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

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**FORM 8-K**

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

Date of report (Date of earliest event reported): **August 10, 2020**

# 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.) |

**2 Gansevoort Street, 9th Floor**
**New York, New York 10014**
(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 August 10, 2020, TG Therapeutics, Inc. ("TG" or the "Company") issued a press release announcing results of operations for the three and six months ended June 30, 2020. The Company will host an investor conference call today, August 10, 2020, at 8:30am ET, during which the Company will provide a brief overview of its second quarter financial results and provide a business outlook for the remainder of 2020. A copy of such press release is being furnished as Exhibit 99.1.

**Item 9.01. Financial Statements and Exhibits.**

| Exhibit No. | Description |
|---|---|
| 99.1 | Press Release, dated August 10, 2020. |
| 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: August 10, 2020

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

**Exhibit 99.1**

**TG Therapeutics Provides Business Update and Reports Second Quarter 2020 Financial Results**

New York, NY, (**August 10, 2020**)– TG Therapeutics, Inc. (NASDAQ: TGTX) today announced its financial results for the second quarter ended June 30, 2020 and recent company developments.

Michael S. Weiss, the Company's Executive Chairman and Chief Executive Officer, stated, “We are extremely pleased by the progress made thus far in 2020 and are looking forward to an impactful end of year and into 2021. Completing the NDA rolling submission this past June for umbralisib in previously treated Marginal Zone Lymphoma and Follicular Lymphoma was a major milestone for our Company.” Mr. Weiss continued, “With one completed NDA submission, positive topline data from our UNITY-CLL Phase 3 trial, and a healthy balance sheet with over $275 million in cash, we are well positioned to execute on our remaining milestones for this year as well as transition from a development stage company to a fully-integrated commercial organization. For the remainder of this year, we look forward to reporting topline data from our Phase 3 ULTIMATE program in Multiple Sclerosis, full data presentations from the UNITY-NHL FL and MZL single agent umbralisib cohorts, data presentation from the UNITY-CLL Phase 3 trial, as well as updated data from our triple combination trials, which we believe set the stage for the future of U2 in CLL and non-Hodgkin’s Lymphoma.”

**Recent Developments and Highlights**

- **Marginal Zone Lymphoma & Follicular Lymphoma:**
  - In June 2020, completed rolling submission of New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for umbralisib as a treatment for patients with previously treated marginal zone lymphoma (MZL) and follicular lymphoma (FL).

- **Chronic Lymphocytic Leukemia**:
  - In May 2020, reported positive topline results from the Company’s UNITY-CLL Phase 3 trial evaluating U2 (the combination of umbralisib and ublituximab) in patients with previously untreated and relapsed/refractory chronic lymphocytic leukemia (CLL). The trial met its primary endpoint of improved progression-free survival (PFS) ($p<.0001$), as determined by an Independent Review Committee (IRC).
  - In May 2020, reported final results from the GENUINE Phase 3 study evaluating the combination of ublituximab plus ibrutinib compared to ibrutinib alone in patients with relapsed/refractory CLL with high-risk cytogenetics. Results indicated the addition of ublituximab to ibrutinib as compared to ibrutinib alone improved PFS, overall response rate, complete response rate and the number of patients with undetectable minimal residual disease.

- **Multiple Sclerosis:**
  - In May 2020, announced the publication of results from the multicenter Phase 2 trial evaluating ublituximab in patients with relapsing forms of multiple sclerosis (RMS) in the *Multiple Sclerosis* Journal.

- **Bolstered Balance Sheet:**
  - In May 2020, strengthened balance sheet with more than $240 million in gross proceeds through a public offering and the Company’s At-the-Market (ATM) facility.

- **Publication:**
  - In July 2020, published preclinical data describing the unique immunomodulatory effects of umbralisib, in Blood Advances, a Journal of the American Society of Hematology.

- **Board of Directors & Management:**
  - In May 2020, appointed Sagar Lonial, MD, FACP, Professor and Chair of the Department of Hematology and Medical Oncology at the Emory University School of Medicine, as well as the Chief Medical Officer at Winship Cancer Institute of Emory University, to the Company's Board of Directors.
  - In May 2020, strengthened executive team with the addition of Owen A. O'Connor, MD, PhD as Chief Scientific Officer. Dr. O'Connor most recently served as a Professor of Medicine and Experimental Therapeutics, the Director of the Center for Lymphoid Malignancies, and Co-Program Director of the Lymphoid Development and Malignancy Program in the Herbert Irving Comprehensive Cancer Center at Columbia University Medical Center.

**Key Objectives for Remainder of 2020 and Early 2021**

- Report topline results from the Phase 3 ULTIMATE I & II trials in Multiple Sclerosis.
- Present full data from the UNITY-CLL Phase 3 trial and present full data from the FL and MZL single agent umbralisib cohorts of the UNITY-NHL trial at a major medical meeting.
- Target an NDA/Biologics Licensing Application (BLA) submission of U2 for the treatment of patients with CLL (including both previously untreated and relapsed/refractory patients)
- Continue to advance our early pipeline candidates including our anti-PD-L1 monoclonal antibody, cosibelimab (TG-1501), our Bruton's Tyrosine Kinase (BTK) inhibitor, TG-1701, and our anti-CD47/CD19 bispecific antibody, TG-1801.

