UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

EUGENE SHAPIRO, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. TG THERAPEUTICS, INC., MICHAEL S. WEISS, and SEAN A. POWER, Defendants.	**Case No.** **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Eugene Shapiro ("Plaintiff"), individually and on behalf of all others similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, conference calls and announcements made by Defendants, United States ("U.S.") Securities and Exchange Commission ("SEC") filings, wire and press releases published by and regarding TG Therapeutics, Inc. ("TG Therapeutics" or the "Company"), analysts' reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of a class consisting of all persons and entities other than Defendants that purchased or otherwise acquired TG Therapeutics securities between January 15, 2020 and May 31, 2022, both dates inclusive (the "Class Period"), seeking to

recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

2. TG Therapeutics, a commercial stage biopharmaceutical company, focuses on the acquisition, development, and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. The Company's therapeutic product candidates include Ublituximab, an investigational glycoengineered monoclonal antibody for the treatment of B-cell non-hodgkin lymphoma, chronic lymphocytic leukemia ("CLL"), and relapsing forms of multiple sclerosis; and Umbralisib, or UKONIQ, an oral inhibitor of PI3K-delta and CK1-epsilon for the treatment of CLL, marginal zone lymphoma, and follicular lymphoma.

3. In January 2020, TG Therapeutics initiated a rolling submission of a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA"), requesting accelerated approval of Umbralisib as a treatment for patients with previously treated marginal zone lymphoma ("MZL") and follicular lymphoma ("FL") (the "Umbralisib MZL/FL NDA").

4. In December 2020, TG Therapeutics initiated a rolling submission of a Biologics License Application ("BLA") to the FDA for Ublituximab in combination with Umbralisib (together, "U2"), as a treatment for patients with CLL (the "U2 BLA").

5. In May 2021, TG Therapeutics submitted a supplemental New Drug Application ("sNDA") for Umbralisib to add an indication for CLL and small lymphocytic lymphoma ("SLL") in combination with Ublituximab (the "U2 sNDA").

6. In September 2021, TG Therapeutics submitted a BLA to the FDA for Ublituximab as a treatment for patients with relapsing forms of multiple sclerosis ("RMS") (the "Ublituximab RMS BLA").

7. Throughout the Class Period, Defendants made materially false and misleading statements regarding the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) clinical trials revealed significant concerns related to the benefit-risk ratio and overall survival data of Ublituximab and Umbralisib; (ii) accordingly, it was unlikely that the Company would be able to obtain FDA approval of the Umbralisib MZL/FL NDA, the U2 BLA, the U2 sNDA, or the Ublituximab RMS BLA in their current forms; (iii) as a result, the Company had significantly overstated Ublituximab and Umbralisib's clinical and/or commercial prospects; and (iv) therefore, the Company's public statements were materially false and misleading at all relevant times.

8. On November 30, 2021, TG Therapeutics issued a press release "announc[ing] the U.S. Food and Drug Administration (FDA) has notified the Company that it plans to host a meeting of the Oncologic Drugs Advisory Committee (ODAC) in connection with its review of the pending Biologics License Application (BLA)/supplemental New Drug Application (sNDA) for the combination of ublituximab and UKONIQ® (umbralisib) (combination referred to as U2) for the treatment of adult patients with chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)." TG Therapeutics advised that "[t]he FDA has notified the Company that potential questions and discussion topics for the ODAC include: the benefit-risk of the U2 combination in the treatment of CLL or SLL, and the benefit-risk of UKONIQ in relapsed/refractory marginal zone lymphoma (MZL) or follicular lymphoma (FL). In addition, as part of the benefit-risk analysis, the overall safety profile of the U2 regimen, including adverse events (serious and Grade 3-4), discontinuations due to adverse events, and dose modifications, is expected to be reviewed", stating that "[t]he FDA's concern giving rise to the ODAC meeting appears to stem from an early analysis of overall survival from the UNITY-CLL trial."

9. On this news, TG ’Therapeutics’ stock price fell $8.16 per share, or 34.93%, to close at $15.20 per share on November 30, 2021.

10. Then, on April 15, 2022, TG Therapeutics issued a press release “announc[ing] that the Company has voluntarily withdrawn the pending Biologics License Application (BLA)/supplemental New Drug Application (sNDA) for the combination of ublituximab and UKONIQ® (umbralisib) (combination referred to as U2) for the treatment of adult patients with chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL).” The press release stated that “[t]he decision to withdraw was based on recently updated overall survival (OS) data from the UNITY-CLL Phase 3 trial that showed an increasing imbalance in OS.”

11. On this news, TG Therapeutics’ stock price fell $1.93 per share, or 21.81%, to close at $6.92 per share on April 18, 2022.

12. Then, on May 31, 2022, TG Therapeutics issued a press release announcing that the FDA extended the Prescription Drug User Fee Act date for Ublituximab to December 28, 2022 “to allow time to review a submission provided by the Company in response to an FDA information request, which the FDA deemed a major amendment.”

13. On this news, TG Therapeutics’ stock price fell $0.75 per share, or 14.51%, to close at $4.42 per share on May 31, 2022.

14. Finally, on June 1, 2022, the FDA announced that, due to safety concerns, it had withdrawn its approval for Umbralisib for the treatment of MZL and FL. Specifically, the FDA provided that “[u]pdated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving [UKONIQ]. As a result, we determined the risks of treatment with [UKONIQ] outweigh its benefits.”

15. On this news, TG 'Therapeutics' stock price fell $0.51 per share, or 11.53%, to close at $3.91 per share on June 1, 2022.

16. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

17. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act.

19. Venue is proper in this Judicial District pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1391(b). TG Therapeutics is headquartered in this Judicial District, Defendants conduct business in this Judicial District, and a significant portion of Defendants' actions took place within this Judicial District.

20. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

PARTIES

21. Plaintiff, as set forth in the attached Certification, acquired TG Therapeutics securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosures.

22. Defendant TG Therapeutics is a Delaware corporation with principal executive offices located at 2 Gansevoort Street, 9th Floor, New York, New York 10014. TG Therapeutics' securities trade in an efficient market on the Nasdaq Capital Market ("NASDAQ") under the trading symbol "TGTX".

23. Defendant Michael S. Weiss ("Weiss") has served as TG 'Therapeutics' Chairman, Chief Executive Officer, and President at all relevant times.

24. Defendant Sean A. Power ("Power") has served as TG 'Therapeutics' Chief Financial Officer, Corporate Secretary, and Treasurer at all relevant times.

25. Defendants Weiss and Power are sometimes referred to herein as the "Individual Defendants."

26. The Individual Defendants possessed the power and authority to control the contents of TG 'Therapeutics' SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of TG Therapeutics' SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with TG Therapeutics, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

27. TG Therapeutics and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

28. TG Therapeutics, a commercial stage biopharmaceutical company, focuses on the acquisition, development, and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. The Company's therapeutic product candidates include Ublituximab, an investigational glycoengineered monoclonal antibody for the treatment of B-cell non-hodgkin lymphoma, CLL, and RMS; and Umbralisib, or UKONIQ, an oral inhibitor of PI3K-delta and CK1-epsilon for the treatment of CLL, MZL, and FL.

