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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549

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FORM 8-K

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CURRENT REPORT  
Pursuant to Section 13 or 15(d) of the  
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **September 17, 2015**

**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.)

**3 Columbus Circle, 15<sup>th</sup> Floor**  
**New York, New York 10019**  
(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.
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**Item 8.01. Other Events.**

On September 17, 2015, TG Therapeutics, Inc. (the “Company”) issued a press release announcing it has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of a Phase 3 clinical trial for its proprietary combination of TG-1101 (ublituximab), its glycoengineered anti-CD20 monoclonal antibody, plus TGR-1202, the Company’s once-daily PI3K-delta inhibitor, for the treatment of Chronic Lymphocytic Leukemia (CLL). A copy of the press release is being filed as Exhibit 99.1 and is incorporated herein by reference.

**Item 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

99.1 Press release issued by the Company on September 17, 2015.

**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: September 17, 2015

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

INDEX TO EXHIBITS

**Exhibit Number**

**Description**

99.1

Press release issued by TG Therapeutics, Inc. on September 17, 2015.

**TG Therapeutics Announces Special Protocol Assessment (SPA) Agreement with the FDA for the First Phase 3 Clinical Trial of Its Proprietary Combination Regimen of TG-1101 (ublituximab) in Combination with TGR-1202 for Patients with Chronic Lymphocytic Leukemia (CLL)**

*Novel Design Allows for Simultaneous Approval of Two Investigational Agents in a Single Phase 3 Study Under SPA*

*Study Will Include Both Front-Line and Previously Treated Patients With CLL*

*Interim Analysis Following Completion of Enrollment Could be Used to Support Accelerated Approval of the Combination of TG-1101 +TGR-1202*

*International Phase 3 Study Entitled “UNITY-CLL” to be Led by John Gribben, MD, PhD of Barts Cancer Institute, London, UK*

NEW YORK, September 17, 2015– TG Therapeutics, Inc. (Nasdaq: TGTX) announced today that it has reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of a Phase 3 clinical trial for its proprietary combination of TG-1101 (ublituximab), its glycoengineered anti-CD20 monoclonal antibody, plus TGR-1202, the Company’s once-daily PI3K-delta inhibitor, for the treatment of Chronic Lymphocytic Leukemia (CLL). The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that, if met, would support the regulatory submission for drug approval of both TG-1101 and TGR-1202 in combination.

Full details of the Phase 3 clinical trial, called the UNITY-CLL trial, will be released at the launch of the study. The general study design is a randomized controlled clinical trial that includes two key objectives: first, to demonstrate contribution of each agent in the TG-1101 + TGR-1202 regimen (the combination sometimes referred to as “1303”), 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. The study will randomize patients into four treatment arms: TG-1101 + TGR-1202, TG-1101 alone, TGR-1202 alone, and an active control arm of obinutuzumab + chlorambucil. An early interim analysis will assess contribution of each single agent in the TG-1101 + TGR-1202 combination regimen, which, if successful, will allow early termination of both single agent arms. A second interim analysis will be conducted following full enrollment into the study, which, if positive, the Company plans to utilize for accelerated approval. Assuming early termination of the TG-1101 and TGR-1202 single agent arms, the study will enroll approximately 450 patients.

Dr. John Gribben, Professor of Medicine and the Gordon Hamilton Fairley Chair of Medical Oncology at St. Bartholomew’s Hospital, Barts Cancer Institute in London, UK, will lead the UNITY-CLL Phase 3 as Study Chair. Dr. Gribben commented, “The recent introduction of novel targeted agents has already dramatically improved the standard of care for patients with relapsed or refractory CLL, and we have seen even greater activity when these agents are used in combination. Both ublituximab and TGR-1202 have demonstrated unique activity and tolerability as single agents, and in combination together. We are excited to lead this important and innovative trial, which has the potential to bring greater advances to patients in both the front-line and relapsed/refractory CLL setting.”

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Michael S. Weiss, Executive Chairman and Interim Chief Executive Officer of TG Therapeutics, stated, "Our number one goal has always been to accelerate the development of novel non-chemotherapy-based combination treatments for patients with B-cell malignancies. The UNITY-CLL study and the related SPA marks a major milestone for the Company and, if successful, could lead to a very broad label in the treatment of CLL, providing patients and physicians a new treatment option, and the Company a platform to build additional proprietary combinations in our continued effort to drive towards a cure. Our path to achieving this SPA, which we believe is the first for two novel investigational agents in the oncology division, was the result of a true collaboration with the FDA, for which we would like to recognize and thank the agency for its invaluable guidance throughout this process." Mr. Weiss continued, "Our clinical team has been hard at work preparing for the launch of this study, and we look forward to enrolling our first patients as soon as possible. Lastly, we are thrilled to have Dr. Gribben, a world-renowned authority in CLL, lead this important international study and share in his excitement in bringing our novel, non-chemotherapy combination regimen to patients in need."

#### **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. 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. The Company also has pre-clinical programs to develop IRAK4 inhibitors, and anti-PD-L1 and anti-GITR antibodies. TG Therapeutics is headquartered in New York City.

#### **About Special Protocol Assessments**

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application.

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Final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessment, please visit: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080571.pdf>.

### **Cautionary Statement**

Some of the statements included in this press release, particularly those with respect to anticipating future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101, TGR-1202, the IRAK4 inhibitor program, and the anti-PD-L1 and anti-GITR antibodies 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 pre-clinical and clinical trials for TG-1101, TGR-1202, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies will not be reproduced in additional patients or in future studies; the risk that trends observed which underlie certain assumptions of future performance of TGR-1202 will not continue, the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current Phase 1 study; 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 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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CONTACT: Jenna Bosco  
Director- Investor Relations  
TG Therapeutics, Inc.  
Telephone: 212.554.4351  
Email: [ir@tgtxinc.com](mailto:ir@tgtxinc.com)

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