

# 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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Symbol	TGTX
SIC Code	2834 - Pharmaceutical Preparations
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): **August 9, 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 August 9, 2017, TG Therapeutics, Inc. (“TG” or the “Company”) issued a press release announcing results of operations for the second quarter ended June 30, 2017. TG also announced that on Wednesday, August 9, 2017 at 8:30am ET, TG would host an investor conference call during which the Company would provide a brief overview of its second 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 August 9, 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: August 9, 2017

INDEX TO EXHIBITS

**Exhibit  
Number**

**Description**

99.1

Press release issued by TG Therapeutics, Inc., dated August 9, 2017.

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

*Investor Conference Call to be Held Today, Wednesday, August 9, 2017 at 8:30am ET*

New York, NY, ( **August 9, 2017** ) – TG Therapeutics, Inc. (NASDAQ:TGTX) today announced its financial results for the second quarter ended June 30, 2017 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "The second quarter was a busy and exciting time for the Company, with the full presentation of the GENUINE data at ASCO coupled with additional important data presentations for TGR-1202 in various combinations. In addition, we were pleased to announce a successful outcome to the interim analysis in the UNITY-CLL program, allowing us to drop the two single agent arms and confirming that there were no safety issues requiring a modification of the trial. The UNITY-CLL study continues to enroll very robustly and we look forward to completing enrollment into the study by the end of the year." Mr. Weiss continued, "For the remainder of the year we look forward to our discussions with the FDA around the positive GENUINE Phase 3 results and the imminent commencement of the Phase 3 program of TG-1101 in RMS, for which we recently announced an SPA agreement with the FDA."

### **Recent Developments and Highlights**

- Presented positive data from the Phase 3 GENUINE Trial of TG-1101 in combination with Ibrutinib in patients with high risk Chronic Lymphocytic Leukemia (CLL)
- Presented follow-up data for combination of TGR-1202 (umbralisib) plus Ibrutinib in patients with relapsed or refractory CLL and Mantle Cell Lymphoma (MCL)
- Presented follow-up data for the triple combination of TG-1101, TGR-1202, and Bendamustine in patients with DLBCL and FL
- Presented follow-up data from the chemo-free triple combination of TG-1101, TGR-1202, and Ibrutinib
- Announced the successful outcome from the pre-planned interim analysis by an independent DSMB in the UNITY-CLL Phase 3 Trial which allowed for closing of enrollment to the single agent arms in this study
- Presented preliminary data from the ongoing Phase 2 study of TG-1101 in patients with Multiple Sclerosis (MS)
- Announced a Special Protocol Assessment (SPA) agreement with the FDA for a Phase 3 program for TG-1101 in relapsing forms of MS

### **Key Remaining 2017 Milestones**

- Complete the first interim analysis in the UNITY-NHL trial for the DLBCL cohort
  - Initiate a global Phase 3 program in MS, to be conducted under SPA agreement with the FDA
  - Present updated clinical data from the Phase 2 MS trial
  - Meet with the FDA to review the GENUINE Phase 3 data and discuss suitability for filing for accelerated approval
  - Complete enrollment into UNITY-CLL
  - Present new and updated data from ongoing trials at various scientific meetings throughout the year, including the American Society of Hematology (ASH) annual meeting in December
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## **Financial Results for the Second Quarter 2017**

