

# TG THERAPEUTICS, INC.

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

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Address	2 GANSEVOORT STREET, 9TH FLOOR NEW YORK, NY, 10014
Telephone	(212) 554-4484
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Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

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): **November 8, 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 2.02. Results of Operations and Financial Condition.**

On November 8, 2017, TG Therapeutics, Inc. (“TG” or the “Company”) issued a press release announcing results of operations for the third quarter ended September 30, 2017. TG also announced that on Wednesday, November 8, 2017 at 8:30am ET, TG would host an investor conference call during which the Company would provide a brief overview of its third quarter financial results and provide a business outlook for the remainder of 2017. A copy of such press release is being furnished as Exhibit 99.1.

**Item 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

99.1 Press release issued by TG Therapeutics, Inc., dated November 8, 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)

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

Date: November 8, 2017

## TG Therapeutics, Inc. Provides Business Update and Reports Third Quarter 2017 Financial Results

*Investor Conference Call to be Held Today, Wednesday, November 8, 2017 at 8:30am ET*

New York, NY, ( **November 8, 2017** ) – TG Therapeutics, Inc. (NASDAQ:TGTX) today announced its financial results for the third quarter ended September 30, 2017, and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "The third quarter was an extremely productive and exciting time for the Company highlighted by the completion of enrollment into our UNITY-CLL Phase 3 study, the commencement of our global Phase 3 trials in multiple sclerosis, and the additional clarity we received from the FDA regarding the GENUINE study. We look forward, over the next 6-12 months, to what we believe will be a number of value creating milestones, including overall response data from UNITY-CLL and additional data supporting our strategy in NHL." Mr. Weiss continued, "From a financial perspective, we remain well positioned through these important milestones."

### Third Quarter and Recent Highlights

- **ASH 2017:** The Company looks forward to the upcoming American Society of Hematology (ASH) Annual Meeting where data presentations will include three clinical poster presentations and three pre-clinical poster presentations.
- **TG-1101 Data at ECTRIMS:** Updated results from the ongoing Phase 2 Study of TG-1101 in patients with Multiple Sclerosis were presented at the 7<sup>th</sup> Joint ECTRIMS-ACTRIMS Meeting demonstrating robust activity on B-cell depletion, reduction of T1 Gd enhancing lesions, and positive effects on disability measurements.
- **UNITY-CLL Enrollment:** Full enrollment in the UNITY-CLL Phase 3 Trial was completed in October, which should allow for top-line data on Overall Response Rate (ORR) in Q2 2018.
- **GENUINE Update:** The Company met with the FDA and confirmed that accelerated approval based on the ORR results from GENUINE would be a review issue and that the potential may exist for full approval based on the PFS results from the GENUINE study.
- **TGR-1202 Grant:** TGR-1202 (umbralisib) was selected for a grant by the National Multiple Sclerosis Society to support the development of TGR-1202 as an oral B-Cell targeted treatment option in progressive Multiple Sclerosis (PMS).
- **Anti-PD-L1 Entered the Clinic :** The Company's anti-PD-L1 monoclonal antibody commenced clinical development, with the first patient being dosed in a Phase I clinical trial.
- **ULTIMATE Phase 3 Trials in MS:** Received a Special Protocol Assessment (SPA) for the Phase 3 ULTIMATE I and II studies in relapsing forms of multiple sclerosis and commenced enrollment into the global studies.
- **UNITY-NHL:** Announced successful outcome from the first pre-planned interim analysis by independent DSMB of the DLBCL cohort in the UNITY-NHL Phase 2b trial, where based on pre-set hurdles of ORR, the DSMB recommended continued enrollment in the TG-1101 plus TGR-1202 combination arm (also referred to as the U2 combination) and replacement of the single agent TGR-1202 arm with U2 plus bendamustine.

### Financial Results for the Third Quarter 2017

- **Cash Position:** Cash, cash equivalents, investment securities, and interest receivable were \$91.8 million as of September 30, 2017, as compared to \$86.5 million at June 30, 2017.
  - **R&D Expenses:** Research and development (R&D) expenses were \$27.1 million and \$76.5 million for the three and nine months ended September 30, 2017, respectively, compared to \$21.8 million and \$46.9 million for the three and nine months ended September 30, 2016. Included in research and development expense for the three and nine months ended September 30, 2017 was \$7.1 million and \$20.4 million, respectively, of manufacturing and CMC expenses for Phase 3 clinical trials and potential commercialization. The increase in R&D expenses for both the three and nine months ended September 30, 2017, is primarily due to the ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202.
  - **G&A Expenses:** General and administrative (G&A) expenses were \$4.5 million and \$11.3 million for the three and nine months ended September 30, 2017, respectively, as compared to \$3.2 million and \$8.1 million for the three and nine months ended September 30, 2016. The increase in G&A expenses for the nine months ended September 30, 2017 relates primarily to non-cash compensation expenses related to equity incentive grants recognized during 2017. We expect G&A expenses to remain relatively constant through the remainder of 2017.
  - **Net Loss:** Net loss was \$31.5 million and \$87.6 million for the three and nine months ended September 30, 2017, respectively, compared to a net loss of \$24.8 million and \$54.6 million for the three and nine months ended September 30, 2016, respectively.
  - **Financial Guidance:** The Company believes its cash and cash equivalents will be sufficient to fund the Company's planned operations through 2018.
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## **Conference Call Information**