Materially False and Misleading Statements Issued During the Class Period

29. The Class Period begins on January 16, 2020, when TG Therapeutics issued a press release announcing that it had initiated its rolling submission of the Umbralisib MZL/FL NDA to the FDA. The press release stated, in relevant part:

> TG Therapeutics [. . .] announced that the Company has initiated a rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) requesting accelerated approval of umbralisib, the Company's oral, once-daily, dual inhibitor of PI3K-delta and CK1-epsilon, as a treatment for patients with previously treated marginal zone lymphoma (MZL) and follicular lymphoma (FL). The Company has received guidance from the FDA that submission of a single NDA for both the MZL and FL indications is acceptable. Umbralisib has previously been granted both orphan drug designation and breakthrough therapy designation by the FDA for MZL. The Company expects to complete the NDA rolling submission in the first half of 2020.
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> [Defendant Weiss] stated, "We are extremely pleased to have initiated our first NDA submission for umbralisib and to have received guidance from the FDA to include both MZL and FL in a single NDA. This is an extremely important milestone for us, as it brings us one step closer to potentially offering a novel treatment option to patients with previously treated MZL and FL." Mr. Weiss continued, "I want to thank the patients, their families and the research teams who participated in these important trials and helped advance umbralisib, and the TG team for working tirelessly to initiate this NDA submission. This is the beginning of an impactful 2020 as we look forward to topline Phase 3 data from both the UNITY-CLL trial and the ULTIMATE I & II trials in multiple sclerosis, as well as potential regulatory submissions based off these data."

30. On March 2, 2020, TG Therapeutics filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2019 (the "2019 10-K"). In providing an overview of the Company, the 2019 10-K stated, in relevant part:

> We are a biopharmaceutical company dedicated to developing and delivering medicines for patients with B-cell mediated diseases, including Chronic Lymphocytic Leukemia (CLL), non-Hodgkin Lymphoma (NHL) and Multiple Sclerosis (MS). We have developed a robust B-cell directed research and development (R&D) platform for identification of key B-cell pathways of interest and rapid clinical testing. Currently, we have five B-cell targeted drug candidates in clinical development, with the lead two therapies, ublituximab (TG-1101) and umbralisib (TGR-1202), in pivotal trials for CLL, NHL and MS. Ublituximab is a novel anti-CD20 monoclonal antibody (mAb) that has been glycoengineered for enhanced potency over first generation antibodies. Umbralisib is an oral, once daily, dual inhibitor of PI3K-delta and CK1-epsilon, which may lead to a differentiated safety profile. When used together in combination therapy, ublituximab and umbralisib are referred to as "U2". Additionally, in early clinical development we have an anti-PD-L1 monoclonal antibody referred to as cosibelimab (TG-1501), an oral Bruton's Tyrosine Kinase ("BTK") inhibitor referred to as TG-1701, and an anti-CD47/CD19 bispecific antibody referred to as TG-1801.

31. Further, in discussing the Company's strategy, the 2019 10-K stated, in relevant part:

- Completing our current Phase 3 and registration-directed trials for umbralisib and ublituximab, including, UNITY-CLL, UNITY-NHL, and the ULTIMATE Phase 3 Program in MS;
- Gaining regulatory approval for umbralisib in NHL, umbralisib plus ublituximab ("U2") in CLL, and ublituximab in MS;
- Preparing for commercial launch and building commercial capability to ensure, when approved, broad access to patients for the approved indications for umbralisib and ublituximab;
- Developing U2 in NHL;
- Advancing cosibelimab (TG-1501), TG-1701, and TG-1801 through clinical development and defining potential regulatory paths for these drug candidates both as single agents and in combination with umbralisib, ublituximab, and/or U2;
- Building upon the MS program to expand ublituximab into additional MS indications and other autoimmune diseases;

- Continuing to expand our pipeline with mechanisms of importance to B-cell mediated diseases;
- Evaluating potential strategic collaborations to maximize the value of our programs and B-cell directed platform; and
- Maintaining our "patient first" culture as we grow our business.

Our Approach and Platform

Our approach to drug development is centered on developing solutions for patients rather than developing single therapies for a disease. Our process begins by identifying validated targets against B-cell diseases, and then searching for and, ideally, acquiring what we believe to be "best-in-class" compounds with complementary mechanisms against these targets, with the goal of developing multi-drug proprietary targeted combinations, which can potentially offer better outcomes for patients.

Our preference is to identify targets for which there is human clinical proof of concept that the mechanism is active in B-cell diseases and then to identify drug candidates that effectively modulate the desired molecular target. We identify these drug candidates at academic centers of excellence or in development at biotech companies or pharmaceutical companies globally. Our current drug candidates were acquired through license agreements, collaborations, or joint ventures with biopharmaceutical companies located in the US, France, Switzerland, India, and China. This approach enables us to minimize target risk while looking for the best available drug candidates around the world. By focusing on B-cell diseases and targets with a known activity profile, we believe that we can quickly identify the patients most likely to respond, resulting in a more efficient development path with the potential for a greater likelihood of success. Importantly, since all our drug candidates are focused in one disease area, we can rapidly explore combination therapies, which we believe is essential to improving outcomes for patients and holds the key to identifying cures for patients with B-cell diseases.

Our approach is enabled by our clinical development platform which includes:

- An internal team with a deep understanding of B-cell diseases and the treatment of patients; and
- An external network of more than 350 community and academic clinical trial sites globally.

32. Appended to the 2019 10-K as exhibits were signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") by the Individual Defendants, attesting that "[t]he

information contained in the [2019 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

33. On March 3, 2020, TG Therapeutics issued a press release announcing the Company's Q4 2019 results and providing a business update. The press release quoted Defendant Weiss stating, in relevant part:

> "2019 was a transformational year for TG as we were able to report positive outcomes for umbralisib in both previously treated marginal zone lymphoma and follicular lymphoma from the UNITY-NHL trial. We also confirmed a submission pathway with the FDA and early this year commenced a single rolling submission based on these data, which we hope to complete in the first half of this year." Mr. Weiss continued, "Looking forward, we expect 2020 to be yet another impactful year as we await the topline results from our Phase 3 programs in CLL and MS and potentially our first FDA approval around year-end."

34. That same day, TG Therapeutics hosted an earnings call with investors and analysts to discuss the Company's Q4 2019 results (the "Q4 2019 Earnings Call"). During the scripted portion of the Q4 2019 Earnings Call, Defendant Weiss stated, in relevant part:

> For the MZL cohort, we announced we received breakthrough therapy designation and presented preliminary data during oral presentations at AACR, ASCO and ICML demonstrating approximately a 50% overall response rate and approximately a 20% complete response rate with a generally well-tolerated safety profile. We also received orphan drug designation for umbralisib to treat MZL
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> For the follicular lymphoma cohort, we announced towards the end of the year, that it too met the primary endpoint of 40% to 50% overall response. And importantly, for both cohorts, we initiated a rolling submission of a new drug application for umbralisib. Initiating our first-ever NDA was a major milestone for us. And we're extremely pleased by the FDA's guidance to include both MZL and follicular in a single submission.
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> As you can see, 2019 was an exciting and impactful year for us, but we believe 2020 is the year for TG to really shine. Our hard work over the past 8 years has brought us here, and we look forward to an exciting 2020 where we should see pivotal data for UNITY-CLL, followed by completion of our MZL, FL NDA submission, all of which we are targeting for the first half of this year; followed in the second half by pivotal data from our ULTIMATE-MS clinical trial, possibly

our first NDA approval; and if all goes well with UNITY-CLL, an NDA/BLA submission for CLL before year-end.

