UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **February 28, 2023**

TG Therapeutics, Inc.
(Exact Name of Registrant as Specified in Charter)

Delaware	**001-32639**	**36-3898269**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3020 Carrington Mill Blvd, Suite 475
Morrisville, North Carolina
(Address of Principal Executive Offices)

(212) 554-4484
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities filed pursuant to Section 12(b) of the Act:

Title of Class	Trading Symbol(s)	Exchange Name
Common Stock	TGTX	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2). Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On February 28, 2023, TG Therapeutics, Inc. issued a press release announcing results of operations for the three and twelve months ended December 31, 2022. A copy of such press release is being furnished as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information included in Item 2.02 of this Current Report on Form 8-K (including Exhibit 99.1 hereto), shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing made by the Company under the Exchange Act or Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated February 28, 2023.
Exhibit 104	The cover page from this Current Report on Form 8-K formatted in Inline XBRL

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

TG THERAPEUTICS, INC.
(Registrant)

Date: February 28, 2023

By: /s/ Sean A. Power
Name: Sean A. Power
Title: Chief Financial Officer

TG Therapeutics Provides Business Update and Reports Fourth Quarter and Year-End 2022 Financial Results

Conference call to be held today, Tuesday, February 28, 2023, at 8:30 AM ET

New York, NY, (**February 28, 2023)** – TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the fourth quarter and year ended December 31, 2022, and recent company developments.

Michael S. Weiss, the Company's Chairman and Chief Executive Officer, stated, "2022 was a pivotal year for TG with the approval of BRIUMVI for relapsing forms of Multiple Sclerosis, and 2023 is off to an exciting start with the commercial launch of BRIUMVI. Our teams are hard at work introducing BRIUMVI to the MS community and while we are only 4 weeks into the launch, we are encouraged by the early feedback from providers, payors and advocates." Mr. Weiss continued, "Our highest priority is our commitment to patients and to ensure that patients who want BRIUMVI will have access to BRIUMVI. We look forward to building on the foundation we are developing in this early launch phase and extending it throughout 2023 and beyond."

2022 Highlights & Recent Developments

- U.S. Food and Drug Administration (FDA) approved BRIUMVI™ (ublituximab-xiiy), for the treatment of relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
- Commercially launched BRIUMVI making it available for patients and physicians.
- Presented additional data, including new analyses, from the ULTIMATE I and II Phase 3 trials at the 2022 Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) and at the 2023 Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) annual forum.

Key Objectives for 2023

- Execute a strong commercial launch of BRIUMVI in RMS
- Obtain broad payor coverage for BRIUMVI
- Continue to present additional data from the ULTIMATE I & II Phase 3 trials of BRIUMVI in RMS

Financial Results for the Fourth Quarter and Full Year 2022

- **Product Revenue, net:** Product revenue, net was approximately zero and $2.6 million for the three and twelve months ended December 31, 2022. Net product revenues during the year represent U.S. sales of UKONIQ, which received approval in February of 2021 and was withdrawn from the U.S. market effective May 31, 2022.

- **R&D Expenses:** Total research and development (R&D) expense was $29.6 million and $125.4 million for the three and twelve months ended December 31, 2022, compared to $62.6 million and $222.6 million for the three and twelve months ended December 31, 2021. The decrease in R&D expense is primarily attributable to reduced clinical trial related expenses, license milestones and manufacturing expense, decreased headcount and lower fees paid to consultants and outside service providers, as well as a decrease in non-cash compensation R&D expense during the twelve months ended December 31, 2022 over the comparable period in 2021.

- **SG&A Expenses:** Total selling, general and administrative (SG&A) expense was $22.5 million and $70.0 million for the three and twelve months ended December 31, 2022, and $32.4 million and $128.1 million for the three and twelve months ended December 31, 2021. The decrease was primarily attributable to reduced other selling, general and administrative costs as a result of our withdrawal of UKONIQ and decreased headcount during the period ended December 31, 2022, as well as decreased non-cash compensation G&A expense during the twelve months ended December 31, 2022 over the comparable period in 2021.

