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): **January 7, 2024**

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 27560
(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 1.01. Entry into a Material Definitive Agreement.

On January 7, 2024, TG Therapeutics, Inc. (the "Company") and its wholly-owned subsidiary, TG Cell Therapy, Inc., entered into a License Agreement (the "License Agreement") with Precision BioSciences, Inc. ("Precision"), pursuant to which Precision granted the Company certain exclusive and non-exclusive license rights to develop, manufacture, and commercialize Precision's allogeneic CAR T therapy azercabtagene zapreleucel ("azer-cel") for the treatment of autoimmune and other non-oncology diseases and conditions (collectively, the "Field").

Pursuant to the License Agreement, the Company will make an upfront payment to Precision of $7.5 million, consisting of (i) $5.25 million in cash and (ii) $2.25 million, as an equity investment, for the purchase of 2,920,816 shares of Precision's common stock at a price of $0.77 per share. Within 12 months of the License Agreement, the Company will make a deferred payment of $2.5 million to Precision, consisting of an equity investment in Precision's common stock at a 100% premium to the 30-day volume-weighted average price (the "30-day VWAP") prior to purchase. Upon achievement of certain near-term clinical or time-based milestones, the Company will make a $7.5 million payment to Precision, a portion of which will also be an equity investment in Precision's common stock at a 100% premium to the 30-day VWAP prior to purchase. Precision will be eligible to receive up to $288 million in additional milestone payments based on the achievement of certain clinical, regulatory, and commercial milestones. In addition, the Company is obligated to pay Precision high-single-digit to low-double-digit royalties on net sales of the licensed product on a country-by-country basis until the latest to occur of patent expiration, loss of regulatory exclusivity, and a period of ten years following the first commercial sale of the licensed product in such country. The Company has also agreed to make certain payments to Precision's licensors during the term of the License Agreement.

Pursuant to the terms of the License Agreement, manufacturing for near-term clinical supply will be provided by a third party that recently acquired the manufacturing facility for azer-cel from Precision at a pre-determined cost.

The License Agreement also grants the Company a right of reference to the third party's regulatory filings for the development of azer-cel in the Field. The Company must use commercially reasonable efforts to develop and commercialize azer-cel in the Field, including initiation of a Phase 1 clinical trial within a pre-specified timeframe following the effective date of the License Agreement.

Unless earlier terminated, the License Agreement will remain in effect on a licensed product-by-licensed product and country-by-country basis until the expiration of a defined royalty term for each licensed product and country. Precision may terminate the entire License Agreement if: (i) the Company brings a challenge to its patents brought or (ii) the Company ceases active development of azer-cel for a specified period of time. Either party may terminate the License Agreement (i) for material breach by the other party and a failure to cure such breach within the time period specified in the agreement or (ii) the other party's insolvency.

The Company expects to file the Agreement as an exhibit to its Annual Report on Form 10-K for the year ended December 31, 2023. The foregoing is a description of certain terms of the Agreement and is intended to be a summary of the material terms and is qualified in its entirety by reference to the text of the Agreement when filed.

Item 7.01 Regulation FD Disclosure.

On January 10, 2024, the Company issued a press release entitled "TG Therapeutics Provides Preliminary Fourth Quarter and Full Year 2023 Net Revenue and 2024 Anticipated Milestones."

For purposes of this Item 7.01, the Company is furnishing a copy of the press release, which is attached hereto as Exhibit 99.1. In accordance with General Instruction B.2 of Form 8-K, the information included in Item 7.01 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 issued by TG Therapeutics, Inc., dated January 10, 2024.
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: January 10, 2024

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

Exhibit 99.1

TG Therapeutics Provides Preliminary Fourth Quarter and Full Year 2023 Net Revenue and 2024 Anticipated Milestones

Preliminary U.S. BRIUMVI fourth quarter and full year 2023 net product revenue of approximately $40 million and $89 million, respectively

Preliminary year-end 2023 cash position of approximately $215 million

NEW YORK, January 10, 2024 -- TG Therapeutics, Inc. (NASDAQ: TGTX), yesterday announced preliminary U.S. net product revenue for BRIUMVI® for the fourth quarter and full year ended December 31, 2023 (unaudited), as well as financial guidance and development milestones for 2024, during a preannounced presentation at the 42nd Annual J.P Morgan Healthcare Conference. An audio replay of the event, as well as the corresponding slide deck are available on the Investors and Media section of the TG corporate website at ir.tgtherapeutics.com/events.

