TG THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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Address	2 GANSEVOORT STREET, 9TH FLOOR NEW YORK, NY 10014
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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): **June 14, 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 June 14, June 15, and June 16, 2017, TG Therapeutics, Inc. issued press releases announcing certain data regarding its clinical studies of TGR-1202 plus ibrutinib, TG-1101 in combination with TGR-1202 and bendamustine, TG-1101 plus ibrutinib (the GENUINE trial), and TGR-1202 in combination with TG-1101 and ibrutinib, respectively, at the 14 th International Conference on Malignant Lymphoma (ICML), in Lugano, Switzerland . Copies of the press releases are being filed as Exhibits 99.1, 99.2 and 99.3 and incorporated in this Item by reference.

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

99.1 Press Release, dated June 14, 2017.

99.2 Press Release, dated June 15, 2017.

99.3 Press Release, dated June 16, 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: June 16, 2017

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release, dated June 14, 2017.
99.2	Press Release, dated June 15, 2017.
99.3	Press Release, dated June 16, 2017.

TG Therapeutics, Inc. Announces Follow-Up Data for Combination of TGR-1202 (umbralisib) plus Ibrutinib in Patients with Relapsed or Refractory CLL and MCL at the 14 th International Conference on Malignant Lymphoma

Combination of TGR-1202 (umbralisib) plus ibrutinib appears well tolerated with no Grade 3/4 transaminitis, pneumonitis, diarrhea, or colitis observed, with longest patients on study 29.5+ months

94% of the CLL patients achieved a CR, PR or PR-L, including 1 patient with a CR, and 3 additional patients with radiographic CR's

79% ORR in patients with MCL, including 1 patient with a CR and 1 additional patient with a radiographic CR

NEW YORK, June 14, 2017-- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated clinical data from its ongoing Phase I/Ib trial of TGR-1202 (umbralisib), the Company's oral, next generation PI3K delta inhibitor, in combination with ibrutinib, a BTK inhibitor, in patients with Chronic Lymphocytic Leukemia (CLL) and Mantle Cell Lymphoma (MCL). This study is being run in collaboration with the Blood Cancer Research Partnership (BCRP) and Dana-Farber Cancer Institute (DFCI), in Boston, MA. Data from this trial were presented today by the Principal Investigator, Matthew S. Davids, MD, of Dana-Farber Cancer Institute, during an oral session at the 14 th International Conference on Malignant Lymphoma (ICML), in Lugano, Switzerland.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "We continue to be impressed with the safety, tolerability and activity of the combination of TGR-1202 and ibrutinib. With this all oral combination, we are seeing high response rates, including in those patients with prior PI3K inhibitor or ibrutinib exposure. Additionally, the combination was well tolerated with over 30 patients now treated and for durations upwards of 2.5 years in this independently run, investigator initiated study." Mr. Weiss continued, "We want to thank Dr. Davids and his collaborators at DFCI and the Leukemia & Lymphoma Society for leading this important investigator driven research. Dr. Davids' research provides another important piece of information as we try to identify the best way to use these drugs, alone or in combination. These data complement the recently reported results at ASCO from the triple combination of TGR-1202, ibrutinib and TG-1101, our anti-CD20 monoclonal antibody, which showed that the three-drug combination was also well-tolerated and appeared to induce even higher rates of response, with 100% ORR by iwCLL criteria and deeper responses with 26% of the CLL patients achieving a CR. We look forward to continuing to explore these combinations to drive better outcomes for patients."

Highlights from today's presentation include the following:

***Oral Presentation:* Updated results of a multicenter phase I/Ib study of TGR-1202 in combination with ibrutinib in patients with relapsed or refractory MCL or CLL (Abstract #040)**

This oral presentation includes data from patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) or Mantle Cell Lymphoma (MCL) treated with TGR-1202 in combination with ibrutinib. 32 patients were evaluable for safety (18 CLL patients and 14 MCL patients), of which 31 patients were available for efficacy (17 CLL patients and 14 MCL patients). CLL patients had a median of 1.5 prior lines of therapy (range 1-6), with 2 patients receiving prior ibrutinib and 4 receiving prior PI3K inhibitors. MCL patients had a median of 3 prior lines of therapy (range 2-5), with 2 patients also receiving prior ibrutinib.