- **Net Loss:** Net loss was $53.0 million and $198.3 million for the three and twelve months ended December 31, 2022, compared to $93.3 million and $348.1 million for the three and twelve months ended December 31, 2021. Excluding non-cash compensation, the net loss for the three and twelve months ended December 31, 2022 was approximately $41.9 million and $179.2 million, compared to a net loss of $79.0 million and $286.8 million for the three and twelve months ended December 31, 2021.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $174.1 million as of December 31, 2022. We anticipate that our cash, cash equivalents and investment securities as of December 31, 2022, combined with the $45.0 million of available capacity under our existing term loan facility and projected revenues, will be sufficient to fund the Company′s planned operations into mid-2024.

CONFERENCE CALL INFORMATION

The Company will host a conference call today, February 28, 2023, at 8:30 AM ET, to discuss the Company's fourth quarter and year-end 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 BRIUMVI™ (ublituximab-xiiy) 150 mg/6 mL Injection for IV

BRIUMVI is a novel monoclonal antibody that targets a unique epitope on CD20-expressing B-cells. Targeting CD20 using monoclonal antibodies has proven to be an important therapeutic approach for the management of autoimmune disorders, such as RMS. BRIUMVI is uniquely designed to lack certain sugar molecules normally expressed on the antibody. Removal of these sugar molecules, a process called glycoengineering, allows for efficient B-cell depletion at low doses.

BRIUMVI is indicated for the treatment of adults with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

A list of authorized specialty distributors can be found at www.briumvi.com.

IMPORTANT SAFETY INFORMATION

Contraindications: BRIUMVI is contraindicated in patients with:

- Active HBV infection
- A history of life-threatening infusion reaction to BRIUMVI

WARNINGS AND PRECAUTIONS

Infusion Reactions: BRIUMVI can cause infusion reactions, which can include pyrexia, chills, headache, influenza-like illness, tachycardia, nausea, throat irritation, erythema, and an anaphylactic reaction. In MS clinical trials, the incidence of infusion reactions in BRIUMVI-treated patients who received infusion reaction-limiting premedication prior to each infusion was 48%, with the highest incidence within 24 hours of the first infusion. 0.6% of BRIUMVI-treated patients experienced infusion reactions that were serious, some requiring hospitalization.

Observe treated patients for infusion reactions during the infusion and for at least one hour after the completion of the first two infusions unless infusion reaction and/or hypersensitivity has been observed in association with the current or any prior infusion. Inform patients that infusion reactions can occur up to 24 hours after the infusion. Administer the recommended pre-medication to reduce the frequency and severity of infusion reactions. If life-threatening, stop the infusion immediately, permanently discontinue BRIUMVI, and administer appropriate supportive treatment. Less severe infusion reactions may involve temporarily stopping the infusion, reducing the infusion rate, and/or administering symptomatic treatment.

Infections: Serious, life-threatening or fatal, bacterial and viral infections have been reported in BRIUMVI-treated patients. In MS clinical trials, the overall rate of infections in BRIUMVI-treated patients was 56% compared to 54% in teriflunomide-treated patients. The rate of serious infections was 5% compared to 3% respectively. There were 3 infection-related deaths in BRIUMVI-treated patients. The most common infections in BRIUMVI-treated patients included upper respiratory tract infection (45%) and urinary tract infection (10%). Delay BRIUMVI administration in patients with an active infection until the infection is resolved.

Consider the potential for increased immunosuppressive effects when initiating BRIUMVI after immunosuppressive therapy or initiating an immunosuppressive therapy after BRIUMVI.

Hepatitis B Virus (HBV) Reactivation: HBV reactivation occurred in an MS patient treated with BRIUMVI in clinical trials. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with anti-CD20 antibodies. Perform HBV screening in all patients before initiation of treatment with BRIUMVI. Do not start treatment with BRIUMVI in patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for surface antigen [HBsAg] and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], consult a liver disease expert before starting and during treatment.

Progressive Multifocal Leukoencephalopathy (PML): Although no cases of PML have occurred in BRIUMVI-treated MS patients, JCV infection resulting in PML has been observed in patients treated with other anti-CD20 antibodies and other MS therapies.

