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 5, 2020**

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, 9th 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.

Securities filed pursuant to Section 12(b) of the Act:

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	TGTX	Nasdaq Capital Market

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 5, 2020, TG Therapeutics, Inc. issued a press release announcing positive topline data from the UNITY-CLL Phase 3 study evaluating the combination of umbralisib and ublituximab (U2) for the treatment of patients with chronic lymphocytic leukemia. 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.

Exhibit No.	Description
99.1	Press Release, dated May 5, 2020.
Exhibit 104	The cover page from this Current Report on Form 8-K formatted in Inline XBRL

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 5, 2020

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

Exhibit 99.1

TG Therapeutics Announces Positive Topline Results from the UNITY-CLL Phase 3 Study Evaluating the Combination of Umbralisib and Ublituximab (U2) for the Treatment of Patients with Chronic Lymphocytic Leukemia

UNITY-CLL trial met the primary endpoint of improved progression-free survival (PFS) (p<.0001) and will be stopped early for superior efficacy observed at the interim analysis

PFS benefit seen across both previously untreated and relapsed/refractory patient populations

Regulatory submission and full data presentation targeted by year-end 2020

Conference call to be held today, Tuesday, May 5, 2020 at 8:30 AM ET

New York, NY, (**May 5, 2020**) TG Therapeutics, Inc. (NASDAQ: TGTX), today announced positive topline results from the global UNITY-CLL Phase 3 trial evaluating the combination of umbralisib plus ublituximab (U2) compared to obinutuzumab plus chlorambucil in patients with previously untreated and relapsed/refractory chronic lymphocytic leukemia (CLL). The trial met its primary endpoint at a prespecified interim analysis demonstrating a statistically significant improvement in progression-free survival (PFS) (p<.0001), and will be stopped early for superior efficacy. PFS was assessed by an Independent Review Committee (IRC), and benefit was also seen across both previously untreated and relapsed/refractory patient populations. The UNITY-CLL Phase 3 trial is being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

An independent data safety monitoring board (DSMB) conducted the interim analysis and made the recommendation to stop the trial early based on the positive results. Secondary endpoints, including safety, were not reviewed by the DSMB at this meeting. Data from this study is intended to support a regulatory submission targeted by year-end 2020 for U2 in both previously untreated and relapsed/refractory CLL patients and will be submitted for presentation at a future medical conference.

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, “We could not be more excited to share the positive topline results. As a company we have been focused on developing the best possible treatments, including novel combinations for individuals with B-cell diseases, and today’s announcement truly marks the culmination of years of hard work and a major step forward in our mission. This outcome sets the stage for the potential approval of U2 as a novel, chemotherapy-free, treatment regimen for patients with CLL, whether they have relapsed from or are refractory to a prior therapy or have never been treated before.” Mr. Weiss continued, “We are extremely pleased with the performance of U2 in this study and very happy we were able to stop the study at this interim analysis due to the superior efficacy observed. We want to thank the patients, their families, and the doctors and research teams who participated in this trial, as well as our extraordinary team at TG who made this study a success. We look forward to submitting this data to the FDA and presenting the full results at a major medical meeting targeted by year-end 2020.”

John Gribben, MD, DSc, FRCP, FRCPath, FMed Sci, Professor of Medical Oncology, Barts Cancer Institute, London, UK, and Global Study Chair for the UNITY-CLL study stated, "It’s extremely gratifying to see positive results for this important trial exploring the combination of umbralisib and ublituximab in patients with both front-line and relapsed/refractory CLL. Today’s outcome marks the first successful Phase 3 trial of a PI3K delta-based regimen in a CLL patient population that included previously untreated patients.” Dr. Gribben continued, “CLL remains incurable and new treatment options are still very much needed, particularly those that provide a differentiated mechanism and safety profile from our currently available treatment options.”

ABOUT UNITY-CLL PHASE 3 TRIAL
UNITY-CLL is a global Phase 3 randomized controlled clinical trial comparing the combination of ublituximab plus umbralisib, or U2, to an active control arm of obinutuzumab plus chlorambucil in patients with both treatment-naïve and relapsed or refractory chronic lymphocytic leukemia (CLL). The trial randomized patients into four treatment arms: ublituximab single agent, umbralisib single agent, ublituximab plus umbralisib and an active control arm of obinutuzumab plus chlorambucil. A prespecified analysis was conducted to assess the contribution of ublituximab and umbralisib in the U2 combination arm and allowed for the termination of the single agent arms. Accordingly, the UNITY-CLL Phase 3 trial continued enrollment in a 1:1 ratio into the two combination arms: the investigational arm of U2 and the control arm of obinutuzumab plus chlorambucil. Full enrollment into the UNITY-CLL Phase 3 trial completed in October of 2017 with approximately 420 subjects enrolled to the two combinations arms. This trial enrolled approximately 60% treatment-naïve CLL patients and 40% relapsed or refractory CLL patients. The primary endpoint for this study was superior Progression Free Survival (PFS) for the U2 combination compared to the control arm to support the submission for full approval of the U2 combination in CLL. The UNITY-CLL Phase 3 trial is being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA).

CONFERENCE CALL INFORMATION
The Company will host a conference call today, Tuesday, May 5, 2020 at 8:30 AM ET to discuss the UNITY-CLL Phase 3 Trial. In order to participate in the conference call, please call 1-877-407-8029 (U.S.), 1-201-689-8029 (outside the U.S.), Conference Title: TG Therapeutics.

A live webcast of this presentation will be available on the Events page, located within the Investors & Media section, of the Company's website at www.tgtherapeutics.com. An audio recording of the conference call will also be available for replay at www.tgtherapeutics.com, for a period of 30 days after the call.

ABOUT CHRONIC LYMPHOCYTIC LEUKEMIA
Chronic lymphocytic leukemia (CLL) is the most common type of adult leukemia, and in 2020 it is estimated there will be more than 20,000 new cases of CLL diagnosed in the United States[1]. Although signs of CLL may disappear for a period of time after initial treatment, the disease is considered incurable and many people will require additional treatment due to the return of malignant cells.

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 multiple 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 oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon, which may lead to a differentiated safety profile. 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 into Phase 1 clinical development its anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), its covalently-bound Bruton’s Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801. TG Therapeutics is headquartered in New York City.

Cautionary Statement

This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. 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. These forward-looking statements include, but may not be limited to, statements anticipating the intended activities with respect to the UNITY-CLL trial following the interim analysis, expected timelines for regulatory submissions and publications of the data from UNITY-CLL, and potential regulatory approvals that may result from regulatory submissions. These forward-looking statements are subject to a number of risks and uncertainties that could cause our actual results to differ materially, including: our ability to successfully deliver the complete data set from the UNITY-CLL trial on schedule as planned; the risk that safety issues or trends will be observed in the UNITY-CLL study when the full safety dataset is available or from any other on-going studies that prevent approval of either ublituximab and/or umbralisib; the risk that the safety and efficacy profile observed in the UNITY-CLL study is not supportive of a differentiated profile; the risk that the UNITY-CLL trial, or any of our other registration-directed clinical trials as designed or amended may not be sufficient or acceptable to support regulatory submission or approval; our ability to achieve the milestones we project, including the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones; our ability to manage our cash in line with our projections and meet our development milestones or continue our operations without raising capital; the risk that we are unable to raise capital on acceptable terms; 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. 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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[1] Cancer Stat Facts: Leukemia – Chronic Lymphocytic Leukemia
https://seer.cancer.gov/statfacts/html/clyl.html