

# TG THERAPEUTICS, INC.

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

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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): **November 7, 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, 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.
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**Item 2.02. Results of Operations and Financial Condition.**

On November 7, 2016, TG Therapeutics, Inc. (“TG” or the “Company”) issued a press release announcing results of operations for the third quarter ended September 30, 2016. TG also announced that on Monday, November 7, 2016 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 2016. 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 7, 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)

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

Date: November 7, 2016

**INDEX TO EXHIBITS**

<b><u>Exhibit Number</u></b>	<b><u>Description</u></b>
99.1	Press release issued by TG Therapeutics, Inc., dated November 7, 2016.

## TG Therapeutics, Inc. Provides Business Update and Reports Third Quarter 2016 Financial Results

*Investor Conference Call to be Held Today, Monday, November 7, 2016 at 8:30am ET*

New York, NY, ( **November 7, 2016** ) – TG Therapeutics, Inc. (NASDAQ:TGTX) today announced its financial results for the third quarter ended September 30, 2016 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer, stated, "The third quarter was a pivotal one for the company, particularly with the amendment of the GENUINE Phase 3 trial that will enable the rapid conclusion of the study while also maintaining the possibility for accelerated approval for TG-1101 in combination with ibrutinib. Importantly, with GENUINE enrollment wrapping up, we can dedicate our resources and focus to our proprietary UNITY program, which we believe offers the potential for highly active, well-tolerated therapy with certain pricing advantages over competitors. As a result, we see our value proposition rising as the concern around pharmaceutical pricing continues to grow." Mr. Weiss continued, "We see important value creating milestones over the next 12 months, including completion of enrollment of GENUINE expected by year end 2016 to be followed by top line data in the first half of 2017. During the course of 2017, we should also report early data from our UNITY-DLBCL study and our MS pivotal program should take full form supported by B-cell depletion data from our ongoing Phase 2 study in RRMS. With all these events lining up, we believe 2017 will be our most impactful year to date."

### Third Quarter and Recent Highlights

- **ASH 2016:** The Company looks forward to the upcoming American Society of Hematology (ASH) Annual Meeting where data presentations will include three oral presentations and three poster presentations. All clinical presentations will highlight the safety and efficacy for combinations of TGR-1202 with novel targeted agents including oral presentations with TGR-1202 in combination with ibrutinib and TGR-1202 in combination with ruxolitinib.
- **TGR-1202 Pre-Clinical Differentiation:** An October publication in *Blood* presented preclinical data describing the synergy of TGR-1202 with carfilzomib and the unique effects of the combination to silence c-Myc in various preclinical lymphoma and myeloma models. In addition, the publication described TGR-1202's unique complimentary mechanism of inhibiting the protein kinase casein kinase-1 (CK1) epsilon, which may contribute to the silencing of c-Myc and explain TGR-1202's clinical activity in aggressive lymphoma.
- **TGR-1202 + Carfilzomib:** Based on the pre-clinical work on TGR-1202 published in *Blood* , a Phase 1/2 study of TGR-1202 and Carfilzomib in patients with relapsed or refractory lymphoma was launched.
- **GENUINE Study Amendment:** The Company amended the ongoing GENUINE Phase 3 Clinical Trial by revising the primary endpoint to Overall Response Rate (ORR), with enrollment expected to be completed before year end 2016 and top-line data available in first half of 2017. The study is well powered to detect a difference in ORR, which, if successful, would potentially support a filing for accelerated approval.
- **Clinical Data Presentation of TG-1101 in NMO:** During the 32nd Congress of the European Committee for Treatment and Research in Multiple Sclerosis, the Company presented clinical data from the Phase 1b study of TG-1101 in patients with NMO with TG-1101 demonstrating rapid and effective depletion of B-cells during acute NMO relapse. The Company has an on-going Phase 2 study of TG-1101 in multiple sclerosis.
- **Orphan Drug Designations:** The Company received Orphan Drug Designation for TGR-1202 for treatment of Chronic Lymphocytic Leukemia and for TG-1101 for treatment of Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorder (NMOSD).
- **UNITY-DLBCL:** Patient enrollment began for the registration-directed UNITY-DLBCL Phase 2b clinical study evaluating TG-1101 and TGR-1202 in combination compared to TGR-1202 monotherapy in patients with advanced relapsed/refractory DLBCL.

