

# TG THERAPEUTICS, INC.

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

Filed 03/10/17 for the Period Ending 03/10/17

Address	787 SEVENTH AVENUE NEW YORK, NY 10019
Telephone	(212) 554-4484
CIK	0001001316
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

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): **March 10, 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.
-

**Item 8.01. Other Events.**

On March 10, 2017, TG Therapeutics, Inc. (“TG” or the “Company”) issued a press release announcing results of operations for the fourth quarter and year ended December 31, 2016. TG also announced that on Friday, March 10, 2017 at 8:30am ET, TG would host an investor conference call during which the Company would provide a brief overview of its fourth quarter and year-end 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, dated March 10, 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: March 10, 2017

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

---

## INDEX TO EXHIBITS

**Exhibit  
Number**

**Description**

99.1. Press Release, dated March 10, 2017

---

## TG Therapeutics, Inc. Announces Fourth Quarter and Year-End 2016 Financial Results and Business Update

*Company solidifies balance sheet with approximately \$89M in gross proceeds through the combination of \$57.5M public offering and \$31M from at-the-market (ATM) sales facility completed prior to the offering*

*Investor conference call to be held today, Friday March 10, 2017 at 8:30am ET*

New York, NY, ( **March 10, 2017** ) – TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the fourth quarter and year ended December 31, 2016 and provided recent company developments along with a business outlook for 2017.

The Company announced that through the combination of an underwritten public offering, and proceeds raised through the utilization of an ATM program, the Company raised combined gross proceeds of approximately \$89M before deducting underwriting discounts and commissions and other estimated offering expenses. The underwritten offering consisted of 5,128,206 shares of its common stock (plus a 30-day option to purchase up to an additional 769,230 shares of common stock, which has been exercised) at a price of \$9.75 per share, with expected gross proceeds to TG Therapeutics of \$57.5 million, less underwriting discounts and commissions. The offering is expected to close on or about March 14, 2017, subject to the satisfaction of customary closing conditions. Prior to the public offering, the Company also issued approximately 3,000,000 shares through the ATM program for gross proceeds of approximately \$31 million at an average price of \$10.27, these shares were issued on March 9, 2017.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "2016 was a very productive year for the Company, laying the foundation for pivotal data read-outs in 2017 and 2018. The first of which were reported earlier this week, with the announcement of the positive topline results from our Phase 3 GENUINE clinical trial. For the remainder of 2017, we look forward to the full data presentation from the GENUINE trial in the summer and then in the second half to a meeting with the FDA to discuss a filing for accelerated approval. All along we will continue to remain highly focused on enrolling into our proprietary UNITY programs, which are proceeding nicely and on schedule." Mr. Weiss continued, "This week we also had the opportunity to solidify our cash reserves with the recently conducted offerings, which should provide us with sufficient capital to advance our key programs and get us closer to our goal of bringing our novel treatment options to patients with B-cell malignancies."

### **2016 Highlights**

- Completed enrollment in our Phase 3 GENUINE clinical trial, which resulted in positive topline data
- Launched the UNITY-CLL Phase 3 and UNITY-DLBCL Phase 2b trials for the combination of TG-1101 + TGR-1202
- Announced the positive outcome of our UNITY-CLL Phase 3 DSMB safety review meeting, pursuant to which the study was recommended to continue enrolling both front-line and previously treated patients with no changes recommended to the study
- Launched our first clinical trial in Multiple Sclerosis (MS) for TG-1101
- Announced the issuance of composition of matter patents for both TG-1101 and TGR-1202 providing protection through 2029 and 2033, respectively, both exclusive of available patent term extensions
- Announced two publications in prestigious journals, the first in *BLOOD* describing a novel mechanism of TGR-1202 with potential in cMYC driven malignancies, and the second in the British Journal of Haematology with data from our Phase 2 clinical trial of TG-1101 plus ibrutinib in patients with Chronic Lymphocytic Leukemia (CLL)
- Presented data at the ASH annual meeting including 3 oral presentations and 3 poster presentations, with a focus on combination therapy

### **Key Objectives for 2017**

- Present updated clinical data including the full Phase 3 GENUINE data at a major medical meeting in the first half of 2017
  - Present clinical data from the Phase 2 Multiple Sclerosis (MS) trial
  - Initiate a global Phase 3 trial in MS
  - Complete the first interim analysis in the UNITY-CLL Phase 3 trial
  - Complete the first interim analysis in the UNITY-DLBCL trial
  - Meet with the FDA to review the GENUINE Phase 3 data and discuss suitability for filing for accelerated approval
  - Present new and updated data from ongoing trials at various scientific meetings throughout the year, including the ASH annual meeting in December
-

