TG THERAPEUTICS, INC.

FORM 8-K
(Current report filing)

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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 11, 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 December 11, 2017, TG Therapeutics, Inc. (the "Company") issued a press release announcing clinical and preclinical data presented involving the Company's lead compounds, TGR-1202 (umbralisib), the Company's once-daily PI3K delta inhibitor, and TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, at the 59 th American Society of Hematology (ASH) annual meeting, being held at the Georgia World Congress Center in Atlanta, Georgia. 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 December 11, 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: December 11, 2017

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

TG Therapeutics, Inc. Announces Preclinical & Clinical Data Presentations at the 59 h American Society of Hematology Annual Meeting

Clinical presentations continue to underscore safety profile of TGR-1202 as monotherapy and in combination, including in long-term follow-up

Preclinical advances may offer rationale for the differentiated activity and safety of TGR-1202

ATLANTA, GA (December11, 2017) - TG Therapeutics, Inc. (NASDAQ:TGTX), announces the presentation of six posters highlighting preclinical and clinical data sets for TGR-1202 (umbralisib), the Company's once-daily PI3K delta inhibitor, and TG-1101 (ublituximab), the Company's novel glycoengineered anti-CD20 monoclonal antibody, at the 59 th American Society of Hematology (ASH) annual meeting, currently being held at the Georgia World Congress Center in Atlanta, Georgia.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are very pleased by the data presented yesterday and today during the ASH annual meeting. The preclinical data help us to better understand the difference between TGR-1202 and other agents in the class and offers a more complete rationale for the differentiated safety profile seen in the clinic. With the updated and expanded integrated safety analysis of TGR-1202 alone and in combination with other agents, we believe we have provided the long-term follow-up sufficient to allay any lingering safety concerns related to TGR-1202 caused by the toxicity profile of first generation PI3K delta inhibitors." Mr. Weiss continued, "In 2018, with registration-directed data expected in CLL and NHL, our focus will turn to showcasing the efficacy of TGR-1202 and our proprietary combination of TG-1101 plus TGR-1202, our U2 combination, ideally leading to NDA/BLA filings in CLL and NHL."

The following summarizes the highlights from each poster presented at the ASH 2017 meeting.

Clinical Data Presentations:

An Integrated Safety Analysis of the Next Generation PI3K Delta Inhibitor Umbralisib (TGR-1202) in Patients with Relapsed/Refractory Lymphoid Malignancies

This presentation includes data that were pooled from 5 completed or ongoing Phase 1 or 2 studies containing TGR-1202, including a total of 347 patients with relapsed or refractory hematologic malignancies. Patients were heavily pretreated, with 50% of patients having seen 3 or more prior lines of therapy.

Highlights from this poster include:

- 347 patients have been treated with TGR-1202 across the 5 studies in this pooled analysis, with median duration of exposure of 6.5 months, and 176 patients on drug for 6+ months, 104 patients for 12+ months, with the longest patients on daily TGR-1202 for 4+ years
- In longer follow-up and in an expanded patient population, TGR-1202 exhibits a differentiated safety profile compared to prior generation PI3K delta inhibitors
- Discontinuations due to adverse events (AEs) were rare at under 10% for all studies
- Grade 3/4 AEs commonly associated with PI3K delta inhibitors have been rare, with pneumonitis (< 0.5%), transaminitis (~2%) and colitis (< 1%), the latter occurring with no apparent association to time on therapy
- Improved tolerability with few discontinuations due to AEs has allowed patients to remain on continuous dosing to achieve and sustain promisingly high rates of response:
    - 85% Overall Response Rate (ORR) for single agent TGR-1202 in relapsed/refractory Chronic Lymphocytic Leukemia (CLL)
    - 53% ORR for single agent TGR-1202 in relapsed/refractory Follicular Lymphoma (FL)

KI Intolerance Study: A Phase 2 Study to Assess the Safety and Efficacy of Umbralisib (TGR-1202) In Patients with Chronic Lymphocytic Leukemia (CLL) Who Are Intolerant to Prior BTK or PI3K-delta Inhibitor Therapy (Abstract Number 4314)

This poster presentation includes data from patients with CLL who are intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent TGR-1202. To be eligible for the study patients had to have received prior treatment with a BTK inhibitor (ibrutinib, acalabrutinib) or a PI3K delta inhibitor (idelalisib, duvelisib) and discontinued therapy due to intolerance within 12 months of starting treatment on this study. Thirty-three patients were evaluable for safety (30 patients with ibrutinib intolerance, and 3 patients with idelalisib intolerance) of which 32 were evaluable for efficacy (1 patient had a confirmed Richter's Transformation (RT) at enrollment which did not meet eligibility criteria). TGR-1202 appears to demonstrate a favorable safety profile in patients intolerant to prior ibrutinib or idelalisib, with only 2 patients (6%) discontinuing due to an adverse event, neither of which was a recurrent AE from prior TKI therapy.

