

# TG THERAPEUTICS, INC.

## **FORM 8-K** (Current report filing)

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Address	2 GANSEVOORT STREET, 9TH FLOOR NEW YORK, NY 10014
Telephone	(212) 554-4484
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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, 2017**

**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 3, 2017, TG Therapeutics, Inc. (the “Company”) issued a press release announcing positive results from its Phase 3 GENUINE trial of TG-1101 (ublituximab) plus ibrutinib in patients with previously treated high risk Chronic Lymphocytic Leukemia (CLL) presented in an oral session during the 53rd American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. On June 5, 2017, the Company announced updated clinical data from its ongoing Phase I/Ib trial of TG-1101 (ublituximab) in combination with TGR-1202 (umbralisib) in patients with CLL and Non-Hodgkin’s Lymphoma (NHL) presented during the 53rd ASCO Annual Meeting. Copies of the press releases are being filed as Exhibits 99.1 and 99.2 and incorporated in this Item by reference.

**Item 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

99.1 Press Release, dated June 3, 2017.

99.2 Press Release, dated June 5, 2017.

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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 5, 2017

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

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## INDEX TO EXHIBITS

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Press Release, dated June 3, 2017.
99.2	Press Release, dated June 5, 2017 .

**TG Therapeutics Announces Positive Data from Phase 3 GENUINE Trial of TG-1101 in Combination with Ibrutinib in Patients with High Risk Chronic Lymphocytic Leukemia at the 53rd Annual Meeting of the American Society of Clinical Oncology**

***Study met its primary endpoint with TG-1101 (ublituximab) plus ibrutinib increasing Overall Response Rate (ORR) by >70% over ibrutinib alone***

***TG-1101 plus ibrutinib achieved 78% ORR, with 7% Complete Responses (CR), compared to 45% ORR with 0% CR's for Ibrutinib Alone,  $p < 0.001$  (median follow-up 11.4 months), with all responses now confirmed as per iwCLL 2008 criteria***

***Combination of TG-1101 and ibrutinib resulted in 19% Minimal Residual Disease (MRD) negativity compared to 2% for Ibrutinib Alone,  $p < 0.01$***

***A trend in improvement of PFS was observed with the combination of TG-1101 plus ibrutinib compared to ibrutinib alone (Hazard Ratio=0.559;  $p = NS$ )***

***The combination was well tolerated and TG-1101 did not appear to alter the safety profile of ibrutinib monotherapy, apart from infusion related reactions associated with TG-1101 which were primarily Grade 1/2***

New York, NY, June 3, 2017 – TG Therapeutics (NASDAQ: TGTX) today announced positive results from its Phase 3 GENUINE trial of TG-1101 (ublituximab) plus ibrutinib in patients with previously treated high risk Chronic Lymphocytic Leukemia (CLL). Data from this trial was presented today by Dr. Jeff Sharman, Medical Director, Hematology Research, US Oncology in an oral session during the 53<sup>rd</sup> American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, “Patients with high-risk CLL have the poorest outcomes on ibrutinib and are in need of a more efficacious treatment. We believe the data presented today demonstrate that the addition of TG-1101 to ibrutinib improves patient outcomes across multiple measures.” Mr. Weiss continued, “In addition to increasing the overall number of patients that responded to treatment with ibrutinib, adding TG-1101 to ibrutinib increased the number of patients with bone marrow confirmed CR’s, MRD negativity in peripheral blood, deepened nodal responses, and resulted in fewer patients progressing on therapy. Collectively, we see the consistent pattern of enhanced benefit as providing a compelling case for combining TG-1101 with ibrutinib in these hard to treat patients with high-risk CLL. We look forward to sharing these data with the FDA later this year to discuss filing for accelerated approval. We would like to thank our investigators and their patients for their participation in this important clinical trial.”