Michael S. Weiss, Chairman and Chief Executive Officer of TG Therapeutics stated, “We are excited to share our preliminary fourth quarter and year end U.S. BRIUMIVI net product revenue. As we head into 2024, we have our sights set on achieving revenue and expense targets and have built an ambitious plan to potentially expand the utility of BRIUMVI into new indications and for use as a subcutaneous injection. We are also excited to expand our R&D program with the recent licensing of azer-cel, an allogeneic CD19 CAR T therapy which we believe has the potential to become a meaningful therapy to treat various autoimmune disorders.”

Preliminary Fourth Quarter and Full Year 2023 Updates (based on unaudited financial information)

- BRIUMVI U.S. net product revenue expected to be approximately $40 million and $89 million for the fourth quarter and full year of 2023, respectively
- Year-end 2023 cash position of approximately $215 million

Preliminary selected financial information presented in this release are unaudited, subject to financial closing procedures and adjustment, and provided as an approximation in advance of the Company's announcement of complete financial results planned to occur February 2024.

2024 Target Guidance

- BRIUMVI U.S. net product revenue targets of approximately $41-$46 million and $220-$260 million for the first quarter and full year 2024, respectively
- Full year 2024 target operating expense of approximately $250 million

2024 Development Pipeline Anticipated Milestones

- Commence clinical development of subcutaneous BRIUMVI
- Commence a trial evaluating BRIUMVI in additional autoimmune diseases outside of Multiple Sclerosis (MS)
- Commence a trial evaluating azer-cel in autoimmune disease
- Present data from the ENHANCE Phase 3b CD20 switch trial at multiple conferences throughout the year

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 relapsing forms of multiple sclerosis (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 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 Hepatitis B Virus 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.

The full SmPC approved in the EU for BRIUMVI can be found here Briumvi | European Medicines Agency (europa.eu).

ABOUT BRIUMVI PATIENT SUPPORT in the U.S.
BRIUMVI Patient Support is a flexible program designed by TG Therapeutics to support U.S. 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 U.S. Food and Drug Administration (FDA) approval for BRIUMVI® (ublituximab-xiiy), for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, as well as approval by the European Commission (EC) and the Medicines and Healthcare Products Regulatory Agency (MHRA) BRIUMVI to treat adult patients with RMS who have active disease defined by clinical or imaging features in Europe and the United Kingdom, respectively. For more information, visit www.tgtherapeutics.com, and follow us on Twitter @TGTherapeutics and on LinkedIn.

BRIUMVI® is a registered trademark of TG Therapeutics, Inc.

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 success of our commercial launch and availability of BRIUMVI® (ublituximab-xiiy) for relapsing forms of multiple sclerosis (RMS); and anticipated healthcare professional and patient acceptance and use of BRIUMVI for the FDA-approved indications, expectations of future revenue for BRIUMVI, expenses or profits, and our statements regarding our potential revenue targets, operating expenses and cash position.

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, market and sell BRIUMVI; the risk that early trends in prescriptions are not maintained or that prescriptions are not filled; the failure to obtain and maintain payor coverage; the risk that early healthcare professional interest in BRIUMVI will not be sustained; the risk that momentum in sales for BRIUMVI will not build during the course of the year; the risk that the BRIUMVI launch does not continue to exceed expectations; the risk that our BRIUMVI revenue targets will not be achieved; 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; the risk that subcutaneous BRIUMVI does not exhibit favorable safety, efficacy, or pharmacokinetic properties when evaluated in humans; the risk that the safety or tolerability profile of BRIUMVI differs in other autoimmune disorders compared to what has been observed in patients with MS; the risk that the Company is delayed in initiating a clinical trial for azer-cel in non-oncology indications; 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, 2022 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 and should not be relied upon as representing its views as of any subsequent date. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof except as required by law. No representations or warranties (expressed or implied) are made about the accuracy of any such forward-looking statements. 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.