TG THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

Filed 05/24/17 for the Period Ending 05/23/17

Address	2 GANSEVOORT STREET, 9TH FLOOR NEW YORK, NY 10014
Telephone	(212) 554-4484
CIK	0001001316
Symbol	TGTX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): **May 23, 2017**

TG Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-32639**	**36-3898269**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2 Gansevoort Street, 9 th 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. ☐

Item 8.01. Other Events.

On May 23, 2017, TG Therapeutics, Inc. (the "Company") issued a press release announcing that the independent Data Safety Monitoring Board (DSMB) of the UNITY-CLL Phase 3 trial has successfully completed a pre-specified interim analysis to assess the contribution of TG-1101 (ublituximab) and TGR-1202 in the combination regimen of TG-1101 plus TGR-1202. A copy of the press release is being filed as Exhibit 99.1 and incorporated in this Item by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

99.1 Press Release, dated May 23, 2017.

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: May 24, 2017

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1.	Press Release, dated May 23, 2017

TG Therapeutics, Inc. Announces Successful Outcome from Pre-Planned Interim Analysis by Independent DSMB in the UNITY-CLL Phase 3 Trial

Contribution of single agents in the combination regimen successfully established pursuant to the UNITY-CLL Special Protocol Assessment; DSMB recommends no further enrollment to single agent arms

DSMB reviewed updated safety data from more than 270 patients, finding no safety concerns and recommended continuation of enrollment without modification

Target timeline to complete enrollment updated to by Year-End 2017

New York, NY, (**May 23, 2017**) TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that the independent Data Safety Monitoring Board (DSMB) of the UNITY-CLL Phase 3 trial has successfully completed a pre-specified interim analysis to assess the contribution of TG-1101 (ublituximab) and TGR-1202 in the combination regimen of TG-1101 plus TGR-1202. In conducting the analysis, the DSMB reviewed efficacy data from approximately 50 patients per arm in the UNITY-CLL study who were eligible for at least one response evaluation. Based on the overall response rate data available, and in accordance with the statistical analysis plan in the study's Special Protocol Assessment (SPA), the DSMB determined that contribution has been established and recommended the Company cease enrollment into the single agent arms. Accordingly, the study will now continue enrollment in a 1:1 ratio to only the two combination arms: the investigational arm of TG-1101 (ublituximab) plus TGR-1202 and the control arm of obinutuzumab plus chlorambucil. Additionally, the DSMB reviewed safety data from all patients on study (n>270) as of the data cut-off date, including patients with both treatment naive and relapsed/refractory Chronic Lymphocytic Leukemia (CLL), and again identified no safety concerns in any treatment group (treatment naïve or previously treated) and recommended the continuation of the study without modification.

"We are extremely pleased that the DSMB has once again found no safety concerns that would require modifying the study. This is particularly comforting when we consider that the safety population now includes over 60 front-line CLL patients treated for more than 6 weeks with TGR-1202 alone or in combination with TG-1101. As most who have followed this area will recall, treatment naïve CLL patients appear to be exquisitely sensitive to the autoimmune mediated side effects of idelalisib, with approximately 50% experiencing Grade 3/4 liver toxicity by week 6 in a published study," stated Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer. Mr. Weiss continued, "We are also very pleased that, in accordance with our SPA, the DSMB has determined that contribution has been adequately demonstrated, enabling us to eliminate the single agent arms from continued enrollment. We are also excited to report that we continue to see strong interest in the study and enrollment remains robust. We continue to view the demand for this study as a strong indication of the need for alternative treatments for patients with CLL, even in the front-line setting. Given the current rate of enrollment, we are now targeting complete enrollment by year end, ahead of our previous guidance, which would put us in a position to report pivotal Overall Response Rate (ORR) data in the third quarter of 2018."

ABOUT UNITY-CLL PHASE 3 TRIAL

UNITY-CLL is a Global Phase 3 randomized controlled clinical trial in patients with Chronic Lymphocytic Leukemia (CLL) that includes two key objectives: first, to demonstrate contribution of each agent in the TG-1101 + TGR-1202 regimen, and second, to demonstrate superiority in Progression Free Survival (PFS) over the standard of care to support the submission for full approval of the combination. In addition, upon completion of enrollment, this trial will evaluate Overall Response Rate (ORR) for accelerated approval. The study initially randomized patients into four treatment arms: TG-1101 plus TGR-1202, TG-1101 single agent, TGR-1202 agent, and an active control arm of obinutuzumab plus chlorambucil. Pursuant to the Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA), an early interim analysis was conducted to assess contribution of each single agent which, upon success, allowed for early termination of both single agent arms.

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, 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: our ability to successfully and cost effectively enroll and complete the UNITY-CLL trial on-time or at all or deliver pivotal data on schedule; the risk that early clinical trial results, that may have influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies; the risk that safety and/or efficacy data from the interim analyses from the UNITY-CLL trial will not be consistent with the final results and/or that the data will not support regulatory approval; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303, and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination treatment option for any indication. 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 . The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

TGTX - G

CONTACT:

Jenna Bosco
Vice President, Investor Relations
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com