TG THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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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): **August 10, 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 August 10, 2017, TG Therapeutics, Inc. (the "Company") issued a press release announcing that the independent Data Safety Monitoring Board (DSMB) of the UNITY-NHL Phase 2b registration directed trial has successfully completed the first pre-specified interim analysis to evaluate the Overall Response Rate (ORR) in the cohort enrolling patients with relapsed or refractory Diffuse Large B-cell Lymphoma (DLBCL) that are not eligible for high-dose chemotherapy or transplant. 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 August 10, 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: August 10, 2017

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated August 10, 2017.

TG Therapeutics, Inc. Announces Successful Outcome from the First Pre-Planned Interim Analysis by Independent DSMB of the DLBCL Cohort in the UNITY-NHL Phase 2b Trial

Based on pre-set hurdles of Overall Response Rate (ORR) the DSMB recommends continued enrollment in the TGR-1202 + TG-1101 ("U2") arm and no further enrollment into the single agent TGR-1202 arm

As set forth in the protocol, single agent TGR-1202 arm will be replaced with the triple combination of TG-1101, TGR-1202 and bendamustine

New York, NY, (**August 10, 2017**) TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that the independent Data Safety Monitoring Board (DSMB) of the UNITY-NHL Phase 2b registration directed trial has successfully completed the first pre-specified interim analysis to evaluate the Overall Response Rate (ORR) in the cohort enrolling patients with relapsed or refractory Diffuse Large B-cell Lymphoma (DLBCL) that are not eligible for high-dose chemotherapy or transplant. Upon review of the available ORR data, based on pre-specified efficacy thresholds of ORR, the DSMB recommended the Company cease enrollment into the single agent TGR-1202 arm, while continuing enrollment into the TG-1101 + TGR-1202 arm which has demonstrated an acceptable level of efficacy to warrant continued evaluation. Per the UNITY-NHL protocol, the single agent TGR-1202 arm will be replaced by an arm evaluating the triple combination arm of TG-1101, TGR-1202, and bendamustine.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "The DLBCL cohort in our UNITY-NHL trial was designed to evaluate the contribution of TGR-1202 in our combination 'U2' regimen. We are extremely pleased that the DSMB has recommended continued enrollment in the U2 arm, while allowing us to proceed with replacing the single agent TGR-1202 arm with the triple combination of TG-1101, TGR-1202, and bendamustine (also referred to as U2 + Benda) as planned. As recently presented, the triplet combination of U2 + Benda was highly active, with a 50% ORR in patients with refractory DLBCL and a 100% ORR in relapsed DLBCL patients. We have long believed that patients with aggressive DLBCL in particular are best treated with combination therapy rather than single agents and are pleased to see our UNITY-NHL study advancing to the next level."

ABOUT UNITY-NHL PHASE 2b TRIAL

UNITY-NHL is a global Phase 2bclinical trial evaluating TG-1101 and TGR-1202, ("U2"), in patients with various types of B-cell lymphoma. The trial consists of three independent cohorts enrolling patients with relapsed or refractory Diffuse Large B-cell Lymphoma (DLBCL), Follicular Lymphoma (FL), Small Lymphocytic Lymphoma (SLL), and Marginal Zone Lymphoma (MZL). The study is evaluating the U2 combination and the combination of U2 + bendamustine in patients with DLBCL; TGR-1202 monotherapy and in the U2 combination in patients with FL and SLL; and TGR-1202 monotherapy in patients with MZL.

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: our ability to successfully and cost effectively enroll and complete the UNITY-NHL trial on-time or at all or deliver 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 DLBCL cohort of the UNITY-NHL trial will not be consistent with the final results and/or that the final data will not support regulatory approval; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 or “U2”, 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.

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