### Key Remaining 2016 Milestones

- Complete enrollment into the GENUINE Phase 3 clinical trial
  - Aggressively enroll into the Company's registration directed trials, including the UNITY-CLL Phase 3, and the UNITY-DLBCL Phase 2b
  - Continue enrollment into the Phase 2 clinical trial in Multiple Sclerosis
  - Present clinical data from a variety of Phase 1 and 2 clinical trials at the American Society of Hematology Annual Meeting in December 2016, held in San Diego, CA
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## **Financial Results for the Third Quarter 2016**

- **Cash Position:** Cash, cash equivalents, investment securities, and interest receivable were \$60.7 million as of September 30, 2016.
- **R&D Expenses:** Research and development (R&D) expenses were \$21.8 million and \$46.9 million for the three and nine months ended September 30, 2016, respectively, compared to \$11.6 million and \$32.5 million for the three and nine months ended September 30, 2015, respectively. Included in research and development expenses for the three and nine months ended September 30, 2016, are \$10.2 million and \$17.9 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, 2016, 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 \$3.2 million and \$8.1 million for the three and nine months ended September 30, 2016, respectively, as compared to \$2.3 million and \$13.2 million for the three and nine months ended September 30, 2015, respectively. The period-over-period decrease in G&A expenses from the nine months ended September 30, 2015 relates primarily to non-cash compensation expenses related to equity incentive grants recognized during 2015. G&A expenses for the three months ended September 30, 2016 remained relatively flat compared to the second quarter of 2015, and we expect G&A expenses to remain relatively constant through the fourth quarter of 2016.
- **Net Loss:** Net loss was \$24.8 million and \$54.6 million for the three and nine months ended September 30, 2016, respectively, compared to a net loss of \$13.7 million and \$45.3 million for the three and nine months ended September 30, 2015, respectively.
- **Financial Guidance:** The Company believes its cash, cash equivalents, investment securities, and interest receivable of \$60.7 million as of September 30, 2016 will be sufficient to fund the Company's planned operations into the first half of 2018.

## **Conference Call Information**

The Company will host an investor conference call today, November 7, 2016, at 8:30am ET, to discuss the Company's third quarter 2016 financial results and provide a business outlook for the remainder of 2016.

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 2016 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, 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 .

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## 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 topline data for the GENUINE study, the usability of the results from GENUINE for accelerated approval, timing of initial data from the UNITY-DLBCL study, timing of the release of data and commencement of our MS pivotal program 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, the UNITY-CLL or the UNITY-DLBCL trials; the risk that the clinical results from the GENUINE, UNITY-CLL and/or UNITY-DLBCL 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, the UNITY-CLL and/or the UNITY-DLBCL 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 or the UNITY-DLBCL 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 or the UNITY-DLBCL studies, 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.tgetherapeutics.com](http://www.tgetherapeutics.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>2016</u>	<u>2015</u>	<u>2016</u>	<u>2015</u>
	\$ 38,096	\$ 38,096	\$ 114,286	\$ 114,286
License revenue				
Costs and expenses:				
Research and development:				
Noncash compensation	919,648	35,756	1,873,730	2,733,110
Other research and development	<u>20,878,108</u>	<u>11,538,246</u>	<u>45,075,097</u>	<u>29,719,891</u>
Total research and development	<u>21,797,756</u>	<u>11,574,002</u>	<u>46,948,827</u>	<u>32,453,001</u>
General and administrative:				
Noncash compensation	1,914,390	1,204,278	4,307,670	10,106,938
Other general and administrative	<u>1,251,421</u>	<u>1,085,400</u>	<u>3,798,859</u>	<u>3,094,362</u>
Total general and administrative	<u>3,165,811</u>	<u>2,289,678</u>	<u>8,106,529</u>	<u>13,201,300</u>
Total costs and expenses	<u>24,963,567</u>	<u>13,863,680</u>	<u>55,055,356</u>	<u>45,654,301</u>
Operating loss	<u>(24,925,471)</u>	<u>(13,825,584)</u>	<u>(54,941,070)</u>	<u>(45,540,015)</u>
Other (income) expense:				
Interest income	(87,965)	(55,977)	(265,456)	(109,660)
Other income	(33,042)	--	(33,042)	--
Interest expense	211,538	246,527	674,699	730,710
Change in fair value of notes payable	<u>(184,975)</u>	<u>(360,218)</u>	<u>(738,520)</u>	<u>(824,231)</u>
Total other income	<u>(94,444)</u>	<u>(169,668)</u>	<u>(362,319)</u>	<u>(203,181)</u>
Net loss	<u>\$ (24,831,027)</u>	<u>\$ (13,655,916)</u>	<u>\$ (54,578,751)</u>	<u>\$ (45,336,834)</u>

	\$ <u>(0.50)</u>	\$ <u>(0.28)</u>	\$ <u>(1.11)</u>	\$ <u>(1.01)</u>
Basic and diluted net loss per common share	)	)	)	)
	= <u>49,203,277</u>	= <u>47,946,309</u>	= <u>48,961,582</u>	= <u>44,810,352</u>
Weighted average shares used in computing basic and diluted net loss per common share				

**Condensed Balance Sheet Information:**

	<u>September 30, 2016</u> <u>(unaudited)</u>	<u>December 31, 2015*</u>
Cash, cash equivalents, investment securities and interest receivable	\$ 60,710,595	\$ 102,416,894
Total assets	75,687,094	113,473,201
Accumulated deficit	(212,712,677)	(158,133,926)
Total equity	56,754,721	101,573,302

\* Condensed from audited financial statements.