Inc. (the “Company”) issued a press release announcing updated clinical data from its Phase I/II trial of ublituximab (TG-1101), the Company’s novel glycoengineered anti-CD20 monoclonal antibody in combination with umbralisib (TGR-1202), the Company’s oral, next generation PI3K delta inhibitor, and pembrolizumab, in patients with relapsed/refractory Chronic Lymphocytic Leukemia (CLL) and Richter’s Transformation (RT) presented during the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition. On December 4, 2018 the Company also announced updated clinical data from its Phase I/Ib trial of ublituximab in combination with umbralisib, and bendamustine, in patients with Diffuse Large B-cell Lymphoma (DLBCL) and Follicular Lymphoma (FL) also presented during the 60<sup>th</sup> Annual ASH Meeting. Copies of the press releases are being filed as Exhibit 99.1 and Exhibit 99.2 and incorporated in this Item by reference.

**Item 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

[99.1](#) Press Release, dated December 3, 2018.

[99.2](#) Press Release, dated December 4, 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: December 4, 2018

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

**TG Therapeutics, Inc. Announces Oral Presentation of Follow-Up Data from the Triple Combination of Ublituximab, Umbralisib, and Pembrolizumab in Patients with Relapsed/Refractory CLL and Richter's Transformation at 60<sup>th</sup> American Society of Hematology Annual Meeting and Exposition**

NEW YORK, NY (December 3, 2018) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated clinical data from its Phase I/II trial of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with umbralisib (TGR-1202), the Company's oral, next generation PI3K delta inhibitor, and pembrolizumab, in patients with relapsed/refractory Chronic Lymphocytic Leukemia (CLL) and Richter's Transformation (RT). Data from this trial were presented yesterday during an oral session at the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We were excited to share the data presented from the combination of U2 plus pembrolizumab. Due to potentially overlapping immune-mediated toxicity, this is the first trial where a PI3K delta inhibitor has been combined with a PD-1/PD-L1 inhibitor, again highlighting the unique combinability of the U2 regimen. In addition to demonstrating that these drugs could be safely combined, we were encouraged to see favorable response rates in both RT and BTK refractory CLL patients, a subset of patients that are historically challenging to treat." Mr. Weiss continued, "Our proprietary anti-PD-L1, TG-1501, has now completed Phase 1 dose escalation, and we believe the data presented today set the stage for the commencement of the combination of U2 plus TG-1501, in the coming months."

Below summarizes the oral presentation.

***Phase I/II Study of Umbralisib (TGR-1202) in Combination with Ublituximab (TG-1101) and Pembrolizumab in Patients with Relapsed/Refractory CLL and Richter's Transformation (Publication Number: 297)***

This oral presentation includes data from patients with relapsed or refractory CLL or Richter's Transformation treated with the triple combination of ublituximab, umbralisib, and pembrolizumab. Fifteen patients were evaluable for safety (10 CLL patients and 5 RT patients) and 14 were evaluable for efficacy (10 CLL and 4 RT), with one RT patient too early to evaluate. Data highlights include:

- The triple combination was well tolerated, with immune mediated toxicities not appearing above what would be expected with either umbralisib or pembrolizumab alone
  - 90% (9 of 10) Overall Response Rate (ORR) in patients with relapsed/refractory CLL, including one Complete Response (CR)
  - 80% (4 of 5) ORR in BTK refractory CLL patients, of which 3 of 4 BTK refractory CLL responders achieved their response to U2 alone prior to introduction of pembrolizumab
  - 50% (2 of 4) ORR in RT, with both responses being a CR
  - Responses have been durable, and a median progression-free survival has not yet been reached
  - The first patient treated remains progression-free for 36+ months, having now been off therapy for more than 24 months
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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, TG-1501, as well as its covalently-bound Bruton Tyrosine Kinase (BTK) inhibitor, TG-1701, 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 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. In addition to the risk factors identified from time to time in our reports filed with the Securities and Exchange Commission, 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 the highlighted early clinical trial results, 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 combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2 and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination, or backbone for triple therapy combinations; the risk that TG-1501 will not demonstrate acceptable safety or efficacy as either a single agent or in combination with any other agents; the risk that a trial evaluating the combination of U2 plus TG-1501 will not commence. 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 Follow-Up Data from the Triple Combination of Ublituximab, Umbralisib, and Bendamustine in Patients with DLBCL and FL at 60<sup>th</sup> American Society of Hematology Annual Meeting and Exposition**

NEW YORK, December 4, 2018 -- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated clinical data from its Phase I/Ib trial of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with umbralisib (TGR-1202), the Company's oral, next generation PI3K delta inhibitor, and bendamustine, in patients with Diffuse Large B-cell Lymphoma (DLBCL) and Follicular Lymphoma (FL). Data from this trial was presented yesterday evening during a poster session at the 60<sup>th</sup> American Society of Hematology (ASH) Annual Meeting and Exposition.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "The data presented yesterday further supports our belief that our proprietary U2 combination is an ideal backbone regimen on which to build novel multi-drug combinations. The triple therapy of U2 plus bendamustine is highly active and well tolerated in advanced patients, resulting in durable responses with some patients on study 36+ months." Mr. Weiss continued, "We are looking forward to an exciting 2019, with pivotal data expected from the ongoing UNITY-NHL registration directed program in the first half of the year."

Below summarizes the data from the poster presentation.

***Combination of Umbralisib, Ublituximab, and Bendamustine is Safe and Highly Active in Patients with Advanced DLBCL and Follicular Lymphoma (Abstract 4197)***

This poster presentation includes data from patients with relapsed or refractory DLBCL or FL treated with the triple combination of umbralisib, ublituximab and bendamustine. Thirty-nine patients were evaluable for safety of which 38 were evaluable for efficacy (one patient discontinued due to a treatment-related adverse event (AE), neutropenia, prior to first efficacy assessment). Twenty-two patients (56%) were refractory to prior treatment. Overall, the triple combination was well tolerated and highly active in patients with advanced indolent and aggressive NHL, including those not eligible for HD/SCT or CD19 CART therapy.

Efficacy highlights from this poster include:

- 85% (11 of 13) ORR, including a 54% CR rate, observed in patients with relapsed or refractory FL
- 48% (12 of 25) ORR, including a 36% CR rate, observed in patients with relapsed or refractory DLBCL

**PRESENTATION DETAILS:**

The above referenced presentation is 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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