35. On May 11, 2020, TG Therapeutics issued a press release announcing the Company's Q1 2020 financial results and providing a business update. The press release quoted Defendant Weiss stating, in relevant part:

> "The first few months of 2020 have undoubtedly been the most impactful and exciting in our Company's history. We kicked off the year with the initiation of our first rolling regulatory submission for umbralisib in both MZL and FL and most recently reported positive topline results from our UNITY-CLL Phase 3 trial evaluating our proprietary U2 combination in patients with CLL. This positive outcome marks a major step forward in our mission of developing the best possible combination treatment options for patients with B-cell diseases." Mr. Weiss continued, "We now have three successful pivotal data sets which we believe have the potential to support regulatory approvals across MZL, FL and CLL. With more than $150 million proforma in cash on our balance sheet, we are well funded through and beyond our next set of key milestones, including the release of topline data from the ULTIMATE MS Phase 3 program, submission of an NDA/BLA for U2 in CLL, and hopefully, our first approval for umbralisib in MZL and FL, all of which are targeted to occur over approximately the next 9 months."

36. On June 17, 2020, TG Therapeutics issued a press release announcing that the Company had completed its rolling submission of the Umbralisib MZL/FL NDA to the FDA. The press release quoted Defendant Weiss stating, in relevant part:

> "The completion of this NDA submission marks an important milestone in bringing us one step closer to providing umbralisib as a potential treatment option for patients with relapsed/refractory MZL and FL. As a company this is a very exciting moment for us, as it marks our very first NDA submission, and I commend our team for all their efforts to get to this point." Mr. Weiss continued, "Importantly, I also want to thank the patients, their families and the research teams who participated in these trials. This has been an incredibly impactful year for TG thus far, with several important milestones yet to come, including topline data from the ULTIMATE trials of ublitximab in multiple sclerosis, presentation of full data from the UNITY-NHL FL/MZL cohorts and from the UNITY-CLL Phase 3 trial of umbralisib plus ublituximab (U2), and a BLA/NDA submission for U2 in chronic lymphocytic leukemia targeted by the end of the year."

37. On August 10, 2020, TG Therapeutics issued a press release announcing the Company's Q2 2020 financial results and providing a business update. The press release quoted Defendant Weiss stating, in relevant part:

> "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."

38. That same day, TG Therapeutics hosted an earnings call with investors and analysts to discuss the Company's Q2 2020 results (the "Q2 2020 Earnings Call"). During the scripted portion of the Q2 2020 Earnings Call, Defendant Weiss stated, in relevant part:

> We completed our first rolling submission of a new drug application for single agent umbralisib in the treatment of patients with previously treated marginal zone lymphoma and follicular lymphoma. This was an incredible achievement for our company and I commend our team's effort in preparing this submission under such challenging circumstances. We also announced that the UNITY-CLL Phase 3 trial evaluating U2 combination in both treatment naïve and previously treated CLL patients met the primary endpoint of improved progression-free survival with a P-value of less than 0.0001.
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> As a reminder, the UNITY-CLL clinical trial is a global Phase 3 randomized study of U2 versus the combination of the chemotherapy chlorambucil plus the CD20 obinutuzumab in patients with treatment-naïve and relapsed or refractory chronic lymphocytic leukemia. This trial is being conducted under special protocol assessment in the FDA. In early May, we announced the UNITY-CLL trial met the primary endpoint at a pre-specified interim analysis demonstrating a statistically significant improvement in PFS with a P-value of less than 0.0001, as assessed by independent review committee. You may recall that the trial enrolled

> approximately 60% previously untreated, or they can be referred to as treatment naïve patients, and 40% who were relapsed or refractory from prior therapy, and we are pleased to note that the PFS benefit was observed across both patient populations. If approved, we believe the U2 combination has the potential to be an important treatment option for patients with CLL. We are extremely pleased with the outcome of the study and look forward to presenting data from this trial by year end with a BLA NDA submission to follow.

39. On August 13, 2020, TG Therapeutics issued a press release announcing the FDA's acceptance of the Umbralisib MZL/FL NDA. The press release press release quoted Defendant Weiss stating, in relevant part:

> "We are extremely pleased with the FDA's acceptance of our first NDA submission and look forward to working with the FDA during the review process. This is a significant achievement in our path towards accomplishing our goal of developing novel treatments for patients with B-cell diseases." Mr. Weiss continued, "If approved, we believe umbralisib could become an important treatment option for patients with previously treated MZL and FL. We look forward to presenting the data from the UNITY-NHL trial that supported this NDA submission by year end."

40. On October 21, 2020, TG Therapeutics issued a press release entitled, "TG Therapeutics Announces Fast Track Designation Granted by the FDA to Ublituximab in Combination with Umbralisib for the Treatment of Adult Patients with Chronic Lymphocytic Leukemia." The press release quoted Defendant Weiss stating, in relevant part:

> "We are extremely pleased to have received Fast Track designation for the ublituximab plus umbralisib regimen, or the U2 combination, to treat adult patients with CLL. The application for Fast Track was based on data from the UNITY-CLL Phase 3 study that we announced earlier this year had met its primary endpoint of progression free survival. This designation holds several important advantages to potentially expedite the development and regulatory review of U2 and underscores the significant unmet medical need that still exists for patients with CLL." Mr. Weiss continued, "We look forward to presenting data from the UNITY-CLL Phase 3 trial later this year, which we plan to use as the basis of a U2 regulatory submission for CLL."

41. On November 9, 2020, TG Therapeutics issued a press release announcing the Company's Q3 2020 financial results and providing a business update. The press release quoted Defendant Weiss stating, in relevant part:

> "This has been a very exciting few months for TG especially sharing the first ever data from the UNITY-CLL Phase 3 trial last week showing that the trial met its primary endpoint of improvement in progression-free survival, as well as data from the UNITY-NHL trial which supported our NDA submission for umbralisib monotherapy. These data sets add to the growing body of evidence suggesting that umbralisib has a differentiated safety profile and support our long-term vision of U2 as a potential backbone for future combination therapies." Mr. Weiss continued, "With PDUFA goal dates in February 2021 and June 2021 now set for our umbralisib NDA for the treatment of relapsed/refractory MZL and FL, respectively, our team is hard at work ensuring we are prepared for a successful launch in these indications. With a healthy balance sheet which includes a proforma cash position of approximately $325 million as of September 30, 2020, we are focused on preparing a BLA/NDA submission for U2 in CLL and importantly delivering on our remaining milestones for the year including topline results from our ULTIMATE I & II Phase 3 trials of ublituximab in MS."

