

# TG THERAPEUTICS, INC.

## **FORM 8-K** (Current report filing)

Filed 10/17/17 for the Period Ending 10/16/17

Address	2 GANSEVOORT STREET, 9TH FLOOR NEW YORK, NY, 10014
Telephone	(212) 554-4484
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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): **October 16, 2017**

**TG Therapeutics, Inc.**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-32639**  
(Commission File Number)

**36-3898269**  
(IRS Employer Identification No.)

**2 Gansevoort Street, 9<sup>th</sup> 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.

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**Item 8.01. Other Events.**

On October 16, 2017, TG Therapeutics, Inc. issued the following press releases: (i) a press release providing an update on an FDA meeting for the GENUINE Phase 3 trial; (ii) a press release announcing the completion of full enrollment in the UNITY-CLL Phase 3 trial; and (iii) a press release recapping clinical data presentations at the upcoming 7<sup>th</sup> Joint ECTRIMS-ACRIMS Meeting (collectively, the “Press Releases”). 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 October 16, 2017.

99.2 Press Release, dated October 16 , 2017.

99.3 Press Release, dated October 16 , 2017.

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## 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: October 17, 2017

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

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## INDEX TO EXHIBITS

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
<a href="#"><u>99.1</u></a>	Press Release, dated October 16 , 2017.
<a href="#"><u>99.2</u></a>	Press Release, dated October 16 , 2017.
<a href="#"><u>99.3</u></a>	Press Release, dated October 16 , 2017.

## **TG Therapeutics Provides Update on FDA Meeting for GENUINE Phase 3 Trial**

### ***Follow-up meeting with FDA expected before year end***

NEW YORK, October 16, 2017 - TG Therapeutics (NASDAQ: TGTX) announced today that it has met with the U.S. Food and Drug Administration (FDA) regarding the use of the results from the GENUINE Phase 3 trial to support a Biologics License Application (BLA) filing for approval of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with ibrutinib. During the meeting, the FDA confirmed that accelerated approval based on Overall Response Rate (ORR) would be a review issue. As part of the discussion, the FDA encouraged the Company to consider future available therapy in its risk/benefit analysis as part of any potential future BLA filing that may impact accelerated approval.

The Company and the FDA also discussed the potential use of Progression Free Survival (PFS) results from the GENUINE trial to support the full approval of TG-1101. The Company plans to have a follow-up meeting with the FDA to discuss the use of the PFS endpoint in more detail before the end of the year and also plans to monitor the regulatory landscape for new approvals of agents for previously treated high-risk Chronic Lymphocytic Leukemia (CLL) while continuing to make preparations for a BLA filing as early as 2Q18.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, "We had a very productive meeting with the FDA regarding the GENUINE study and its use for approval of TG-1101 in combination with ibrutinib. We look forward to our follow-up meeting and working with the FDA in an effort to reach an agreement on the potential use of PFS for full approval in a similar timeframe as accelerated approval." Mr. Weiss continued, "We were also pleased to announce today the early completion of UNITY-CLL, which makes the potential filing timelines for GENUINE and UNITY-CLL now nearly overlapping, setting the stage for an exciting 2018."

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## **ABOUT THE PHASE 3 GENUINE TRIAL**

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.

## **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, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. 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 clinical results from the GENUINE trial or the UNITY-CLL trial may not be sufficient or may not support regulatory approval of TG-1101 or TGR-1202; the risk that the company will not be able to deliver data or updates on schedule as planned; the risk that a filing based on UNITY-CLL, GENUINE or any other registration-direct trials cannot be made on schedule as targeted or at all; the risk that the filing timelines for GENUINE and UNITY-CLL do not overlap or do not occur at all; the risk that the company will not file a BLA for TG-1101 based on the GENUINE trial; the risk that the regulatory landscape for available therapies changes prior to a potential approval of TG-1101 based on GENUINE in a way that prevents an accelerated approval; the risk that the Company and FDA are not able to reach an agreement on the use of the PFS endpoint for full approval or, if an agreement is reached, that the PFS results are not positive and supportive of approval; the risk that safety issues or trends will be observed in the GENUINE or UNITY-CLL studies that prevent approval; the risk that the company decides not to use the GENUINE trial results to seek accelerated approval of TG-1101; the risk that early clinical trial results, that may have influenced our decision to proceed with additional clinical trials, will not be reproduced in the final data. 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](http://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.