Highlight’s from this presentation include the following:

***Oral Presentation: Ublituximab and ibrutinib for previously treated genetically high-risk chronic lymphocytic leukemia: Results of the GENUINE Phase 3 study***

This presentation includes data from the GENUINE Phase 3 trial, a multicenter, randomized trial (NCT02301156), which assessed the efficacy and safety of TG-1101 plus ibrutinib versus ibrutinib alone in patients with high risk CLL. For the trial, high-risk was defined as having any one or more of the following centrally confirmed features: 17p deletion, 11q deletion or p53 mutation. The GENUINE study was designed to demonstrate the value of adding TG-1101, a potent next generation glycoengineered anti-CD20 monoclonal antibody to ibrutinib monotherapy in high-risk CLL, and was powered to show a statistically significant improvement in ORR of 30%, with a minimal absolute detectable difference between the two arms of approximately 20%.

The trial met its primary endpoint, demonstrating a statistically significant improvement in Overall Response Rate (ORR), as assessed by blinded independent central radiology and hematology review by iwCLL (Hallek 2008) criteria, compared to ibrutinib alone in both the Intent to Treat (ITT) population ( $p = 0.001$ ) and Treated population ( $p < 0.001$ ). Per iwCLL guidelines, all responders required confirmation of response for a minimum duration of 2 months. The ITT population includes all 126 randomized patients (64 in the TG-1101 plus ibrutinib arm and 62 in the ibrutinib alone arm) while the Treated population includes all ITT patients that received at least one dose of either study drug (59 in the TG-1101 plus ibrutinib arm and 58 in the ibrutinib alone arm).

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### ***Patient Demographics***

One hundred and twenty-six (126) patients were randomized on the GENUINE Phase 3 trial. 100% of patients were high-risk and had either 17p deletion, 11q deletion, or p53 mutation. Sixty-four percent (64%) of patients in the TG-1101 plus ibrutinib arm and 66% of patients in the Ibrutinib alone arm had 17p deletion and/or a p53 mutation while 36% and 34% of patients in the TG-1101 plus ibrutinib and ibrutinib alone arms, respectively, had an 11q deletion only. The median age of patients on either arm was 67 years and the median number of prior lines of therapy for either arm was 3.

### ***Safety & Tolerability***

One hundred and seventeen (117) patients were evaluable for safety (59 patients in the TG-1101 plus ibrutinib arm, and 58 patients in the ibrutinib alone arm). The combination was well tolerated and, apart from infusion related reactions, the addition of TG-1101 did not appear to alter the safety profile of ibrutinib monotherapy. Neutropenia, occurring in 9% of patients, was the most commonly reported Grade 3/4 Adverse Event (AE) in the combination arm, followed by infusion related reactions and anemia, each reported in 5% of patients. Notably, the majority of infusion related reactions (IRR) were Grade 1 or 2 in severity, with only 5% Grade 3/4 IRR observed. Median follow-up for this study was approximately 11.4 months.

### ***Clinical Activity***

#### Response Rates

	TG-1101 plus Ibrutinib	Ibrutinib	P-value
Treated Population (n)	n=59	n=58	
Overall Response Rate (ORR)	78%	45%	P<0.001
Complete Response (CR)	7%	0%	NS
MRD-Negative	19% (n=53) *	2% (n=53) *	P<0.01

\*Patients evaluable for MRD included those enrolled >4 months prior to data cutoff date of February 15, 2017. MRD analyzed by central lab, 7-color flow cytometry

In addition to the improvements in ORR, CR and MRD-negativity, a trend in improvement of Progression Free Survival (PFS) was observed in the combination arm of TG-1101 plus ibrutinib as compared to ibrutinib alone (Hazard Ratio = 0.559; p=NS).

### **ABOUT THE PHASE 3 GENUINE STUDY**

The Phase 3 GENUINE study is a randomized, open label, multicenter clinical trial to evaluate the safety and efficacy of TG-1101 (ublituximab) plus ibrutinib compared to ibrutinib alone in adult patients with high-risk Chronic Lymphocytic Leukemia (CLL) who received at least one prior therapy for their disease.

