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 13, 2016**

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.

Item 8.01. Other Events.

On October 13, 2016, TG Therapeutics, Inc. (the "Company") issued a press release announcing amendments to the Company's GENUINE Phase 3 clinical trial to accelerate study completion. 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 October 13, 2016.

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 13, 2016

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1.	Press Release, dated October 13, 2016

Exhibit 99.1

TG Therapeutics, Inc. Amends the GENUINE Phase 3 Clinical Trial to Accelerate Study Completion by Revising Primary Endpoint to Overall Response Rate

FDA agrees that Overall Response Rate (ORR) data from revised GENUINE study can be used to request pre-BLA (Biologics License Application) meeting

If results of the revised GENUINE study are positive, the Company plans to file a BLA for accelerated approval based on the outcome of the pre-BLA meeting

Enrollment expected to be completed before year end 2016 with top-line data available in first half of 2017

Amendments expected to save the Company more than $10 million over the next 2 years, and allow the Company to focus its resources on the UNITY-CLL program

Conference call to be held today, Thursday, October 13, 2016 at 8:30am ET

New York, NY, (**October 13, 2016**) – TG Therapeutics, Inc. (NASDAQ:TGTX) today announced that it has filed with the FDA an amended protocol for the GENUINE Phase 3 trial. Prior to the amendments, the GENUINE study consisted of two parts:

- Part I to evaluate the effect of the addition of TG-1101 to ibrutinib on overall response rate (ORR) in approximately the first 200 patients enrolled, to support a filing for accelerated approval of TG-1101; and
- Part II to evaluate the effect of the addition of TG-1101 to ibrutinib on progression-free survival (PFS) in all study patients (approximately 330), to support a filing for full approval of TG-1101.

The amended protocol contains the following substantive changes:

- Part II of the study has been eliminated, and accordingly, the study's sole primary endpoint will be ORR as originally contemplated in Part I; and
- Target enrollment has been reduced to approximately 120 randomized patients.

At the new study size, the study is 90% powered to show a statistically significant improvement in ORR, with the minimal detectable difference of approximately 20% (absolute difference between the arms). Additionally, patients will be followed until progression, but the study will no longer be powered for PFS.

The Company expects that it will complete enrollment in the revised trial by year end 2016, and will have topline data available in the first half of 2017. If the results of the study are positive, the Company plans to request a pre-BLA meeting to discuss the data and a filing strategy with the FDA. The Company has communicated with the FDA regarding its intention to file a BLA for accelerated approval if the results are positive and the FDA has agreed that a pre-BLA meeting can be requested based on ORR data from the GENUINE study. Assuming a positive outcome of a pre-BLA meeting, targeted to occur in the fourth quarter of 2017, the Company believes it could file a BLA in the first half of 2018.

Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer, stated, "Today's announcement marks an important milestone for the Company. Given the GENUINE enrollment challenges we've faced to date, we are very excited to accelerate the trial to a rapid conclusion, while also maintaining the ability to potentially file the data for accelerated approval. The GENUINE study, as amended, remains a robust, randomized clinical trial, which we believe, if positive, could support accelerated approval for patients with relapsed/refractory high-risk CLL. Moreover, we believe the amended study and revised regulatory strategy is consistent with the recent accelerated approvals for novel agents in CLL, which notably were not pursuant to an SPA but occurred after the finding of positive ORR results. Importantly, with completion of enrollment now expected by year end, we and our clinical trial sites can focus our resources on completing our UNITY-CLL Phase 3 trial as quickly as possible. Early enrollment in UNITY-CLL is very encouraging and we anticipate that study will be fully enrolled before filing a BLA for the GENUINE study. UNITY-CLL remains unchanged and unaffected by the amendments to the GENUINE study, and if positive, could support full approval for both TG-1101 and TGR-1202 based on its primary endpoint of PFS." Mr. Weiss continued, "We have greatly appreciated all of the guidance and counsel from the FDA in designing our clinical programs and we look forward to continuing our collaborative working relationship as we accelerate toward the conclusion of enrollment into the GENUINE study this year and ORR data in the first half of 2017."

Conference Call Information

The Company will host a conference call today, Thursday, October 13, 2016 at 8:30am ET to discuss the amendments to the GENUINE Phase 3 Trial.

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 GENUINE Update Call. A live webcast of this presentation will be available on the Events page, located within the Investors & Media section, of the Company's website at www.tgtherapeutics.com. 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.

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, 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 recently entering 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, particularly those with respect to anticipating the timing of the completion of the GENUINE study, timing of the completion of the UNITY-CLL study, timing of filing of a BLA for TGR-1101, and projected cost savings from amending the GENUINE study 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 GENUINE or the UNITY-CLL trials; the risk that the clinical results from the GENUINE or UNITY-CLL studies will be not positive and/or will not support regulatory approval of TG-1101 or TGR-1202; the risk that the FDA will not grant us a pre-BLA meeting to discuss the results of the GENUINE study,; the risk that we will not file a BLA for TG-1101 or an NDA for TGR-1202 based on either the GENUINE or the UNITY-CLL; the risk that despite early positive trends in enrollment in the UNITY-CLL study that enrollment will be delayed beyond our projections; the risk that the planned interim analysis will not allow early closure of the single agent arms in the UNITY-CLL study, necessitating enrollment beyond the projected 450 patients, which would extend enrollment beyond our projections; the risk that safety issues or trends will be observed in the GENUINE study or the UNITY-CLL study that prevent approval of either TG-1101 and/or TGR-1202 or require us to terminate either the GENUINE study or the UNITY-CLL study prior to completion;the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior pre-clinical and clinical trials; the risk that the GENUINE study, as amended or 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 trials will take longer to enroll than expected;the risk that the projected cost savings to be realized by amending the GENUINE trial will not be realized;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. 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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