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): **December 7, 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 (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 December 7, 2020, TG Therapeutics, Inc. (the "Company") issued a press release announcing two triple therapy combination data presentations. The first evaluated the investigational combination of umbralisib plus ublituximab (U2) plus venetoclax in patients with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL); and the second evaluated the investigational combination of U2 plus TG-1701, the Company's once daily, oral, BTK inhibitor, in patients with R/R CLL or B-cell lymphoma.. On December 7, 2020, the Company also announced the presentation of data from the UNITY-CLL Phase 3 trial evaluating the investigational combination of umbralisib and ublituximab (U2) in patients with chronic lymphocytic leukemia (CLL) and the UNITY-NHL Phase 2b trial evaluating single agent umbralisib in patients with relapsed or refractory marginal zone lymphoma (MZL), small lymphocytic lymphoma (SLL) and follicular lymphoma (FL). Both press releases summarized data presented during the 62nd American Society of Hematology (ASH) annual meeting and exposition. Copies of the press releases are being filed as Exhibit 99.1 and Exhibit 99.2 and incorporated in this Item by reference.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated December 7, 2020.
99.2	Press Release, dated December 7, 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: December 8, 2020

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

Exhibit 99.1

TG Therapeutics Announces Triple Combination Data Presentations at the at the 62nd American Society of Hematology Annual Meeting

U2 + Venetoclax: 100% ORR at cycle 12 (n=27), including 41% CR rate, and 96% of patients achieving undetectable MRD in the peripheral blood and 77% achieving undetectable MRD in bone marrow

U2 + TG-1701 (BTKi): Dose escalation cohort (n=14) resulted in 79% ORR, with 22% CR rate, including 100% ORR in patients WM, CLL, MZL and DLBCL (n=7)

NEW YORK, NY (December 7, 2020) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced two triple therapy combination data presentations. The first evaluated the investigational combination of umbralisib plus ublituximab (U2) plus venetoclax in patients with relapsed or refractory (R/R) chronic lymphocytic leukemia (CLL); and the second evaluated the investigational combination of U2 plus TG-1701, the Company's once daily, oral, BTK inhibitor, in patients with R/R CLL or B-cell lymphoma. Data from these trials were presented at the 62nd American Society of Hematology (ASH) annual meeting and exposition. Presentation highlights are included below.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased by the triple therapy data presented today demonstrating the potential of U2 with both venetoclax and our BTK inhibitor, TG-1701." Mr. Weiss continued, "Our mission continues to be to drive toward better outcomes for patients with B-cell malignancies by developing multi-drug combinations. We believe the data with these triple combinations highlights our approach of leveraging our portfolio and standard of care therapies to build on the U2 backbone with the goal of creating potentially best in class treatments for patients in need."

PRESENTATION HIGHLIGHTS:

Poster Presentation Title: A Phase 1/2 Study of Umbralisib, Ublituximab, and Venetoclax (U2-Ven) in Patients with Relapsed or Refractory Chronic Lymphocytic Leukemia (CLL)

- Regimen was administered with 3 cycles of U2 as induction in cycles 1 through 3, U2 plus venetoclax in cycles 4, 5 and 6, followed by umbralisib plus venetoclax in cycles 7 through 12 in patients with R/R CLL. Patients with centrally confirmed undetectable minimal residual disease (uMRD) in the bone marrow after cycle 12 were permitted to stop all therapy, while MRD detectable patients continued on single agent umbralisib.
- 43 patients have been treated as of the data cutoff with 58% of patients previously exposed to a BTK inhibitor
- Among evaluable patients, ORR was 77% (30/39) after cycle 3 (U2 only), 100% (31/31) after cycle 7, and 100% (27/27) after cycle 12
- Among the 27 patients who finished 12 cycles of therapy:
  - 41% achieved Complete Response (CR) by iwCLL criteria
  - 96% achieved undetectable MRD in the peripheral blood
  - 77% achieved undetectable MRD in the bone marrow
- At a median follow up of 15.6 months (n=43), only 1 patient has progressed 10 months after stopping treatment
- Grade 3/4 adverse events occurring in $\geq$ 5% of patients were neutropenia (21%), leukopenia (12%), infusion related reactions (7%), anemia (5%), and diarrhea (5%). No TLS events were observed during venetoclax administration, with one TLS event occurring prior to venetoclax administration.

