TG Therapeutics Provides Business Update and Reports Second Quarter 2022 Financial Results

August 8, 2022

Conference call to be held today, August 8, 2022 at 8:30 AM ET

NEW YORK, Aug. 08, 2022 (GLOBE NEWSWIRE) -- TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the second quarter ended June 30, 2022 and recent company developments, along with a business outlook for the remainder of 2022.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, "Our primary focus for the remainder of this year is working toward the approval of ublituximab, which has a PDUFA goal date of December 28, 2022, and preparing for its potential launch in early 2023. If approved, we believe ublituximab has the potential to be a meaningful treatment option for patients with relapsing forms of multiple sclerosis." Mr. Weiss continued, "During the first half of the year we implemented a number of cost-saving measures, and we are pleased to report those efforts have resulted in a lower than expected 2Q burn, which we believe puts us in a good financial position as we approach the potential launch of ublituximab."

Recent Highlights

Ublituximab in Multiple Sclerosis

- U.S. Food and Drug Administration (FDA) accepted the Biologics License Application (BLA) for ublituximab, as a treatment for patients with relapsing forms of multiple sclerosis (RMS) and set a Prescription Drug User Fee Act (PDUFA) goal date of December 28, 2022.
- Presented new exploratory analyses, from the ULTIMATE I and II Phase 3 trials at the 2022 Consortium of Multiple Sclerosis Centers Annual Meeting (CMSC) and the 8th Congress of the European Academy of Neurology (EAN). As previously reported, both trials met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate (ARR) over a 96-week period compared to teriflunomide in patients with RMS.

Key Objectives for 2022

- Obtain FDA approval of ublituximab to treat relapsing forms of multiple sclerosis by the PDUFA goal date of December 28, 2022
- Strengthen our commercial infrastructure to support the potential launch of ublituximab

Financial Results for the Three and Six Months Ended June 30, 2022

- **Net Loss:** Net loss was $40.5 million and $109.5 million for the three and six months ended June 30, 2022, respectively, compared to $78.5 million and $169.1 million for the three and six months ended June 30, 2021. The decrease in net loss in both periods is primarily the result of our cost-savings measures implemented and the withdrawal of UKONIQ from the market.

- **R&D Expenses:** Total research and development (R&D) expense was $26.9 million and $74.9 million for the three and six months ended June 30, 2022, respectively, compared to $44.9 million and $108.0 million for the three and six months ended June 30, 2021, respectively. The decrease was due primarily to decreases in licensing milestone fees, clinical trial expenses and non-cash compensation R&D expense during the three and six months ended June 30, 2022.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $12.6 million and $33.2 million for the three and six months ended June 30, 2022, respectively, compared to $34.0 million and $60.8 million for the three and six months ended June 30, 2021, respectively. The decrease was due primarily to decreased selling, general and administrative costs, including personnel, associated with withdrawal of UKONIQ during the three and six months ended June 30, 2022. We expect our selling, general and administrative expenses to increase slightly for the remainder of 2022 as we prepare for the potential launch of ublituximab in RMS.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $231.8 million as of June 30, 2022, which the Company believes will be sufficient to fund the Company's planned operations into the second half of 2023.

CONFERENCE CALL INFORMATION
The Company will host a conference call today, August 8, 2022, at 8:30 AM ET, to discuss the Company’s second quarter 2022 financial results.

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. A live audio webcast will be available on the Events page, located within the Investors & Media section, of the Company's website at http://ir.tgtherapeutics.com/events. 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
TG Therapeutics is a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell diseases. In addition to a research pipeline including several investigational medicines, TG has completed a Phase 3 program for ublituximab, an investigational glycoengineered monoclonal antibody that targets a unique epitope on CD20-expressing B-cells, to treat patients with relapsing forms of multiple sclerosis (RMS). For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and LinkedIn.

