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): **April 1, 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.

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 April 1, 2019, TG Therapeutics, Inc. (the "Company") issued a press release announcing the presentation of positive interim data from its ongoing single-arm marginal zone lymphoma (MZL) cohort of its Phase 2b clinical trial known as UNITY-NHL, at the 2019 American Association of Cancer Research (AACR) Annual Meeting. 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 April 1, 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: April 1, 2019

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

Exhibit 99.1

TG Therapeutics Reports Positive Interim Data from UNITY-NHL Phase 2b Trial Evaluating Umbralisib Monotherapy in Patients with Marginal Zone Lymphoma at the 2019 AACR Annual Meeting

Overall response rate (ORR) of 52% (N=42), with complete response (CR) rate of 19%, by central independent review committee (IRC)

Responses were durable, with median duration of response (DOR) not reached at median 12.5 months follow-up, and all patients in complete response remain on study

Umbralisib was well tolerated with a safety profile that appeared to be maintained with prolonged exposure

Umbralisib previously granted Breakthrough Therapy Designation for the treatment of patients with relapsed/refractory MZL

Company to host conference call today, April 1, 2019 at 12:00pm (noon) ET, with Dr. Nathan Fowler of MD Anderson Cancer Center and Study Chair of the MZL cohort, to discuss the interim results

NEW YORK, NY, April 1, 2019 (GLOBE NEWSWIRE) – TG Therapeutics, Inc. (NASDAQ: TGTX) today reported positive interim data from the ongoing single-arm marginal zone lymphoma (MZL) cohort of its Phase 2b clinical trial known as UNITY-NHL. The MZL cohort of UNITY-NHL is designed to investigate umbralisib as a single agent in patients with relapsed or refractory MZL. Umbralisib is an investigational, oral, once daily PI3K delta inhibitor with unique inhibition of CK1 epsilon and is currently under development for the treatment of non-Hodgkin lymphoma (NHL) and chronic lymphocytic leukemia (CLL).

The interim data were reported this morning by Dr. Nathan Fowler, Associate Professor of Medicine and Director of Clinical Research in the Department of Lymphoma/Myeloma at the University of Texas MD Anderson Cancer Center and Study Chair of the UNITY-NHL MZL cohort, during this morning's official 2019 Press Program at the American Association of Cancer Research (AACR) Annual Meeting. Dr. Fowler will also present the data during an oral session this afternoon (details below).

Summary of Data Presented:

The MZL cohort of UNITY-NHL enrolled patients with relapsed or refractory MZL who had received prior treatment with one or more lines of therapy including at least one anti-CD20 regimen. In August 2018, the trial completed enrollment with 69 treated patients. The interim data reported today included safety and tolerability data on all 69 treated patients (safety population) and efficacy data on 42 patients who were enrolled at least 9 cycles (28 day cycles) prior to the data cut-off date (interim efficacy population). The primary endpoint is overall response rate (ORR) as assessed by IRC using criteria adopted from the International Working Group criteria for malignant lymphoma.

Efficacy

Analysis of the interim efficacy population (n=42) with a median follow-up of 12.5 months showed the following:

	Interim Efficacy Population (n=42)
Overall Response Rate by IRC (CR + PR), %	52%
Complete Response by IRC (CR), (%)	19%
Partial Response by IRC (PR), (%)	33%
Median duration of response, months	NR (95% CI: 8.4 – NE)

CI = confidence interval; NR = not reached; NE = not estimable; SD = stable disease

Additional Efficacy Highlights:

- 88% clinical benefit rate by IRC (defined as patients obtaining Complete Response + Partial Response + Stable Disease)
- All patients achieving a Complete Response by IRC remain on study (range: 10.1+ to 15.7+ months)
- 86% of patients had a reduction in tumor burden
- Median time to initial response was 2.7 months
- Kaplan-Meier (KM) estimate of progression-free survival (PFS) at 12 months was 66%, with the median PFS not reached

Safety

Interim safety data were presented for all 69 treated patients with a median duration of exposure of 6.9 months. No unexpected toxicities were observed. The most common adverse events were diarrhea, nausea, and fatigue, with the majority of events Grade 1 in severity. The most frequent grade 3 or higher adverse events were neutropenia, diarrhea and ALT/AST increase, observed in 13%, 10% and 10% of patients, respectively.

A subgroup analysis of patients treated for greater than 6 cycles (n=41) was also conducted to evaluate long-term incidence of key toxicities of interest occurring after 6 cycles of treatment. Median duration of treatment of this subgroup was 10.1 months (range: 5.6 – 19.1 months). In this subgroup, grade 3 or higher adverse events of interest were rare, limited to 2 patients with diarrhea and 1 patient with pneumonitis, with no events of ALT/AST elevation, pneumonia, or colitis.

Key Safety Findings (n=69):

- No events of colitis were reported and only 1 event of Grade 3 pneumonitis was reported
- Grade 3 infections were limited, occurring in 3 patients (bronchitis, pneumonia, and influenza)
- Discontinuations due to umbralisib-related AEs were limited (14%) with no discontinuations after 6 months due to a treatment-related AE
- No deaths occurred on study

Dr. Nathan Fowler, Associate Professor of Medicine and Director of Clinical Research in the Department of Lymphoma/Myeloma at The University of Texas MD Anderson Cancer Center and the Study Chair of the UNITY-NHL MZL cohort, stated, “MZL remains an incurable disease with few treatment options for patients who relapse after first-line chemoimmunotherapy. The exciting results presented today suggest that this oral targeted therapeutic has significant activity against relapsed/refractory marginal zone lymphoma and offers hope for patients.” Dr. Fowler continued, “The adverse event and clinical activity data are highly encouraging at this point and we are excited to continue following patients for a longer time. With the results reported thus far, umbralisib has the potential to make a real difference for patients with relapsed/refractory marginal zone lymphoma.”