42. On December 1, 2020, TG Therapeutics issued a press release announcing that the Company had initiated its rolling submission of the U2 BLA to the FDA. The press release quoted Defendant Weiss stating, in relevant part:

> "The initiation of a BLA submission for ublituximab in combination with umbralisib is an important milestone for us, and one that brings us one step closer to our goal of developing combination therapies for patients in need. This application, as well as the recently granted Fast Track Designation, is supported by the UNITY-CLL Phase 3 trial which met its primary endpoint of improvement in progression-free survival compared to obinutuzumab plus chlorambucil and will be presented in an oral presentation at the 2020 American Society of Hematology (ASH) annual meeting beginning this weekend." Mr. Weiss continued, "I want to thank the patients, caregivers and research teams who participated in our clinical trials and helped to advance the U2 combination to this stage. We believe, if approved, U2 has the potential to become an important treatment option to both front line and relapsed/refractory patients with CLL."

43. On March 1, 2021, TG Therapeutics filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2020 (the "2020 10-K"). The 2020 10-K contained substantively similar discussions of the Company's business overview and strategy as discussed, *supra*, in ¶¶ 30-31.

44. Appended to the 2020 10-K as exhibits were signed certifications pursuant to SOX by the Individual Defendants, attesting that "[t]he information contained in the [2020 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

45. On March 2, 2021, TG Therapeutics issued a press release announcing the Company's Q4 and year end 2020 financial results and providing a business update. The press release quoted Defendant Weiss stating, in relevant part:

> "2020 was a year of data and regulatory execution for us as we delivered results from our UNITY-NHL study that led to the approval of UKONIQ in relapsed/refractory MZL and FL and from UNITY-CLL that will be used to support the current rolling BLA submission for ublituximab in combination with umbralisib for patients with CLL. We also announced the top line results from our ULTIMATE MS Phase 3 trials that will be used to support a BLA submission for ublituximab in MS. These successful outcomes were made possible by the hard work of everyone at TG over many years and has positioned us for an exciting 2021." Mr. Weiss continued, "With the UKONIQ launch underway, we are excited to keep the momentum going and expect this year to complete our BLA submission for U2 in CLL, present final results from the ULTIMATE trials and then submit a BLA for ublituximab in MS, and continue to advance our triple therapy combination trials and our early pipeline."

46. That same day, TG Therapeutics hosted an earnings call with investors and analysts to discuss the Company's Q4 2020 results (the "Q4 2020 Earnings Call"). During the scripted portion of the Q4 2020 Earnings Call, Defendant Weiss stated, in relevant part:

> 2021 is certainly off to an exciting start with the recent accelerated approval of our first medicine, umbralisib, now called UKONIQ, for the treatment of relapsed or refractory marginal zone and follicular lymphoma. This was an incredible achievement for the team and we are thankful to everyone who helped along the way to reach this exciting milestone.
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> First and foremost, I mentioned at the outset of these prepared remarks, we received the exciting news early last month that the FDA granted accelerated approval of UKONIQ for the treatment of adult patients with relapsed or refractory marginal zone lymphoma or received at least one prior anti-CD20 based regimen and adults with relapsed or refractory follicular lymphoma, who have received at least three prior lines of systemic therapy.

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> For UNITY-CLL, we presented data demonstrating that U2 achieve the primary endpoint of improving progression-free survival over standard of care chemoimmunotherapy and those results were consistent for patients with treatment naïve CLL, as well as relapsed or refractory CLL. In addition, there was a significant improvement in overall response rate, the secondary end point.

47. On March 29, 2021, TG Therapeutics issued a press release announcing that it had completed its rolling submission of the U2 BLA to the FDA. The press release quoted Defendant Weiss stating, in relevant part:

> "The rapid completion of this BLA submission is a critical step forward in our mission to bring our first proprietary combination regimen to patients with both treatment naïve and relapsed or refractory chronic lymphocytic leukemia. The FDA has previously granted the U2 combination both fast track designation as well as orphan drug designation for patients with CLL and we look forward to continuing to work closely with the FDA with the goal of bringing this novel treatment regimen to patients as quickly as possible." Mr. Weiss continued, "I want to thank the patients, their families and caregivers, as well as the research teams who participated in the UNITY-CLL trial, and also commend the TG team for their hard work to get this submission completed ahead of schedule."

48. On May 10, 2021, TG Therapeutics issued a press release announcing the Company's Q1 2021 financial results and providing a business update. The press release quoted Defendant Weiss stating, in relevant part:

> "2021 has been an incredibly impactful year, kicking off with our first approval coming ahead of schedule for UKONIQ to treat both relapsed or refractory Marginal Zone Lymphoma and Follicular Lymphoma. That was followed by the completion of a BLA submission for ublituximab in combination with UKONIQ (U2) to treat patients with CLL, and the full presentation of positive results from the ULTIMATE I & II Phase 3 trials in relapsing forms of MS. As a fully integrated commercial organization we are pleased with our progress thus far with the UKONIQ launch and we look forward to continuing to build our commercial infrastructure to support the potential approval and commercialization of U2 in CLL and ublituximab in RMS."

49. That same day, TG Therapeutics hosted an earnings call with investors and analysts to discuss the Company's Q1 2021 results (the "Q1 2021 Earnings Call"). During the scripted portion of the Q1 2021 Earnings Call, Defendant Weiss stated, in relevant part:

> With the recent accelerated approval of UKONIQ, for the treatment of relapsed or refractory marginal Marginal Zone Lymphoma and Follicular Lymphoma, TG has transitioned into a full integrated commercial organization.
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> We are extremely pleased to now have UKONIQ, the first and only dual inhibitor of PI3K-delta and CK1-epsilon available to patients. We see the approval of UKONIQ as the first step and our broader mission of developing novel treatment for patients with B-cell diseases.
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> With successful Phase 3 studies in chronic lymphocytic leukemia refer to CLL and multiple sclerosis, MS, already completed and reported. We see the potential to positively impact, a significantly larger group patient on the horizon. Beyond that our pipeline has the potential to deliver novel combinations building up of a foundation of UKONIQ and ublituximab, our U2 combination that can further enhance outcomes for patient with B-cell diseases.
>
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>
> The combination as many of you know referred to as U2, as a treatment for patients with chronic lymphocytic leukemia. This BLA submission was based primarily on the results of the UNI-CLL trial, which was conducted under special protocol assessment. And as a reminder, the FDA previously granted Fast Track designation to the U2 combination for the treatment of adult patients with chronic lymphocytic leukemia and orphan drug designation for the U2 combination for the treatment of CLL.
>
> The next step is we expect to hear from the FDA later this month on whether they have accepted the submission for filing. With approximately 185,000 Americans living with CLL and approximately 40,000 patients seeking treatment annually, CLL remains an incurable disease and represents a large patient population where we believe U2 will provide a needed treatment option for these patients.
>
> Now, I'd like to turn to our MS program, where our BLA submission is slated for the third quarter of this year. That BLA will be supported by the positive results from our ultimate 1 and 2 Phase 3 trials, evaluating ublituximab and relapsing forms of MS, which were presented during the AAN conference last month.
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> For our part, we are extremely pleased with the results from the ULTIMATE I and II trials. And believe these data showcase the potential of ublituximab and to provide a highly efficacious treatment option with a generally well tolerated safety profile.
>
> If approved, ublituximab will be the only CD20 offered in a convenient one-hour infusion every six months, of course following the first infusion, which treating physicians have shared as an important benefit for them and their patients.

