August 8, 2016

TG Therapeutics, Inc. Announces Second Quarter 2016 Financial Results and Business Update

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

NEW YORK, Aug. 08, 2016 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ:TGTX) today announced its financial results for the second quarter ended June 30, 2016 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Interim Chief Executive Officer, stated, "The second quarter was a busy time for the Company, with data presented at both the ASCO and EHA meetings on the safety and activity of TGR-1202 alone and in combination with TG-1101, which we believe continues to show that TGR-1202 is a differentiated PI3K delta inhibitor. With the recent high profile setbacks encountered for both idelalisib and duvelisib, more than ever there is a need for a PI3K delta inhibitor with a favorable therapeutic index. Outside of mantle cell lymphoma, BTK inhibitors have shown limited activity in lymphoma, making a safe and effective PI3K delta inhibitor critically important. We are committed to bringing TGR-1202 forward in CLL and across aggressive and indolent lymphomas. Accordingly, we remain highly focused on executing our ongoing Phase 3 clinical programs in CLL, our registration directed UNITY-DLBCL study, and commencing additional registration programs in iNHL in the future." Mr. Weiss continued, "During the second quarter we were also very excited to commence our first study of TG-1101 in patients with multiple sclerosis, which we intend to utilize to inform our plans for a registration study in multiple sclerosis, which we hope to commence in the first half of 2017."

Recent Developments and Highlights

- Presented long-term follow-up data of TGR-1202 both alone and in combination with TG-1101 in an integrated analysis at the 2016 American Society of Clinical Oncology (ASCO) Annual Meeting and at the European Hematology Association (EHA) Annual Congress demonstrating a differentiated safety profile and high response rates in CLL and NHL
- Presented clinical data from the study of TGR-1202 in combination with ibrutinib in patients with advanced CLL and Mantle Cell Lymphoma at the EHA Annual Congress demonstrating the safety and efficacy of this all oral combination
- Entered into a global collaboration to develop and commercialize novel BET inhibitors for the treatment of hematological malignancies
- Enrolled the first patient in the registration-directed UNITY-DLBCL Phase 2b clinical study evaluating TG-1101 and TGR-1202 as a combination compared to TGR-1202 monotherapy in patients with advanced relapsed/refractory DLBCL
- Commenced the Company's first clinical trial evaluating TG-1101 in patients with relapsing remitting multiple sclerosis

Key Remaining 2016 Milestones

- Aggressively enroll into our Phase 3 and registration directed trials, including the GENUINE Phase 3, 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

Financial Results for the Second Quarter 2016

At June 30, 2016 the Company had cash, cash equivalents, investment securities, and interest receivable of $75.8 million, which we believe will be sufficient to fund our operations into the second quarter of 2018.

Our net loss for the second quarter ended June 30, 2016, excluding non-cash items, was approximately $14.3 million, which included approximately $3.4 million of manufacturing and CMC expenses for Phase 3 clinical trials and in preparation for potential commercialization. The GAAP net loss for the second quarter ended June 30, 2016, inclusive of non-cash items,

was $15.9 million, or $0.33 per basic and diluted share, compared to a net loss of $17.1 million, or $0.38 per basic and diluted share during the comparable quarter in 2015. The decrease in net loss during the second quarter ended June 30, 2016 was the result of a decrease in non-cash compensation expense related to equity incentive grants over the comparable period in 2015, partially offset by an increase in clinical trial expenses (other research and development expenses) related to ongoing and planned future Phase 3 registration programs.

Our net loss for the six months ended June 30, 2016, excluding non-cash items, was approximately $26.4 million, which included approximately $7.7 million of manufacturing and CMC expenses for Phase 3 clinical trials and in preparation for commercialization. The GAAP net loss for the six months ended June 30, 2016, inclusive of non-cash items, was $29.7 million, or $0.61 per diluted share, compared to a consolidated net loss of $31.7 million, or $0.73 per basic and diluted share during the comparable period in 2015. The decrease in net loss of $1.9 million during the six months ended June 30, 2016 was the result of a decrease in non-cash compensation expense related to equity incentive grants over the comparable period in 2015, partially offset by an increase in clinical trial expenses (other research and development expenses) related to ongoing and planned future Phase 3 registration programs.

Conference Call Information

The Company will host an investor conference call today, August 8, 2016, at 8:30am ET, to discuss the Company's second 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 Second 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. 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 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.

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, the BET 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, the BET 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, the BET 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 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 June 30,		Six months ended June 30,	
	2016	2015	2016	2015
License revenue	$ 38,095	$ 38,095	$ 76,190	$ 76,190
Costs and expenses:				
Research and development:				
Noncash compensation	567,157	1,359,446	954,082	2,697,354
Other research and development	12,966,574	9,902,214	24,196,989	18,181,645
Total research and development	13,533,731	11,261,660	25,151,071	20,878,999
General and administrative:				
Noncash compensation	1,081,240	4,883,540	2,393,280	8,902,660
Other general and administrative	1,446,567	1,004,475	2,547,438	2,008,962
Total general and administrative	2,527,807	5,888,015	4,940,718	10,911,622
Total costs and expenses	16,061,538	17,149,675	30,091,789	31,790,621
Operating loss	(16,023,443)	(17,111,580)	(30,015,599)	(31,714,431)
Other (income) expense:				
Interest income	(92,629)	(31,551)	(177,491)	(53,683)
Interest expense	220,756	246,526	463,161	484,183
Change in fair value of notes payable	(252,508)	(223,372)	(553,545)	(464,013)
Total other income	(124,381)	(8,397)	(267,875)	(33,513)
Net loss	$ (15,899,062)	$ (17,103,183)	$ (29,747,724)	$ (31,680,918)
Basic and diluted net loss per common share	$ (0.33)	$ (0.38)	$ (0.61)	$ (0.73)
Weighted average shares used in computing basic and diluted net loss per common share	48,769,948	45,320,637	48,838,731	43,216,385

Condensed Balance Sheet Information:

	June 30, 2016 (unaudited)	December 31, 2015*
Cash, cash equivalents, investment securities and interest receivable	$ 75,826,932	$ 102,416,894
Total assets	94,797,540	113,473,201
Accumulated deficit	(187,881,650)	(158,133,926)
Total equity	78,701,085	101,573,302

* Condensed from audited financial statements.

CONTACT:

Jenna Bosco

Vice President, Investor Relations

TG Therapeutics, Inc.

Telephone: 212.554.4351

Email: ir@tgtxinc.com

Primary Logo

Source: TG Therapeutics, Inc.

News Provided by Acquire Media