TG Therapeutics, Inc. Provides Business Update and Reports Second Quarter 2018 Financial Results

August 7, 2018

Investor Conference Call to be Held Today, Tuesday, August 7, 2018 at 4:30pm ET

NEW YORK, Aug. 07, 2018 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the second quarter ended June 30, 2018 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, "We are extremely pleased with the progress made in the first half of 2018 and believe we have many value creating milestones achievable in the near future. This morning's announcement of complete target enrollment in the ULTIMATE I & II Phase 3 trials in MS well ahead of our projections, similar to the rapid enrollment we had seen in our UNITY-CLL Phase 3 trial, reinforces our belief in the great need for our product candidates." Mr. Weiss continued, "We believe TG has never been better positioned for success and look forward to an impactful remainder of the year, and importantly the announcement of topline overall response rate data from the UNITY-CLL Phase 3 trial before the end of the summer."

Recent Developments and Highlights

- **ULTIMATE I & II:** Completed target enrollment into the ULTIMATE I & II Phase 3 trials in Multiple Sclerosis (MS).
- **Anti-CD47/CD19 License:** Entered into an exclusive global license agreement with Novimmune SA to collaborate on the development and commercialization of Novimmune's novel first-in-class anti-CD47/anti-CD19 bispecific antibody known as TG-1801 (previously NI-1701).
- **Ublituximab Data in Multiple Sclerosis:** Presented updated clinical data from the Phase 2 trial of ublituximab in RMS at the 4thCongress of European Academy of Neurology Meeting.
- **TG-1701 Preclinical Data**: Presented the first preclinical data presentation of TG-1701, the Company's orally available and covalently-bound BTK inhibitor, at the 23rd Congress of the European Hematology Association (EHA).
- **Umbralisib Data in CLL Patients Intolerant to Prior BTK/PI3K**: Presented clinical data from the Phase 2 trial of umbralisib in CLL Patients Intolerant to Prior BTK or PI3K Delta Inhibitor Therapy at the 54th Annual Meeting of the American Society of Clinical Oncology and at the 23rd Congress of the EHA.
- **Umbralisib plus RuxolitinibData in Patients with Myelofibrosis:** Presented updated clinical data from its ongoing Phase I study evaluating umbralisib with ruxolitinib, the JAK 1/2 inhibitor, in ruxolitinib experienced patients with myelofibrosis at the 23rd Annual EHA Congress.
- **Umbralisib Safety Data**: Presented an integrated analysis of long term safety data of umbralisib, either dosed as a single agent and in combination, in patients with relapsed or refractory lymphoid malignancies at the 23rd Annual EHA Congress.
- **Chief Commercial Officer**: Announced the hiring of Adam Waldman, former Celgene executive, as our Chief Commercial Officer.

Key Remaining 2018 Milestones

- Present top-line overall response rate results from our UNITY-CLL Phase 3 trial in front line and relapsed or refractory Chronic Lymphocytic Leukemia (CLL).
- Prepare and potentially file the Company's first BLA and/or NDA.
- Complete enrollment in the current arms of the UNITY-NHL trial, including the Follicular Lymphoma, Marginal Zone Lymphoma, and Diffuse Large B-Cell Lymphoma cohorts.
- Present updated clinical data from ongoing oncology trials and final results from the Phase 2 trial of ublituximab in Multiple Sclerosis (MS) at major medical meetings during 2018.

Financial Results for the Second Quarter 2018

- **Cash Position:** Cash, cash equivalents, investment securities, and interest receivable were $126.3 million as of June 30, 2018.

- **R&D Expenses:** Research and development (R&D) expenses were $38.7 million and $73.7 million for the three and six months ended June 30, 2018, respectively, compared to $26.7 million and $49.4 million for the three and six months ended June 30, 2017. The increase in R&D expense is primarily attributable to an increase in clinical trial expenses of $10.0 million and $15.7 million, respectively during the three and six months ended June 30, 2018, as compared to prior periods. In addition, included in R&D expenses for the three and six months ended June 30, 2018 are $1.8 million and $11.4 million, respectively, of manufacturing and CMC expenses for Phase 3 clinical trials and potential commercialization.

Also included in R&D expense for the six months ended June 30, 2018 was $4 million ($3 million of which was recorded in the three months ended June 30, 2018) of non-cash stock expense recorded in conjunction with the licenses to the BTK and CD47/CD19 programs.