TGTX - G

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## **TG Therapeutics Announces Completion of Full Enrollment in the UNITY-CLL Phase 3 Trial**

*Top-Line ORR data from the UNITY-CLL trial expected in 2Q18*

*Targeting an NDA/BLA filing for combination of TGR-1202 + TG-1101 in 2H18*

NEW YORK, October 16, 2017 - TG Therapeutics (NASDAQ: TGTX) announced today that it has completed full enrollment in the UNITY-CLL Phase 3 clinical trial. The UNITY-CLL Phase 3 trial is a randomized study of TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, in combination with TGR-1202 (umbralisib), the Company's PI3K delta inhibitor (together referred to as the U2 regimen), compared to an active control arm of obinutuzumab plus chlorambucil, in patients with both treatment naïve and relapsed or refractory Chronic Lymphocytic Leukemia (CLL). The UNITY-CLL trial is being conducted under Special Protocol Assessment (SPA) agreement with the Food and Drug Administration (FDA).

Last month, the Company announced that target enrollment of 175 patients in each of the TG-1101 plus TGR-1202 and obinutuzumab plus chlorambucil arms was achieved, however, enrollment was extended to allow eligible patients who were already identified or in screening the ability to participate in the study. Completion of full enrollment has now been achieved with more than 200 patients in each of the two combination arms. Approximately 60% of patients enrolled in the combination arms were front-line and 40% were previously-treated. As per the SPA, the primary and secondary endpoint analyses will include all patients. Top-line Overall Response Rate (ORR) data from the UNITY-CLL trial is expected in the second quarter of 2018 and the company is targeting a New Drug Application (NDA)/ Biologics License Application (BLA) filing for the combination of TGR-1202 and TG-1101 in the second half of 2018.

Michael S. Weiss, Executive Chairman and Chief Executive Officer, stated, “We are pleased to report that UNITY-CLL has now completed full enrollment, far exceeding the original targeted enrollment and doing so much faster than anticipated. We believe the tremendous demand for this study underscores the need for new treatment options for CLL patients as well as the enthusiasm specifically for the U2 regimen. Additionally, with the early completion of UNITY-CLL, the potential filing timelines for GENUINE and UNITY-CLL are now nearly overlapping, with a UNITY-CLL filing based on ORR possible as early as 3Q18.” Mr. Weiss continued, “Our goal is to extend quality life for patients with CLL by developing efficacious treatments that are well-tolerated, easy to use and don’t require harsh chemotherapy or hospital admission to receive therapy. We believe U2 possesses these attributes and has the potential to become one of the dominant treatment options for first and second line CLL.”

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## **ABOUT UNITY-CLL PHASE 3 TRIAL**

UNITY-CLL is a global Phase 3 randomized controlled clinical trial in patients with Chronic Lymphocytic Leukemia (CLL) that includes two key objectives: first, was to demonstrate contribution of each agent in the TG-1101 (ublituximab) + TGR-1202 (umbralisib) or U2 regimen, and second, to demonstrate superiority in Progression Free Survival (PFS) over the standard of care to support the submission for full approval of the combination. In addition, upon completion of enrollment, this trial will evaluate Overall Response Rate (ORR) for accelerated approval. The study initially randomized patients into four treatment arms: TG-1101 plus TGR-1202, TG-1101 single agent, TGR-1202 agent, and an active control arm of obinutuzumab plus chlorambucil. Pursuant to the Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA), an early interim analysis was conducted to assess contribution of each single agent which allowed for early termination of both single agent arms.

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### **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 the UNITY-CLL trial or deliver data on schedule as planned; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 or "U2", and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination treatment option for any indication; the risk that UNITY-CLL does not demonstrate an ORR advantage or that even if an ORR advantage is shown that the results do not support accelerated approval; the risk that Unity-CLL will not demonstrate a PFS advantage; the risk that safety issues or trends will be observed in the UNITY-CLL study or any other on-going studies that prevent approval of either TG-1101 and/or TGR-1202; the risk that the UNITY-CLL study, or any of our other registration-directed clinical trials as designed or amended may not be sufficient or acceptable to support regulatory approval; the risk that a filing based on UNITY-CLL, GENUINE or any other registration-direct trials cannot be made on schedule as targeted or at all; the risk that the filing timelines for GENUINE and UNITY-CLL do not overlap or do not occur at all; the risk that early clinical trial results, that may have influenced our decision to proceed with additional clinical trials, will not be reproduced in the final data presented; the risk that the final data will not support regulatory 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](http://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. Recaps Clinical Data Presentations at the Upcoming 7<sup>th</sup> JointECTRIMS – ACTRIMS Meeting

*B-cell depletion data and MRI data at 24 weeks (6 months) to be presented*

*Abstract data shows complete (100%) elimination of T1 Gd-enhancing lesions at week 24*

New York, NY, ( **October 16, 2017** ) TG Therapeutics, Inc. (NASDAQ: TGTX), today announced that clinical abstracts featuring data from the Phase 2 multicenter trial of TG-1101 (ublituximab), the Company’s novel glycoengineered anti-CD20 monoclonal antibody, in relapsing forms of Multiple Sclerosis (RMS) have been selected for presentation at the upcoming 7<sup>th</sup> JointECTRIMS – ACTRIMS meeting, to be held next week, October 25 – 28, 2017, at the Le Palais de Congrès de Paris, in Paris, France. Abstracts are now available online and can be accessed on theECTRIMS meeting website at [www.ectrims-congress.eu](http://www.ectrims-congress.eu). Details of the poster presentations are outlined below.