50. During the Q&A portion of the Q1 2021 Earnings Call, when asked how the Company was thinking about commercialization preparation, Defendant Weiss responded, in relevant part:

> So obviously, we were super pleased with the results from ULTIMATE I and ULTIMATE II. The easiest differentiator in the marketplace would be certainly the one-hour infusion. We're also working. Our pair group is actively studying and meeting with payers to better understand what it will take to create the best access possible for patients with ublituximab. So, as we've noted multiple times that if we can identify a price that will enhance access for patients, we will do that. So we think that there's a price differentiator. And then on the on the clinical profile, look, we'll leave it to the experts to say. But in our opinion, we've got some of the best data that's ever been seen in the treatment of MS.
>
> We think that the annualized relapse rates are incredibly low in ublituximab arm under .10, which is, as many of you have heard and listened to the calls, its a pretty big hurdle in the MS landscape. With relapses, the lower patients who see lots of relapses, it's usually connected with disability progression. These are relapsing remitting disease. We have a relapse. Not every relapse results in disability progression. So -- but very few patients will progress with their disability without the absence of relapse. So keeping those relapses down is obviously super important. That's why it's primarily for these trials. So yes, we think that-- the profile across the board, everyone in the influence on the efficacy side looks as good, if not better than anything else that's out there today. So we feel that safety and efficacy will look quite good. We got really nice differentiation on convenience. And hopefully we'll have a differentiate on price.

51. On May 25, 2021, TG Therapeutics issued a press release announcing the FDA's acceptance of the U2 BLA. The press release quoted Defendant Weiss stating, in relevant part, "[w]e are extremely pleased that the ublituximab BLA has been accepted by the FDA. This is an important milestone for us as it brings us one step closer to our goal of providing a novel

combination treatment option to patients with both treatment naive and relapsed or refractory CLL and SLL. We look forward to collaborating with the FDA throughout this review process."

52. On August 2, 2021, TG Therapeutics issued a press release announcing the Company's Q2 2021 financial results and providing a business update. The press release stated, in relevant part:

> [Defendant Weiss] stated, "We are pleased with the progress made throughout the second quarter, including our ongoing launch of UKONIQ in relapsed or refractory MZL and FL, FDA's acceptance of our BLA/sNDA for the combination of ublituximab and UKONIQ (U2) to treat CLL and SLL, and the continued advancement of our clinical programs. We have built a strong commercialization infrastructure to launch UKONIQ and have received positive feedback from healthcare providers on their experiences with the product and with the TG team. We believe this solid commercialization foundation will support, if approved, the launch of U2 in CLL and ublituximab in relapsing forms of multiple sclerosis."
>
> Mr. Weiss continued, "We look forward to an exciting second half of 2021, during which we plan to submit a BLA for ublituximab to treat patients with relapsing forms of multiple sclerosis, continue executing on the launch of UKONIQ in MZL and FL, and continue preparations for potential commercialization of U2 in CLL and ublituximab in RMS."

53. That same day, TG Therapeutics hosted an earnings call with investors and analysts to discuss the Company's Q2 2021 results (the "Q2 2021 Earnings Call"). During the scripted portion of the Q2 2021 Earnings Call, Defendant Weiss stated, in relevant part:

> Our first phase of our multi-phase strategy now complete with the accelerated approval of the UKONIQ, the first and only dual inhibitor of PI3K-delta and CK1-epsilon for the treatment of relapsed or refractory marginal zone lymphoma and follicular lymphoma. We are very proud of these accelerated approvals for patients who have failed prior therapies and have limited treatment options.
>
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>
> We have also submitted a supplemental New Drug Application, sNDA for UKONIQ for the same indication and received the same PDUFA date for the sNDA. We are excited about the potential to bring our novel U2 combination to CLL patients, especially those who have failed or who are not good candidates for current standards of care. CLL is a significantly larger patient population than marginal zone and follicular.

***

> We believe our Phase 3 data supports an attractive treatment option for patients with relapsing forms of MS. Entering MS will also raise our commercial profile significantly as we expect to participate as one of only three anti-CD20 monoclonal antibodies and what is then projected to become a $10 billion to $15 billion per year market just for anti-CD20 molecule antibodies in the treatment of MS. But the core focus will be on the regulatory and then commercial execution of these first three opportunities, especially the larger market opportunities in CLL and MS.
>
> We will continue to seek to enhance our Hematology Oncology franchise by broadening the potential U2 label to new indications such as in marginal zone and follicular lymphoma and also into new combination uses of U2 in CLL, for example, in combination with venetoclax and our very own TG-1701. The ability to combine with standard of care agents in CLL, we hope will bring better outcomes to patients and should also broaden the potential penetration of U2 and CLL. On the MS side, we will seek to build on ublituximab potentially in other auto-inflammatory diseases, as well as seek to build additional programs in MS.

54. On September 30, 2021, TG Therapeutics issued a press release announcing that the Company had submitted the Ublituximab BLA to the FDA. The press release quoted Defendant Weiss stating, in relevant part:

> [Defendant Weiss] stated, "The submission of this BLA for ublituximab to treat patients with RMS marks a major milestone for us, being our first submission of a marketing application for an autoimmune indication and rounds out our near-term U.S. regulatory submissions. Multiple sclerosis is a chronic and potentially disabling disease that affects nearly 1 million Americans. We believe ublituximab has the potential to offer an important new treatment option for these patients, and we look forward to working closely with the FDA on this submission." Mr. Weiss continued, "We want to thank the patients and their families, as well as the physicians and their research teams, who participated in our ULTIMATE I and II trials."

55. On November 4, 2021, TG Therapeutics issued a press release announcing the Company's Q3 2021 financial results and providing a business update. The press release stated, in relevant part:

> [Defendant Weiss] stated, "The third quarter of 2021 was an exciting time for us, as we achieved another major milestone by submitting a Biologics License Application (BLA) with the U.S. FDA for ublituximab to treat patients with relapsing forms of multiple sclerosis (RMS). With an estimated 1 million

> Americans currently living with multiple sclerosis, we believe if approved, ublituximab will provide an attractive new treatment option for patients battling RMS, which is the most common disease course."
>
> Mr. Weiss continued, "For the remainder of 2021 and into 2022, we look forward to continuing to execute on the UKONIQ launch in patients with relapsed or refractory marginal zone and follicular lymphoma, and also continuing to prepare for the potential launches of ublituximab in combination with UKONIQ or U2 in CLL and ublituximab in RMS."

56. That same day, TG Therapeutics hosted an earnings call with investors and analysts to discuss the Company's Q3 2021 results (the "Q3 2021 Earnings Call"). During the scripted portion of the Q3 2021 Earnings Call, Defendant Weiss stated, in relevant part:

> 2021 has been a pivotal year for TG, as we transitioned from a purely development stage company into a fully integrated commercial organization. With the launch of UKONIQ and the continued build of our commercial platform, TG has grown tremendously this year.
>
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>
> The team's hard work and effort this year have established our commercial footprint that I believe will pay dividends in the coming years as we intend to leverage our commercial platform for multiple potential future launches including, of course, U2 and CLL and ublituximab and RMS, both of which we are targeting for 2022 and beyond that, from our robust B-cell pipeline that we will touch briefly on later.