The study was conducted at 160 clinical trial sites in the US and Israel and randomized 126 patients. Patients received ibrutinib orally at 420 mg once daily in both arms and in the combination arm those patients also received intravenous infusions of TG-1101 at 900 mg dosed on days 1, 8 and 15 of cycle 1 and day 1 of cycles 2-6. Patients in the combination arm who had not progressed received quarterly infusions of TG-1101 maintenance at 900 mg.

### **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).

### **TG THERAPEUTICS INVESTOR & ANALYST EVENT**

TG Therapeutics will host a reception on Monday, June 5, 2017 beginning at 7:00pm CT, with featured presentations beginning promptly at 7:05pm CT. The event will take place at the Peninsula Chicago Hotel in the Avenues Ballroom. This event will be webcast live and will be available on the Events page, located within the Investors & Media section of the Company's website at [www.tgtherapeutics.com](http://www.tgtherapeutics.com), as well as archived for future review. This event will also be broadcast via conference call. To access the conference line, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), and reference Conference Title: TG Therapeutics June 2017 Investor & Analyst Event .

## **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. TG-1101 (ublituximab) 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 TGR-1202 (umbralisib), 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 TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies, with TG-1101 also in clinical development for autoimmune disorders. The Company also has pre-clinical programs to develop IRAK4 inhibitors, BET inhibitors, and anti-PD-L1 and anti-GITR antibodies. 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: the risk that 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; the risk that the FDA will not grant us a pre-BLA meeting to discuss the results of the GENUINE study; the risk that we will not file a BLA for TG-1101 based on the GENUINE trial. 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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## **TG Therapeutics, Inc. Announces Follow-Up Data from the Chemo-Free Triple Combination of TG-1101, TGR-1202, and Ibrutinib at the 53<sup>rd</sup> Annual Meeting of the American Society of Clinical Oncology**

*100% ORR (19 of 19) observed in patients with CLL/SLL, including 32% CR rate*

*100% ORR (6 of 6) observed in patients with MZL and MCL, with 50% CR rate*

*80% ORR (4 of 5) observed in patients with FL, with 20% CR rate*

*Favorable safety profile observed in patients treated with the triple combination reinforcing that TG-1101 plus TGR-1202 is a well-tolerated and efficacious backbone for multi-drug combination regimens*

CHICAGO, June 5, 2017-- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated clinical data from its ongoing Phase I/Ib trial of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with TGR-1202 (umbralisib), the Company's oral, next generation PI3K delta inhibitor, and ibrutinib, a BTK inhibitor, in patients with Chronic Lymphocytic Leukemia (CLL) and Non-Hodgkin's Lymphoma (NHL). Data from this trial was presented today during the 53rd American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL. Additionally, a poster was presented describing the design of a study evaluating TGR-1202 in CLL patients who are intolerant to prior kinase inhibitor (KI) therapy, particularly ibrutinib and idelalisib.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "The triple data presented today provides a compelling case for combining our doublet, referred to as TG-1303, with ibrutinib across a number of b-cell malignancies for which ibrutinib is now approved. Importantly, the high rates of complete responses observed across these diseases with the triple therapy may enable some patients to discontinue treatment prior to becoming ibrutinib refractory, a population associated with very poor outcomes." Mr. Weiss continued, "Additionally, the data shown today strengthens our belief that TG-1303 is a safe and efficacious backbone upon which we can build triple and quad therapies, as we continue to strive towards identifying combinations that provide deeper remissions that can ideally avoid lifetime treatment. We look forward to further exploring multi-drug combination therapies both with currently approved agents as well as with our in-house pipeline products."