Michael S. Weiss, Executive Chairman and Chief Executive Officer of TG Therapeutics stated, "We are very excited about these interim data and believe the results today demonstrate the activity and differentiated safety and tolerability profile of umbralisib at our Phase 3 dose of 800 mg once per day.” Mr. Weiss continued, “As announced previously, the efficacy for the entire population has already reached our target range of 40-50% ORR and we look forward to presenting the final data from the entire MZL cohort later this year when all patients have had the opportunity to be followed for at least 9 cycles. In addition, we look forward to discussing the results with the FDA with a goal of filing for accelerated approval by year end.”

CONFERENCE CALL INFORMATION

The Company will host a conference call today, Monday April 1, 2019, at 12:00pm (noon) ET. Michael S. Weiss, Chief Executive Officer of TG Therapeutics, will host the call and Dr. Nathan Fowler, Associate Professor of Medicine and Director of Clinical Research in the Department of Lymphoma/Myeloma at The University of Texas MD Anderson Cancer Center in Houston and Study Chair of the MZL cohort, will review the UNITY-NHL interim MZL data.

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 AACR Update Call.

A live webcast and accompanying slides will be available on the Events page, located within the Investors & Media section, of the Company's website at http://ir.tgtherapeutics.com/events. 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.

2019 AACR ORAL PRESENTATION DETAILS

- **Title:** Umbralisib monotherapy demonstrates efficacy and safety in patients with relapsed/refractory marginal zone lymphoma: A multicenter, open-label, registration directed Phase II study
  - **Session Date and Time:** Monday April 1, 2019 3:00 PM - 5:00 PM ET
  - **Presentation Time:** 4:20 PM ET
  - **Session Title:** The Next Generation of Clinical Trials in Molecularly-driven Therapy
  - **Session Location:** Marcus Auditorium- Bldg A-GWCC
  - **Presenter:** Nathan Fowler, MD, Associate Professor, Department of Lymphoma/Myeloma, The University of Texas MD Anderson Cancer Center, Houston, TX
  - **Abstract Number:** 7821

The full text of the abstract is now available and can be accessed via the AACR meeting website at www.aacr.org. The slides to be presented in this afternoon’s oral presentation are available on the Company’s corporate website at www.tgtherapeutics.com/publications.cfm.

ABOUT THE UNITY-NHL PHASE 2b STUDY—Marginal Zone Lymphoma Cohort

The multicenter, open-label, UNITY-NHL Phase 2b study - Marginal Zone Lymphoma cohort was designed to evaluate the safety and efficacy of single agent umbralisib, in patients with MZL who have received at least one prior anti-CD20 regimen. The primary endpoint is overall response rate (ORR) as determined by central Independent Review Committee (IRC) assessment.

The MZL cohort completed enrollment in August 2018 with a total of 69 patients enrolled and receiving at least one dose of umbralisib. In February of 2019, the Company announced that the MZL cohort met its primary endpoint of ORR as determined by central IRC for all treated patients (n=69). While the study has already met the Company's target guidance of 40-50% ORR, the final analysis of ORR will be conducted when all treated patients have had at least 9 cycles (cycle = 28 days) of follow-up. Secondary endpoints include safety, duration of response, and progression-free survival (PFS).

ABOUT BREAKTHROUGH THERAPY DESIGNATION

The Company announced in January of 2019 that the U. S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for umbralisib for the treatment of adult patients with marginal zone lymphoma who have received at least one prior anti-CD20 regimen.

The FDA's Breakthrough Therapy designation is intended to expedite the development and review of a drug candidate that is planned to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement on one or more clinically significant endpoints over available therapies.

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 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 into Phase 1 clinical development, TG-1501, its anti-PD-L1 monoclonal antibody, TG-1701, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor and TG-1801, its anti-CD47/CD19 bispecific antibody. 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: the risk that the interim data (the "Interim Results") from the UNITY-NHL MZL cohort released today will not be reproduced when the final analysis is conducted on all patients later this year, including the risk that the final results will demonstrate a lower ORR and/or enhanced toxicities, which may not support a filing for accelerated approval; the risk that even if the Interim Results are reproduced in the final analysis of the UNITY-NHL MZL cohort or that the final results otherwise meet the Company's target ORR of 40-50%, that the final results will still be insufficient to support a filing for accelerated approval; the risk that umbralisib will not receive accelerated approval based on data from the UNITY-NHL MZL cohort even if the final results are deemed positive by the Company and support a filing for accelerated approval; the risk that the positive Interim Results from the UNITY-NHL MZL cohort will not be reproduced in other cohorts of the UNITY-NHL study or in other studies being conducted by the Company; the risk that duration of response or progression free survival data from the UNITY-NHL cohort when available for all patients will not be positive or supportive of accelerated approval; the risk that safety issues will arise when the final safety data are cleaned and analyzed for all patients in the UNITY-NHL MZL cohort; the risk that our belief that umbralisib has a differentiated safety profile will not be shared by physicians or the FDA or will not be reproduced in the final analysis of the UNITY-NHL MZL cohort, in other cohorts of the UNITY-NHL study, in the UNITY-CLL study or in any other of our on-going studies; the risk that we are not able to successfully and cost effectively complete all the preclinical, clinical and CMC requirements necessary to support accelerated approval. 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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