If PML is suspected, withhold BRIUMVI and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

MRI findings may be apparent before clinical signs or symptoms; monitoring for signs consistent with PML may be useful. Further investigate suspicious findings to allow for an early diagnosis of PML, if present. Following discontinuation of another MS medication associated with PML, lower PML-related mortality and morbidity have been reported in patients who were initially asymptomatic at diagnosis compared to patients who had characteristic clinical signs and symptoms at diagnosis.

If PML is confirmed, treatment with BRIUMVI should be discontinued.

Vaccinations: Administer all immunizations according to immunization guidelines: for live or live-attenuated vaccines at least 4 weeks and, whenever possible at least 2 weeks prior to initiation of BRIUMVI for non-live vaccines. BRIUMVI may interfere with the effectiveness of non-live vaccines. The safety of immunization with live or live-attenuated vaccines during or following administration of BRIUMVI has not been studied. Vaccination with live virus vaccines is not recommended during treatment and until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with BRIUMVI During Pregnancy: In infants of mothers exposed to BRIUMVI during pregnancy, assess B-cell counts prior to administration of live or live-attenuated vaccines as measured by $CD19^+$ B-cells. Depletion of B-cells in these infants may increase the risks from live or live-attenuated vaccines. Inactivated or non-live vaccines may be administered prior to B-cell recovery. Assessment of vaccine immune responses, including consultation with a qualified specialist, should be considered to determine whether a protective immune response was mounted.

Fetal Risk: Based on data from animal studies, BRIUMVI may cause fetal harm when administered to a pregnant woman. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. A pregnancy test is recommended in females of reproductive potential prior to each infusion. Advise females of reproductive potential to use effective contraception during BRIUMVI treatment and for 6 months after the last dose.

Reduction in Immunoglobulins: As expected with any B-cell depleting therapy, decreased immunoglobulin levels were observed. Decrease in immunoglobulin M (IgM) was reported in 0.6% of BRIUMVI-treated patients compared to none of the patients treated with teriflunomide in RMS clinical trials. Monitor the levels of quantitative serum immunoglobulins during treatment, especially in patients with opportunistic or recurrent infections, and after discontinuation of therapy until B-cell repletion. Consider discontinuing BRIUMVI therapy if a patient with low immunoglobulins develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

Most Common Adverse Reactions: The most common adverse reactions in RMS trials (incidence of at least 10%) were infusion reactions and upper respiratory tract infections.

Physicians, pharmacists, or other healthcare professionals with questions about BRIUMVI should visit www.briumvi.com.

ABOUT BRIUMVI PATIENT SUPPORT

BRIUMVI Patient Support is a flexible program designed by TG Therapeutics to support patients through their treatment journey in a way that works best for them. More information about the BRIUMVI Patient Support program can be accessed at www.briumvipatientsupport.com.

ABOUT MULTIPLE SCLEROSIS

Relapsing multiple sclerosis (RMS) is a chronic demyelinating disease of the central nervous system (CNS) and includes people with relapsing-remitting multiple sclerosis (RRMS) and people with secondary progressive multiple sclerosis (SPMS) who continue to experience relapses. RRMS is the most common form of multiple sclerosis (MS) and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. It is estimated that nearly 1 million people are living with MS in the United States and approximately 85% are initially diagnosed with RRMS.[1,2] The majority of people who are diagnosed with RRMS will eventually transition to SPMS, in which they experience steadily worsening disability over time. Worldwide, more than 2.3 million people have a diagnosis of MS.[1]

ABOUT TG THERAPEUTICS

TG Therapeutics is a fully integrated, commercial stage, 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 received approval from the U.S. FDA for BRIUMVI™ (ublituximab-xiiy), for the treatment of adult patients with relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease. For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and on 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.

Any forward-looking statements in this press release are based on management's current expectations and beliefs and are subject to a number of risks, uncertainties and important factors that may cause actual events or results to differ materially from those expressed or implied by any forward-looking statements contained in this press release. In addition to the risk factors identified from time to time in our reports filed with the U.S. Securities and Exchange Commission (SEC), factors that could cause our actual results to differ materially include the below.