Cautionary Statement
This press release contains 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. Such forward looking statements include but are not limited to statements regarding the Company's plans, goals, strategies, timelines, anticipated milestones, and expectations for our current or future approved drugs and drug candidates, including; plans and timelines for potential approval of ublituximab monotherapy in RMS and, if approved, plans and timelines for commercializing ublituximab in RMS; the timing of initiation of clinical trials or the results of ongoing and planned clinical trials; the potential benefits of ublituximab in RMS or any of the Company's drug candidates in treating patients; and financial guidance regarding the period in which we will have sufficient capital resources to fund our operations.

All forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks and uncertainties. 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 from those expressed or implied by any forward-looking statements contained in this press release include the following: our ability to, if approved, establish, maintain and enhance our commercial infrastructure, to market and sell ublituximab; the potential for variation from the Company's projections and estimates about the potential market for ublituximab due to a number of factors, including for example, limitations that regulators may impose on the required labeling for the product; our ability to reach certain regulatory milestones at all or within the timelines projected; our ability to obtain, or to obtain within the timeline projected or for the indications sought, marketing authorization for our product candidates, including ublituximab monotherapy in RMS; our ability to successfully complete analyses of our clinical study results and present data within the timeframes projected; the risk that the interim, top-line and preliminary data from our clinical trials that we announce or publish may change, or the perceived product profile may be impacted, as more patient data or additional endpoints are analyzed; the risk that regulatory authorities disagree with the conclusions we have reached or data we have publicly disclosed and we are unable to obtain approval for, or successfully commercialize, our product candidates; the risk that preclinical and clinical results for the Company's drug candidates may not support further development of such drug candidates; actions of regulatory agencies, which may affect the initiation, timing and progress of clinical trials; the Company's reliance on third parties to perform manufacturing, distribution and supply services, and a range of other support functions for its clinical products; the risk that the ongoing COVID-19 pandemic and associated government control measures or other global issues such as the ongoing conflict in the Ukraine have an adverse impact on our clinical trials and other research and development plans or our regulatory filings and commercialization efforts; the accuracy of our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; our financial performance; and the sufficiency of our existing capital resources to fund our future operating expenses for the timelines projected. Further discussion about these and other risks and uncertainties can be found in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and in our other filings with the U.S. Securities and Exchange Commission, including the most recent quarterly report on Form 10-Q for the second quarter ended June 30, 2022.

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 Condensed 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,	
	2022	2021	2022	2021
Revenue				
Product revenue, net	$556	$1,507	2,534	$2,262
License revenue	38	38	76	76
Total revenue	594	1,545	2,610	2,338

Costs and expenses:

Cost of product revenue	23	148	260	288
Research and development:				
Noncash compensation	2,328	7,016	4,223	14,527
Other research and development	24,546	37,855	70,693	93,438
Total research and development	26,874	44,871	74,916	107,965
Selling, general and administrative:				
Noncash compensation	(3,304)	9,288	(3,077)	18,395
Other selling, general and administrative	15,942	24,729	36,324	42,384
Total selling, general and administrative	12,638	34,017	33,247	60,779
Total operating expenses	39,535	79,036	108,423	169,032
Operating loss	(38,941)	(77,492)	(105,813)	(166,694)
Other expense (income):				
Interest expense	3,017	1,623	5,681	3,521
Other income	(1,448)	(618)	(1,971)	(1,090)
Total other expense (income), net	1,569	1,005	3,710	2,431
Consolidated net loss	$(40,510)	$(78,497)	$(109,523)	$(169,125)
Net loss per common share:				
Basic and diluted	$(0.30)	$(0.59)	$(0.81)	$(1.28)
Weighted average shares used in computing basic and diluted net loss per common share	137,779,904	132,072,996	134,591,250	131,986,293

Condensed Balance Sheet Information (in thousands):

	June 30, 2022 (Unaudited)	December 31, 2021*
Cash, cash equivalents and investment securities	231,787	350,296
Total assets	251,666	379,629
Accumulated deficit	(1,438,221)	(1,328,698)
Total equity	129,035	237,153

* Condensed from audited financial statements