<u>Poster Presentation Title</u>: Clinical Activity of TG-1701, As Monotherapy and in Combination with Ublituximab and Umbralisib (U2), in Patients with B-Cell Malignancies

- A total of 102 patients with R/R CLL or b-cell lymphoma have been treated with TG-1701, with patients receiving monotherapy in the dose-escalation cohort (n=25) or in the 200 mg dose-expansion cohort (n=61), or TG-1701 in combination with U2 in the dose escalation cohort (n=16)
- TG-1701 monotherapy was well tolerated and the maximum tolerated dose was not reached up through 400 mg QD
- Grade 3/4 adverse events (AE) occurring in >10% of patients treated with TG-1701 monotherapy were limited and included ALT increase (12%), all of which were patients treated with 400 mg QD. At the target single-agent Phase 2 dose of 200mg (QD) (n=61), AEs of special interest included Grade 3 hypertension (1.6%), atrial fibrillation (1.6%), and no instances of major bleeding observed. Grade 3/4 AEs occurring in >10% of patients treated with U2+1701 were ALT increase (25%), AST increase (19%) and neutropenia (12%).
- At a median follow up of 7 months in the 200 mg QD monotherapy expansion cohorts, preliminary overall response rates (ORR) were: 95% (19/20) in CLL, 50% (6/12) in mantle cell lymphoma (MCL), and 95% (18/19) in Waldenstrom macroglobulinemia (WM)
- At a median follow up of 12 months, the 1701+U2 dose escalation (using doses of 100mg to 300 mg QD of TG-1701) resulted in 79% ORR, with 22% CR rate across patients with WM, CLL, marginal zone lymphoma (MZL), diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) (n=14)

Data presented at ASH 2020 will be available on the Publications page of the Company's website at https://www.tgtherapeutics.com/publications/.

<u>CONFERENCE CALL REPLAY INFORMATION</u>

The Company hosted a conference call on November 5, 2020, with leading investigators from the UNITY-NHL and UNITY-CLL trials to discuss the data included in the ASH 2020 abstracts. A recording of the conference call is available for replay at https://ir.tgtherapeutics.com/events.

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 in late stage clinical development with two investigational compounds, ublituximab and umbralisib, the combination of which is referred to as "U2", targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a glycoengineered monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. Umbralisib (TGR-1202) is an oral, once-daily dual inhibitor of PI3K-delta and CK1-epsilon. Umbralisib is currently under review by the U.S. Food and Drug Administration (FDA) for accelerated approval as a treatment for patients with previously treated marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 based regimen or follicular lymphoma (FL) who have received at least two prior systemic therapies. The Company also has a fully enrolled Phase 3 clinical trial evaluating U2 in patients with treatment naïve and relapsed/refractory chronic lymphocytic leukemia (CLL), and two fully enrolled identical Phase 3 trials evaluating ublituximab monotherapy in patients with relapsing forms of multiple sclerosis (RMS). 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 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 include the following: the risk that we will not be able to meet the clinical trial or regulatory submission timelines that we project or achieve other anticipated milestones, including the risk that interim, top-line, or other 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 final data sets or in future studies; the risk that the safety profile observed with umbralisib, ublituximab or TG-1701, or combinations thereof, may change as additional patients are exposed for longer durations; the risk that the U2 combination will not prove to be a safe and efficacious combination, or backbone for triple therapy combinations, including with venetoclax and TG-1701; and the risk that the evolving and unpredictable COVID-19 pandemic delays achievement of those milestones. 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.

CONTACT:

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Corporate Communications
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Exhibit 99.2

TG Therapeutics Announces Pivotal Data from the UNITY-CLL and UNITY-NHL Clinical Trials Presented at the 62nd American Society of Hematology Annual Meeting

UNITY-CLL: U2 significantly improved progression-free survival over obinutuzumab plus chlorambucil (HR=0.54, p<0.0001) as well as ORR (p<0.001) in patients with CLL; with consistent PFS improvement across treatment naïve CLL (HR=0.48) and relapsed/refractory CLL (HR=0.60)

UNITY-NHL: Umbralisib monotherapy demonstrated ORR of 49.3% in patients with relapsed/refractory MZL and 45.3% in relapsed/refractory FL patients

Umbralisib monotherapy and the U2 combination exhibited a manageable safety profile with low incidence of immune-mediated toxicities and AE-related discontinuations

NEW YORK, NY (December 7, 2020) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced the presentation of data from the UNITY-CLL Phase 3 trial evaluating the investigational combination of umbralisib and ublituximab (U2) in patients with chronic lymphocytic leukemia (CLL) and the UNITY-NHL Phase 2b trial evaluating single agent umbralisib in patients with relapsed or refractory marginal zone lymphoma (MZL), small lymphocytic lymphoma (SLL) and follicular lymphoma (FL), at 62nd American Society of Hematology (ASH) annual meeting and exposition. Presentation highlights are included below.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased by the pivotal data presented today for our two lead hematology programs, the UNITY-NHL and the UNITY-CLL trials. We believe these data showcase the differentiated profile of umbralisib as a dual PI3K-delta/CK1-epsilon inhibitor and the potential of the U2 regimen in CLL." Mr. Weiss continued, "The UNITY-NHL data presented today supported our current NDA for umbralisib monotherapy, and we continue to work towards our PDUFA goal date of February 15, 2021 for MZL and June 15, 2021 for FL. Additionally, we plan to complete our BLA/NDA submission for the U2 combination in CLL in the first half of 2021."

