

# TG Therapeutics, Inc. Announces Third Quarter 2015 Financial Results and Business Update

# Investor Conference Call to be Held Today, Monday, November 9, 2015 at 8:30am ET

NEW YORK, Nov. 09, 2015 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced its financial results for the third quarter ended September 30, 2015 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer, stated, "During the third quarter, we achieved another major milestone for the Company in obtaining a Special Protocol Assessment for our UNITY-CLL trial, a study evaluating the safety and efficacy of our proprietary '1303' combination regimen in patients with front-line as well as previously treated CLL. This is a very important and exciting clinical trial for the Company, as it represents our first pivotal trial for our proprietary combination and, if successful, should provide a broad approval in CLL offering patients in both first-line and relapsed/refractory setting, a novel, non-chemotherapy treatment option. Further, it would provide us a broad label for building additional three and, possibly, four drug proprietary combinations to further improve outcomes for patients with CLL. With Phase 3 programs in oncology now underway for both TG-1101 and TGR-1202, we're excited to begin exploring the potential of our pipeline products for the treatment of autoimmune disease, an area where B-cell targeted therapies have proven highly effective, and anticipate commencing our first trial in Multiple Sclerosis in the near-term." Mr. Weiss continued, "We also remain focused on aggressively enrolling into our ongoing GENUINE Phase 3 clinical trial, and expect top-line data from this study in the second half of 2016. Finally, from a financial perspective, with more than \$115 million in cash and investments we have enough cash to execute on our business plan."

#### **Recent Developments and Highlights**

- In September 2015, we announced a Special Protocol Assessment (SPA) agreement with the FDA for the first Phase 3 clinical trial of our proprietary combination regimen of TG-1101 (ublituximab) with TGR-1202 ("1303") for patients with chronic lymphocytic leukemia, the UNITY-CLL study.
- In September 2015, we announced the initiation of a Phase 1/2 clinical trial investigating the use of TG-1101 and TGR-1202 in combination with pembrolizumab, the anti-PD-1 immune checkpoint inhibitor, in patients with relapsed or refractory CLL, the first clinical trial evaluating the safety, tolerability and effectiveness of the triple combination of a PI3K delta inhibitor with an anti-CD20 mAb and an anti-PD-1 checkpoint inhibitor.

#### Goals/Objectives for the Remainder of 2015

- Continue to aggressively recruit into the GENUINE Phase 3 Clinical Trial of TG-1101 in combination with ibrutinib
- Enroll the first patient by year end in our UNITY-CLL Phase 3 clinical trial of TG-1101 plus TGR-1202 in front-line and relapsed/refractory CLL
- Announce our next registration trial evaluating 1303 in patients with NHL
- Continue to recruit into the triple combination cohort of 1303 plus ibrutinib as well as the triple combination study of 1303 plus pembrolizumab, as well as seek to evaluate additional novel triple combinations of interest
- Expand into autoimmune diseases with the first Phase 2 trial in Multiple Sclerosis to commence in the near-term
- Continue to advance our pre-clinical compounds, including IRAK4, anti PD-L1 and anti-GITR forward towards clinical development
- Continue to seek additional compounds to further complement our current portfolio

## Financial Results for the Third Quarter 2015

At September 30, 2015 the Company had cash, cash equivalents, investment securities, and interest receivable of \$115.4 million, which includes approximately \$67.0 million of net proceeds from the utilization of the Company's at-the-market ("ATM") sales facility during the year (all of which was previously disclosed in connection with our last quarterly update), as compared to December 31, 2014 when we had \$78.9 million.

Our consolidated net loss for the third quarter ended September 30, 2015, excluding non-cash items, was approximately \$12.4 million, which included approximately \$6.9 million of manufacturing and CMC expenses in preparation for Phase 3 clinical trials and potential commercialization. The consolidated net loss for the third quarter ended September 30, 2015, inclusive of non-cash items, was \$13.7 million, or \$0.28 per diluted share, compared to a consolidated net loss of \$17.5 during the comparable quarter in 2014, representing a decrease in consolidated net loss of \$3.8 million. The decrease in consolidated net loss during

the third quarter ended September 30, 2015 was primarily the result of \$8.1 million of expense (\$4.1 million of which was noncash stock expense) recorded during the quarter ended September 30, 2014 in conjunction with the Company's licensing agreement for TGR-1202, and a \$2.9 million decrease in non-cash compensation expense related to equity incentive grants over the comparable period in 2014. Partially offsetting the aforementioned decreases, other research and development expenses for TG-1101 and TGR-1202 increased \$4.8 million and \$2.1 million, respectively, over the comparable period in 2014.

