

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): **June 7, 2018**

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

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-32639**  
(Commission File Number)

**36-3898269**  
(IRS Employer Identification No.)

**2 Gansevoort Street, 9<sup>th</sup> 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.
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act.
- Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

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.

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**Item 8.01. Other Events.**

On June 7, 2018, TG Therapeutics, Inc. (the "Company") presented at the Jefferies 2018 Global Healthcare Conference, held at the Grand Hyatt Hotel, in New York City. A copy of the Corporate Presentation is being filed as Exhibit 99.1 and incorporated in this Item by reference.

**Item 9.01 Financial Statements And Exhibits.**

(d) Exhibits.

[99.1](#) Corporate Presentation, dated June 7, 2018.

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**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: June 7, 2018

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



# TG Therapeutics

Jefferies Global Healthcare Conference

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June 2018

**Tar**Geting B-Cell Diseases

# Forward Looking Safe Harbor Statement

*This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are often, but not always, made through the use of words or phrases such as “anticipates”, “expects”, “plans”, “believes”, “intends”, and similar words or phrases. Such statements involve risks and uncertainties that could cause TG Therapeutics’ actual results to differ materially from the anticipated results and expectations expressed in these forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. Actual events or results may differ materially from those projected in any of such statements due to various factors, including the risks and uncertainties inherent in clinical trials, drug development, and commercialization. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement and TG Therapeutics undertakes no obligation to update these statements, except as required by law.*

## Our Goal

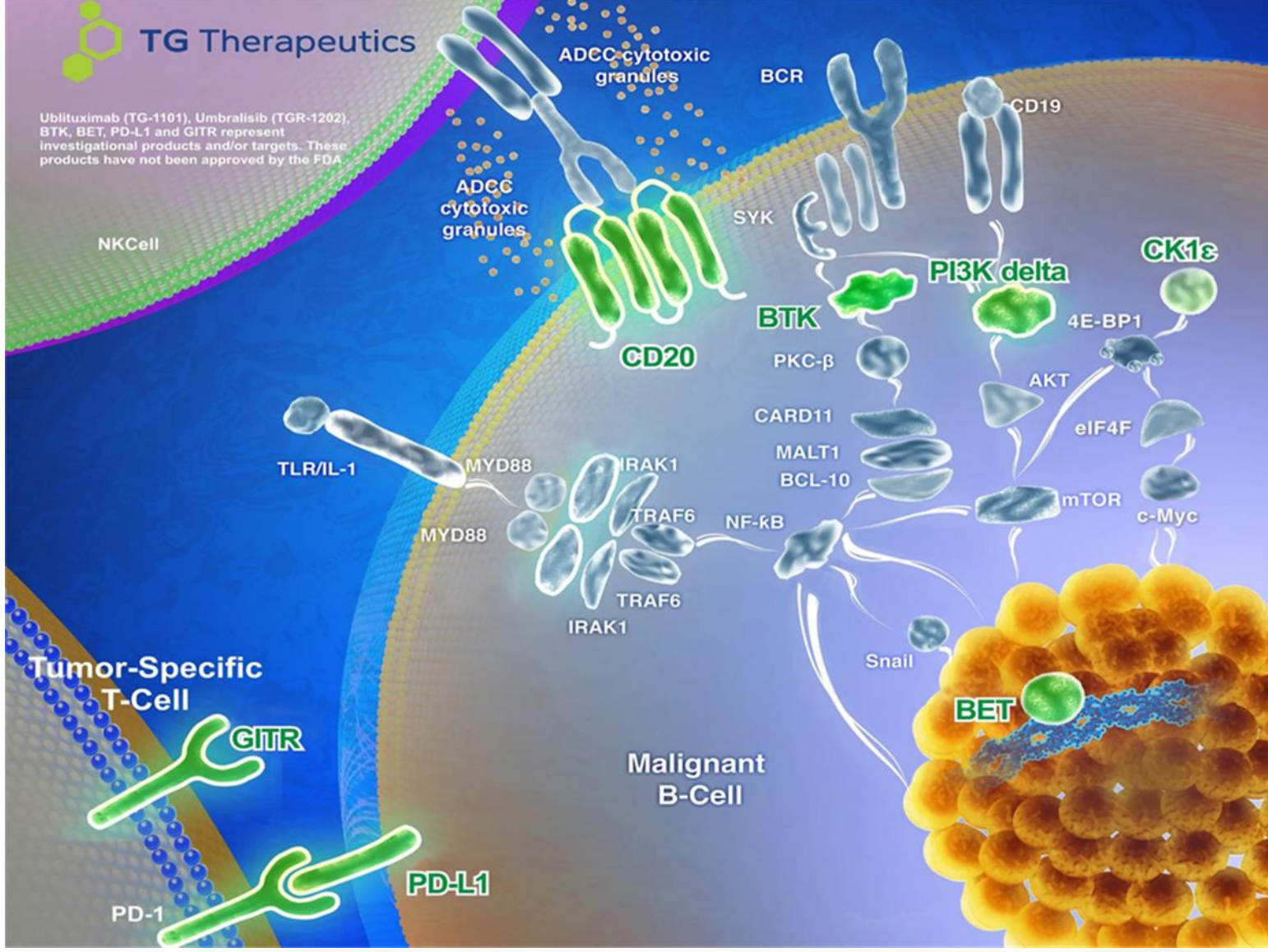
# ***To develop the best possible treatment for B-cell diseases***

