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 8, 2019**

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.

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock, par value $0.001	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 8, 2019, TG Therapeutics, Inc. (the "Company") issued a press release announcing data from the Phase 1/2 study of the triple combination of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with umbralisib (TGR-1202), the Company's oral, dual inhibitor of PI3K delta and CK1 epsilon, and venetoclax, in patients with relapsed/refractory chronic lymphocytic leukemia (CLL). On December 9, 2019, the Company also announced Phase 1 clinical data for TG-1701, the Company's covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, in patients with relapsed/refractory B-cell malignancies. Both press releases summarized data presented during the 61st 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.

(d) Exhibits.

99.1 Press Release, dated December 8, 2019.

99.2 Press Release, dated December 9, 2019.

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 9, 2019

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

Exhibit 99.1

TG Therapeutics Announces Oral Presentation of Umbralisib, Ublituximab and Venetoclax Triple Combination Phase I/II Data in Relapsed/Refractory CLL at the 61st American Society of Hematology Annual Meeting and Exposition

100% overall response rate (ORR) in relapsed/refractory CLL patients treated with U2 (umbralisib + ublituximab) plus venetoclax at cycle 7 (n=13)

100% of patients (n=9) achieved undetectable MRD in the peripheral blood after 12 months of therapy and 78% achieved undetectable MRD in bone marrow and have stopped all therapy

No patients have progressed to date

Investor and analyst event to be held on Monday, December 9, 2019 at 7:30 PM ET at the Hyatt Regency Orlando featuring a fireside chat with leading clinical investigators

NEW YORK, NY (December 8, 2019) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced triple therapy data from the Phase I/II study of ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with umbralisib (TGR-1202), the Company's oral, dual inhibitor of PI3K delta and CK1 epsilon, and venetoclax, in patients with relapsed/refractory chronic lymphocytic leukemia (CLL). Data from this trial were presented this morning during an oral session at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased to share the first data from the triple combination of U2 (umbralisib and ublituximab) and venetoclax, which we believe has the potential to offer patients with CLL a highly active, time-limited, and generally well tolerated treatment option. It was exciting to see that for those patients followed for at least 12 months at the time of the presentation, there was a 100% ORR, and all of those patients achieved MRD negativity in the peripheral blood, with 7 of those 9 patients also achieving MRD negativity in the bone marrow. We look forward to updating these data at future conferences as more patients are followed for 12 months and longer." Mr. Weiss continued, "We were also excited to see that 87% of patients responded to the U2 combination after just three months of treatment prior to the introduction of venetoclax. We believe this further demonstrates the activity of the U2 combination that is being studied in our UNITY-CLL Phase 3 trial, which we expect data from in the coming weeks or months."

Below are highlights from the oral presentation.

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

This oral presentation includes data from patients with relapsed or refractory CLL treated with the triple combination of ublituximab, umbralisib, and venetoclax. Twenty-seven patients were evaluable for safety and 23 were evaluable for efficacy. Data highlights include:

- *Regimen was administered with 3 cycles of U2 induction/debulking to reduce the risk of tumor lysis syndrome (TLS), followed by the combination of umbralisib and venetoclax starting in cycle 4. Patients who were bone marrow MRD negative after cycle 12 stopped all therapy.*

- *Overall response rate (ORR) of 87% (20/23) after U2 induction period at cycle 3, prior to introduction of venetoclax, in relapsed/refractory CLL patients, including patients refractory to ibrutinib*
- *U2 induction appeared to reduce venetoclax TLS risk, with no patients remaining as TLS high-risk following 3 cycles of U2*
- *13 patients treated for >7 cycles and 9 patients for ≥ 12 cycles:*
    - *100% ORR (13/13) after cycle 7 for the triple combination*
    - *100% ORR (9/9) including 44% Complete Response (CR) after cycle 12 for the combination*
    - *100% (9/9) of patients had undetectable minimal residual disease (MRD) (<0.01%) in peripheral blood after 12 cycles of therapy; and*
    - *78% (7/9) of patients who completed 12 cycles of therapy had undetectable MRD in bone marrow and have stopped therapy*
- *No patients (n = 27) have progressed to date with a median follow-up of 6.4 months*
- *Triple combination was generally well tolerated with no events of TLS observed*

An open-label, multicenter, Phase 2 study evaluating U2 plus venetoclax (ULTRA-V) in treatment naïve and previously treated CLL is now open for enrollment.

Remaining ASH Presentation Details

- Title: Phase 1 Study of TG-1701, a Selective Irreversible Inhibitor of Bruton's Tyrosine Kinase (BTK), in Patients with Relapsed/Refractory B-Cell Malignancies
    - Publication Number: 4001
    - Session: 623. Mantle Cell, Follicular, and Other Indolent B-Cell Lymphoma—Clinical Studies: Poster III
    - Date and Time: Monday, December 9, 2019; 6:00 PM - 8:00 PM ET
    - Location: Orange County Convention Center, Hall B
    - Presenter: Chan Cheah, MD, Sir Charles Gairdner Hospital, Hollywood Private Hospital, University of Western Australia, Blood Cancer Research Western Australia

Following the presentation, the data presented will be available on the Publications page of the Company's website at https://www.tgtherapeutics.com/publications/.