## **Financial Results for the Fourth Quarter and Full Year 2016**

- **Cash Position:** Cash, cash equivalents, investment securities, and interest receivable were \$45.0 million as of December 31, 2016. During the first quarter of 2017 the Company raised approximately \$84 million of net proceeds from the underwritten public offering of the Company's common stock and the utilization of the Company's at-the-market ("ATM") sales.
- **R&D Expenses:** Research and development (R&D) expenses were \$22.3 million and \$69.2 million for the three and twelve months ended December 31, 2016, respectively, compared to \$15.3 million and \$47.7 million for the three and twelve months ended December 31, 2015, respectively. Included in research and development expenses for the three and twelve months ended December 31, 2016, are \$9.1 million and \$27.0 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 twelve months ended December 31, 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 \$1.8 million and \$9.9 million for the three and twelve months ended December 31, 2016, respectively, as compared to \$2.4 million and \$15.6 million for the three and twelve months ended December 31, 2015, respectively. The period-over-period decrease in G&A expenses from three and twelve months ended December 31, 2015 relates primarily to non-cash compensation expenses related to equity incentive expense recognized during 2015.
- **Net Loss:** Net loss was \$23.7 million and \$78.3 million for the three and twelve months ended December 31, 2016, respectively, compared to a net loss of \$17.6 million and \$62.9 million for the three and twelve months ended December 31, 2015, respectively.
- **Financial Guidance:** The Company believes its cash, cash equivalents, investment securities, and interest receivable on hand as of December 31, 2016 combined with the additional capital raised in the first quarter of 2017 will be sufficient to fund the Company's planned operations for approximately the next 24 months.

## **Conference Call Information**

The Company will host an investor conference call today, Friday, March 10, 2017 at 8:30am ET, to discuss the Company's 2016 financial results and provide a business outlook for 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 Year-End 2016 Earnings Call. A live audio webcast of this conference call 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 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.

---

## 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 presentation of the data for the GENUINE study, the timing of meeting with the FDA to discuss the GENUINE data, the usability of the results from GENUINE for accelerated approval, timing of initial data from the UNITY-DLBCL study, timing of the interim analysis from the UNITY-CLL, timing of the release of Phase 2 data and commencement of our MS pivotal program and the timing of how long our cash resources will carry the Company 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.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.

TGTX - G

CONTACT:

Jenna Bosco  
Vice President, Investor Relations  
TG Therapeutics, Inc.  
Telephone: 212.554.4351  
Email: [ir@tgtxinc.com](mailto:ir@tgtxinc.com)

---

**TG Therapeutics, Inc.**  
**Selected Consolidated Financial Data**

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

	Three Months Ended December 31,		Year Ended December 31,	
	2016	2015	2016	2015
License revenue	\$ 38,095	\$ 38,095	\$ 152,381	\$ 152,381
Costs and expenses:				
Research and development:				
Noncash compensation	868,624	1,528,296	2,742,354	4,261,406
Other research and development	<u>21,414,723</u>	<u>13,725,926</u>	<u>66,489,820</u>	<u>43,445,817</u>
Total research and development	<u>22,283,347</u>	<u>15,254,222</u>	<u>69,232,174</u>	<u>47,707,223</u>
General and administrative:				
Noncash compensation	459,975	1,328,748	4,767,645	11,435,686
Other general and administrative	<u>1,322,831</u>	<u>1,095,126</u>	<u>5,121,690</u>	<u>4,189,488</u>
Total general and administrative	<u>1,782,806</u>	<u>2,423,874</u>	<u>9,889,335</u>	<u>15,625,174</u>
Total costs and expenses	<u>24,066,153</u>	<u>17,678,096</u>	<u>79,121,509</u>	<u>63,332,397</u>
Operating loss	<u>(24,028,058)</u>	<u>(17,640,001)</u>	<u>(78,969,128)</u>	<u>(63,180,016)</u>
Other (income) expense:				
Interest income	(57,576)	(64,993)	(323,032)	(174,653)
Other (income) expense	<u>(296,339)</u>	<u>36,804</u>	<u>(393,202)</u>	<u>(56,717)</u>
Total other (income) expense	<u>(353,915)</u>	<u>(28,189)</u>	<u>(716,234)</u>	<u>(231,370)</u>
Net loss	<u>\$ (23,674,143)</u>	<u>\$ (17,611,812)</u>	<u>\$ (78,252,894)</u>	<u>\$ (62,948,646)</u>
Basic and diluted net loss per common share	<u>\$ (0.48)</u>	<u>\$ (0.37)</u>	<u>\$ (1.60)</u>	<u>\$ (1.38)</u>
Weighted average shares used in computing basic and diluted net loss per common share	<u>49,278,068</u>	<u>48,127,335</u>	<u>49,041,354</u>	<u>45,646,414</u>

**Balance Sheet Information:**

	<b>December 31, 2016</b> <b>(Unaudited)</b>	<b>December 31, 2015</b>
Cash, cash equivalents, investment securities and interest receivable	\$ 44,968,992	\$ 102,416,894
Total assets	54,781,547	113,473,201
Accumulated deficit	(236,386,820)	(158,133,926)
Total equity	35,867,802	101,573,302

---