Speaking to the UNITY-CLL data presented, John Gribben, MD, DSc, Professor of Medical Oncology at St Bartholomew's Hospital, Barts Cancer Institute, Queen Mary, University of London, and Global Study Chair for the UNITY-CLL Phase 3 trial stated, "Despite recent advances, CLL remains an incurable disease and new treatment options are still very much needed for both relapsed or refractory and treatment naïve patients. The data presented today highlight the first successful Phase 3 trial evaluating a PI3K-delta inhibitor in treatment naïve CLL, a setting where previous PI3K inhibitors have not been able to be safely administered." Dr. Gribben continued, "The successful outcome of the UNITY-CLL trial therefore introduces a novel mechanism of action for treatment naïve CLL patients, and if approved, I believe the U2 combination will be a valuable addition to our armamentarium of treatment options for patients with CLL."

Speaking to the UNITY-NHL data presented, Pier Luigi Zinzani, MD, PhD, Professor, Institute of Hematology, "L. e A. Seràgnoli", University of Bologna, and Global Chair of the UNITY-NHL study stated, "The data presented today demonstrate that umbralisib was active and generally well tolerated in patients with heavily pre-treated indolent non-Hodgkin lymphoma. Patients with advanced relapsed follicular or marginal zone lymphoma have limited treatment options. Umbralisib produced durable responses with a manageable safety profile, and low rates of adverse event related discontinuations. Of particular importance is the depth of response achieved in relapsed or refractory MZL, where no patients who achieved a CR have progressed to date at a median follow-up of over two years."

PRESENTATION HIGHLIGHTS:

Oral Presentation Title: Umbralisib Plus Ublituximab (U2) Is Superior to Obinutuzumab Plus Chlorambucil (O+Chl) in Patients with Treatment Naïve (TN) and Relapsed/Refractory (R/R) Chronic Lymphocytic Leukemia (CLL): Results from the Phase 3 UNITY-CLL Study

- 421 patients were randomized to the U2 (n=210) or O+Chl (n=211) arms; 57% of patients were treatment-naïve and 43% had relapsed/refractory (R/R) CLL
- At a median follow-up of 36.7 months, U2 significantly prolonged independent review committee (IRC) assessed progression-free survival (PFS) vs O+Chl (median 31.9 months vs 17.9 months; hazard ratio 0.546 ($p<0.0001$))
- PFS improvement with U2 vs O+Chl was consistent across all subgroups examined including treatment naïve patients (median 38.5 months vs 26.1 months, hazard ratio 0.482) and relapsed/refractory patients (median 19.5 months vs 12.9 months, hazard ratio 0.601)
- Overall response rate (ORR) was significantly higher with U2 compared to O+Chl (83.3% vs 68.7%; $p<0.001$)
- For the U2 arm, at a median treatment exposure of 21 months, most adverse events (AEs) were Grade 1 or 2 in severity and were relatively balanced between the treatment naïve and previously treated populations
- Grade 3/4 Adverse Events (AEs) of clinical interest (U2 vs O+Chl) included elevated ALT (8.3% vs 1.0%), elevated AST (5.3% vs 2.0%), non-infectious colitis (1.9% vs 0%), infectious colitis (0.5% vs 0.5%), pneumonitis (0.5% vs 0%), rash (2.4% vs 0.5%), and opportunistic infections (5.8% vs. 1.5%)

Poster Presentation Title: Umbralisib, the Once Daily Dual Inhibitor of PI3Kδ and Casein Kinase-1ε Demonstrates Clinical Activity in Patients with Relapsed or Refractory Indolent Non-Hodgkin Lymphoma: Results from the Phase 2 Global UNITY-NHL Trial

- A total of 208 patients with iNHL received at least 1 dose of umbralisib, including 69 marginal zone lymphoma (MZL), 117 follicular lymphoma (FL), and 22 small lymphocytic lymphoma (SLL) patients
- MZL patients were relapsed/refractory to $\geq$1 prior lines of treatment, including an anti-CD20. At a median follow up of 27.8 months, the following was observed:
    - 49.3% ORR with 16% Complete response (CR) rate (independent review committee (IRC) assessed)
    - Median PFS was not reached, no patients who achieved a CR have experienced disease progression to date
- FL patients were relapsed or refractory to $\geq$2 prior lines, including an anti-CD20 and an alkylating agent. At a median follow up of 27.5 months the following was observed:
    - 45.3% ORR with 5.1% achieving a CR (IRC-assessed)
    - Median PFS was 10.6 months
- Grade 3/4 AEs in $\geq$5% of patients included neutropenia (11.5%), diarrhea (10.1%), increased ALT (6.7%), and increased AST (7.2%). Other AEs of clinical interest included opportunistic infections (Grade3/4, 3.4%), rash (Grade 3/4, 1.9%), pneumonitis (Grade 3/4 1.0%) and non-infectious colitis (all Grades 1.9%, of which 3 of 4 patients resolved and remained on umbralisib)

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