*(Cancers: CLL, FL, MZL, DLBCL and  
Autoimmune: MS, RA, Lupus, etc.)*

# ***Ideally, developing curative combination regimens***

*(solutions development v. drug development)*

Ublituximab (TG-1101), Umbralisib (TGR-1202), BTK, BET, PD-L1 and GITR represent investigational products and/or targets. These products have not been approved by the FDA.






<b>Umbralisib (TGR-1202)</b>	<b>Ublituximab (TG-1101)</b>
Next Generation PI3K delta inhibitor	Next Generation anti-CD20 monoclonal antibody
Overcomes 1 <sup>st</sup> generation Toxicity	Glycoengineered for enhanced potency over 1 <sup>st</sup> generation
Activity across NHL and CLL	Activity in Rituxan refractory patients
Once daily oral dosing vs. BID	Shorter infusions than all other anti-CD20s (1.5 v 3-4 hours)





## For the Treatment of CLL

- There are ~115,000 Americans living with CLL and ~20,000 newly diagnosed each year
- UNITY-CLL trial conducted under Special Protocol Assessment (SPA)
-  expected to be the only novel doublet approved for **BOTH** newly-diagnosed and relapsed patients
- Possible accelerated approval based on ORR; Full approval based on PFS

### UNITY-CLL

*Enrollment Complete*

Randomize

U2

Gazyva +  
CHL

<b>Total Enrollment</b>	<b>420</b>
Target ORR Improvement	15%
Completed Enrollment	4Q17
Top-Line ORR	Summer18
Target NDA/BLA Filing	4Q18

# Company's Assumptions

## UNITY-CLL: ORR Endpoint

**Targeting ~15% improvement in ORR**

*(minimum detectable difference of ~13%)*

Comps	Gazyva+ CHL	Population	U2	Comps
CLL-11: Gazyva + Chl: ORR 78%	75-78%	Treatment Naïve	88-92%	1202+G+Chl: ORR100% RESONATE 2: IB ORR 82%
HELIOS: Benda Ritx: ORR 67%	55-60%	Relapsed/ Refractory	78-82%	U/U2 ORR: 80- 88% GENUINE: Ubli+Ib ORR: 81%
	67-71%	Blended ORR	84-88%	

*Actual results may differ materially from those assumed by the Company and should not be relied upon for any purpose.*

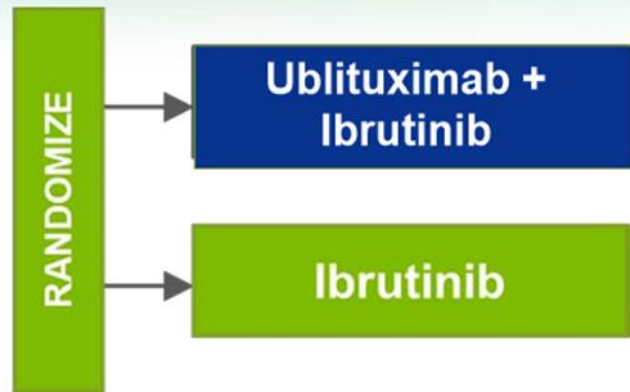
# UNITY-CLL: PFS Endpoint

<b>Integrated Analysis: Umbralisib &amp; U2 (n=27)</b>	<b>Helios: Benda + Rituxan (n=183)</b>	<b>Umbralisib + Gazyva + CHL (n=15)</b>	<b>CLL-11: Gazyva + CHL (n=289)</b>
Rel/Ref		Front Line	
24+ months*	13.3 months	~36+months**	26.7months

\* Median PFS for Umbralisib Monotherapy: 24 Months; Median PFS not reached for Umbralisib + Ublituximab ('U2')

\*\* Median PFS not reached with longest patient on 43+ months

# GENUINE Phase 3 Trial



## Status:

- **Phase 3 Trial in Relapsed/Refractory High Risk CLL**
- Positive ORR Data Presented at ASCO 2017
- Potential Accelerated Approval Filing based on ORR (Primary Endpoint)
- Filing decision pending outcome of UNITY-CLL and KOL outreach
- Our goal is to put our best filing package in first (if possible)
  - Including, filing accelerated approval based on the GENUINE ORR data and/or UNITY-CLL ORR data or neither.