TG THERAPEUTICS INVESTOR & ANALYST EVENT

TG Therapeutics will host an event on Monday, December 9, 2019 beginning at 7:30 PM ET with a featured fireside chat beginning promptly at 8:00 PM ET. The event will take place at the Hyatt Regency Orlando, in the Plaza International Ballroom I. A live webcast will be available on the Events page, located within the Investors & Media section of the Company's website at http://ir.tgtherapeutics.com/events, 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 December 2019 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. 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 inhibitor of PI3K-delta. Umbralisib uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K-delta inhibitors. 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 its anti-PD-L1 monoclonal antibody, TG-1501, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, as well as its anti-CD47/CD19 bispecific antibody, TG-1801, into Phase 1 development. 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 complete preclinical and clinical trials; the risk that data from the UNITY-CLL Phase 3 trial will not be available in the planned timeframe or not be sufficient to support a regulatory filing; the risk that the highlighted 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 or in the final presentations; the risk that the combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2 and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination, or backbone for triple therapy combinations; the risk that the combination of U2 plus venetoclax will not prove to be a safe or efficacious treatment and will not warrant further testing; the risk that the combination of U2 plus venetoclax will not ultimately result in a time limited therapy; the risk that the combination of U2 plus venetoclax, if approved, will not be utilized broadly or at all by academic or community physicians;. 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
TG Therapeutics, Inc.
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Exhibit 99.2

TG Therapeutics Announces Phase I Data Presentation for TG-1701, a Once-Daily BTK Inhibitor, as a Single Agent and in Triple Combination with Ublituximab and Umbralisib (U2), at the 61st American Society of Hematology Annual Meeting and Exposition

Proprietary triplet of U2 plus TG-1701 (BTK inhibitor) induced 86% ORR (6 of 7) in patients with relapsed/refractory NHL and CLL at the lowest dose of TG-1701 tested

Single agent TG-1701 induced responses at multiple dose levels (including the lowest dose tested) across multiple B-cell diseases

TG-1701 demonstrates an encouraging safety profile to date, with dose escalation continuing for the combination with U2

Yesterday, TG announced positive early data from the combination of U2 plus venetoclax in an oral presentation at ASH (click here for PR)

Investor and analyst event to be held today, Monday, December 9, 2019 at 7:30 PM ET at the Hyatt Regency Orlando, featuring a fireside chat with leading clinical investigators

NEW YORK, NY (December 9, 2019) - TG Therapeutics, Inc. (NASDAQ: TGTX), today announced the first clinical data from the Company's once daily, oral, BTK inhibitor, TG-1701, as a single agent and as a triple therapy in combination with ublituximab (TG-1101), the Company's novel glycoengineered anti-CD20 monoclonal antibody, and umbralisib (TGR-1202), the Company's oral, dual inhibitor of PI3K delta and CK1 epsilon, in patients with relapsed/refractory non-Hodgkin's lymphoma (NHL) and chronic lymphocytic leukemia (CLL). Data from this Phase I trial are being presented this evening during a poster session at the 61st American Society of Hematology (ASH) Annual Meeting and Exposition.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, "We are highly encouraged by the first clinical data presented from our once daily, BTK inhibitor, TG-1701, which has demonstrated superior selectivity for BTK compared to ibrutinib in an *in vitro* whole kinome screening. The data presented today show that TG-1701 is an active BTK inhibitor as a single agent and that the combination of U2 plus TG-1701 has been generally well tolerated and active with 6 of 7 patients responding to the triple therapy at 100 mg QD, the lowest dose of TG-1701 tested. We look forward to continuing dose escalation of TG-1701 in the combination arm and identifying the optimal dose for this therapy." Mr. Weiss continued, "Our goal has always been to develop the best possible combination treatment options for patients, and we are excited to present the first data from a triple combination study in which all of the agents are being developed by TG. We believe this proprietary combination has the potential to enhance the results of BTK inhibitor therapy alone and offer patients early and deep responses with a tolerable safety profile."

Below are highlights from today's poster presentation.

Poster Presentation: Phase 1 Study of TG-1701, a Selective Irreversible Inhibitor of Bruton's Tyrosine Kinase (BTK), in Patients with Relapsed/Refractory B-Cell Malignancies

This presentation includes safety information from 30 patients, 21 patients treated with single agent TG-1701, and 9 patients treated with the triple combination of TG-1701 plus U2.

- *TG-1701, a once daily BTK inhibitor, demonstrates an encouraging safety profile to date, with clinical and pharmacodynamic activity at all dose levels evaluated*
- *30 patients have been treated with TG-1701 at doses that ranged from 100mg to 400mg once daily for TG-1701 monotherapy; dose escalation continues in the triple combination arm*
- *Single agent TG-1701 produced partial responses at multiple dose levels (including the lowest dose tested) across multiple B-cell diseases, including mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL), Waldenström's macroglobulinemia (WM), and small lymphocytic lymphoma (SLL)*
- *86% (6/7) of patients treated with 100 mg TG-1701 plus U2 have achieved a response*
    - *4 patients with follicular lymphoma (FL): 2 Complete Responses (CR), 1 Partial Response (PR) and 1 Stable Disease (SD)*
    - *1 PR in marginal zone lymphoma (MZL); 1 PR in Waldenström's macroglobulinemia (WM); and 1 PR in diffuse large B-cell lymphoma (DLBCL)*
- *All patients treated with the triple combination of TG-1701 plus U2 remain on study*

ASH Poster Presentation Details

- Title: Phase 1 Study of TG-1701, a Selective Irreversible Inhibitor of Bruton's Tyrosine Kinase (BTK), in Patients with Relapsed/Refractory B-Cell Malignancies
    - Publication Number: 4001
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    - Location: Orange County Convention Center, Hall B
    - Presenter: Chan Cheah, MD, Sir Charles Gairdner Hospital, Hollywood Private Hospital, University of Western Australia, Blood Cancer Research Western Australia

Below recaps highlights from yesterday's oral presentation of U2 plus venetoclax.

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

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