

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 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 June 4, 2018, TG Therapeutics, Inc. (the "Company") issued a press release announcing updated 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 presented during the 54th American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. A copy of the press release is being filed as Exhibit 99.1 and incorporated in this Item by reference. Filed as Exhibit 99.2 and incorporated in this Item by reference are slides utilized at the Company's Investor and Analyst event on June 3, 2018.

**Item 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

[99.1](#) Press Release, dated June 4, 2018.

[99.2](#) Slides from Analyst and Investor Event, dated June 3, 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 4, 2018

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

**TG Therapeutics, Inc. Announces Umbralisib Clinical Data Presentation at the 54th Annual Meeting of the American Society of Clinical Oncology**

CHICAGO, IL (June 4, 2018) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated 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 are being presented today during the 54<sup>th</sup> American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased with the data presented today during the ASCO annual meeting. We believe there is a need for novel treatment options for patients who are intolerant to the currently approved BTK and PI3K therapies and believe the data shown today demonstrates that umbralisib can be used effectively in these patients." Mr. Weiss, continued, "We continue to be pleased with the safety and efficacy profile of umbralisib and believe umbralisib single agent, or umbralisib plus ublituximab referred to as 'U2', can become important treatment options across multiple b-cell malignancies. We also look forward to presenting updated umbralisib integrated safety data at the European Hematology Association (EHA) annual congress in a couple of weeks, as well as the topline response rate data from the UNITY-CLL Phase 3 trial by the end of summer 2018."

Highlights from today's presentation include the following:

**Poster Presentation: KI Intolerance Study: 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 4314)**

This poster 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 poster 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 KI therapy
- Nodal reductions were seen in nearly all patients evaluable for response with 3 patients achieving complete resolution of nodal disease, of which 1 patient with 17p del achieved a bone marrow confirmed Complete Response (CR)
- Median progression free survival (PFS) 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, 68% 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 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; 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 will not be proven to be effective in the treatment of patients intolerant to prior kinase inhibitors; 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 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

**Investor & Analyst Event June 2018**

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**Michael S. Weiss**  
Executive Chairman & CEO

 **UNITY** CLL  
TG THERAPEUTICS  
GLYCOENGINEERED UBIQUITINOMAB + PSK DELTA TCR-1202  
PHASE 3 TRIAL IN CLL

 **UNITY** NHL  
TG THERAPEUTICS  
GLYCOENGINEERED UBIQUITINOMAB + PSK DELTA TCR-1202  
PREVIOUSLY TREATED NHL PATIENTS

## Forward Looking Safe Harbor Statement

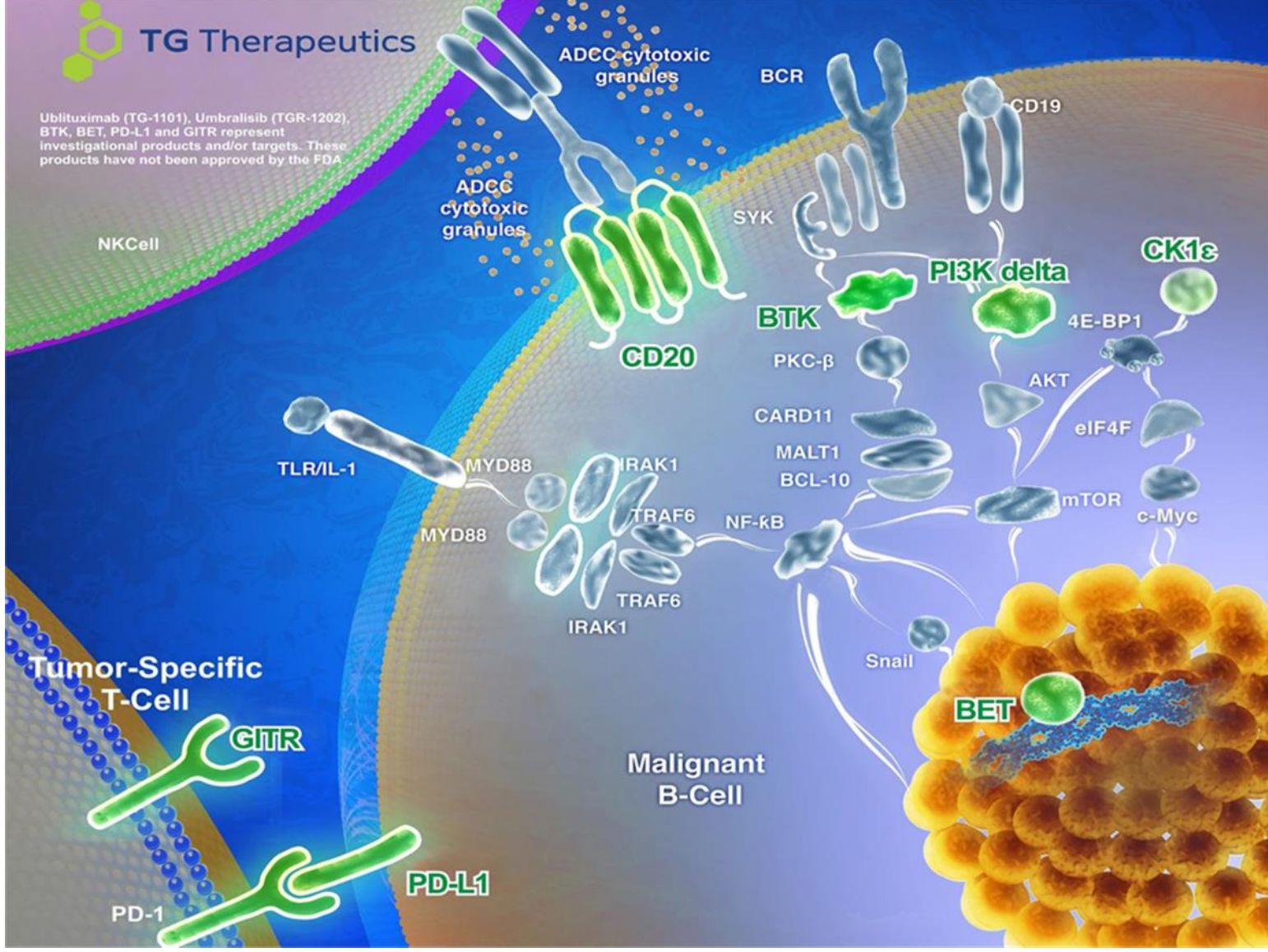
*This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often, but not always, made through the use of words or phrases such as “anticipates”, “expects”, “plans”, “believes”, “intends”, and similar words or phrases. Such statements involve risks and uncertainties that could cause TG Therapeutics’ actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in clinical trials, drug development, and commercialization. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and TG Therapeutics undertakes no obligation to update these statements, except as required by law.*