# Umbralisib and U2 in Rel/Ref NHL



GLYCOENGINEERED UBLITUXIMAB + PI3K DELTA UMBRALISIB (TGR-1202)

**PREVIOUSLY TREATED NHL PATIENTS**

**Includes three cohorts: FL, MZL and DLBCL**

# Umbralisib and U2 in Relapsed/Refractory Follicular Lymphoma (FL)

- Approximately 15,000 new cases per year with ~7,500 relapsed patients needing treatment per year
- 53% ORR for umbralisib single agent at higher doses in r/r FL in Phase 1 at higher doses (*Published in Lancet Oncology February 2018*)
- Defined path for accelerated approval based Copanlisib approval

## UNITY-NHL Trial FL Cohort

*Currently Enrolling*

**Umbralisib  
(TGR-1202)  
Monotherapy**

<b>Target Enrollment</b>	<b>~100</b>
Target ORR	45-55%
Complete Enrollment	Mid-18
Top-Line Data	1H19

# Umbralisib and U2 in Relapsed/Refractory Marginal Zone Lymphoma (MZL)

- Approximately 7,500 new cases per year, with ~3,000 relapsed patients needing treatment each year
- Ibrutinib recently approved with 46% ORR
- Defined path for accelerated approval based on recent ibrutinib approval

**UNITY-NHL Trial  
MZL Cohort**

*Currently Enrolling*

**Umbralisib  
(TGR-1202)  
Monotherapy**

<b>Target Enrollment</b>	<b>~60</b>
Target ORR	40-50%
Complete Enrollment	3Q18
Top-Line Data	1H19

# Umbralisib and U2 in Relapsed/Refractory Diffuse Large B-cell Lymphoma (DLBCL)

- US annual incidence of ~20,000 new cases per year of which ~50-60% cured with front-line treatment
- For those not cured, ~20% will be eligible for, and obtain a cure from, transplant
- Nothing approved for the ~6,000 relapsed/refractory patients who are not eligible for transplant
- Possible accelerated approval

## UNITY-NHL Trial DLBCL Cohort

*Currently Enrolling*

**Ublituximab +  
Umbralisib + Benda**

<b>Target Enrollment</b>	<b>~200</b>
Target ORR	40-50%
Completed Enrollment U2	1Q18
Complete Enrollment U+ Benda	6/30/18
Top-Line Data	1H19



# Umbralisib and U2 in B-cell Cancers

## U.S. Market Opportunity

(Company Estimates)

Current Regimen	Disease	Patients Needing Treatment/Year
U2	CLL	~20,000
Umbra	FL	~7,500
Umbra	MZL	~3,000
U2 + Benda	DLBCL	~6,000

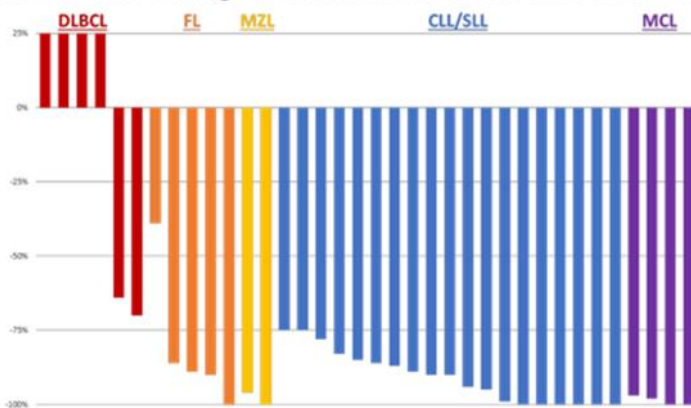
***CLL & NHL represents a multi-billion dollar opportunity for Umbralisib and U2***

# Newly In-Licensed BTK inhibitor (TG-1701)

- **TG-1701: orally available, covalently-bound BTK inhibitor**
  - Phase 1 currently enrolling in China
  - TG sponsored Phase 1/2 trial to open 3Q18