Our consolidated net loss for the nine months ended September 30, 2015, excluding non-cash items, was approximately \$32.5 million, which included approximately \$16.0 million of manufacturing and CMC expenses in preparation for Phase 3 clinical trials and potential commercialization. The consolidated net loss for the nine months ended September 30, 2015, inclusive of non-cash items, was \$45.3 million, or \$1.01 per diluted share, compared to a consolidated net loss of \$37.0 million during the comparable period in 2014, representing an increase in consolidated net loss of \$8.3 million. The increase in consolidated net loss during the nine months ended September 30, 2015 was primarily the result of other research and development expenses for TG-1101 and TGR-1202 increasing approximately \$14.6 million and \$4.5 million, respectively, over the comparable period in 2014. This was offset by \$9.3 million of expense (\$5.3 million of which was non-cash stock expense) recorded in conjunction with the Company's licensing agreements for TGR-1202 and the IRAK4 inhibitors program during the nine months ended September 30, 2014, and a decrease of \$3.2 million in non-cash compensation expense related to equity incentive grants over the comparable period in 2014.

### **Conference Call Information**

The Company will host an investor conference call today, November 9, 2015, at 8:30am ET, to discuss the Company's third quarter 2015 financial results and provide a business outlook for the remainder of 2015.

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 2015 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 <u>www.tgtherapeutics.com</u>. An audio recording of the conference call will also be available for replay at <u>www.tgtherapeutics.com</u>, 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 business prospects for TG-1101, TGR-1202, 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, 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, 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 will not continue, the risk that TGR-1202 will not produce satisfactory safety and efficacy results to warrant further development following the completion of the current Phase 1 study; the risk that the combination of TG-1101 and TGR-1202, referred to as TG-1303, will not prove to be a safe and efficacious backbone for triple and guad 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 forwardlooking 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 <u>www.tgtherapeutics.com</u>. 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):

	Thre	Three months ended September 30,		tember 30,	Nine months ended September 30,		
		2015		2014	2015		2014
License revenue	\$	38,096	\$	38,096	\$ 114,286	\$	114,286
Costs and expenses:							
Research and development:							
Noncash stock expense associated with in-licensing							
agreements				4,138,844			5,350,094
Noncash compensation		35,756		1,200,575	2,733,110		6,402,296
Other research and development		11,538,246		8,352,154	29,719,891		13,197,183
Total research and development		11,574,002		13,691,573	32,453,001		24,949,573
General and administrative:							
Noncash compensation		1,204,278		2,895,997	10,106,938		9,664,560
Other general and administrative		1,085,400		889,872	3,094,362		2,500,121
Total general and administrative		2,289,678		3,785,869	13,201,300		12,164,681
Total costs and expenses		13,863,680		17,477,442	45,654,301		37,114,254
Operating loss		(13,825,584)		(17,439,346)	(45,540,015)		(36,999,968)
Other (income) expense:							
Interest income		(55,977)		(12,107)	(109,660)		(38,308)
Other income							(95,427)
Interest expense		246,527		234,787	730,710		695,914
Change in fair value of notes payable		(360,218)		(210,857)	(824,231)		(577,299)
Total other (income) expense		(169,668)		11,823	(203,181)		(15,120)
Consolidated net loss	\$	(13,655,916)	\$	(17,451,169)	\$ (45,336,834)	\$	(36,984,848)
Basic and diluted net loss per common share	\$	(0.28)	\$	(0.51)	\$ (1.01)	\$	(1.14)
Weighted average shares used in computing basic and diluted net loss per common share		47,946,309		34,188,108	44,810,352		32,436,420

#### **Condensed Balance Sheet Information:**

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	September 30, 2015	December 31, 2014*	
	(unaudited)		
Cash, cash equivalents, investment securities and interest receivable	e \$ 115,409,868	\$ 78,861,334	
Total assets	127,407,138	86,746,890	
Accumulated deficit	(140,522,114)	(95,185,280)	
Total equity	116,311,812	80,101,884	

\* Condensed from audited financial statements.

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