Highlights from this oral presentation include:

- 94% (16 of 17) of CLL patients achieved a Complete Response (CR), Partial Response (PR), or a Partial Response with lymphocytosis (PR-L), with 1 patient achieving a CR and 3 additional patients with radiographic CR
- All 3 patients with prior PI3K inhibitor therapy that were evaluable for efficacy, and 1 of the 2 patients with prior ibrutinib exposure responded
- 1-year progression free survival (PFS) for CLL is 88% and overall survival (OS) at 1-year is 94%, (n=17), with the longest patient on study 29.5+ months
- 79% (11/14) ORR in patients with MCL, including 1 CR and 1 additional radiographic CR, with marked clinical benefit observed in two additional patients
- Median PFS and OS for MCL is 8.4 and 11.6 months, respectively (n=11)
- The combination appears well tolerated across all patients with no grade 3/4 transaminitis (liver toxicity), diarrhea, colitis or pneumonitis observed

PRESENTATION DETAILS:

The above referenced presentation is now available on the Publications page, located within the Pipeline section, of the Company's website at www.tgtherapeutics.com/publications.cfm.

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 complete preclinical and clinical trials; the risk that early clinical trial results, including the safety and efficacy results seen with the combination of TGR-1202 plus ibrutinib 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; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 or as the U2 regimen and being studied in the chemo-free triple combination of TG-1101 plus TGR-1202 plus ibrutinib and in the UNITY clinical trials and other combination trials, will not prove to be safe and efficacious for any indication or as a backbone for current or future combination trials. 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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TG Therapeutics, Inc. Announces Follow-Up Data from the Triple Combination of TG-1101, TGR-1202, and Bendamustine in Patients with DLBCL and FL at the 14 th International Conference on Malignant Lymphoma

100% (4 of 4) ORR, including 50% CR rate in patients with relapsed Diffuse Large B-Cell Lymphoma (DLBCL)

50% (6 of 12) ORR, including 42% CR rate in patients with chemo and/or SCT refractory DLBCL

88% (7 of 8) ORR, including 50% CR rate in patients with relapsed or refractory Follicular Lymphoma (FL)

The triple combination of TG-1101, TGR-1202 and bendamustine was generally well-tolerated with the only Gr 3/4 event >10% being neutropenia

NEW YORK, June 15, 2017-- TG Therapeutics, Inc. (NASDAQ: TGTX), today announced updated clinical data from its Phase I/Ib trial of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with TGR-1202 (umbralisib), the Company's oral, next generation PI3K delta inhibitor, and bendamustine, in patients with Diffuse Large B-cell Lymphoma (DLBCL) and Follicular Lymphoma (FL). Data from this trial was presented today during a poster session at the 14 th International Conference on Malignant Lymphoma (ICML).

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "Relapsed and refractory DLBCL remains one of the most difficult to treat lymphoid malignancies, with a uniformly poor prognosis, particularly for patients with refractory disease who are not eligible for high-dose chemotherapy or stem-cell transplantation." Mr. Weiss continued, "The data presented today by Dr. Lunning supports our belief that the combination of TG-1101 (ublituximab) and TGR-1202 (umbralisib), our 'U2 regimen', with bendamustine is a highly active and well tolerated treatment for patients with aggressive lymphomas. We are excited to be able to rapidly bring this combination forward in the DLBCL arm of our randomized registration-directed UNITY-NHL program and hope to be enrolling patients into this cohort before the end of the summer."