Highlights from today's presentations include the following:

***Poster Presentation: Tolerability and activity of chemo-free triplet combination of TGR-1202, ublituximab, and ibrutinib in patients with advanced CLL and NHL (Abstract #7511)***

***Poster Viewing & Discussion Details: Monday, June 5, 2017 8:00 AM-11:30 AM CT (Poster Viewing); 1:15 PM-2:30 PM CT (Poster Discussion)***

This poster presentation includes data from patients with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) and Non-Hodgkin's Lymphoma (NHL) treated with the triple combination of TGR-1202, TG-1101 and ibrutinib. All patients were relapsed or refractory to prior therapy, except 3 CLL patients who were treatment naïve. Three cohorts for each CLL/SLL and NHL were evaluated with TGR-1202 dose escalation starting with doses of 400 mg (cohort 1), followed by 600 mg (cohort 2) and 800 mg (cohort 3), in combination with TG-1101 at 900 mg and ibrutinib daily at 420 mg (CLL) and 560 mg (NHL).

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### ***Safety & Tolerability***

Thirty-eight (38) patients were evaluable for safety (20 CLL/SLL patients, and 18 NHL patients). The triple combination appeared to be well tolerated in all patients, with neutropenia (32% all grades, 18% Grade 3/4) and pneumonia (18% all grades, 11% Grade 3/4), being the only Grade 3/4 AEs in >10% of patients. Of the 38 patients treated to date, only two AEs (sepsis and pneumonia) led to treatment discontinuation. Median time on study was 11.1 months (range 0.4 – 30+ months) with 81% of patients on study >6 months.

### ***Clinical Activity***

Clinical activity was observed at all dose levels with 36 of 38 patients evaluable for efficacy (19 CLL/SLL patients, and 17 NHL patients), with 2 patients having discontinued prior to first efficacy assessment (1 pneumonia, and 1 investigator discretion).

#### CLL/SLL Efficacy highlights include:

- 100% (19 of 19) Overall Response Rate (ORR), including a 32% Complete Response (CR) rate observed in patients with CLL/SLL (4 of 6 CR's pending bone marrow confirmation)
- 50% of the CLL patients had a 17p and/or 11q deletion
- 3 CLL patients had prior BTK and/or PI3Kd i nhibitor therapy, including one patient refractory to both idelalisib and ibrutinib who attained a complete response (ongoing for 1.5+ years)

#### NHL Efficacy highlights include:

- Response Rates observed in patients with NHL:
  - 100% (2 of 2) ORR, including one CR in patients with Marginal Zone Lymphoma (MZL)
  - 100% (4 of 4) ORR, including 50% CR rate in patients with Mantle Cell Lymphoma (MCL)
  - 80% (4 of 5) ORR, including 20% CR rate in patients with Follicular Lymphoma (FL)
  - 17% (1 of 6) ORR in patients with Diffuse Large B-cell Lymphoma (DLBCL)
- FL patients were heavily pretreated including 2 with prior Autologous Stem Cell Transplant (ASCT), 1 refractory to prior ibrutinib, and 1 with 5 prior lines of rituximab based therapy
- DLBCL patients had a median of 4 prior therapies, and 4 of 6 were of non-GCB subtype

#### ***Poster Presentation: KI intolerance study: A phase 2 study to assess the safety and efficacy of TGR-1202 in pts with chronic lymphocytic leukemia (CLL) who are intolerant to prior BTK or PI3K-delta inhibitor therapy (Abstract: TPS7569)***

This poster details the study design for an ongoing Phase II, multicenter, single-arm trial of TGR-1202 (umbralisib) in CLL patients requiring therapy who are intolerant to prior Kinase Inhibitor (KI) therapy. The study will enroll approximately 50 patients who have discontinued prior therapy with a BTK or PI3K delta inhibitor due to intolerance and not disease progression. The primary objective of the study is to determine the progression free survival (PFS) of TGR-1202 in this patient population. Key secondary objectives such as overall response rate, duration of response, time to treatment failure and safety of TGR-1202 as compared to the prior KI therapy will also be evaluated.

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