

TG THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Address	787 SEVENTH AVENUE NEW YORK, NY 10019
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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): **December 6, 2016**

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, 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.
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Item 8.01. Other Events.

On December 6, 2016, TG Therapeutics, Inc. issued press releases announcing presented data from three combination studies involving the Company's lead compounds, TGR-1202 and TG-1101 (ublituximab) in combination with other compounds, at the 58th American Society of Hematology (ASH) Annual Meeting, being held in San Diego, CA. A copy of the press release is being filed as Exhibit 99.1 and incorporated in this Item by reference. In addition, on December 6, 2016 the Company also issued a press releasing announcing that the target enrollment for the GENUINE Phase 3 study has been met and enrollment will be closed shortly. A copy of the press release is being filed as Exhibit 99.2 and incorporated in this Item by reference .

Item 9.01 Financial Statements And Exhibits.

(d) Exhibits.

99.1 Press Release, dated December 6, 2016.

99.2 Press Release, dated December 6, 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: December 6, 2016

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

INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
99.1.	Press Release, dated December 6, 2016.
99.2	Press Release, dated December 6, 2016 .

TG Therapeutics, Inc. Announces Double & Triple Combination Therapy Data Presentations at the 58th American Society of Hematology Annual Meeting

Combination of TG-1101, TGR-1202 and bendamustine resulted in 71% ORR, including 43% complete response rate, in relapsed or refractory DLBCL

TGR-1202 continues to demonstrate a favorable and differentiated safety profile when combined with a variety of agents

SAN DIEGO, CA (December 6, 2016) - TG Therapeutics, Inc. (NASDAQ:TGTX), announced the presentation yesterday of data from three combination studies involving the Company's lead compounds, TGR-1202, the Company's once-daily PI3K delta inhibitor, and TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody at the 58th American Society of Hematology (ASH) Annual Meeting, in San Diego, California.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO stated, "We are very pleased to continue to see a highly differentiated safety profile for TGR-1202 across multiple double and triple combination studies with a high level of activity. Each of the four clinical studies presented at the ASH meeting, enhanced our overall understanding of the breadth of activity of TGR-1202. In addition to DLBCL, FL and CLL, where we have already shown data previously, it was nice to see the flexibility of TGR-1202 and its ability to be combined with brentuximab vedotin in relapsed or refractory Hodgkin's and with ruxolitinib in Myelofibrosis." Mr. Weiss continued, "We are also encouraged by the triple combination data of TG-1101, TGR-1202, and bendamustine in relapsed or refractory, difficult to treat, DLBCL and FL patients which showed no discontinuations for a treatment related adverse event, as well as an 80% overall response rate across both DLBCL and FL patients and a high level of CR's. We, and our investigators, believe this triplet combination is a promising regimen and plan to study it in this patient population in a registration-directed trial."

Highlights from yesterday's presentations include the following:

Poster Presentation: Combination of Ublituximab, TGR-1202, and Bendamustine Demonstrates Significant Activity in Patients with Advanced DLBCL and Follicular Lymphoma (Abstract Number 4197)

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 and bendamustine. Nineteen patients were evaluable for safety of which 15 were evaluable for efficacy (3 patients were too early to evaluate and 1 patient had a non-related adverse event (AE) prior to efficacy assessment). The triple combination appears well tolerated with no discontinuations for a treatment related AE. Neutropenia and anemia were the only Grade 3/4 AE's occurring in more than 1 patient. Importantly, no Grade 3/4 transaminitis was reported, no events of pneumonia or pneumonitis, and only 1 transient event of Grade 3 diarrhea, with a duration of 1 day, was observed. Eleven patients (58%) were refractory to prior treatment. Median time on study at the data cut off was approximately 6 months with the majority of patients continuing on study and follow-up ongoing.

Efficacy highlights from this poster include:

- 71% (5 of 7) Overall Response Rate (ORR), including a 43% Complete Response (CR) rate observed in patients with relapsed or refractory DLBCL
 - 88% (7 of 8) ORR, including a 37% CR rate observed in patients with relapsed or refractory FL 4/6 CR's that were achieved between the DLBCL and FL groups occurred at the first 8 week efficacy assessment
 - First response assessment occurred at Month 3 following initiation of therapy, with durable responses observed notably amongst DLBCL patients.
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Poster Presentation: A Phase I Trial of TGR-1202, a Next Generation Once-Daily PI3Kd Inhibitor, in Combination with Brentuximab Vedotin, in Patients with Relapsed/Refractory Hodgkins Lymphoma (Abstract Number 4146)

This poster presentation includes data from patients with relapsed and refractory Hodgkin's Lymphoma (HL) treated with TGR-1202 at either 400mg or 600mg dosed orally once daily in combination with brentuximab vedotin in continuous 21 day cycles. 14 patients were evaluable for safety, of which 11 were evaluable for efficacy (3 discontinued prior to disease evaluation (2 AE's and 1 withdrew consent)). 43% (6 of 14) of patients had prior exposure to brentuximab vedotin and all were refractory to prior brentuximab vedotin therapy. The combination demonstrated tolerability with nausea, diarrhea, and neutropenia being the most prevalent adverse events. Notably all but one case of diarrhea was Grade 1 or 2 in severity.