Dr. Matthew Lunning, of the University of Nebraska Medical Center, stated, "I am extremely pleased with the durable responses seen with this novel triplet regimen, especially in patients with aggressive DLBCL who may not have been candidates for more intensive chemotherapy, transplantation, or CAR-T therapy, due to poor performance status or need for urgent therapy, a truly unmet medical need. Many patients had high-risk molecular features and some have obtained sustained responses. In addition to being highly active, the triplet regimen of U2-benda was very well tolerated, with a low incidence of Grade 3 or greater adverse events, particularly those that have been associated with the PI3K-delta class. I look forward to the possibility of testing this regimen earlier in relapsed and refractory DLBCL and am excited to see it advance into registration directed studies."

Highlights from today's presentation include the following:

***Poster Presentation:* Combination of TGR-1202, Ublituximab, and Bendamustine is safe and highly active in patients with advanced DLBCL and Follicular Lymphoma (Abstract 277)**

This poster presentation includes data from patients with relapsed or refractory Diffuse Large B-Cell Lymphoma (DLBCL) or Follicular Lymphoma (FL) treated with the triple combination of TG-1101 (ublituximab), TGR-1202 (umbralisib) and bendamustine. Thirty-three patients were evaluable for safety of which 24 were evaluable for efficacy (9 patients were note evaluable; 7 were too early to evaluate and 2 patients were off study prior to an efficacy assessment: 1 non-related adverse event (AE) and 1 investigator decision). The triple combination appears well tolerated with no discontinuations for a treatment related AE. No events of pneumonitis and no Grade 3/4 transaminitis were reported. Twenty-one patients (64%) were refractory to prior treatment. Mean time on study was approximately 6 months.

Efficacy highlights from this poster include:

- 100% (4 of 4) ORR, including a 50% CR rate, observed in patients with relapsed DLBCL
- 50% (6 of 12) ORR, including a 42% CR rate, observed in patients with refractory DLBCL with durable CR and PR responses observed (PR on-going for >16+ months)
- 88% (7 of 8) ORR, including a 50% CR rate, observed in patients with relapsed or refractory FL

PRESENTATION DETAILS:

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TG Therapeutics, Inc. Recaps Positive Data from the Phase 3 GENUINE Trial and Data from the Triple Combination of TG-1101, TGR-1202, and Ibrutinib at the 14 th International Conference on Malignant Lymphoma

GENUINE Phase 3 trial met its primary endpoint with TG-1101 (ublituximab) plus ibrutinib increasing Overall Response Rate (ORR) by >70% over ibrutinib alone in patients with high-risk CLL

Triple combination of TG-1101, TGR-1202 and ibrutinib produced 100% ORR (19 of 19) in patients with CLL/SLL, including 32% CR rate, with a favorable safety profile observed

NEW YORK, June 16, 2017-- TG Therapeutics, Inc. (NASDAQ: TGTX), today recapped clinical data from its Phase 3 GENUINE trial of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody in combination with Ibrutinib, the BTK inhibitor, as well as data from the chemo-free triple combination of TGR-1202 (umbralisib), the Company's oral, next generation PI3K delta inhibitor, TG-1101, and ibrutinib. Data from these trials were presented today during oral sessions at the 14 th International Conference on Malignant Lymphoma (ICML) in Lugano, Switzerland. These data sets were presented previously at the American Society of Clinical Oncology (ASCO) annual meeting earlier this month. Highlights from each of these data sets are included below.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer stated, "CLL patients with high-risk cytogenetics continue to represent a challenge and continue to progress more rapidly on ibrutinib than other patients. Improving ibrutinib therapy for these hard to treat patients still represents an unmet medical need. We are pleased to be the first Company to demonstrate in a randomized Phase 3 trial an approach to potentially improve outcomes for those patients. As presented today at ICML, and last week at ASCO, the GENUINE Phase 3 trial showed that by adding TG-1101 to ibrutinib, we could improve overall response rate, CR rate, and MRD negativity in high risk patients. We believe the data provide a compelling case for accelerated approval given the demonstrated clinical benefit with limited additional safety risk, and we look forward to sharing these data formally with the FDA later this year." Mr. Weiss continued, "Additionally, at ICML today, and last week at ASCO, we had an opportunity to present data on a triple therapy where we layered our proprietary PI3K-delta inhibitor, TGR-1202, to the TG-1101 plus Ibrutinib combination, and demonstrated even further enhanced activity, with 100% ORR by iwCLL criteria and a high level of complete responses. These data further confirm our approach of building toward multi-drug regimens to enhance the outcome for patients, ideally achieving CRs and avoiding lifelong therapy. We look forward to continuing to explore unique combinations, with TG-1101 (ublituximab) plus TGR-1202 (umbralisib) or 'U2' as the backbone."