57. During the Q&A portion of the Q3 2021 Earnings Call, when asked how Ublituximab is differentiated with respect to infusion-related reactions and infusion times, Defendant Weiss responded, in relevant part:

> I think overall, people are excited about the infusion times and the associated infusion-related reactions. I think when you talk to folks, OCRE definitely has its issues on the infusion side that people are pretty aware of and somewhat vocal about. So, I think they looked at the IRR data, and we are actually quite comforted by it. So I think all systems are go from what I could tell.
>
> Again, I think key attributes, the activity profile, safety, everything has got to be in line and should do better, and I think that's where people perceive it. And then, the hour infusion is extremely attractive and – but the big one, as I mentioned earlier,

> is all about access, right? So to the extent we can drive great access, ideally through price, then we'll be in a great position.
>
> We'll be in a great position regardless, but it is an access game as people want to just make sure they can pick the drug that they want at the time they want to give it and they don't want to have too many hassles, which is understandable. When you think about 500 centers treating 80% of the patients, the throughput volume is really tremendous.

58. On December 14, 2021, TG Therapeutics issued a press release announcing the FDA's acceptance of the Ublituximab RMS BLA. The press release quoted Defendant Weiss stating, in relevant part, "[w]e are excited to share that we have received formal communication from the FDA, and the BLA for ublituximab to treat relapsing forms of MS has been accepted and granted a standard review. This is a major milestone for us as it is our first U.S. marketing application for an autoimmune indication. We look forward to working with the FDA throughout this review process."

59. On March 1, 2022, TG Therapeutics filed an Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the year ended December 31, 2021 (the "2021 10-K"). The 2021 10-K contained substantively similar descriptions of the Company's business overview and strategy as discussed, *supra*, in ¶¶ 30-31.

60. Appended to the 2021 10-K as exhibits were signed certifications pursuant to SOX by the Individual Defendants, attesting that, "[t]he information contained in the [2021 10-K] fairly presents, in all material respects, the financial condition and results of operations of the Company."

61. That same day, TG Therapeutics issued a press release announcing the Company's Q4 and year-end 2021 financial results and providing a business update. The quoted Defendant Weiss stating, in relevant part:

> "While we've faced numerous challenges over the last several months, we continued to progress our programs forward toward commercialization. With both MS and CLL BLA/sNDA submissions pending at the FDA, we continue to see

> 2022 as potentially the most transformative year in the Company's history." Mr. Weiss continued, "We are looking forward to the upcoming ODAC meeting where we can showcase the clinical profile of UKONIQ® monotherapy in its approved indications and in combination with ublituximab in CLL. We are also very excited about the evolving profile of ublituximab and its potential role in the treatment of RMS. We continue to receive positive feedback from the MS community about the safety, efficacy and one hour infusion offered by ublituximab."

62. Also that same day, TG Therapeutics hosted an earnings call with investors and analysts to discuss the Company's Q4 2021 results (the "Q4 2021 Earnings Call"). During the scripted portion of the Q4 2021 Earnings Call, Defendant Weiss stated, in relevant part:

> Most recently, in Ag terms, we presented additional analysis of the data from the ULTIMATE I and II Phase III trials of ublituximab and relapsing forms of MS, which we believe continue to highlight and support the potential utility of ublituximab as a treatment option for patients with RMS.
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> So let's begin with a discussion of the ultimate I and II Phase III trials which evaluated ublituximab monotherapy compared to teriflunomide [ph] in relapsing forms of MS. As noted in the past, both studies met their primary endpoint with ublituximab treatment demonstrating a statistically significant reduction in annualized relapse rate, referred to as ARR, with ublituximab treatment resulting in historically low levels of annualized relapse rate. In addition to the primary endpoint, we've had the opportunity over the past year to present several different sub-analysis of this data, all of which have strengthened our confidence in the utility of ublituximab to provide a meaningful treatment option to patients with RMS, if approved.
>
> On the regulatory front, we were extremely pleased to announce the FDA accepted our BLA for ublituximab to treat patients with RMS and granted a PDUFA goal date as I mentioned earlier of September 28, 2022. Adam will discuss our launch prep activities, but let me highlight again that we have built an all-star team of MS talent from around the industry. These folks have fantastic relationships in the MS community which have enabled us to gain invaluable insights. After spending several days last week at ECTRIMS [ph] in back to back to back meetings, I'm more confident than ever in the potential of ublituximab in RMS. With the CD-20 [ph] class already accounting for the largest portion of new starts and switches, which is sometimes referred to as the dynamic market, we see ublituximab as having the potential to play an important role in the treatment of relapsing forms of MS.

All right, now, let's talk about our CLL BLA/sNDA and the upcoming ODAC. So I just want to remind everyone, first and foremost, that the UNITY CLL study, which was -- which is the primary study supporting the BLA/sNDA was conducted under special protocol assessment and met it's primary endpoint of progression-free survival, and all key secondary endpoints. We submitted a BLA/sNDA for the U2 combination in the treatment of CLL and received a PDUFA goal date of March 25, 2022.

In September of 2021, we received a request from the FDA to conduct an analysis of overall survival. While OS is stated as a secondary endpoint, there was no plan to analyze it prior to the end of the trial, which has not yet occurred. Importantly, the UNITY CLL study was not powered for overall survival which would have required dramatically more overall survival events. And in addition, a significant number of patients on the control arm crossed over to the U2 arm collectively making the OS results hard to interpret. Furthermore, since we were not planning an OS analysis until the end of the trial, not all the data was collected at the time FDA requested the overall survival analysis, leaving about 15% of the patients with outdated or missing survival status.

Despite these material shortcomings, we conducted the analysis and sent it to the FDA as requested. As has been reported previously, that analysis showed an imbalance in favor of the control arm, the hazard ratio was 1.23, but when excluding COVID, it was 1.0; a hazard ratio above 1.0 implies potential harm of a therapy, and below 1.0 a potential benefit. Given the shortcomings of the OS analysis, and similar results from other pivotal Phase III studies in CLL, we didn't see this OS imbalance as concerning. Some of those examples included the original overall survival analysis from CLL-14 which was the approval study for venetoclax plus obinutuzumab. Similar to our trial, the control arm was obinutuzumab + chlorambucil, and at the time of approval, the hazard ratio was 1.24. No adjustment there because of course, that study was conducted before COVID, so that would not have been a confounding factor.

We also took a look at the overall survival results from the ILLUMINATE study, which was used for approval of ibrutinib plus obinutuzumab. Again, similarly, the control arm was obinutuzumab clamber cell [ph], same as ours. The overall survival outcome in this study was even more peculiar. Here, the hazard ratio was 0.921 to below 1.0 at the time of approval, but in long-term follow-up turned negative against ibrutinib with a hazard ratio of 1.083. Both of these instances highlight the challenges of using underpowered overall survival analysis. So, I think everyone could imagine our surprise when in November of 2021 the FDA notified us that they plan to host a meeting of the Oncologic Drugs Advisory Committee, referred to as ODAC. And ODAC being much easier to say, of course, in connection with it's review of the BLA for ublituximab and the sNDA [indiscernible] stemming from the OS imbalance. It is also evident what the regulatory action see for other PI3K inhibitors, that there is a concern with the overall class that is influencing the way the FDA is viewing this data.