- **Cash Position:** Cash, cash equivalents, investment securities, and interest receivable were \$86.5 million as of June 30, 2017. Pro-forma cash, cash equivalents, investment securities, and interest receivable as of June 30, 2017 are approximately \$97.4 million, after giving effect to \$10.9 million of net proceeds from the utilization of the Company's at-the-market ("ATM") sales facility during the third quarter of 2017.
- **R&D Expenses:** Research and development (R&D) expenses were \$26.7 million and \$49.4 million for the three and six months ended June 30, 2017, respectively, compared to \$13.5 million and \$25.2 million for the three and six months ended June 30, 2016. Included in research and development expense for the three and six months ended June 30, 2017 was \$8.1 million and \$13.3 million, respectively, of manufacturing and CMC expenses for Phase 3 clinical trials and potential commercialization, and \$2.4 million and \$3.4 million, respectively, in expenses related to commencement of the Phase 3 program for TG-1101 in MS. The increase in R&D expenses for both the three and six months ended June 30, 2017, is primarily due to the ongoing clinical development programs, including the start-up costs in preparation for the TG-1101 MS Phase 3 program, as well as manufacturing costs for both TG-1101 and TGR-1202.
- **G&A Expenses:** General and administrative (G&A) expenses were \$1.8 million and \$6.8 million for the three and six months ended June 30, 2017, respectively, as compared to \$2.5 million and \$4.9 million for the three and six months ended June 30, 2016. The increase in G&A expenses for the six months ended June 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 \$28.4 million and \$56.1 million for the three and six months ended June 30, 2017, respectively, compared to a net loss of \$15.9 million and \$29.7 million for the three and six months ended June 30, 2016, respectively.
- **Financial Guidance:** The Company believes its cash, cash equivalents, investment securities, and interest receivable inclusive of the proceeds raised subsequent to the quarter-end will be sufficient to fund the Company's planned operations through 2018.

## **Conference Call Information**

The Company will host an investor conference call today, August 9, 2017, at 8:30am ET, to discuss the Company's second 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 Second 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 are in clinical development for patients with hematologic malignancies, with TG-1101 also in 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.

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## 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 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; 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 June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
	\$ <u>38,095</u>	\$ <u>38,095</u>	\$ <u>76,190</u>	\$ <u>76,190</u>
License revenue				
Costs and expenses:				
Research and development:				
Noncash compensation	1,266,322	567,157	3,572,421	954,082
Other research and development	<u>25,439,477</u>	<u>12,966,574</u>	<u>45,815,271</u>	<u>24,196,989</u>
Total research and development	<u>26,705,799</u>	<u>13,533,731</u>	<u>49,387,692</u>	<u>25,151,071</u>
General and administrative:				
Noncash compensation	223,406	1,081,240	3,912,762	2,393,280
Other general and administrative	<u>1,534,261</u>	<u>1,446,567</u>	<u>2,867,529</u>	<u>2,547,438</u>
Total general and administrative	<u>1,757,667</u>	<u>2,527,807</u>	<u>6,780,291</u>	<u>4,940,718</u>
Total costs and expenses	<u>28,463,466</u>	<u>16,061,538</u>	<u>56,167,983</u>	<u>30,091,789</u>
Operating loss	<u>(28,425,371)</u>	<u>(16,023,443)</u>	<u>(56,091,793)</u>	<u>(30,015,599)</u>
Other (income) expense:				
Interest income	(50,197)	(92,629)	(94,893)	(177,491)
Other (income) expense	<u>(22,090)</u>	<u>(31,752)</u>	<u>83,693</u>	<u>(90,384)</u>
Total other (income) expense	<u>(72,287)</u>	<u>(124,381)</u>	<u>(11,200)</u>	<u>(267,875)</u>
Net loss	<u>\$ (28,353,084)</u>	<u>\$ (15,899,062)</u>	<u>\$ (56,080,593)</u>	<u>\$ (29,747,724)</u>
Basic and diluted net loss per common share	<u>\$ (0.45)</u>	<u>\$ (0.33)</u>	<u>\$ (0.96)</u>	<u>\$ (0.61)</u>
Weighted average shares used in computing basic and diluted net	<u>63,288,269</u>	<u>48,769,948</u>	<u>58,251,045</u>	<u>48,838,731</u>

loss per common share

**Condensed Balance Sheet Information:**

	<u>June 30 2017</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2016*</u>
	\$ 86,454,583	\$ 44,968,992
Cash, cash equivalents, investment securities and interest receivable		
Total assets	101,197,751	54,781,547
Accumulated deficit	(292,467,413 )	(236,386,820 )
Total equity	77,975,018	35,867,802

\* Condensed from audited financial statements.

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