# AGENDA

Topic	Presenter
Welcome / Introductions	Michael S. Weiss, CEO TG Therapeutics
KI Intolerant Review	Anthony Mato, MD
Emerging Challenges in CLL: Drug Drug Interactions	Alexey Danilov, MD, PhD
Questions & Answer Session	
Closing Remarks	Michael S. Weiss



Ublituximab (TG-1101), Umbralisib (TGR-1202), BTK, BET, PD-L1 and GITR represent investigational products and/or targets. These products have not been approved by the FDA.



# TG Therapeutics, Inc.

- Biopharmaceutical company focused on B-cell cancers (CLL and NHL) & autoimmune-related diseases (MS, RA, Lupus)
- **Headquarters:** New York, NY
- **NASDAQ:** TGTX
- Developing portfolio of B-cell targeted agents
- **Ublituximab (TG-1101) – Novel Glycoengineered, Anti-CD20 monoclonal antibody**
  - Enhanced ADCC profile for increased potency, similar to Gazyva® (GA101)
  - Robust activity demonstrated in CLL and NHL
  - **GENUINE Phase 3 Registration Trial in CLL positive results announced!**
  - **ULTIMATE I & II Phase 3 Trials Ongoing in Multiple Sclerosis under SPA**
- **Umbralisib (TGR-1202) – Novel PI3K $\delta$  inhibitor**
  - Highly active and well tolerated as monotherapy and in combination treatment
  - Demonstrated best-in-class attributes
  - **UNITY- CLL Phase 3 trial under FDA-Special Protocol Assessment (SPA)**
    - Full Enrollment reached- October 2017

# TG Therapeutics Update

## ▪ **UNITY-CLL**

- On target for ORR data this summer

## ▪ **GENUINE**

- Filing decision pending outcome of UNITY-CLL and KOL outreach
- Our goal is to put our best filing package in first (if possible)
  - Including, filing accelerated approval based on the UNITY-CLL ORR data and/or GENUINE ORR data or neither.

## ▪ **UNITY-NHL**

- DLBCL- on track to complete target enrollment of U2+B by end of June
- FL/SLL- on track to complete target enrollment in Umbralisib monotherapy arm by mid-2018 and commence U2 single arm
- MZL- on track to complete Umbra monotherapy in 3Q

# TG Therapeutics Update

## ▪ MS Program

- Phase 2 final data expected before YE
- **ULTIMATE I & II Phase 3 Program Update!**
  - Complete enrollment now targeted by YE 2018 (prior guidance by end of 1Q19)

## ▪ Pipeline Update

- **Anti PD-L1 monoclonal antibody:**
  - Phase 1 dose escalation complete
  - Commencement of heme focused cohort by YE 2018
- **TG-1701- BTK inhibitor**
  - Phase 1 currently enrolling in China
  - TG sponsored Phase 1/2 trial to open in 3Q18

## ▪ Corporate Update

- Appointment of Adam Waldman as Chief Commercial Officer
  - Most recently, Adam led Marketing for the US Hematology-Oncology franchise at Celgene Corporation, where he spent the prior 13 years of his career

# ASCO & EHA Upcoming Presentations

## ASCO:

- Poster: 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 #: S808)
  - Date & Time: Monday June 4, 2018; 8:00 – 11:30 CT

## EHA:

- Oral: 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 #: S808)
  - Date & Time: Saturday June 16, 2018; 12:30 – 12:45 CEST
- Oral: Resurrecting response to ruxolitinib: a phase I study testing the combination of ruxolitinib and the PI3Kdelta inhibitor umbralisib in ruxolitinib-experienced myelofibrosis (Abstract #: S133)
  - Date & Time: Friday June 15, 2018, 12:30 – 12:45 CEST
- Poster: 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 (Abstract #: PF444)
  - Date & Time: Friday June 15, 2018; 17:30 – 19:00 CEST
- Poster: TG-1701 a novel, orally available, and covalently-bound BTK inhibitor (Abstract #: PF638)
  - Date & Time: Friday June 15, 2018; 17:30 – 19:00 CEST