- **G&A Expenses:** General and administrative (G&A) expenses were $5.7 million and $12.3 million for the three and six months ended June 30, 2018, respectively, as compared to $1.8 million and $6.8 million for the three and six months ended June 30, 2017. The increase in G&A expenses for the three and six months ended June 30, 2018 relates primarily to non-cash compensation expenses related to equity incentive expense recognized during the three and six months ended June 30, 2018.

- **Net Loss:** Net loss was $44.1 million and $85.7 million for the three and six months ended June 30, 2018, respectively, compared to a net loss of $28.4 million and $56.1 million for the three and six months ended June 30, 2017, respectively. Excluding non-cash items, the net loss for the three and six months ended June 30, 2018 was approximately $36.9 million and $70.1 million.

- **Financial Guidance:** Net cash utilized for operating activities during the six months ended 2018 was approximately $62.2 million. The Company believes its cash, cash equivalents, investment securities, and interest receivable on hand as of June 30, 2018 will be sufficient to fund the Company's planned operations into the second half of 2019.

Conference Call Information

The Company will host an investor conference call today, August 7, 2018, at 4:30pm ET, to discuss the Company's second quarter 2018 financial results and provide a business outlook for the remainder of 2018.

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 2018 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. Ublituximab (TG-1101) 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 umbralisib (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 ublituximab and umbralisib, or the combination of which is referred to as "U2", are in Phase 3 clinical development for patients with hematologic malignancies, with ublituximab also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future. 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 of1995. 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, including early data that may have supported the acceptance of our data for presentation or publication or may have influenced our decision to proceed with additional clinical trials, will not be reproduced in future studies; the risk that the combination of ublituximab (TG-1101) and umbralisib (TGR-1202), referred to as U2 or formerly TG-1303 and being studied in the UNITY clinical trials and other studies, will not prove to be safe and efficacious for any indication or will not prove to be safe and effective for use as part of triple and quad treatment regimens; the risk that we are unable to present overall response rate data from the UNITY-CLL trial within the projected timeline; the risk that the final data from either GENUINE or UNITY-CLL will not support a regulatory filing or approval or that the company will choose not to file a BLA/NDA or seek accelerated approval based on those studies; the risk that the topline overall response rate data from the UNITY-CLL trial is not be statistically significant; the risk that the early Phase 2 data of ublituximab in MS will not be reproduced in the Phase 3 MS trial; the risk that the ULTIMATE Phase 3 trials will not complete full enrollment on time; the risk that top-line data from the ULTIMATE Phase 3 trials will not be available within projected timelines, 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.

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TG Therapeutics, Inc.
Selected Consolidated Financial Data

Statements of Operations Information (in thousands, except share and per share amounts; unaudited):

	Three months ended June 30,		Six months ended June 30,	
	2018	**2017**	**2018**	**2017**
License revenue	$ 38	$ 38	$ 76	$ 76
Costs and expenses:				
Research and development:				
Non-cash stock expense associated with in-licensing agreements	3,000	-	4,000	-
Noncash compensation	888	1,266	3,747	3,573
Other research and development	34,812	25,440	65,971	45,815
Total research and development	38,700	26,706	73,718	49,388
General and administrative:				
Noncash compensation	3,375	223	7,854	3,913
Other general and administrative	2,308	1,534	4,426	2,867
Total general and administrative	5,683	1,757	12,280	6,780
Total costs and expenses	44,383	28,463	85,998	56,168
Operating loss	(44,345)	(28,425)	(85,922)	(56,092)
Other (income) expense:				
Interest income	(189)	(50)	(333)	(95)
Other (income) expense	(14)	(22)	82	84
Total other (income) expense	(203)	(72)	(251)	(11)
Net loss	$ (44,142)	$ (28,353)	$ (85,671)	$ (56,081)
Basic and diluted net loss per common share	$ (0.59)	$ (0.45)	$ (1.18)	$ (0.96)
Weighted average shares used in computing basic and diluted net loss per common share	72,256,348	63,288,269	72,456,657	58,251,045

Condensed Balance Sheet Information (in thousands):

	June 30, 2018	**December 31, 2017***
	(unaudited)	
Cash, cash equivalents, investment securities and interest receivable	$ 126,332	$ 84,825
Total assets	140,715	97,381
Accumulated deficit	(440,534)	(354,863)
Total equity	101,376	66,993

Primary Logo

Source: TG Therapeutics, Inc.