## Ublituximab + Umbralisib + Ibrutinib

Best Percent Change from Baseline in Disease Burden



Response Rate Observed with Triple Therapy

Type	Pts (n)	CR <sup>†</sup> (n)	PR (n)	ORR n (%)	SD (n)	PD (n)
CLL/SLL	19	6	13	19 (100%)	-	-
MZL	2	1	1	2 (100%)	-	-
MCL	4	2	2	4 (100%)	-	-
FL	5	1	3	4 (80%)	1	-
DLBCL	6	-	1	1 (17%)	-	5
<b>Total</b>	<b>36</b>	<b>10</b>	<b>20</b>	<b>30 (83%)</b>	<b>1</b>	<b>5</b>

<sup>†</sup>CLL: 4/6 CR's pending bone marrow confirmation

# Ublituximab in Multiple Sclerosis

- A new study by the Nat'l MS Society estimates that ~1,000,000 Americans are living with MS
- Recently approved anti-CD20 (ocrelizumab) with first year sales approaching \$1B
- Will compete on price and convenience
- Phase 3 ULTIMATE Trials under Special Protocol Assessment

## ULTIMATE I & II Phase 3 Clinical Trials

*Currently Enrolling*

Randomize

Ublituximab  
+  
Placebo

Placebo  
Infusion +  
Teriflunomide

**Target Enrollment** ~850

Updated Complete Enrollment Target YE-18

## Ublituximab Phase 2: Clinical Endpoints at Week 24

Endpoint	Ublituximab Phase 2 (N=48) (24 Weeks)	Ocrelizumab Phase 2 (N=55) (24 Weeks)	Opera I&II (96 Weeks)
Annualized Relapse Rate	0.05	0.13	0.156
% Relapse Free	98%	87%	80%

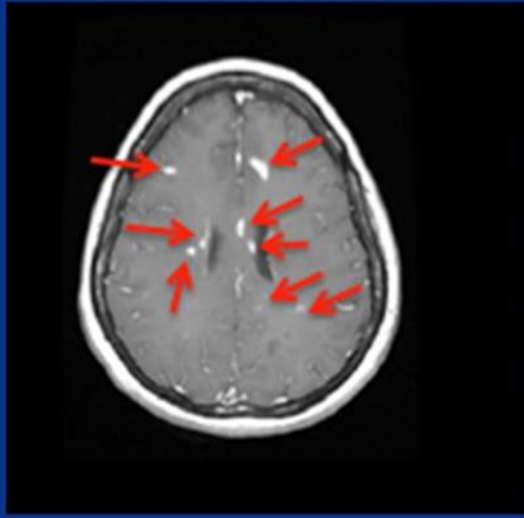
*Inglese et al., Presented at AAN Annual Meeting April 2018*

*Kappos L et al. Lancet. 2011; 378:1779-1787*

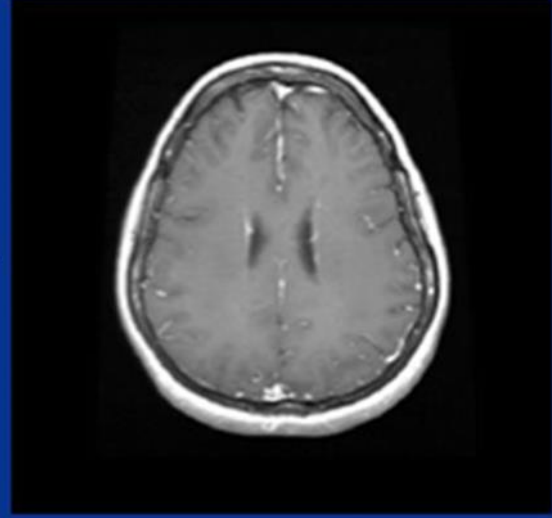
*Hauser SL et al. NEJM. 2017; 376:221-234*

# T1-Gd MRI at Baseline and Week 24: Study Subject

## Subject T1 Gd MRI at Baseline and Week 24



**Baseline**



**Week 24**

# Corporate & Financial

## Key Financial Statistics

**Ticker:** TGTX (NASDAQ)

**Price:** \$14.55 (close on June 6, 2018)

**Shares:** ~78M (fully-diluted)

**Cash:** ~\$123.3M (pro forma as of 3/31/18)

**Runway:** Through mid-2019



# TG Therapeutics

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NASDAQ: TGTX

A blue trapezoidal shape on the left and a green trapezoidal shape on the right, both pointing towards the center, are positioned above a thin black horizontal line.