

TG THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Address	787 SEVENTH AVENUE NEW YORK, NY 10019
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Sector	Healthcare
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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): **May 5, 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, 9th 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 May 5, 2017, TG Therapeutics, Inc. TG Therapeutics, Inc. (“TG” or the “Company”) issued a press release announcing results of operations for the first quarter ended March 31, 2017. TG also announced that on Friday, May 5, 2017 at 8:30am ET, TG would host an investor conference call during which the Company would provide a brief overview of its first 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 May 5, 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: May 5, 2017

INDEX TO EXHIBITS

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release issued by TG Therapeutics, Inc., dated May 5, 2017.

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

Investor Conference Call to be Held Today, Friday, May 5, 2017 at 8:30am ET

New York, NY, (**May 5, 2017**) – TG Therapeutics, Inc. (NASDAQ:TGTX) today announced its financial results for the first quarter ended March 31, 2017 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "2017 has been an exciting and busy year for us already, with both the announcement of the positive topline data from the Phase 3 GENUINE trial and the subsequent \$89M capital raise. Having achieved these two important milestones, we believe the company is well positioned for a successful remainder of the year and beyond." Mr. Weiss continued, "We plan to focus our attention on advancing our clinical programs towards success and look forward to a data and news rich summer where we will be presenting a more detailed analysis of the GENUINE data, announcing the interim analysis data from both our UNITY-CLL Phase 3 trial and UNITY-DLBCL trial, as well as commencing our global Phase 3 program in MS."

Recent Developments and Highlights

- Received orphan drug designation for the combination of TG-1101 and TGR-1202 for the treatment of CLL and DLBCL
- Announced the publication of clinical data from the Phase 1/2 trial of TG-1101 monotherapy in the British Journal of Haematology
- Announced positive topline data from Phase 3 GENUINE study of TG-1101 in combination with ibrutinib in patients with high risk CLL.
- Solidified the Company's balance sheet raising approximately \$89M in gross proceeds through the combination of a public offering and an at-the-market sales facility
- Presented preclinical data on our anti-PD-L1 monoclonal antibody at the American Association for Cancer Research (AACR) annual meeting
- Presented preliminary results, including B-cell depletion data from ongoing Phase 2 study of TG-1101 in patients with MS at the American Academy of Neurology (AAN) annual meeting

Reaffirming 2017 Milestones

- 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 Phase 3 GENUINE 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 American Society of Hematology (ASH) annual meeting in December
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Financial Results for the Third Quarter 2016

- **Cash Position:** Cash, cash equivalents, investment securities, and interest receivable were \$109.5 million as of March 31, 2017.
- **R&D Expenses:** Research and development (R&D) expense was \$22.7 million for the three months ended March 31, 2017 compared to \$11.6 million for the three months ended March 31, 2016. Included in research and development expense for the three months ended March 31, 2017 and 2016, was \$5.3 million and \$4.3 million, respectively, of manufacturing and CMC expenses for Phase 3 clinical trials and potential commercialization. The increase in R&D expenses for the three months ended March 31, 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) expense was \$5.0 million for the three months ended March 31, 2017 as compared to \$2.4 million for the three months ended March 31, 2016. The period-over-period increase in G&A expenses for the three months ended March 31, 2017 relates primarily to non-cash compensation expenses related to equity incentive grants recognized during 2017. Other G&A expenses for the three months ended March 31, 2017 remained relatively flat compared to the first quarter of 2016, and we expect G&A expenses to remain relatively constant through the remainder of 2017.
- **Net Loss:** Net loss was \$27.7 million for the three months ended March 31, 2017 compared to a net loss of \$13.8 million for the three months ended March 31, 2016.
- **Financial Guidance:** The Company believes its cash, cash equivalents, investment securities, and interest receivable of \$109.5 million as of March 31, 2017 will be sufficient to fund the Company's planned operations through 2018.

Conference Call Information

The Company will host an investor conference call today, May 5, 2017, at 8:30am ET, to discuss the Company's first 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 First Quarter 2017 Earnings Call. A live webcast of this call will be available on the Events page, located within the Investors & Media section, of the Company's website at www.tgtherapeutics.com. An audio recording of the conference call will also be available for replay at 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 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; our ability to manage cash in line with our expectations; the risk that early 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 the final presentations; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303 and being studied in the UNITY clinical trials, will not prove to be a safe and efficacious combination or backbone for triple and quad therapies; the risk that any interim analyses from ongoing clinical trials will not produce the desired or predicted result; the risk that we will not obtain the benefit of receiving orphan drug designation. 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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CONTACT:

Jenna Bosco
Vice President, Investor Relations
TG Therapeutics, Inc.
Telephone: 212.554.4351
Email: ir@tgtxinc.com

TG Therapeutics, Inc.
Selected Consolidated Financial Data

Statements of Operations Information (Unaudited):

	Three months ended March 31, 2017	
	2017	2016
	\$ <u>38,095</u>	
License revenue		\$ <u>38,095</u>
Costs and expenses:		
Research and development:		
Noncash compensation	2,306,099	386,925
Other research and development	<u>20,375,794</u>	<u>11,230,415</u>
Total research and development	<u>22,681,893</u>	<u>11,617,340</u>
General and administrative:		
Noncash compensation	3,689,356	1,312,040
Other general and administrative	<u>1,333,268</u>	<u>1,100,871</u>
Total general and administrative	<u>5,022,624</u>	<u>2,412,911</u>
Total costs and expenses	<u>27,704,517</u>	<u>14,030,251</u>
Operating loss	<u>(27,666,422)</u>	<u>(13,992,156)</u>
Other (income) expense:		
Interest income	(44,696)	(84,862)
Other (income) expense	<u>105,783</u>	<u>(58,632)</u>
Total other income	<u>61,087</u>	<u>(143,494)</u>
Net loss	<u><u>(27,727,509)</u></u>	<u><u>(13,848,662)</u></u>
Basic and diluted net loss per common share	<u><u>(0.52)</u></u>	<u><u>(0.28)</u></u>

	<u>53,157,851</u>	<u>48,908,278</u>
Weighted average shares used in computing basic and diluted net loss per common share		

Condensed Balance Sheet Information:

	<u>March 31, 2017</u> <u>(unaudited)</u>	<u>December 31,</u> <u>2016*</u>
Cash, cash equivalents, investment securities and interest receivable	\$ 109,483,728	\$ 44,968,992
Total assets	123,256,432	54,781,547
Accumulated deficit	(264,114,329)	(236,386,820)
Total equity	101,041,759	35,867,802

* Condensed from audited financial statements.