Highlights from this poster include:

- 94% (30 of 32) of patients remain progression-free
- 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
- No patient discontinued TGR-1202 due to a recurrent AE which led to discontinuation from their prior kinase inhibitor

Phase I/II Study of Pembrolizumab in Combination with Ublituximab (TG-1101) and Umbralisib (TGR-1202) in Patients with Relapsed/Refractory CLL (Abstract Number 3010)

This presentation includes data from patients with relapsed or refractory Chronic Lymphocytic Leukemia (CLL) or Richter's Transformation (RT) treated with the triple combination of TG-1101, TGR-1202, and pembrolizumab. Eleven patients were evaluable for safety (9 CLL patients and 2 RT patients) and 10 were evaluable for efficacy (9 CLL and 1 RT), with one patient too early to evaluate.

Highlights from this poster include:

- One AE of increased LFTs was observed which met criteria for DLT; patient was re-challenged and remains on study treatment with TGR-1202 maintenance now 15+ months
- 78% (7 of 9) ORR in patients with relapsed/refractory CLL
- 75% (3 of 4) ORR in BTK refractory CLL patients
- Responses have been durable with the first patient progression-free for 24+ months

Preclinical Data Presentations:

Differential Regulation of T Cells By PI3K Delta Inhibitors in a CLL Murine Model (Abstract Number: 3009)

This poster presentation included preclinical data describing the differential regulation of human T cells by TGR-1202 in a preclinical CLL murine model.

Highlights from this poster include:

- TGR-1202 oral treatment induced less incidence of toxicity in CLL mice compared to other PI3K delta inhibitors
- TGR-1202 relatively preserved Treg quantity and function in a dose dependent manner compared to other PI3K delta inhibitors in normal and murine CLL T cells
- Inhibition of casein-kinase 1 epsilon (CK1e) by TGR-1202 may explain the relative preservation of Treg cells in these in-vivo models

Umbralisib/TGR-1202 As a Novel Dual PI3K/CK1 Inhibitor Has a Unique Therapeutic Role in Silencing Oncogenes in Aggressive Lymphomas (Abstract Number 2809)

This poster presentation expanded on existing preclinical data demonstrating that TGR-1202 is synergistic with carfilzomib in certain aggressive lymphoma cell lines.

Highlights from this poster include:

- TGR-1202 is highly synergistic with the proteasome inhibitor carfilzomib in cell line models of double hit lymphoma and mantle cell lymphoma
- Based on this preclinical work, a Phase 1 clinical study to evaluate the safety and efficacy of TGR-1202 in combination with carfilzomib is currently enrolling patients

PI3K Delta Inhibitors Induce Primary Monocyte Cytotoxicity but Do Not Alter Monocyte Differentiation (Abstract Number 4284)

This poster presentation included preclinical data exploring the effect of PI3K delta inhibitors on monocyte activity.

Highlights from this poster include:

- The clinical benefit and initial lymphocytosis seen with PI3K delta inhibitors in CLL may be related in part to direct effects on monocyte derived cells
- Idelalisib and TGR-1202 differed in the extent of monocyte cytotoxicity induced and inhibition of pAKT
- The direct effects of PI3K delta inhibitors on monocytes suggests these drugs may have efficacy beyond B-cell malignancies, including in monocytic neoplasms or other malignancies with monocyte derived cells in the tumor microenvironment

The above referenced presentations, are available on the Publications page of the Company's website at www.tgtherapeutics.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 (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: our ability to successfully and cost effectively complete preclinical and clinical trials; the risk that early preclinical and clinical trial results, 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 or in future data presentations; the risk that preclinical findings may not translate into predicted potential clinical outcomes or be reproduced in future experiments; 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 double combination or backbone for triple therapies;the risk that early clinical data from triple combination studies will not be reproduced in additional patients or future clinical trials; the risk that TGR-1202 will not maintain its differentiated safety profile as patients continue to be treated on drug for longer durations and more patients are enrolled; the risk that any interim analyses from ongoing clinical trials will not produce the desired or predicted result in the final analysis; the risk that the company will not be able to deliver data or updates on schedule as planned; the risk projected BLA/NDA filings cannot be made on schedule as targeted or at all. 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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