Highlights from today's presentations include the following:

Oral Presentation: ***Ublituximab and ibrutinib for previously treated genetically high-risk chronic lymphocytic leukemia: Results of the GENUINE Phase 3 study (Abstract #101)***

This presentation includes data from the GENUINE Phase 3 trial, a multicenter, randomized trial (NCT02301156), which assessed the efficacy and safety of TG-1101 plus ibrutinib versus ibrutinib alone in patients with high-risk CLL. For the trial, high-risk was defined as having any one or more of the following centrally confirmed features: 17p deletion, 11q deletion, or p53 mutation. The GENUINE study was designed to demonstrate the value of adding TG-1101, a potent next generation glycoengineered anti-CD20 monoclonal antibody to ibrutinib monotherapy in high risk CLL, and was powered to show a statistically significant improvement in ORR of 30%, with a minimal absolute detectable difference between the two arms of approximately 20%.

The trial met its primary endpoint, demonstrating a statistically significant improvement in Overall Response Rate (ORR), as assessed by blinded independent central radiology and hematology review by iwCLL (Hallek 2008) criteria, compared to ibrutinib alone in both the Intent to Treat (ITT) population ($p=0.001$) and Treated population ($p<0.001$). Per iwCLL guidelines, all responders required confirmation of response for a minimum duration of 2 months. The ITT population includes all 126 randomized patients (64 in the TG-1101 plus ibrutinib arm and 62 in the ibrutinib alone arm) while the Treated population includes all ITT patients that received at least one dose of either study drug (59 in the TG-1101 plus ibrutinib arm and 58 in the ibrutinib alone arm).

Patient Demographics

One hundred and twenty-six (126) patients were randomized on the GENUINE Phase 3 Trial. 100% of patients were high risk and had either 17p deletion, 11q deletion or p53 mutation. Sixty-four percent (64%) of patients in the TG-1101 plus ibrutinib arm and 66% of patients in the Ibrutinib alone arm had 17p deletion and/or a p53 mutation while 36% and 34% of patients in the TG-1101 plus ibrutinib and ibrutinib alone arms, respectively, had an 11q deletion only. The median age of patients on either arm was 67 years and the median number of prior lines of therapy for either arm was 3.

Safety & Tolerability

One hundred and seventeen (117) patients were evaluable for safety (59 patients in the TG-1101 plus ibrutinib arm, and 58 patients in the ibrutinib alone arm). The combination was well tolerated and, apart from infusion related reactions, the addition of TG-1101 did not appear to alter the safety profile of ibrutinib monotherapy. Neutropenia, occurring in 9% of patients, was the most commonly reported Grade 3/4 Adverse Event (AE) in the combination arm, followed by infusion related reactions and anemia, each reported in 5% of patients. Notably, the majority of infusion related reactions (IRR) were Grade 1 or 2 in severity, with only 5% Grade 3/4 IRR observed. Median follow-up for this study was approximately 11.4 months.

Clinical Activity

Response Rates

	TG-1101 plus Ibrutinib	Ibrutinib	P-value
Treated Population (n)	n=59	n=58	
Overall Response Rate (ORR)	78%	45%	P<0.001
Complete Response (CR)	7%	0%	NS
MRD-Negative	19% *(n=53) **	2% *(n=53) **	P<0.01

**Patients evaluable for MRD included those enrolled >4 months prior to data cutoff date of February 15, 2017. MRD analyzed by central lab, 7-color flow cytometry*

In addition to the improvements in ORR, CR, and MRD-negativity, a trend in improvement of Progression-Free Survival (PFS) in the combination arm of TG-1101 plus ibrutinib as compared to ibrutinib alone, however it was not statistically significant at the time of the analysis.