### **Abstract Highlights:**

- *TG-1101 completely eliminated all (100%) of T1 Gd-enhancing lesions at week 24 (n=16)*
- *At week 4, median 99% B-cell depletion was observed and maintained at week 24 (6 months) (n=24)*
- *TG-1101 was well tolerated with no study drug related SAE’s reported and accelerated infusions times as short as 1 hour for the 450mg Phase 3 dose and regimen did not increase the rate of Infusion Related Reactions (IRR) (n=24)*

Michael S. Weiss, the Company’s Executive Chairman and Chief Executive Officer stated, “We are excited to release the first clinical MRI data of TG-1101 in patients with RMS as we believe the abstract data presents an extremely compelling case for the use of TG-1101 in the treatment of patients with MS. While still early, the data thus far is setting the stage for a best-in-class profile for TG-1101 in treating MS. We are looking forward to presenting the full data on the first three cohorts (n=24) through 24 weeks (6 months) of treatment at theECTRIMS-ACTRIMS meeting next week.” Mr. Weiss continued, “We will continue to update these data at multiple conferences over the next year as we treat and follow the full 48 patients (from the 6 cohorts) for up to 1 year. With our Phase 3 program now underway pursuant to a Special Protocol Assessment (SPA), we believe MS represents the next level of growth for the Company.”

### **Poster Presentation Details:**

- Title: Patient characteristics, safety, and preliminary results of a placebo controlled, phase 2a multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis
  - Presentation Date & Time: Thursday, October 26<sup>th</sup>, 2017; 15:30-17:00 CEST
  - Session Title: Poster Session 1
  - Presenter: Edward Fox, MD, PhD, Central Texas Neurology Consultants, Round Rock, Texas
- Title: Preliminary results of phase 2 multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis (RMS) demonstrates rapid Gd-enhancing lesions decrease
  - Presentation Date & Time: Thursday, October 26<sup>th</sup>, 2017; 15:30-17:00 CEST
  - Session Title: Poster Session 1
  - Presenter: Matilde Inglese, MD, PhD, Icahn School of Medicine at Mount Sinai, New York, NY
- Placebo controlled, phase 2a multicenter study of ublituximab (UTX), a novel glycoengineered anti-CD20 monoclonal antibody (mAb), in patients with relapsing forms of multiple sclerosis (RMS): 6 months analysis of B cell subsets
  - Presentation Date & Time: Friday, October 27<sup>th</sup>, 2017; 15:30-17:00 CEST
  - Session Title: Poster Session 2
  - Presenter: Amy E. Lovett-Racke, PhD, The Ohio State University, Columbus, OH

These data presentations support the recently announced international Phase 3 program evaluating TG-1101 (ublituximab) for the treatment of relapsing form of Multiple Sclerosis (RMS). The Phase 3 trials, entitled ULTIMATE I and ULTIMATE II, are being conducted under Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA) and will be led by Lawrence Steinman, MD, of Stanford University.

A copy of the above abstracts can be found on theECTRIMS meeting website at [www.ectrims-congress.eu](http://www.ectrims-congress.eu). Following each poster presentation, the data presented will be available on the Publications page, located within the Pipeline section, of the Company’s website at [www.tgtherapeutics.com](http://www.tgtherapeutics.com).

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### **Cautionary Statement**

Statements included in this press release, particularly those with respect to anticipating the benefit of the early data seen in the Phase 2 MS trial and anticipating the timing of our MS Phase 3 program 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. Among the factors that could cause our actual results to differ materially are the following: our ability to successfully and cost-effectively complete the MS Phase 2 and Phase 3 trials; the risk that early clinical results that supported our decision to move forward will not be reproduced in additional patients in expansion cohorts or in the MS Phase 3 program; the risk that data included in the abstract submission will not be reproduced in the full data presentation; the risk that the clinical results from the MS Phase 3 program, will not be positive and/or will not support regulatory approval of TG-1101 for MS; the risk that TG-1101 will not have a differentiated profile from the other drugs in the class and that early signs of best-in-class attributes will not be supported by future results; the risk that trials will take longer to enroll than expected; our ability to achieve the milestones we project over the next year; our ability to manage our cash in line with our projections, 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](http://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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