The Company will host an investor conference call today, November 8, 2017, at 8:30am ET, to discuss the Company's third quarter 2017 financial results and provide a business outlook for the remainder of 2017.

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 Third Quarter 2017 Earnings 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](http://www.tgtherapeutics.com). An audio recording of the conference call will also be available for replay at [www.tgtherapeutics.com](http://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 (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 clinical trials; our ability to manage cash in line with our expectations; the risk that we don't achieve expected milestones or that even if achieved they are not value creating; the risk that early clinical trial results from interim analysis or from the review of a DSMB or similar safety monitoring committee will not ultimately be reflective of the results of the entire study when completed; the risk that results from earlier clinical trials, including those that may have supported the acceptance of our data for presentation or publication or may have influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies; 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 and other studies, will not prove to be a safe and efficacious for any indication or prove to be an safe and effective for use as part of triple and quad treatment regimens; the risk that any interim analyses from ongoing clinical trials will not produce the desired or predicted result; the risk the results of the GENUINE trial will not be adequate to support the filing of a BLA of TG-1101 in combination with ibrutinib or that we choose not to file a BLA based on the GENUINE trial; the risk that the early Phase 2 data of TG-1101 in MS will not be reproduced in the Phase 3 MS trial. 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.**  
**Selected Consolidated Financial Data**

**Statements of Operations Information (Unaudited) :**

	<u>Three months ended September 30,</u>		<u>Nine months ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
License revenue	\$ 38,096	\$ 38,096	\$ 114,286	\$ 114,286
Costs and expenses:				
Research and development:				
Noncash compensation	1,814,288	919,648	5,386,709	1,873,730
Other research and development	<u>25,334,762</u>	<u>20,878,108</u>	<u>71,150,033</u>	<u>45,075,097</u>
Total research and development	<u>27,149,050</u>	<u>21,797,756</u>	<u>76,536,742</u>	<u>46,948,827</u>
General and administrative:				
Noncash compensation	3,075,835	1,914,390	6,988,597	4,307,670
Other general and administrative	<u>1,398,438</u>	<u>1,251,421</u>	<u>4,265,967</u>	<u>3,798,859</u>
Total general and administrative	<u>4,474,273</u>	<u>3,165,811</u>	<u>11,254,564</u>	<u>8,106,529</u>
Total costs and expenses	<u>31,623,323</u>	<u>24,963,567</u>	<u>87,791,306</u>	<u>55,055,356</u>
Operating loss	<u>(31,585,227)</u>	<u>(24,925,471)</u>	<u>(87,677,020)</u>	<u>(54,941,070)</u>
Other (income) expense:				
Interest income	(79,163)	(87,965)	(174,056)	(265,456)
Other	<u>29,588</u>	<u>(6,479)</u>	<u>113,281</u>	<u>(96,863)</u>
Total other income	<u>(49,575)</u>	<u>(94,444)</u>	<u>(60,775)</u>	<u>(362,319)</u>
Net loss	\$ (31,535,652)	\$ (24,831,027)	\$ (87,616,245)	\$ (54,578,751)
Basic and diluted net loss per common share	<u>\$(0.48)</u>	<u>\$(0.50)</u>	<u>\$(1.45)</u>	<u>\$(1.11)</u>
Weighted average shares used in computing basic and diluted net	<u>65,079,128</u>	<u>49,203,277</u>	<u>60,552,084</u>	<u>48,961,582</u>

loss per common share

**Condensed Balance Sheet Information:**

	<b>September 30, 2017</b> <b>(unaudited)</b>	<b>December 31, 2016*</b>
	\$ 91,842,167	\$ 44,968,992
Cash, cash equivalents, investment securities and interest receivable		
<b>Total assets</b>	<b>101,781,514</b>	<b>54,781,547</b>
Accumulated deficit	(324,003,065 )	(236,386,820 )
<b>Total equity</b>	<b>79,545,766</b>	<b>35,867,802</b>

\* Condensed from audited financial statements.

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