ABOUT THE PHASE 3 GENUINE STUDY

The Phase 3 GENUINE study is a randomized, open label, multicenter clinical trial to evaluate the safety and efficacy of TG-1101 (ublituximab) plus ibrutinib compared to ibrutinib alone in adult patients with high risk Chronic Lymphocytic Leukemia (CLL) who received at least one prior therapy for their disease.

The study was conducted at 160 clinical trial sites in the US and Israel and randomized 126 patients. Patients received ibrutinib orally at 420 mg once daily in both arms and in the treatment arm those patients also received intravenous infusions of TG-1101 at 900 mg dosed on days 1, 8 and 15 of cycle 1 and day 1 of cycles 2-6. Patients in the treatment arm who had not progressed received quarterly infusions of TG-1101 maintenance at 900 mg.

<u>Oral Presentation:</u> Chemo-free triplet combination of TGR-1202, ublituximab, and ibrutinib is well tolerated and highly active in patients with advanced CLL and NHL (Abstract #102)

This oral presentation includes data from patients with Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) and Non-Hodgkin's Lymphoma (NHL) treated with the triple combination of TGR-1202, TG-1101 and ibrutinib. All patients were relapsed or refractory to prior therapy, except 3 CLL patients who were treatment naïve. Three cohorts for each CLL/SLL and NHL were evaluated with TGR-1202 dose escalation starting with doses of 400 mg (cohort 1), followed by 600 mg (cohort 2) and 800 mg (cohort 3), in combination with TG-1101 at 900 mg and ibrutinib daily at 420 mg (CLL) and 560 mg (NHL).

Safety & Tolerability

Thirty-eight (38) patients were evaluable for safety (20 CLL/SLL patients, and 18 NHL patients). The triple combination appeared to be well tolerated in all patients, with neutropenia (32% all grades, 18% Grade 3/4) and pneumonia (18% all grades, 11% Grade 3/4), being the only Grade 3/4 AEs in >10% of patients. Of the 38 patients treated to date, only two AEs (sepsis and pneumonia) led to treatment discontinuation. Median time on study was 11.1 months (range 0.4 – 30+ months) with 81% of patients on study >6 months.

Clinical Activity

Clinical activity was observed at all dose levels with 36 of 38 patients evaluable for efficacy (19 CLL/SLL patients, and 17 NHL patients), with 2 patients having discontinued prior to first efficacy assessment (1 pneumonia, and 1 investigator discretion).

<u>CLL/SLL Efficacy highlights include:</u>

- 100% (19 of 19) Overall Response Rate (ORR), including a 32% Complete Response (CR) rate observed in patients with CLL/SLL (4 of 6 CR's pending bone marrow confirmation)
- 50% of the CLL patients had a 17p and/or 11q deletion
- 3 CLL patients had prior BTK and/or PI3Kd inhibitor therapy, including one patient refractory to both idelalisib and ibrutinib who attained a complete response (ongoing for 1.5+ years)

<u>NHL Efficacy highlights include:</u>

- Response Rates observed in patients with NHL:
    - 100% (2 of 2) ORR, including one CR in patients with Marginal Zone Lymphoma (MZL)
    - 100% (4 of 4) ORR, including 50% CR rate in patients with Mantle Cell Lymphoma (MCL)
    - 80% (4 of 5) ORR, including 20% CR rate in patients with Follicular Lymphoma (FL)
    - 17% (1 of 6) ORR in patients with Diffuse Large B-cell Lymphoma (DLBCL)
- FL patients were heavily pretreated including 2 with prior Autologous Stem Cell Transplant (ASCT), 1 refractory to prior ibrutinib, and 1 with 5 prior lines of rituximab based therapy
- DLBCL patients had a median of 4 prior therapies, and 4 of 6 were of non-GCB subtype

<u>PRESENTATION DETAILS:</u>

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