

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 15, 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 15, 2018, TG Therapeutics, Inc. (the “Company”) issued a press release announcing the presentation of an integrated analysis of long term safety data of umbralisib (TGR-1202), the Company’s PI3K delta inhibitor, as well as the first preclinical data presentation of TG-1701, the Company’s orally available and covalently-bound BTK inhibitor, at the 23rd Congress of European Hematology Association (EHA). On June 15, 2018, the Company also announced updated clinical data from its ongoing Phase I study evaluating umbralisib (TGR-1202), the Company’s PI3K delta inhibitor in combination with ruxolitinib, the JAK 1/2 inhibitor, in ruxolitinib experienced patients with myelofibrosis (MF), at the 23rd Congress of EHA. 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 15, 2018.

[99.2](#) Press Release, dated June 15, 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 15, 2018

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

## TG Therapeutics, Inc. Announces Clinical and Preclinical Data Presentations at the 23<sup>rd</sup> Congress of the European Hematology Association

NEW YORK, NY (June 15, 2018) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced the presentation of an integrated analysis of long term safety data of umbralisib (TGR-1202), the Company's PI3K delta inhibitor, either dosed as a single agent and in combination, in patients with relapsed or refractory lymphoid malignancies, as well as the first preclinical data presentation of TG-1701, the Company's orally available and covalently-bound BTK inhibitor. Data from these trials are being presented today during 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 extremely pleased to present updated data from our integrated safety analyses of umbralisib. There is a generally held belief that severe toxicities are more common following 6 months of exposure on a PI3K delta inhibitor. While this has held true for first generation delta inhibitors, we are pleased to present data from 177 patients on daily umbralisib for more than 6 months, ranging upwards of 5+ years, and believe the long-term follow-up data demonstrates that umbralisib has a differentiated safety profile, uniquely distinct from prior generation PI3K delta inhibitors." Mr. Weiss continued, "The differentiated safety profile of umbralisib is critical as we think about potential triple and quad combination strategies, especially in combination with our novel, proprietary BTK inhibitor, TG-1701, for which we also presented some exciting pre-clinical data. The kinase profile of TG-1701 looks quite competitive with the most specific BTK inhibitors and more selective than ibrutinib. We look forward to seeing more data on TG-1701 and expect to open a TG sponsored Phase 1/2 trial later this year."

Highlights from today's presentations include the following:

***Poster Presentation: Long term integrated safety analysis of umbralisib (TGR-1202), a PI3K delta/CK1-epsilon inhibitor with a differentiated safety profile in patients with relapsed/refractory lymphoid malignancies***

This presentation builds on a prior integrated analysis of 347 patients with relapsed or refractory lymphoid malignancies presented last year. The presentation includes data that were pooled from 4 completed or ongoing Phase 1 or 2 studies containing umbralisib, focusing on 177 patients who have been on daily umbralisib for a minimum of 6 months. Patients were heavily pretreated, with 45% of patients having seen 3 or more prior lines of therapy.

Highlights from this poster include:

- Umbralisib continues to exhibit a differentiated safety profile compared to prior generation PI3K delta inhibitors
- 177 patients have been treated with daily umbralisib for 6+ months, with a median duration of exposure of 1.3 years, and 33% patients on drug 2+ years and the longest patients on daily umbralisib for over 5 years
  - o Serious adverse events occurring in >1% of patients were limited to pneumonia (3%), diarrhea (2%), and cellulitis (2%)
  - o Only 2% of patients discontinued as a result of diarrhea/colitis after being on umbralisib for more than 6 months
  - o Discontinuations due to other adverse events (AEs) of interest for prior generation PI3K inhibitors were also rare

***Poster Presentation: TG-1701 is a novel, orally available, and covalently-bound BTK inhibitor***

- TG-1701, a novel, specific and covalent BTK inhibitor, is more selective than ibrutinib toward a set of kinases
- BTK occupancy assays in vitro and in vivo suggest that 100% occupancy can be reached using low doses of TG-1701 in human dose escalation clinical trial
- In pre-clinical experiments, TG-1701 inhibited the phosphorylation of BTK and other kinases downstream of the BCR pathway.
- In cellular and animal models of b-cell malignancies, TG-1701 demonstrated similar antitumor efficacy to ibrutinib and acalabrutinib

### PRESENTATION DETAILS

The above referenced presentations are 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 umbralisib is not a differentiated PI3K delta inhibitor; 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 and other studies, will not prove to be safe and efficacious for any indication or will not prove to be a safe and efficacious backbone for future triple or quad therapies; the risk that we will not open a TG sponsored Phase 1/2 trial of TG-1701; the risk that we will not study the triple combination of ublituximab, umbralisib and TG-1701 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 Oral Presentation of Umbralisib plus Ruxolitinib in Patients with Myelofibrosis at the 23<sup>rd</sup> Congress of the European Hematology Association**

*Data demonstrates that the addition of umbralisib to ruxolitinib can induce responses in patients with sub-optimal response to ruxolitinib single agent*

NEW YORK, NY (June 15, 2018) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated clinical data from its ongoing Phase I study evaluating umbralisib (TGR-1202), the Company's PI3K delta inhibitor in combination with ruxolitinib, the JAK 1/2 inhibitor, in ruxolitinib experienced patients with myelofibrosis (MF). Data from this trial are being presented this morning during 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, "The data presented in patients with myelofibrosis represents yet another unique opportunity for umbralisib, in this case providing a treatment option to patients who are not achieving an optimal response to ruxolitinib monotherapy. This type of study highlights the unique breadth of activity of PI3K delta inhibition across hematological malignancies and underscores the importance of umbralisib's safety profile, that permits a wide range of combinations." Mr. Weiss continued, "We look forward to evaluating this combination further, potentially in a randomized pivotal setting."

Highlights from this morning's presentation include the following:

***Oral Presentation: Resurrecting response to ruxolitinib: a phase I study testing the combination of ruxolitinib and the PI3Kdelta inhibitor umbralisib in ruxolitinib-experienced myelofibrosis (Abstract Number S133)***

This oral presentation includes data from patients with myelofibrosis treated with the combination of ruxolitinib, the JAK1/2 inhibitor and umbralisib (TGR-1202). Importantly, per protocol, all enrolled patients were on a stable dose of ruxolitinib monotherapy and had achieved their best response to ruxolitinib prior to enrolling to receive umbralisib. Presentation highlights included:

- The combination of umbralisib + ruxolitinib was well-tolerated with limited Grade 3/4 adverse events;
  - Dose-limiting toxicities of asymptomatic amylase/lipase elevations were observed of unclear clinical consequence;
  - Only one event of colitis (in a patient with underlying GI disorder at study entry) and no pneumonitis was observed.
- Increases in hemoglobin, improvements in spleen size, and reduction in symptoms meeting IWG-MRT criteria for clinical improvement were seen in 13 (57%) ruxolitinib-experienced myelofibrosis patients;
- Importantly, 2 patients (9%) achieved a durable complete remission after progressing on ruxolitinib;
- The addition of umbralisib to ruxolitinib demonstrates the ability to augment or resurrect a response in myelofibrosis patients who had suboptimal or lost response to ruxolitinib alone.

**PRESENTATION DETAILS**

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