March 7, 2016

TG Therapeutics, Inc. Announces Fourth Quarter and Year-End 2015 Financial Results and Business Update

Ended 2015 in a Strong Financial Position, With More Than $100 Million in Cash and Investments

Investor Conference Call to be Held Today, Monday, March 7, 2016 at 4:30pm ET

NEW YORK, March 07, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced its financial results for the fourth quarter and year ended December 31, 2015 and provided recent company developments along with a business outlook for 2016.

Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer, stated, "2015 was a transformational year for our Company as we launched our first registration study, the GENUINE Phase 3 study, and also obtained an SPA for our proprietary combination of TG-1101 and TGR-1202, the '1303' regimen, enabling our UNITY-CLL trial for patients with front-line and previously treated CLL. During 2016 we will be focused on executing our ongoing Phase 3 clinical programs as well as expanding our '1303' regimen into registration-directed trials for both diffuse large b-cell lymphoma and indolent lymphomas." Mr. Weiss continued, "We are also very excited to begin exploring the potential of our products in autoimmune disorders. Our IND has been cleared by the FDA Division of Neurology and we plan to launch our first Phase 2 trial in multiple sclerosis (MS) for TG-1101 in the next 30-60 days. We believe this Phase 2 study could support the commencement of a Phase 3 program next year. From a financial perspective, with more than $100 million in cash and investments we remain well positioned to execute on our business plan."

2015 Highlights

- Expanded our product portfolio through a global collaboration with Checkpoint Therapeutics to develop and commercialize anti-PDL1 and anti-GITR antibody research programs from Dana Farber Cancer Institute in hematologic malignancies
- Commenced enrollment into the GENUINE Phase 3 clinical trial, which is now open in over 150 sites throughout the US
- Presented the first data from the triple combination study of TG-1101 + TGR-1202 + ibrutinib showing not only that the combination was well tolerated, but produced a 100% ORR in patients with high-risk CLL/SLL and a 75% ORR in indolent NHL, which includes Follicular Lymphoma and Marginal Zone Lymphoma
- Obtained an SPA for the UNITY-CLL Phase 3 clinical trial of the Company's proprietary combination of TG-1101 + TGR-1202 (aka "TG-1303")
- Launched a new Phase 1/2 triple therapy study of TG-1101 + TGR-1202 + the PD-1 checkpoint inhibitor pembrolizumab, the first clinical trial to evaluate the safety and efficacy of the triple combination of a PI3K delta inhibitor with an anti-CD20 mAb and an anti-PD-1 checkpoint inhibitor
- Announced key data updates at the major medical conferences throughout 2015

Key Objectives for 2016

- Aggressively recruit into the GENUINE Phase 3 clinical trial
- Aggressively enroll into the UNITY-CLL Phase 3 clinical trial
- Commence the UNITY- DLBCL Phase 2b clinical trial
- Initiate a Phase 2 clinical trial in Multiple Sclerosis (MS)
- Commence a registration trial for iNHL
- Present updated data on the Phase 1 and 2 clinical trials at major hematology/oncology conferences during 2016

Financial Results for the Fourth Quarter and Full Year 2015

At December 31, 2015, the Company had cash, cash equivalents, investment securities, and interest receivable of $102.4 million, as compared to $78.9 million at December 31, 2014.

Our consolidated net loss for the year ended December 31, 2015, excluding non-cash items, was approximately $47.3 million, including other research and development expenses of $43.4 million, of which approximately $23.4 million related to

manufacturing and CMC expenses in preparation for Phase 3 clinical trials and potential commercialization. The consolidated net loss for the year ended December 31, 2015, inclusive of non-cash items, was $63.0 million, or $1.38 per diluted share, compared to a consolidated net loss of $55.8 million for the year ended December 31, 2014. The increase in consolidated net loss during the year ended December 31, 2015 was primarily driven by increases in other research and development expenses for both TG-1101 and TGR-1202 as a result of manufacturing and clinical trial expenses related to ongoing and planned future Phase 3 registration programs as well as launch preparation activities. The increase in other research and development expenses was partially offset by expenses recorded during 2014 in conjunction with the Company's licensing agreements for TGR-1202 and the IRAK4 inhibitors program, and a decrease in non-cash compensation expense related to equity incentive grants over the comparable period in 2014.