Such forward looking statements include but are not limited to statements regarding expectations for the timing and success of our commercial launch and availability of BRIUMVI™ (ublituximab-xiiy) for relapsing forms of multiple sclerosis (RMS); anticipated healthcare professional and patient acceptance and use of BRIUMVI for the FDA-approved indications, and statements regarding the results of the ULTIMATE I & II Phase 3 studies and BRIUMVI as a potential treatment for RMS.

Additional factors that could cause our actual results to differ materially include the following: the Company's ability to establish and maintain a commercial infrastructure for BRIUMVI, and to successfully or in the timeframe projected, launch, market and sell BRIUMVI; the failure to obtain and maintain requisite regulatory approvals, including the risk that the Company fails to satisfy post-approval regulatory requirements, the potential for variation from the Company's projections and estimates about the potential market for BRIUMVI due to a number of factors, including, further limitations that regulators may impose on the required labeling for BRIUMVI (such as modifications, resulting from safety signals that arise in the post-marketing setting or in the long-term extension study from the ULTIMATE I and II clinical trials); the Company's ability to meet post-approval compliance obligations (on topics including but not limited to product quality, product distribution and supply chain, pharmacovigilance, and sales and marketing); the Company's reliance on third parties for manufacturing, distribution and supply, and other support functions for our clinical and commercial products, including BRIUMVI, and the ability of the Company and its manufacturers and suppliers to produce and deliver BRIUMVI to meet the market demand for BRIUMVI; potential regulatory challenges to the Company's plans to seek marketing approval for the product in jurisdictions outside of the U.S.; the uncertainties inherent in research and development; the risk that any individual patient's clinical experience in the post-marketing setting, or the aggregate patient experience in the post-marketing setting, may differ from that demonstrated in controlled clinical trials such as ULTIMATE I and II; and general political, economic and business conditions, including the risk that the ongoing COVID-19 pandemic could have on the safety profile of BRIUMVI and any of our other drug candidates as well as any government control measures associated with COVID-19 that could have an adverse impact on our research and development plans or commercialization efforts. 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.

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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1. MS Prevalence. National Multiple Sclerosis Society website. https://www.nationalmssociety.org/About-the-Society/MS-Prevalence. Accessed October 26, 2020. **2.** Multiple Sclerosis International Federation, 2013 via Datamonitor p. 236.

TG Therapeutics, Inc.

Selected Condensed Consolidated Financial Data

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

	Three months ended December 31,		Year ended December 31,	
	2022	2021	2022	2021
Revenues:				
Product revenue, net	$ 42	$ 2,283	$ 2,633	$ 6,537
License revenue	38	38	152	152
Total revenue	80	2,321	2,785	6,689
Costs and expenses:				
Cost of product revenue	3	210	265	790
Research and development:				
Noncash compensation	5,753	4,986	13,224	24,047
Other research and development	23,882	57,660	112,128	198,532
Total research and development	29,635	62,646	125,352	222,579
Selling, General and administrative:				
Noncash compensation	5,298	9,370	5,961	37,227
Other selling, general and administrative	17,206	23,042	64,046	90,863
Total selling, general and administrative	22,504	32,412	70,007	128,090
Total costs and expenses	52,142	95,268	195,624	351,459
Operating loss	(52,062)	(92,947)	(192,839)	(344,770)
Other expense (income):				
Interest expense	2,862	1,079	10,191	5,638
Other expense (income)	(1,930)	(688)	(4,695)	(2,307)
Total other expense, net	932	391	5,496	3,331
Net loss	$ (52,994)	$ (93,338)	$ (198,335)	$ (348,101)
Basic and diluted net loss per common share	$ (0.39)	$ (0.70)	$ (1.46)	$ (2.63)
Weighted average shares used in computing basic and diluted net loss per common share	137,108,759	132,557,597	135,411,258	132,222,753

Condensed Balance Sheet Information (in thousands):

	December 31, 2022 (Unaudited)	December 31, 2021*
Cash, cash equivalents and investment securities	$ 174,082	$ 350,296
Total assets	193,572	379,629
Accumulated deficit	(1,527,033)	(1,328,698)
Total equity	58,587	237,153

* Condensed from audited financial statements