Efficacy highlights from this poster include:

- 60% (3 of 5) ORR, including a 40% CR rate observed across brentuximab vedotin refractory patients
- 64% (7 of 11) ORR, including a 45% CR rate observed across all patients treated

Oral Presentation: Preliminary Results from a Phase I Dose Escalation Trial of Ruxolitinib and the PI3Kd Inhibitor TGR-1202 in Myelofibrosis (Abstract Number 1125)

This oral presentation includes data from patients with myelofibrosis treated with the combination of ruxolitinib, the JAK1/2 inhibitor and TGR-1202. The combination was well tolerated and efficacious in the twelve patients treated. The most prevalent adverse events deemed at least possibly related to TGR-1202 included anemia, thrombocytopenia, neutropenia, AST/ALT elevation and amylase/lipase elevation and diarrhea, all of which were notably Grade 1/2 with the exception of Grade 3 amylase/lipase elevation seen in 2 patients (16.7%), and Grade 3 diarrhea seen in 1 patient (8.3%). Presentation highlights included:

- The patient population enrolled was advanced, with the majority having 2 or more prior mutations at baseline;
 - Per protocol, all enrolled patients were on a stable dose of ruxolitinib monotherapy with best response to ruxolitinib monotherapy achieved prior to enrollment;
 - Following the addition of TGR-1202, 11/12 patients experienced improvement in hemoglobin, many with a concomitant reduction in platelet counts indicating clinical benefit beyond ruxolitinib monotherapy; and
 - 83% of study participants experienced clinical benefit (hematologic improvement, reduced spleen size and/or improvement in symptoms) including one patient who achieved a CR and continues on study, now out 72 weeks
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PRESENTATION DETAILS:

Copies of the above referenced presentations are available on the Company's website at www.tgetherapeutics.com, located on the Publications page.

TG THERAPEUTICS INVESTOR & ANALYST EVENT:

TG Therapeutics held an investor and analyst reception yesterday, at the Marriott Gaslamp, in San Diego, California. The audio file and slide presentation are available for review on the Events page, located within the Investors & Media section of the Company's website at www.tgetherapeutics.com.

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 future clinical trials, the timing of commencing or completing such trials and business prospects for TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET 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 preclinical and clinical trials for TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET inhibitor program, and the anti-PD-L1 and anti-GITR antibodies; the risk that early preclinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, the IRAK4 inhibitor program, the BET 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 combination of TG-1101 and TGR-1202, referred to as TG-1303, will not prove to be a safe and efficacious backbone for triple and quad combination therapies; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data produced from prior preclinical 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. 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
Vice President, Investor Relations
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

TG Therapeutics, Inc. Announces that the GENUINE Phase 3 Study has Reached Target Enrollment

Top-line data expected first half 2017

NEW YORK, NY (December 6, 2016) - TG Therapeutics, Inc. (NASDAQ:TGTX), today announced that the target enrollment of 120 patients in the GENUINE Phase 3 study has been met and enrollment will be closed shortly. The GENUINE Phase 3 study is a randomized study of TG-1101, the Company's novel, glycoengineered anti-CD20 monoclonal antibody in combination with ibrutinib, the oral Bruton's tyrosine kinase (BTK), versus ibrutinib alone in approximately 120 patients with high-risk relapsed or refractory Chronic Lymphocytic Leukemia (CLL). In October, the study was modified to convert the primary endpoint solely to Overall Response Rate (ORR). If the study results are positive, and subject to a positive outcome of pre-BLA meeting with the FDA, the Company plans to utilize the results to file for accelerated approval. The Company expects to release top-line data from the GENUINE Phase 3 study in the first half of 2017.

Michael S. Weiss, the Company's Executive Chairman and Interim CEO commenting on the announcement stated, "Today's news puts us on a clear path toward our first pivotal data for TG-1101. As demonstrated in our Phase 2 study evaluating TG-1101 plus ibrutinib, we believe the addition of an anti-CD20 monoclonal antibody can enhance the clinical response of single agent ibrutinib by more rapidly reducing tumor burden, increasing the rate of response, deepening responses and, ideally, leading to better long-term outcomes. Overall response rate has been utilized as an acceptable surrogate endpoint for improved progression free survival and overall survival for a number of recent approvals in high-risk CLL and we believe the results, if positive, may support an accelerated approvable for the combination. We want to thank our clinical collaborators and their patients for their participation in this study."

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 (ublrituximab) 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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CONTACT:

Jenna Bosco
Vice President, Investor Relations
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com