> We spent the next two months trying to close the information gap. We were pleased to report about a month ago that we're able to reduce the missing survival information from 15% down to 5%. And we were further pleased to report at a high level that the capture of the additional survival data, the overall survival analysis, both in the ITT and the COVID-censored populations, the overall survival hazard ratio has improved from what we had seen in the original submission to the FDA. We provided that update to the FDA late last month.
>
> We also spent considerable amount of time doing a deep dive into the survival data, literally reviewing patient-by-patient to try to understand causality. For now, I will be brief and in summary will say, from TG standpoint, and that of our independent external medical and statistical advisors, that the totality of the UNITY-CLL data suggests that the overall safety profile is generally in line with currently available tumors [ph] for CLL, especially when focusing on treatment-related deaths. Since we received notification of the ODAC, the team has been hard at work preparing for the upcoming meeting and we're looking forward to the opportunity to showcase under critical review that UKONIQ is a unique PI3K inhibitor with a differentiated toxicity and tolerability profile. And with the potential to fill an unmet need in the treatment of CLL.

63. The statements referenced in ¶¶ 29-62 were materially false and misleading because Defendants made false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and compliance policies. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (i) clinical trials revealed significant concerns related to the benefit-risk ratio and overall survival data of Ublituximab and Umbralisib; (ii) accordingly, it was unlikely that the Company would be able to obtain FDA approval of the Umbralisib MZL/FL NDA, the U2 BLA, the U2 sNDA, or the Ublituximab RMS BLA in their current forms; (iii) as a result, the Company had significantly overstated Ublituximab and Umbralisib's clinical and/or commercial prospects; and (iv) therefore, the Company's public statements were materially false and misleading at all relevant times.

The Truth Emerges

64. On November 30, 2021, TG Therapeutics issued a press release providing a regulatory update. The press release stated, in relevant part:

TG Therapeutics [. . .] today announced the U.S. Food and Drug Administration (FDA) has notified the Company that it plans to host a meeting of the Oncologic Drugs Advisory Committee (ODAC) in connection with its review of the pending Biologics License Application (BLA)/supplemental New Drug Application (sNDA) for the combination of ublituximab and UKONIQ® (umbralisib) (combination referred to as U2) for the treatment of adult patients with chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL).

[Defendant Weiss] stated, "We appreciate the FDA's efforts in reviewing the U2 BLA/sNDA and its interest in obtaining the perspective of the ODAC regarding the benefit-risk of UKONIQ and the U2 combination. We believe UKONIQ is a unique PI3K inhibitor, with a differentiated toxicity and tolerability profile and believe the data submitted thus far are supportive of approval of U2 in CLL."

Mr. Weiss continued, "We look forward to the ODAC meeting as we believe it will provide us an opportunity to highlight the important role U2 can play in the treatment of CLL. As we have noted previously, while many patients with CLL are well-served with currently available therapies, there exists an underserved population, which for a variety of reasons, including tolerability concerns, access issues, and treatment failure, would benefit from an alternative treatment option."

ABOUT THE ODAC MEETING

In general, the ODAC reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs. Although the FDA will consider the recommendation of the ODAC Committee, the final decision regarding the approval of a product is made solely by the FDA.

The FDA has notified the Company that potential questions and discussion topics for the ODAC include: the benefit-risk of the U2 combination in the treatment of CLL or SLL, and the benefit-risk of UKONIQ in relapsed/refractory marginal zone lymphoma (MZL) or follicular lymphoma (FL). In addition, as part of the benefit-risk analysis, the overall safety profile of the U2 regimen, including adverse events (serious and Grade 3-4), discontinuations due to adverse events, and dose modifications, is expected to be reviewed. The FDA's concern giving rise to the ODAC meeting appears to stem from an early analysis of overall survival from the UNITY-CLL trial.

Overall survival was designated as a secondary efficacy outcome in the UNITY-CLL protocol but was not part of the primary analysis in accordance with the study's statistical analysis plan agreed upon via a Special Protocol Assessment (SPA), and therefore, was not analyzed or included in the BLA/sNDA. Additionally, the study was not powered for overall survival. As part of the ongoing review of the BLA/sNDA, the FDA requested an early analysis of overall survival from the UNITY-CLL trial. As of September 2021, the cut-off date for the overall

> survival analysis requested by the FDA during their review, there was an imbalance in favor of the control arm (HR: 1.23) though this result was not statistically significant. However, when excluding deaths related to COVID-19, the two arms were approximately balanced (HR: 1.04) with again no statistically significant difference between the treatment groups with regard to overall survival. The overall survival results are preliminary and the Company will continue to evaluate this endpoint over time as more events are available and will continue to analyze how COVID-19 may be impacting the analysis.
>
> The date of the ODAC meeting has not yet been determined, although the FDA has stated that it is targeting holding the ODAC in March or April 2022. Given this timing, we believe it is unlikely that the FDA will make a decision on the BLA/sNDA by the PDUFA goal date of March 25, 2022.

65. On this news, TG Therapeutics' stock price fell $8.16 per share, or 34.93%, to close at $15.20 per share on November 30, 2021.

66. Then, on April 15, 2022, the Company issued a press release entitled, "TG Therapeutics Announces Voluntary Withdrawal of the BLA/sNDA for U2 to Treat Patients with CLL and SLL." The press release stated, in relevant part:

> TG Therapeutics [. . .] today announced that the Company has voluntarily withdrawn the pending Biologics License Application (BLA)/supplemental New Drug Application (sNDA) for the combination of ublituximab and UKONIQ® (umbralisib) (combination referred to as U2) for the treatment of adult patients with chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL). The decision to withdraw was based on recently updated overall survival (OS) data from the UNITY-CLL Phase 3 trial that showed an increasing imbalance in OS. Additional details are included below in the section entitled "ABOUT UNITY-CLL PHASE 3 TRIAL AND THE WITHDRAWAL OF THE BLA/sNDA SUBMISSION."
>
> In addition, the Company announced that it has voluntarily withdrawn UKONIQ from sale for the approved indications of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen and for the treatment of adult patients with follicular lymphoma (FL) who have received at least three prior systemic therapies. UKONIQ was granted accelerated approval in these indications in February 2021. The Company's decision to withdraw UKONIQ from sale was primarily based on the withdrawal of the BLA and sNDA for U2 in CLL.
>
> [Defendant Weiss] stated, "We were very disappointed to see that the recently updated overall survival data showed an increasing survival imbalance in favor of

> the control arm. Accordingly, we and our advisors determined that we should withdraw the BLA/sNDA for U2 in CLL. Additionally, we made the difficult decision to withdraw UKONIQ from sale for the approved indications in MZL/FL. We want to thank the patients, families and practitioners who worked with us in our search for novel treatment options for patients with B-cell malignancies."
>
> Mr. Weiss continued, "While we had hoped to bring U2 to patients with CLL, this will now permit us to focus our attention, passion and energy to building out our multiple sclerosis and autoimmune platform. With our ublituximab BLA pending for patients with relapsing forms of multiple sclerosis and a PDUFA goal date of September 28, 2022, we are excited about the possibility of bringing ublituximab to patients with RMS. If approved, we believe the differentiated profile of ublituximab with its one-hour infusion will be welcomed by the MS community."

67. On this news, TG Therapeutics' stock price fell $1.93 per share, or 21.81%, to close at $6.92 per share on April 18, 2022.