**Financial Results for the Three and Six Months Ended June 30, 2020**

- **R&D Expenses:** Other research and development (R&D) expense (not including non-cash compensation) was $34.9 million and $68.9 million for the three and six months ended June 30, 2020, respectively, compared to $31.4 million and $62.3 million for the three and six months ended June 30, 2019, respectively. The modest increase in R&D expense during the three and six month periods of 2020 is primarily attributable to our ongoing clinical development programs as well as preparations for regulatory filings and potential commercialization. We expect our R&D expenses to decrease during the remainder of 2020 as costs associated with our main pivotal clinical trials continue to decline, partially offset by expenses associated with the expected NDA/BLA filing for U2 in CLL.

- **G&A Expenses:** Other general and administrative (G&A) expense (not including non-cash compensation) was $8.6 million and $13.8 million for the three and six months ended June 30 2020, respectively, as compared to $2.3 million and $4.3 million for the three and six months ended June 30, 2019, respectively. The increase in other G&A expenses is primarily due to increased personnel and other general and administrative costs, associated with preparations for a potential commercial launch. We expect G&A expenses to increase modestly during the remainder of 2020 in preparation for potential launch.

- **Net Loss:** Net loss was $52.9 million and $104.0 million for the three and six months ended June 30, 2020, respectively, compared to a net loss of $36.2 million and $71.4 million for the three and six months ended June 30, 2019, respectively. Excluding non-cash compensation, the net loss for the three and six months ended June 30, 2020 was approximately $45.5 million and $85.6 million, respectively, compared to a net loss of $34.5 million and $67.7 million for the three and six months ended June 30, 2019, respectively.

- **Cash Position and Financial Guidance:** Cash, cash equivalents and investment securities were $275.6 million as of June 30, 2020. The Company believes its cash, cash equivalents and investment securities on hand as of June 30, 2020, as well as future availability under the Company's debt and ATM facility, will be sufficient to fund the Company's planned operations through the end of 2021.

**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 in late stage clinical development with two investigational therapies targeting hematological malignancies and autoimmune diseases. Ublituximab (TG-1101) is a 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 oral, once-daily, dual inhibitor of PI3K-delta and CK1-epsilon. 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 into Phase 1 clinical development, TG-1501, its anti-PD-L1 monoclonal antibody, TG-1701, its covalently-bound Bruton's Tyrosine Kinase (BTK) inhibitor and TG-1801, its anti-CD47/CD19 bispecific antibody. TG Therapeutics is headquartered in New York City.

**Cautionary Statement**

This press release includes 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. 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: the risk that the final analysis of the UNITY-NHL MZL or FL cohorts will be insufficient to support FDA approval of umbralisib, or, if supportive of approval, will not be supportive of a differentiated profile; the risk that we are unable to successfully deliver the complete data set from the UNITY-CLL trial or prepare a regulatory submission on schedule as planned; the risk that the final analysis of the UNITY-CLL study will be insufficient to support FDA approval of the combination regimen of umbralisib and ublituximab in CLL or, if supportive of approval, will not be supportive of a differentiated profile; the risk that any of our other registration-directed clinical trials, including the ULTIMATE I & II trials, as designed or amended may not be positive, or if positive, may not be sufficient or acceptable to support regulatory submission or approval of ublituximab in relapsing forms of MS; the risk that achievement of the clinical development and regulatory milestones we project will be delayed due to a variety of factors, including, without limitation, the evolving and unpredictable COVID-19 pandemic, available resources, program reprioritization, and feedback from the FDA or foreign regulators; the risk that we are not able to successfully and or cost effectively complete all the preclinical, clinical and CMC requirements necessary to support regulatory submissions; the risk that early clinical trial results that may have influenced our decision to proceed with additional clinical trials may not be replicated; the risk that we are unable to manage cash in line with our expectations and meet our development milestones and/or continue our operations without raising capital; and the risk that we are unable to raise capital on acceptable terms. 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, | |
|---|---|---|---|---|
| | **2020** | **2019** | **2020** | **2019** |
| License revenue | $ 38 | $ 38 | $ 76 | $ 76 |
| Costs and expenses: | | | | |
| Research and development: | | | | |
| Noncash stock expense associated with in-licensing agreements | -- | 100 | -- | 100 |
| Noncash compensation | 1,553 | 1,352 | 3,532 | 2,841 |
| Other research and development | 34,896 | 31,414 | 68,939 | 62,310 |
| Total research and development | 36,449 | 32,866 | 72,471 | 65,251 |
| General and administrative: | | | | |
| Noncash compensation | 5,817 | 405 | 14,906 | 797 |
| Other general and administrative | 8,617 | 2,311 | 13,789 | 4,260 |
| Total general and administrative | 14,434 | 2,716 | 28,695 | 5,057 |
| Total costs and expenses | 50,883 | 35,582 | 101,166 | 70,308 |
| Operating loss | (50,845) | (35,544) | (101,090) | (70,232) |
| Other expense (income): | | | | |
| Interest expense | 2,228 | 1,077 | 3,429 | 1,851 |
| Other income | (189) | (408) | (519) | (715) |
| Total other expense (income), net | 2,039 | 669 | 2,910 | 1,136 |
| Net loss | $ (52,884) | $ (36,213) | $ (104,000) | $ (71,368) |
| Basic and diluted net loss per common share | $ (0.47) | $ (0.42) | $ (0.95) | $ (0.85) |
| Weighted average shares used in computing basic and diluted net loss per common share | 112,353,414 | 86,800,017 | 108,926,690 | 84,002,700 |

**Condensed Balance Sheet Information (in thousands):**

| | **June 30, 2020 (Unaudited)** | **December 31, 2019*** |
|---|---|---|
| Cash, cash equivalents and investment securities | $ 275,570 | $ 140,435 |
| Total assets | 294,621 | 163,014 |
| Accumulated deficit | (805,215) | (701,216) |
| Total equity | 194,227 | 38,615 |

* Condensed from audited financial statements