Our consolidated net loss for the fourth quarter ended December 31, 2015, excluding non-cash items, was approximately $14.8 million, including other research and development expenses of $13.7 million, of which approximately $7.4 million related to manufacturing and CMC expenses in preparation for Phase 3 clinical trials and potential commercialization. The consolidated net loss for the fourth quarter ended December 31, 2015, inclusive of non-cash items, was $17.6 million, or $0.37 per diluted share, compared to a consolidated net loss of $18.8 million during the comparable quarter in 2014. The decrease in consolidated net loss during the fourth quarter ended December 31, 2015 was the result of a decrease in non-cash compensation expense related to equity incentive grants over the comparable period in 2014, partially offset by a modest increase in other research and development expenses for TGR-1202 as a result of clinical trial expenses related to ongoing and planned future Phase 3 registration programs.

Conference Call Information

The Company will host an investor conference call today, Monday, March 7, 2016 at 4:30pm ET to discuss the Company's 2015 financial results and provide a business outlook for 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 Year-End 2015 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. 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. 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. The Company also has pre-clinical programs to develop IRAK4 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 future clinical trials, the timing of commencing or completing such trials and possible success of those trials and business prospects for TG-1101, TGR-1202, TG-1303, the IRAK4 inhibitor program, and the anti-PD-L1 and anti-GITR antibodies 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 pre-clinical and clinical trials for TG-1101, TGR-1202, TG-1303, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies; the risk that early pre-clinical and clinical results that supported our decision to move forward with TG-1101, TGR-1202, TG-1303, the IRAK4 inhibitor program and the anti-PD-L1 and anti-GITR antibodies will not be reproduced in additional patients or in future studies; the risk that trends observed which underlie certain assumptions of future performance of TGR-1202 and TG-1303 will not continue, the risk that TGR-1202 or TG-1303 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current Phase 1 studies; the risk that the combination of TG-1303, will not prove to be a safe and efficacious backbone for triple and quad combination therapies; 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 trials will take longer to enroll than expected; 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. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

TGTX - G

TG Therapeutics, Inc.
Selected Consolidated Financial Data

Statements of Operations Information (Unaudited):

	Three Months Ended December 31,		Year Ended December 31,	
	2015	**2014**	**2015**	**2014**
License revenue	$ 38,095	$ 38,095	$ 152,381	$ 152,381
Costs and expenses:				
Research and development:				
Noncash stock expense associated with in-licensing agreements	--	--	--	5,350,094
Noncash compensation	1,528,296	2,329,270	4,261,406	8,731,566
Other research and development	13,725,926	12,807,504	43,445,817	26,004,687
Total research and development	15,254,222	15,136,774	47,707,223	40,086,347
General and administrative:				
Noncash compensation	1,328,748	2,709,166	11,435,686	12,373,726
Other general and administrative	1,095,126	913,279	4,189,488	3,413,400
Total general and administrative	2,423,874	3,622,445	15,625,174	15,787,126
Total costs and expenses	17,678,096	18,759,219	63,332,397	55,873,473
Operating loss	(17,640,001)	(18,721,124)	(63,180,016)	(55,721,092)
Other (income) expense:				
Interest income	(64,993)	(16,741)	(174,653)	(55,049)
Other income	--	--	--	(95,427)
Interest expense	242,026	234,787	972,736	930,701
Change in fair value of notes payable	(205,222)	(142,741)	(1,029,453)	(720,040)
Total other (income) expense	(28,189)	75,305	(231,370)	60,185
Net loss	$ (17,611,812)	$ (18,796,429)	$ (62,948,646)	$ (55,781,277)
Basic and diluted net loss per common share	$ (0.37)	$ (0.48)	$ (1.38)	$ (1.64)
Weighted average shares used in computing basic and diluted net loss per common share	48,127,335	38,913,211	45,646,414	34,068,926

Balance Sheet Information:

	December 31, 2015 (Unaudited)	**December 31, 2014***
Cash, cash equivalents, investment securities and interest receivable	$ 102,416,894	$ 78,861,334
Total assets	113,473,201	86,746,890
Accumulated deficit	(158,133,926)	(95,185,280)
Total equity	101,573,302	80,101,884

* Condensed from audited financial statements.

CONTACT:

Jenna Bosco

Director- Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4351

Email: ir@tgtxinc.com


Primary Logo

Source: TG Therapeutics, Inc.

News Provided by Acquire Media