68. Then, on May 31, 2022, the Company issued a press release entitled, "TG Therapeutics Announces FDA Extension of BLA PDUFA Date for Ublituximab to Treat Patients with RMS." The press release stated, in relevant part:

> TG Therapeutics [. . .] today announced that the U.S. Food and Drug Administration (FDA) has extended the Prescription Drug User Fee Act (PDUFA) goal date to December 28, 2022, for the Biologics License Application (BLA) for ublituximab as a treatment for patients with relapsing forms of multiple sclerosis (RMS).
>
> The FDA extended the PDUFA goal date to allow time to review a submission provided by the Company in response to an FDA information request, which the FDA deemed a major amendment. The submission comprised an integration and summary of certain clinical information that was previously provided to the FDA by the Company.
>
> [Defendant Weiss] stated, "While we are disappointed with the extension of our PDUFA goal date for ublituximab, a delay of this duration is not unprecedented, with both of the currently marketed CD20s in MS experiencing a similar 3-month PDUFA extension prior to approval. As we were targeting a launch for late this year or early next, we do not believe this will impact our overall launch plans for ublituximab in RMS." Mr. Weiss added, "We will continue to work with the FDA to complete the review of the ublituximab BLA and plan to be prepared and ready to launch upon approval. We believe ublituximab has the potential to offer RMS patients a valuable treatment option that can be administered in a one-hour infusion every six months following the first dose."

> The BLA submission was based on the results of the ULTIMATE I & II trials, two identical Phase 3, randomized, global, multi-center, double-blinded, active-controlled trials evaluating ublituximab compared to teriflunomide in patients with RMS.

69. On this news, TG Therapeutics' stock price fell $0.75 per share, or 14.51%, to close at $4.42 per share on May 31, 2022.

70. Finally, on June 1, 2022, the FDA published a drug safety communication entitled, "FDA approval of lymphoma medicine [UKONIQ] (umbralisib) is withdrawn due to safety concerns." The communication stated, in relevant part:

> Due to safety concerns, the U.S. Food and Drug Administration (FDA) has withdrawn its approval for the cancer medicine [UKONIQ] (umbralisib). [UKONIQ] was approved to treat two specific types of lymphoma: marginal zone lymphoma (MZL) and follicular lymphoma (FL).
>
> Updated findings from the UNITY-CLL clinical trial continued to show a possible increased risk of death in patients receiving [UKONIQ]. As a result, we determined the risks of treatment with [UKONIQ]outweigh its benefits. Based upon this determination, the drug's manufacturer, TG Therapeutics, announced it was voluntarily withdrawing [UKONIQ]from the market for the approved uses in MZL and FL.

71. On this news, TG Therapeutics' stock price fell $0.51 per share, or 11.53%, to close at $3.91 per share on June 1, 2022.

72. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

73. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired TG Therapeutics securities during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosures. Excluded from the Class are Defendants

herein, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

74. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, TG Therapeutics securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by TG Therapeutics or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

75. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

76. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

77. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the federal securities laws were violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of TG Therapeutics;

- whether the Individual Defendants caused TG Therapeutics to issue false and misleading financial statements during the Class Period;

- whether Defendants acted knowingly or recklessly in issuing false and misleading financial statements;

- whether the prices of TG Therapeutics securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and

- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

78. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

79. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

- the omissions and misrepresentations were material;

- TG Therapeutics securities are traded in an efficient market;

- the Company's shares were liquid and traded with moderate to heavy volume during the Class Period;

- the Company traded on the NASDAQ and was covered by multiple analysts;

- the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and

- Plaintiff and members of the Class purchased, acquired and/or sold TG Therapeutics securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts.

80. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

81. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

COUNT I

(Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants)

82. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

83. This Count is asserted against Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

84. During the Class Period, Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of TG Therapeutics securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire TG Therapeutics securities and options at artificially inflated prices. In furtherance of this

unlawful scheme, plan and course of conduct, Defendants, and each of them, took the actions set forth herein.

85. Pursuant to the above plan, scheme, conspiracy and course of conduct, each of the Defendants participated directly or indirectly in the preparation and/or issuance of the quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for TG Therapeutics securities. Such reports, filings, releases and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented the truth about TG 'Therapeutics' finances and business prospects.

86. By virtue of their positions at TG Therapeutics, Defendants had actual knowledge of the materially false and misleading statements and material omissions alleged herein and intended thereby to deceive Plaintiff and the other members of the Class, or, in the alternative, Defendants acted with reckless disregard for the truth in that they failed or refused to ascertain and disclose such facts as would reveal the materially false and misleading nature of the statements made, although such facts were readily available to Defendants. Said acts and omissions of Defendants were committed willfully or with reckless disregard for the truth. In addition, each Defendant knew or recklessly disregarded that material facts were being misrepresented or omitted as described above.

87. Information showing that Defendants acted knowingly or with reckless disregard for the truth is peculiarly within Defendants' knowledge and control. As the senior managers and/or directors of TG Therapeutics, the Individual Defendants had knowledge of the details of TG 'Therapeutics' internal affairs.

88. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of TG Therapeutics. As officers and/or directors of a publicly-held company, the Individual Defendants had a duty to disseminate timely, accurate, and truthful information with respect to TG 'Therapeutics' businesses, operations, future financial condition and future prospects. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of TG Therapeutics securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning TG 'Therapeutics' business and financial condition which were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired TG Therapeutics securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Defendants, and were damaged thereby.

89. During the Class Period, TG Therapeutics securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which the Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of TG Therapeutics securities at prices artificially inflated by Defendants' wrongful conduct. Had Plaintiff and the other members of the Class known the truth, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases and/or acquisitions by Plaintiff and the Class, the true value of TG Therapeutics securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of TG Therapeutics securities

declined sharply upon public disclosure of the facts alleged herein to the injury of Plaintiff and Class members.

90. By reason of the conduct alleged herein, Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

91. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases, acquisitions and sales of the Company's securities during the Class Period, upon the disclosure that the Company had been disseminating misrepresented financial statements to the investing public.

COUNT II

(Violations of Section 20(a) of the Exchange Act Against the Individual Defendants)

92. Plaintiff repeats and re-alleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

93. During the Class Period, the Individual Defendants participated in the operation and management of TG Therapeutics, and conducted and participated, directly and indirectly, in the conduct of TG 'Therapeutics' business affairs. Because of their senior positions, they knew the adverse non-public information about TG 'Therapeutics' misstatement of income and expenses and false financial statements.

94. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to TG 'Therapeutics' financial condition and results of operations, and to correct promptly any public statements issued by TG Therapeutics which had become materially false or misleading.

95. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which TG Therapeutics disseminated in the marketplace during the Class Period concerning TG 'Therapeutics' results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause TG Therapeutics to engage in the wrongful acts complained of herein. The Individual Defendants, therefore, were "controlling persons" of TG Therapeutics within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of TG Therapeutics securities.

96. Each of the Individual Defendants, therefore, acted as a controlling person of TG Therapeutics. By reason of their senior management positions and/or being directors of TG Therapeutics, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, TG Therapeutics to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of TG Therapeutics and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complain.

97. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by TG Therapeutics.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

DEMAND FOR TRIAL BY JURY

Plaintiff hereby demands a trial by jury.

Dated: