

TG THERAPEUTICS, INC.

FORM 10-K (Annual Report)

Filed 03/15/18 for the Period Ending 12/31/17

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Telephone	(212) 554-4484
CIK	0001001316
Symbol	TGTX
SIC Code	2834 - Pharmaceutical Preparations
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017.

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____.

Commission File Number 1-32639

TG THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

36-3898269
(I.R.S. Employer
Identification No.)

2 Gansevoort St.
9 th Floor
New York, New York
(Address of principal executive offices)

10014
(Zip Code)

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

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

Common Stock, Par Value \$0.001 Per Share
(Title of Class)

The Nasdaq Capital Market
(Name of Each Exchange on Which Registered)

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes No

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of “large accelerated filer,” “accelerated filer,” “smaller reporting company,” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if smaller reporting company)

Smaller reporting company

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.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are “affiliates”) was \$490,249,542 as of June 30, 2017, based on the closing sale price of such stock as reported on the NASDAQ Capital Market .

There were 75,579,785 shares of the registrant’s common stock, \$0.001 par value, outstanding as of March 1, 2018.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant’s Proxy Statement for the 2018 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

TG THERAPEUTICS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE FISCAL YEAR ENDED DECEMBER 31, 2017

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This Annual Report on Form 10-K contains trademarks and trade names of TG Therapeutics, Inc., including our name and logo. All other trademarks, service marks, or trade names referenced in this Annual Report on Form 10-K are the property of their respective owners.

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products we may acquire or in-license;
- use of clinical research centers and other contractors;
- expectations as to the timing of commencing or completing pre-clinical and clinical trials and the expected outcomes of those trials;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;
- products being accepted by doctors, patients or payors;
- ability to compete against other companies and research institutions;
- ability to secure adequate protection for our intellectual property;
- ability to attract and retain key personnel;
- availability of reimbursement for our products;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating requirements, including expectations regarding the value and liquidity of our investments;
- stock price and its volatility; and
- expectations for future capital requirements.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I

Unless the context requires otherwise, references in this report to "TG," "Company," "we," "us" and "our" refer to TG Therapeutics, Inc. and our subsidiaries.

ITEM 1. BUSINESS.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, we are developing two therapies targeting hematologic malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for patients with multiple sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

CORPORATE INFORMATION

We were incorporated in Delaware in 1993. Our executive offices are located at 2 Gansevoort St., 9 th Floor, New York, New York 10014. Our telephone number is 212-554-4484, and our e-mail address is info@tgtxinc.com.

We maintain a website with the address www.tgtherapeutics.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report. You may read and copy any such reports and amendments thereto at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is <http://www.sec.gov>.

In addition, we intend to use our media and investor relations website, SEC filings press releases, public conference calls and webcasts as well as social media to communicate with our subscribers and the public about the Company, its services and other issues. It is possible that the information we post on social media could be deemed to be material information. Therefore, in light of the SEC's guidance, we encourage investors, the media and others interested in the Company to review the information we post on the U.S. social media channels listed on our website.

PRODUCTS UNDER DEVELOPMENT

TG-1101 (ublrituximab)

Overview

TG-1101 (ublrituximab) is a chimeric, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on the surface of B-lymphocytes developed to aid in the depletion of circulating B-cells. We hold exclusive worldwide rights to develop and commercialize TG-1101 for all indications, except for the territories of France and Belgium which have been retained by LFB Biotechnologies (“LFB”), and South Korea and Southeast Asia which were licensed by us to Ildong Pharmaceutical Co. Ltd (“Ildong”) in November 2012.

Generally, anti-CD20 antibodies are believed to exert their B-cell depleting effects through three primary mechanisms: antibody dependent cell-mediated cytotoxicity (“ADCC”), complement dependent cytotoxicity (“CDC”), and direct or programmed cell death (“DCD” or “PCD”). TG-1101 has been specifically glycoengineered to enhance ADCC activity, which should enhance its ability to deplete B-cells and may improve its anti-cancer effects when compared to Rituxan®, the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2016 of more than \$7 billion.

Two single-agent, dose-escalation, Phase I studies were undertaken with TG-1101 to establish an optimal dose in patients with Non-Hodgkin’s Lymphoma (“NHL”) and Chronic Lymphocytic Leukemia (“CLL”). A two part first-in-human Phase I clinical trial was first completed in France in which TG-1101 was evaluated in relapsed or refractory CLL. Subsequently, a single-agent Phase I study was undertaken in the US enrolling patients with both NHL and CLL. In both studies, single agent therapy with TG-1101 was deemed well tolerated by treating investigators and displayed promising clinical activity in relapsed and refractory patients.

In oncology settings, anti-CD20 therapy is generally used in combination with other anti-cancer agents where it demonstrates maximum activity as opposed to single agent usage. As a result, subsequent clinical development for TG-1101 has focused on combination therapy. Currently, our priority combination trials for TG-1101 are:

- The GENUINE Trial – a randomized controlled Phase 3 trial evaluating TG-1101 in combination with ibrutinib, for previously treated CLL patients with high risk cytogenetics;
- The UNITY-CLL Trial – a randomized controlled Phase 3 trial under Special Protocol Assessment (SPA) evaluating TG-1101 in combination with TGR-1202, the Company’s development stage PI3K delta inhibitor, for patients with front line and previously treated CLL;
- The UNITY-NHL Trial – registration-directed Phase 2b clinical study evaluating TGR-1202 alone and in combination with TG-1101 with or without bendamustine, in patients with previously treated Non-Hodgkin’s Lymphoma (NHL); and
- TG-1101 + TGR-1202 + Pembrolizumab for patients with CLL.

In non-oncology settings, anti-CD20 therapy has generally been used as monotherapy. In addition to the above oncology studies, TG-1101 is being evaluated in a Phase 2 study for the treatment of Multiple Sclerosis (MS) and in an investigator initiated Phase 1 study for the treatment of acute neuromyelitis optica (NMO) relapses, with additional autoimmune related indications planned to be studied. On August 1, 2017, we announced we had reached an agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of two global Phase 3 clinical trials for TG-1101, referred to as the ULTIMATE I and ULTIMATE II Phase 3 clinical trials, both of which are currently open to enrollment.

Manufacturing of TG-1101 is currently performed by a contract manufacturer based in the US and our partner, LFB Biotechnologies.

Pre-Clinical Data Overview

The mechanism of action of anti-CD20 antibodies, including rituximab and TG-1101 has been elucidated and detailed in numerous academic and clinical studies. Upon conjugation of the antibody to the CD20 surface antigen, rituximab has been found to deplete B-lymphocytes through three primary mechanisms: ADCC, CDC, and DCD or PCD.

Antibody dependent cellular cytotoxicity, or ADCC, is a mechanism that is dependent on interactions between the Fc region of the antibody and the FcγR receptors on immune system effector cells, most notably the FcγRIIIA (CD16) receptor found on NK cells. These interactions trigger cells to release cytotoxic molecules and proteases resulting in B-cell death. TG-1101 is a third generation, type I chimeric IgG1 monoclonal antibody with a glycoengineered Fc region designed specifically to induce higher ADCC activity in comparison to rituximab, which has been demonstrated in pre-clinical models.

Clinical Data Overview and Recent Developments

Single Agent TG-1101 in Relapsed/Refractory NHL & CLL

Our first US based trial entitled "An Open Label Phase I/II Trial of the Efficacy and Safety of TG-1101 in Patients with B-cell Non-Hodgkin's Lymphoma who have Relapsed or are Refractory After CD20 Directed Antibody Therapy," was launched in the third quarter of 2012. In July 2014, this trial completed enrollment at 35 patients, of which 12 patients were included in the dose escalation component and 23 patients in various expansion cohorts. All enrolled patients were relapsed or refractory to Rituxan® or a Rituxan® containing regimen, and in most cases multiple other lines of therapy. Dr. Owen O'Connor, Professor of Medicine and Director, Center for Lymphoid Malignancies at New York Presbyterian Columbia Medical Center was the Principal Investigator for the multi-center study.

Data from this study was published in full in the *British Journal of Haematology* in February 2017:

TG-1101 in Combination with TGR-1202 with/without ibrutinib or bendamustine for Relapsed/Refractory NHL & CLL

In November 2013, we initiated a multi-center, Phase I study to evaluate the safety and efficacy of the combination of TG-1101 and TGR-1202, the Company's novel, once per day, PI3K delta inhibitor, for patients with relapsed and/or refractory CLL and NHL. Additional cohorts were added to this study to explore the triple therapy combination of TG-1101, TGR-1202, and ibrutinib and the triple therapy of TG-1101, TGR-1202 and bendamustine.

The MD Anderson Cancer Center is the lead center for the trial with Nathan Fowler, MD, Assistant Professor and Co-Director of Clinical Research in the Department of Lymphoma, as the Study Chair for the NHL patient group and Susan O'Brien, MD, Professor and Medical Director for Cancer Clinical Trials and Research at UC Irvine as the Study Chair for the CLL patient group. The data from this study supports the current Phase 3 UNITY-CLL study of U2 in CLL and the registration-directed UNITY-NHL Phase 2b clinical study of U2 + bendamustine in DLBCL.

Updated data from this study was most recently presented at the 22nd European Hematology Association (EHA) Annual Congress in Madrid, Spain in June 2017.

Both triplet combinations demonstrated acceptable levels of tolerability with promising activity. Enrollment in both cohorts is now closed and patients continued to be followed for safety and efficacy.

TG-1101 in Combination with Ibrutinib for Relapsed/Refractory MCL & CLL

In December 2013, we initiated a multi-center Phase 2 clinical trial to evaluate the safety and efficacy of the combination of TG-1101 and ibrutinib for patients with CLL and MCL. Jeff Sharman, MD, Medical Director for Hematology Research, US Oncology Network, was the Study Chair. This trial has completed enrollment.

Final data from the MCL cohort of this study was presented at the 57th Annual American Society of Hematology (ASH) meeting held in December 2015, with data from the CLL cohort published in full in the *British Journal of Haematology* in December 2016.

Overall, in both CLL and MCL, aside from day 1 Infusion related reactions (IRR), the addition of TG-1101 did not appear to alter the safety profile seen historically with single agent ibrutinib. Of the 60 patients treated, 41 CLL and 15 MCL patients were evaluable for response. The combination displayed marked clinical activity, reporting an 88% (35/41) response rate in patients with CLL, a 95% (19/21) response rate in those CLL patients with high-risk cytogenetics, and an 87% (13/15) response rate in patients with MCL. The data from the CLL cohort of this study supported the Phase 3 GENUINE study of the combination in CLL patients with high-risk cytogenetics.

TG-1101 + Ibrutinib Phase 3 Study Program – The GENUINE Trial

The GENUINE trial is a randomized controlled clinical trial in patients with previously treated CLL with specific high-risk cytogenetic abnormalities, with patients randomized to receive either TG-1101 plus ibrutinib or ibrutinib alone. In October 2016, we announced revisions to the design of the GENUINE study to accelerate its completion. Initially the study was being conducted pursuant to a Special Protocol Assessment (SPA) with the U.S. Food and Drug Administration (FDA), and was designed to enroll approximately 330 patients, with a two-part analysis of both overall response rate (ORR) and progression-free survival (PFS). The trial was amended in October 2016 to enroll approximately 120 patients, with the PFS analysis component removed. Following the revisions, the sole primary endpoint of the study is ORR, and the SPA is no longer in effect.

In June 2017, the positive results from our Phase 3 GENUINE trial were presented by Dr. Jeff Sharman, Medical Director, Hematology Research, US Oncology in an oral session during the 53rd American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, IL.

This presentation included data from the GENUINE Phase 3 trial, a multicenter, randomized trial, which assessed the efficacy and safety of TG-1101 plus ibrutinib versus ibrutinib alone in patients with high risk CLL. For the trial, high-risk was defined as having any one or more of the following centrally confirmed features: 17p deletion, 11q deletion or p53 mutation. The GENUINE study was designed to demonstrate the value of adding TG-1101 to ibrutinib monotherapy in high-risk CLL, and was powered to show a statistically significant improvement in ORR of 30%, with a minimal absolute detectable difference between the two arms of approximately 20%.

The trial met its primary endpoint, demonstrating a statistically significant improvement in Overall Response Rate (ORR), as assessed by blinded independent central radiology and hematology review by iwCLL (Hallek 2008) criteria, compared to ibrutinib alone in both the Intent to Treat (ITT) population ($p=0.001$) and Treated population ($p < 0.001$). Per iwCLL guidelines, all responders required confirmation of response for a minimum duration of 2 months. The ITT population included all 126 randomized patients (64 in the TG-1101 plus ibrutinib arm and 62 in the ibrutinib alone arm) while the Treated population includes all ITT patients that received at least one dose of either study drug (59 in the TG-1101 plus ibrutinib arm and 58 in the ibrutinib alone arm).

One hundred and seventeen (117) patients were evaluable for safety (59 patients in the TG-1101 plus ibrutinib arm, and 58 patients in the ibrutinib alone arm). The combination was well tolerated and, apart from infusion related reactions, the addition of TG-1101 did not appear to alter the safety profile of ibrutinib monotherapy. Neutropenia, occurring in 9% of patients, was the most commonly reported Grade 3/4 Adverse Event (AE) in the combination arm, followed by infusion related reactions and anemia, each reported in 5% of patients. Notably, the majority of infusion related reactions (IRR) were Grade 1 or 2 in severity, with only 5% Grade 3/4 IRR observed. Median follow-up for this study was approximately 11.4 months.

Response Rates

	TG-1101 plus Ibrutinib	Ibrutinib	P-value
Treated Population (n)	n=59	n=58	
Overall Response Rate (ORR)	78%	45%	P<0.001
Complete Response (CR)	7%	0%	NS
MRD-Negative	19% (n=53) *	2% (n=53) *	P<0.01

*Patients evaluable for MRD included those enrolled >4 months prior to data cutoff date of February 15, 2017. MRD analyzed by central lab, 7-color flow cytometry

In October 2017, we announced the outcome of a meeting with the FDA regarding the use of the results from the GENUINE Phase 3 trial to support a Biologics License Application (BLA) filing for approval of TG-1101 in combination with ibrutinib. During the meeting, the FDA confirmed that accelerated approval based on ORR would be a review issue. As part of the discussion, the FDA encouraged us to consider future available therapy in its risk/benefit analysis as part of any potential future BLA filing that may impact accelerated approval.

We continue to follow patients in the GENUINE study for safety and efficacy including Overall Response, MRD and Progression Free Survival (PFS). We are currently working on preparing a Biologics License Application for a potential accelerated approval filing for TG-1101 in combination with ibrutinib in previously treated CLL patients with high-risk cytogenetics, which filing could occur in 2018.

TG-1101 in Combination with TGR-1202 Phase 3 Study Program – The UNITY-CLL Trial

In September 2015, we reached an agreement with the FDA regarding an SPA on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial for the proprietary combination of TG-1101 plus TGR-1202, for the treatment of CLL. The SPA provides agreement that the Phase 3 trial design adequately addresses objectives that, if met, would support the regulatory submission for drug approval of both TG-1101 and TGR-1202 in combination.

The Phase 3 trial, called the UNITY-CLL trial, is a randomized controlled clinical trial that includes two key objectives: first, to demonstrate contribution of each agent in the TG-1101 + TGR-1202 regimen (the combination sometimes referred to as "U2"), and second, to demonstrate superiority in Progression Free Survival (PFS) over the standard of care to support the submission for full approval of the combination. The study will randomize patients into four treatment arms: TG-1101 + TGR-1202, TG-1101 alone, TGR-1202 alone, and an active control arm of obinutuzumab (GAZYVA®) + chlorambucil. An early interim analysis will assess contribution of each single agent in the TG-1101 + TGR-1202 combination regimen, which, if successful, will allow early termination of both single agent arms. A second interim analysis will be conducted following full enrollment into the study, which, if positive, we plan to utilize for accelerated approval.

In May 2017, we announced that the independent Data Safety Monitoring Board (DSMB) of the UNITY-CLL Phase 3 trial had successfully completed a pre-specified interim analysis to assess the contribution of TG-1101 and TGR-1202 in the combination regimen of TG-1101 plus TGR-1202. In conducting the analysis, the DSMB reviewed efficacy data from approximately 50 patients per arm in the UNITY-CLL study who were eligible for at least one response evaluation. Based on the overall response rate data available, and in accordance with the statistical analysis plan in the study's SPA, the DSMB determined that contribution has been established and recommended we cease enrollment into the single agent arms. Accordingly, in May the study began enrolling in a 1:1 ratio to only the two combination arms: the investigational arm of TG-1101 plus TGR-1202 and the control arm of obinutuzumab plus chlorambucil. Additionally, the DSMB reviewed safety data from all patients on study (n > 270) as of the data cut-off date, including patients with both treatment naive and relapsed/refractory Chronic Lymphocytic Leukemia (CLL), and again identified no safety concerns in any treatment group (treatment naive or previously treated) and recommended the continuation of the study without modification.

In September 2017, we announced that target enrollment in the UNITY-CLL trial was met and that we were extending enrollment until October 12, 2017 for any additional identified study patients to be allowed in the trial. We expect top-line ORR data from this study to be reported in 2018.

TG-1101 in Combination with TGR-1202 with or without bendamustine Phase 2b Registration-Directed Program – The UNITY-NHL Trial

In June 2016, we commenced a registration-directed UNITY-DLBCL Phase 2b clinical study evaluating TG-1101 in combination with TGR-1202, as well as TGR-1202 alone, in patients with previously treated DLBCL. In mid-2017, this study was expanded to allow enrollment of patients with follicular lymphoma (FL), small lymphocytic lymphoma (SLL), and marginal zone lymphoma (MZL), as well as to add a cohort evaluating the triplet regimen of TG-1101 + TGR-1202 + bendamustine which has previously been explored in Phase 1. The cohorts of DLBCL, FL/SLL, and MZL are each being enrolled to and evaluated independently.

The updated study, called UNITY-NHL, is entitled "A Phase 2b Randomized Study to Assess the Efficacy and Safety of the Combination of Ublituximab + TGR-1202 with or without bendamustine and TGR-1202 alone in Patients with Previously Treated Non-Hodgkin's Lymphoma." The DLBCL component is being led by Owen A. O'Connor, MD, PhD, Professor of Medicine and Experimental Therapeutics, and Director of the Center for Lymphoid Malignancies at Columbia University Medical Center, while the indolent NHL component of the study is being led by Nathan H. Fowler, MD, Associate Professor, Department of Lymphoma/Myeloma, The University of Texas MD Anderson Cancer Center. The primary objective of the study is to assess the efficacy of TGR-1202 alone, in combination with TG-1101, or in combination with TG-1101 and bendamustine in patients with previously treated NHL as measured by Overall Response Rate (ORR). The study will also provide important information as to the contribution of each agent, TGR-1202 and TG-1101, to the combination regimen of both agents, as well as the contribution of bendamustine to the combination regimen of both agents.

In August 2017, we announced that the study's Data Safety Monitoring Board (DSMB) had met and, based on pre-set hurdles designed to evaluate ORR, the DSMB recommended continued enrollment in the TGR-1202 + TG-1101 ("U2") arm and no further enrollment into the single agent TGR-1202 arm for the DLBCL cohort. As set forth in the protocol, the single agent TGR-1202 arm was replaced with the triple combination of TG-1101 + TGR-1202 + bendamustine.

Single Agent TG-1101 in Relapsing Forms of Multiple Sclerosis

In May 2016, we commenced our first study of TG-1101 in patients with relapsing remitting multiple sclerosis (RRMS), a chronic demyelinating disease of the central nervous system (CNS).

The study, entitled "A Placebo-Controlled Multi-Center Phase 2 Dose Finding Study of Ublituximab, a Third-Generation Anti-CD20 Monoclonal Antibody, in Patients with Relapsing Forms of Multiple Sclerosis," is being led by Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Assistant Professor at the University of Texas Medical Branch in Round Rock, TX. The primary objective of the study is to determine the optimal dosing regimen for TG-1101 with a focus on accelerating infusion times. In addition to monitoring for safety and tolerability at each dosing cohort, B-cell depletion and established MS efficacy endpoints will also be evaluated.

Data from this study was most recently presented at the Third Annual ACTRIMS Forum 2018 meeting in San Diego, CA, with additional data presentations expected at upcoming medical conferences.

TG-1101 in relapsing forms of Multiple Sclerosis Phase 3 Study Program – The ULTIMATE I and ULTIMATE II Trial

In August 2017, we reached an agreement with the FDA regarding an SPA on the design of two Phase 3 clinical trials for TG-1101, for the treatment of relapsing forms of Multiple Sclerosis (RMS). The SPA provides agreement that the two Phase 3 trial designs adequately address objectives that, if met, would support the regulatory submission for approval of TG-1101.

The RMS Phase 3 program consists of two trials, called the ULTIMATE I and ULTIMATE II trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing TG-1101 (ublituximab) to teriflunomide in subjects with RMS. The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment. Each trial is ongoing and will enroll approximately 440 subjects, randomized in a 1:1 ratio, with approximately 880 patients to be enrolled across both trials.

Updates for the combination of TG-1101 and TGR-1202

In January 2017, we announced that the FDA has granted orphan drug designation covering the combination of TG-1101 and TGR-1202 for the treatment of patients with CLL and DLBCL.

TGR-1202

Overview

The phosphoinositide-3-kinases (“PI3Ks”) are a family of enzymes involved in various cellular functions, including cell proliferation and survival, cell differentiation, intracellular trafficking, and immunity. There are four isoforms of PI3K (alpha, beta, delta, and gamma), of which the delta (d) isoform is strongly expressed in cells of hematopoietic origin, and often implicated in B-cell related lymphomas.

TGR-1202 is an orally available PI3K delta inhibitor with nanomolar potency to the delta isoform and high selectivity over the alpha, beta, and gamma isoforms. TGR-1202 has demonstrated activity in several pre-clinical models and primary cells from patients with various hematologic malignancies.

We hold exclusive rights to develop and commercialize TGR-1202 for all indications worldwide, except India which has been retained by Rhizen Pharmaceuticals, SA.

The Company’s Investigational New Drug (“IND”) application for TGR-1202 was accepted by the FDA in December 2012 and a first in-human Phase I clinical trial was initiated in January 2013.

In August 2016, we announced that TGR-1202 had received orphan drug designation for the treatment of CLL.

In October 2016, a manuscript titled, "Silencing c-Myc Translation as a Therapeutic Strategy through Targeting PI3K Delta and CK1 Epsilon in Hematological Malignancies," was published online in the First Edition section of *Blood*, the Journal of the American Society of Hematology. The publication presents preclinical data describing the synergy of TGR-1202 with the proteasome inhibitor carfilzomib and the unique effects of the combination to silence c-Myc in various preclinical lymphoma and myeloma models. In addition, the manuscript for the first time reports on TGR-1202's unique complimentary mechanism of inhibiting the protein kinase casein kinase-1 (CK1) epsilon, which may contribute to the silencing of c-Myc and explain TGR-1202's clinical activity in aggressive lymphoma, including Diffuse Large B-cell Lymphoma (DLBCL).

In February 2018, data from the first-in-human Phase 1 clinical trial of TGR-1202 was published online in *The Lancet Oncology*. The manuscript was titled, "Umbralisib, a novel PI3K and casein kinase-1 epsilon inhibitor, in relapsed or refractory chronic lymphocytic leukaemia and lymphoma: an open-label, phase 1, dose-escalation, first-in-human study," The paper includes safety and efficacy information from 90 patients with relapsed or refractory hematologic malignancies, including patients with CLL and various forms of lymphoma treated with single agent TGR-1202. In this study, the data showed that TGR-1202 was well tolerated with a favorable safety profile distinct from prior generation PI3K delta inhibitors.

Clinical Data Overview and Recent Developments

Initial clinical development of TGR-1202 was focused on establishing preliminary safety and efficacy in a wide variety of hematologic malignancies. Upon identification of safe and active doses of TGR-1202, additional clinical trial programs were opened, exploring TGR-1202 as a single agent and in combination with a variety of agents. In addition to the previously described studies in combination with TG-1101, our current priority clinical trials that are ongoing for TGR-1202 include:

- TGR-1202 as a single agent in CLL patients who are intolerant to prior BTK inhibitor or PI3K delta inhibitor therapy;
- TGR-1202 in combination with the BTK inhibitor, ibrutinib, in patients with previously treated CLL and MCL; and
- TGR-1202 in combination with the JAK inhibitor, ruxolitinib (JAKAFI®), in patients with previously treated Myelofibrosis or Polycythemia Vera.

Single Agent TGR-1202 in Patients with Relapsed/Refractory Hematologic Malignancies

In January 2013, the Company initiated a Phase I, open label, multi-center, first-in-human clinical trial of TGR-1202 in patients with hematologic malignancies. The study entitled TGR-1202-101, "A Phase I Dose Escalation Study Evaluating the Safety and Efficacy of TGR-1202 in Patients with Relapsed or Refractory Hematologic Malignancies," is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Howard "Skip" Burris, MD, Executive Director, Drug Development as the acting Study Chair. Enrollment is open to patients with relapsed or refractory NHL, CLL, and other select hematologic malignancies. As of February 2016, this study has closed to enrollment.

Data from this ongoing Phase I study was published in full in *The Lancet Oncology* in February 2018.

TGR-1202 Long-term Follow-up Integrated Analysis in Patients with Relapsed/Refractory Hematologic Malignancies

In December 2017, at the 59th American Society of Hematology (ASH) Annual Meeting, the Company presented integrated data with long term follow-up from 347 patients exposed to TGR-1202 across 5 studies, which continued to demonstrate high response rates in CLL, and FL coupled with a favorable safety profile distinct from other PI3K delta inhibitors.

TGR-1202 TKI Intolerance Study

In December 2017, at the 59th American Society of Hematology (ASH) Annual Meeting, the Company presented data from 33 patients with CLL who were intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent TGR-1202. TGR-1202 appeared to demonstrate a favorable safety profile in patients intolerant to prior ibrutinib (BTK) or idelalisib (PI3K) with only 2 patients (6%) discontinuing due to an adverse event, neither of which was a recurrent adverse event from their prior BTK or PI3K therapy. Enrollment continues in this Phase 2 study.

TGR-1202 Combination Trials

TGR-1202 is being evaluated in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin, in patients with relapsed or refractory Hodgkin's lymphoma; in combination with the BTK inhibitor, ibrutinib, in patients with CLL and MCL; and in combination with the JAK inhibitor, ruxolitinib, in patients with Myelofibrosis or Polycythemia Vera. Additional investigator sponsored trials are also underway which are combining TGR-1202 with other approved agents for the treatment of B-cell malignancies.

It is anticipated that results from these studies will be presented or updated at future medical conferences.

TGR-1202 in Solid Tumors

In addition to the exploration of TGR-1202 in various hematologic malignancies, a study was opened in October 2015 to evaluate TGR-1202 as a single agent as well as in combination with various chemotherapies for the treatment of select solid tumors. The study, entitled TGR-1202-102, "A Phase I Study Evaluating the Safety and Efficacy of TGR-1202 Alone and in Combination with either nab-paclitaxel + Gemcitabine or with FOLFOX in Patients with Select Relapsed or Refractory Solid Tumors" is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN with Johanna Bendell, MD, Director of GI Oncology Research as the acting study chair. The study is currently closed to enrollment with patients continuing to be followed for safety and efficacy.

Market Opportunity for TG-1101 & TGR-1202

Our lead products under development, TG-1101 and TGR-1202 are for the treatment of B-cell hematologic malignancies. Hematologic malignancies include cancers derived from the bone marrow and lymph tissue. The non-Hodgkin's lymphomas (NHL) represent a heterogeneous subset of these malignancies. Underneath the single rubric of lymphoma exist some of the most aggressive growing cancers (Burkitt's lymphoma, lymphoblastic lymphoma, diffuse large-B-cell lymphoma), as well as some of the most indolent (small lymphocytic lymphoma, follicular lymphoma, and marginal zone lymphoma). In the United States, NHL represents 4-5% of all new cancer cases, and is the eighth leading cause of cancer death. According to the American Cancer Society, it is estimated in 2018 that there will be 74,680 new cases in the United States, and 19,910 deaths from NHL, despite improvements in treatment. Chronic lymphocytic leukemia (CLL) affects mainly older adults and accounts for approximately one quarter of all diagnosed cases of leukemia, of which there are estimated to be about 60,300 new cases and about 24,370 deaths (all kinds of leukemia) according to American Cancer Society estimates. Despite improvements in therapy, up to one third of patients with aggressive NHL continue to die from their disease, and indolent lymphomas remain incurable in the absence of allogeneic stem cell transplant. The treatment paradigm for hematologic malignancies is well standardized in front line settings, with the anti-CD20 monoclonal antibody, rituximab, administered generally in combination with chemotherapeutic agents. While front line therapies are generally efficacious, there are numerous downsides, including a high rate of toxicity associated with exposure to chemotherapeutic agents. While initially responsive, most patients with hematologic malignancies will eventually relapse and require second, third, and sometimes more lines of therapy. As a result, there is a pressing need for new, innovative, targeted therapies for the treatment of this heterogeneous group of diseases.

Anti-CD20 antibodies have been approved and studied in a variety of diseases falling into several therapeutic areas including oncology, autoimmune disorders, and neurologic disease. NHL and CLL are the most common B-cell proliferative diseases for which rituximab, the first anti-CD20 antibody approved by the FDA, is the current gold standard treatment. While the addition of rituximab to chemotherapeutic treatment of NHL has dramatically improved patient outcomes, many patients will relapse or become refractory to rituximab containing regimens.

Rituximab resistance is becoming an increasing concern for clinicians as relapsing patients are exposed to multiple lines of rituximab containing regimens to treat recurrence of disease. It is estimated that over half of patients initially responsive to their first exposure to rituximab do not respond upon retreatment (Davis et al, 2000).

We believe these factors contribute to an immediate and sustained need for an anti-CD20 monoclonal antibody that is differentiated and potentially therapeutically superior to the gold standard rituximab in order to extend and enhance CD20 therapy as it stands today.

In addition to anti-CD20 therapy, novel targeted agents are now being introduced which target specific signaling pathways and enzymes known to exhibit aberrant activity and overexpression in B-cell malignancies such as Bruton's Tyrosine Kinase (BTK), and Phosphoinositide-3-Kinase delta (PI3K delta). The PI3K/AKT/mTOR pathway has been the target of numerous pharmaceutical agents, both approved and in development, however only recently has the delta isoform of PI3K been identified as a potential target for the treatment of hematologic malignancies and other B-cell lymphoproliferative disorders. Idelalisib (ZYDELIG®), a PI3K delta specific inhibitor from Gilead Pharmaceuticals, was approved by the FDA in 2014 for patients with CLL and indolent NHL, and copanlisib (ALIQOPA™) was approved by the FDA in 2017 for patients with advanced follicular lymphoma. Other agents targeting kinases downstream of the B-cell receptor, such as the BTK inhibitor, ibrutinib and acalabrutinib, have displayed high rates of response in patients with relapsed and refractory B-cell malignancies and have been recently approved for indications in lymphoma. While these agents have demonstrated high levels of single agent activity in B-cell disorders, their clinical activity has been shown to be greatly enhanced when utilized in combination with anti-CD20 agents.

As novel targeted agents gain FDA approval for the treatment of relapsed and refractory disease, it is anticipated that the size of this market will expand greatly as branded drugs enter use in multiple lines of therapy. Given the nature of the disease state for patients with hematologic malignancies, characterized by indolent disease progression and chronic relapses, the Company anticipates a great and growing need for novel agents that can be used alone or in combination with approved agents, and those currently under development to enhance the quality of life and extend the length of survival for patients suffering from hematologic malignancies.

IRAK4

Interleukin-1 Receptor Associated Kinase 4, referred to as IRAK4, is a key signaling kinase that becomes inappropriately activated in tumors that carry certain oncogenic mutations of MYD88, which can be found in most patients with Waldenström's Macroglobulinemia, a rare B-cell cancer, as well as in a sub-set of patients with Non-Hodgkin's Lymphoma and Chronic Lymphocytic Leukemia. Additionally, IRAK4 is a key component of signaling pathways which regulate immune and inflammatory processes suggesting that inhibition of IRAK4 may also be useful in the treatment of autoimmune related disorders. We hold global rights to develop and commercialize the IRAK4 program, which was licensed from Ligand Pharmaceuticals. Our IRAK4 program is currently in pre-clinical development. In April 2015, we presented pre-clinical data on the IRAK4 compounds at the 2015 American Association for Cancer Research (AACR) Annual Meeting held in Philadelphia, PA.

PD-L1 and GITR

In March 2015, we entered into a global collaboration agreement for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. Our anti-PD-L1 recently entered the clinic and our anti-GITR program is currently in pre-clinical development, with pre-clinical data most recently presented at the American Association for Cancer Research Annual Meeting in March 2017.

In October 2017, we announced that the first patient has been dosed in a Phase 1 clinical trial evaluating the safety and tolerability of our anti-PD-L1 monoclonal antibody, enrolling patients across sites in Australia and New Zealand.

BET

In May 2016, as part of a broader agreement with Jubilant Biosys (“Jubilant”), an India-based biotechnology company, we entered into a sub-license agreement (“JBET Agreement”) with Checkpoint Therapeutics, Inc. (“Checkpoint”), a subsidiary of Fortress Biotech, Inc. (“FBIO”), for the development and commercialization of Jubilant’s novel BET inhibitor program in the field of hematological malignancies. The BET inhibitor program is the subject of a family of patents covering compounds that inhibit BRD4, a member of the BET (Bromodomain and Extra Terminal) domain for cancer treatment. Our BET inhibitor program is currently in pre-clinical development. Our Executive Chairman and CEO, is also Executive Vice Chairman of FBIO.

BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co., or Jiangsu (“BTK Agreement”), pursuant to which we obtained worldwide rights, excluding Asia but including Japan, for the development of Hengrui’s Bruton’s Tyrosine Kinase (BTK) inhibitor program, including lead candidate TG-1701 (known in China as SHR-1459), as monotherapy and in combination with TG-1101 and TGR-1202. In addition to TG-1701, the global license agreement covers TG-1702 (SHR-1266), another BTK inhibitor in pre-clinical development. Bruton’s tyrosine kinase (BTK) is an essential component of the B-cell receptor signaling pathways that regulate the survival, activation, proliferation, and differentiation of B lymphocytes. Targeting BTK with small molecule inhibitors has been demonstrated to be an effective treatment option for B-cell lymphomas and autoimmune diseases.

COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

The information below provides estimates regarding the costs associated with the completion of the current development phase and our current estimated range of the time that will be necessary to complete that development phase for our key pipeline products. We also direct your attention to the risk factors which could significantly affect our ability to meet these cost and time estimates found in this report in Item 1A under the heading “Risks Related to the Company’s Business and Industry.”

Product candidate	Target indication	Development status	Completion of phase	Estimated cost to complete phase
TG-1101 & TGR-1202	In combination in CLL patients	Phase III	2018*	Approximately \$7 million
TGR-1202 +/- TG-1101	In combination in relapsed/refractory NHL patients	Phase IIb	2019*	Approximately \$10 million
TG-1101	In relapsing forms of Multiple Sclerosis	Phase III	2021	Approximately \$50 million

*Completion of phase for this study indicates completion of portion of study, which, if successful, would support an accelerated approval

Completion dates and costs in the above table are estimates due to the uncertainties associated with clinical trials and the related requirements of development. In the cases where the requirements for clinical trials and development programs have not been fully defined, or are dependent on the success of other trials, we cannot estimate trial completion or cost with any certainty. The actual spending on each trial during the year is also dependent on funding. We therefore direct your attention to Item 7 under the heading “Liquidity and Capital Resources.”

INTELLECTUAL PROPERTY AND PATENTS

General

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and in other countries. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the U.S. and elsewhere in the world.

We also depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. This knowledge and experience we call “know-how.” To help protect our proprietary know-how which is not patentable, and for inventions for which patents may be difficult to enforce, we rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all employees, consultants, advisors and other contractors to enter into confidentiality agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

Patents and other proprietary rights are crucial to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents, supported by regulatory exclusivity or are effectively maintained as trade secrets. We have a number of patents and patent applications related to our compounds and other technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the U.S. are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability to be extended through the patent restoration program, although any such extension could still be minimal.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology. In the event of litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would involve substantial costs.

TG-1101

Pursuant to our license for TG-1101 (ublituximab) with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, we have the exclusive commercial rights to a series of patents and patent applications in the U.S. and in multiple countries around the world, as well as a non-exclusive license to additional background patent rights. These patents and patent protections include composition of matter patents relating to the structure and mechanism of action for TG-1101 as well as method of use patents which cover use of TG-1101 in combination with various agents and for various therapeutic indications.

The composition of matter patent for TG-1101 has been issued in the United States and Europe, which affords patent protection until 2029 in the US and 2025 in Europe, exclusive of patent term extensions. We also have a method of use patent on the combination of TGR-1202 and TG-1101 which has been issued in the United States and is pending in other territories globally. Additionally, we have numerous granted patents and pending patent applications outside the US which include claims directed to the composition of matter and methods of treatment with TG-1101 in various settings.

TGR-1202

Pursuant to our license for TGR-1202 with Rhizen, we have the exclusive commercial rights to a series of patent applications in the U.S. and abroad. The patent applications include composition of matter patents relating to the structure, mechanism of action, and formulation for TGR-1202 as well as method of use patents which cover use of TGR-1202 in combination with various agents and for various therapeutic indications. Our composition of matter patent for TGR-1202 has been issued in the United States and Europe, which affords patent protection until 2033, exclusive of patent term extensions. We also have a method of use patent on the combination of TGR-1202 and TG-1101 which has been issued in the United States and is pending in other territories globally. All other patent applications currently filed for TG-1202 are currently pending. Because the dates for any potential regulatory approval are currently unknown we cannot predict the expected expiration date, and it is possible that the life of these patents following regulatory approval could be minimal.

IRAK4

Pursuant to our license for the IRAK4 program with Ligand, we have the exclusive commercial rights to a patent family which covers the composition of matter and proposed methods of use for various therapeutic indications. All patent applications currently filed for the IRAK4 program are currently pending. Because the date for any potential regulatory approval is currently unknown we cannot predict the expected expiration date, and it is possible that the life of these patents following regulatory approval could be minimal.

PD-L1 and GITR

Pursuant to our Global Collaboration with Checkpoint, the intellectual property includes issued patents in a number of countries, including the United States and Europe, as well as pending patent applications in several countries elsewhere. The PD-L1 segment of the portfolio includes patent applications pending in the United States, Australia, Canada, Europe, Israel and Korea. Any patents maturing from these pending applications will expire no sooner than October 2033. The GITR segment of the portfolio includes an International Application No. PCT/US2015/054010, filed in October 2015. Any national stage applications, which are pursued off of this international application (including one in the United States Patent and Trademark Office), would expire no earlier than October 2035.

BET

Pursuant to our JBET Agreement with Checkpoint, the in-licensed patent estate includes two international (PCT) applications filed in March 2016 (WO 2016/157221) and September 2016, respectively, claiming the benefit of two earlier-filed Indian provisional applications. Any patents maturing from this patent estate are expected to expire no sooner than March 2036.

BTK

Pursuant to our BTK Agreement with Jiangsu, we have the exclusive commercial rights to a patent family which covers the composition of matter and proposed methods of use for various therapeutic indications. All patent applications currently filed for the BTK program are currently pending. Because the date for any potential regulatory approval is currently unknown we cannot predict the expected expiration date, and it is possible that the life of these patents following regulatory approval could be minimal .

The patent rights that we own or have licensed relating to our product candidates are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market these product candidates. See *“Item 1A – Risk Factors -- Risks Related to the Company’s Intellectual Property.”*

Proof of direct infringement by a competitor for method of use patents can prove difficult because the competitors making and marketing a product typically do not engage in the patented use. Additionally, proof that a competitor contributes to or induces infringement of a patented method of use by another can also prove difficult because an off-label use of a product could prohibit a finding of contributory infringement and inducement of infringement requires proof of intent by the competitor.

Moreover, physicians may prescribe such a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent or prosecute.

In addition, the limited patent protection described above may adversely affect the value of our product candidates and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, to provide market exclusivity for certain of our drug candidates. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan-drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product.

Pursuant to these regulations, TG-1101 (ublrituximab) has received Orphan-Drug designation from the FDA for the treatment of Marginal Zone Lymphoma (Nodal and Extranodal) in September 2013, for the treatment of CLL in August of 2010, and Orphan-Drug designation by the European Medicines Agency (“EMA”) for the treatment of CLL in November of 2009. We also obtained Orphan Drug designation for TGR-1202 as monotherapy for the treatment of CLL in August 2016, and in January 2017, we announced that the FDA granted Orphan Drug designation covering the combination of TG-1101 and TGR-1202 for the treatment of patients with CLL and DLBCL. We believe that TG-1101 and TGR-1202, as well as our other pipeline products may be eligible for additional Orphan Drug designations; however, we cannot assure you that TG-1101, TGR-1202, or any other drug candidates we may acquire or in-license, will obtain such orphan drug designations. Additionally, upon FDA approval, we believe that TG-1101 and TGR-1202 each would qualify as a New Chemical Entity, or NCE, which provides for five years of exclusivity following approval.

We cannot assure you that any other drug candidates we may acquire or in-license, will obtain such Orphan Drug designation or that we will be the first to receive FDA approval for such drugs so as to be eligible for market exclusivity protection.

LICENSING AGREEMENTS AND COLLABORATIONS

We have formed strategic alliances with a number of companies for the manufacture and commercialization of our products. Our current key strategic alliances are discussed below.

TG-1101

LFB Biotechnologies S.A.S, GTC Biotherapeutics, LFB/GTC LLC.

In January 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of TG-1101. Under the license agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of TG-1101 (ublrituximab). To date, we have made no payments to LFB Group and LFB Group is eligible to receive payments of up to an aggregate of approximately \$31.0 million upon our successful achievement of certain clinical development, regulatory and sales milestones, in addition to royalty payments on net sales of TG-1101 at a royalty rate that escalates from mid-single digits to high-single digits. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated (i) by LFB if the Company challenges any of the licensed patent rights, (ii) by either party due to a breach of the agreement, or (iii) by either party in the event of the insolvency of the other party.

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong relating to the development and commercialization of TG-1101 in South Korea and Southeast Asia. Under the terms of the sublicense agreement, Ildong has been granted a royalty bearing, exclusive right, including the right to grant sublicenses, to develop and commercialize TG-1101 in South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar. To date, we have received \$2 million in the form of an upfront payment from Ildong, and are eligible to receive sales based milestone payments up to an aggregate of \$5 million and royalty payments on net sales of TG-1101 at a royalty rate that escalates from mid-teens to high-teens upon approval in South Korea and/or Southeast Asia. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated (i) by Ildong if the Company challenges any of the licensed patent rights, (ii) by either party due to a breach of the agreement, or (iii) by either party in the event of the insolvency of the other party.

TGR-1202

In September 2014, we exercised our option to license the global rights to TGR-1202, thereby entering into an exclusive licensing agreement (the "TGR-1202 License") with Rhizen Pharmaceuticals, S A ("Rhizen") for the development and commercialization of TGR-1202. Prior to this, we had been jointly developing TGR-1202 in a 50:50 joint venture with Rhizen.

Under the terms of the TGR-1202 License, Rhizen received a \$4.0 million cash payment and 371,530 shares of our common stock as an upfront license fee. With respect to TGR-1202, Rhizen will be eligible to receive regulatory filing, approval and sales based milestone payments in the aggregate of approximately \$175 million, a small portion of which will be payable on the first New Drug Application (NDA) filing and the remainder on approval in multiple jurisdictions for up to two oncology indications and one non-oncology indication and attaining certain sales milestones. In addition, if TGR-1202 is co-formulated with another drug to create a new product (a "New Product"), Rhizen will be eligible to receive similar regulatory approval and sales based milestone payments for such New Product. Additionally, Rhizen will be entitled to tiered royalties that escalate from high single digits to low double digits on our future net sales of TGR-1202 and any New Product. In lieu of sales milestones and royalties on net sales, Rhizen shall also be eligible to participate in sublicensing revenue, if any, based on a percentage that decreases as a function of the number of patients treated in clinical trials following the exercise of the license option. Rhizen will retain global manufacturing rights to TGR-1202, provided that they are price competitive with alternative manufacturers. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or any other exclusivity right in such country, unless the agreement is earlier terminated (i) by us for any reason, (ii) by either party due to a breach of the agreement.

IRAK4

In June 2014, we entered into an exclusive licensing agreement with Ligand Pharmaceuticals Incorporated ("Ligand") for the development and commercialization of Ligand's interleukin-1 receptor associated kinase-4 ("IRAK4") inhibitor technology, which currently is in preclinical development for potential use against certain cancers and autoimmune diseases. IRAK4 is a serine/threonine protein kinase that is a key downstream signaling component of the interleukin-1 receptor and multiple toll-like receptors.

Under the terms of the license agreement, Ligand received 125,000 shares of our common stock as an upfront license fee. Ligand will also be eligible to receive maximum potential milestone payments of approximately \$207 million upon the achievement of specific clinical, regulatory and commercial milestone events. Additionally, Ligand will be entitled to royalties on our future net sales of licensed products containing IRAK4 inhibitors. The basic royalty rate for licensed products covered by Ligand's issued patents will be 6% for annual sales of up to \$1 billion and 9.5% for annual sales in excess of that threshold. The license will terminate on a country by country basis upon the expiration of the last licensed patent right or 10 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated by either party due to a breach of the agreement in the event of the insolvency of the other party.

PD-L1 and GITR

In March 2015, we entered into a Global Collaboration (the “Collaboration”) with Checkpoint Therapeutics, Inc. (“Checkpoint”), a subsidiary of FBIO for the development and commercialization of Checkpoint’s anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies.

Under the terms of the Collaboration, we made an up-front payment of \$500,000, will make development and sales-based milestone payments up to an aggregate of \$164 million, and will pay a tiered single digit royalty on net sales. The royalty term will terminate on a country by country basis upon the later of (i) ten years after the first commercial sale of any applicable licensed product in such country, or (ii) the expiration of the last-to-expire patent held by Dana Farber containing a valid claim to any licensed product in such country.

BET

In May 2016, as part of a broader agreement with Jubilant Biosys (“Jubilant”), an India-based biotechnology company, we entered into a sub-license agreement (“JBET Agreement”) with Checkpoint for the development and commercialization of Jubilant’s novel BET inhibitor program in the field of hematological malignancies. The BET inhibitor program is the subject of a family of patents covering compounds that inhibit BRD4, a member of the BET (Bromodomain and Extra Terminal) domain for cancer treatment. Our BET inhibitor program is currently in pre-clinical development.

Under the terms of the agreement, we paid Checkpoint an up-front licensing fee of \$1.0 million and will make additional payments contingent on certain preclinical, clinical, and regulatory milestones, including commercial milestones totaling up to approximately \$177 million and a single-digit royalty on net sales. TG will also provide funding to support certain targeted research efforts at Jubilant.

BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co., or Jiangsu, to acquire worldwide intellectual property rights, excluding Asia but including Japan, and for the research, development, manufacturing, and commercialization of products containing or comprising of any of Jiangsu’s Bruton’s Tyrosine Kinase inhibitors containing the compounds of either TG-1701 (SHR-1459 or EBI-1459) or TG-1702 (SHR-1266 or EBI-1266). Pursuant to the agreement, we paid Jiangsu an upfront fee of \$1.0 million in our common stock. Jiangsu is eligible to receive milestone payments totaling approximately \$350 million upon and subject to the achievement of certain milestones. Various provisions allow for payments in conjunction with the agreement to be made in cash or our common stock, while others limit the form of payment. Royalty payments in the low double digits are due on net sales of licensed products and revenue from sublicenses. Additionally, before we can license, sell, develop, or commercialize ublituximab (TG-1101) within China, we must notify Jiangsu, giving Jiangsu the right of first offer.

The term of the agreement expires after the expiration of the last royalty term to expire with respect to any of the patent rights under the agreement. We or Jiangsu may terminate the agreement upon notice to the other upon breach without remedy or upon insolvency. In addition, either party may terminate the agreement upon a material breach, after providing the other party with adequate notice and allowing 45 days to cure.

COMPETITION

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier.

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan® (rituximab) and Gazyva® (obinutuzumab or GA-101), and Novartis' Arzerra® (ofatumumab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing antibodies targeting CD20, CD19, and other B-cell associated targets, chimeric antigen receptor T-cell (CAR-T) immunotherapy, and other B-cell ablative therapy which, if approved, would potentially compete with TG-1101 both in oncology settings as well as in autoimmune disorders. Earlier this year, the Roche Group's anti-CD20 antibody ocrelizumab was approved for the treatment of MS. Genmab and GSK's (ofatumumab) is also under clinical development for patients with MS. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

With respect to TGR-1202, there are several PI3K delta targeted compounds both approved, such as Gilead's Zydelig® (idelalisib) and Bayer's Aliqopa™ (copanlisib), and in development, including, but not limited to, Verastem's duvelisib which if approved we would expect to compete directly with TGR-1202. In addition, there are numerous other novel therapies targeting similar pathways to TGR-1202 both approved and in development, which could also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (FDA approved for MCL, CLL, Marginal Zone Lymphoma and WM and marketed by AbbVie and Janssen), the BTK inhibitor acalabrutinib (FDA approved for MCL and marketed by AstraZeneca), or the BCL-2 inhibitor venetoclax (FDA approved for CLL and marketed by AbbVie and Roche).

Additional information can be found under Item "1A - Risk Factors – Other Risks Related to Our Business" within this report.

SUPPLY AND MANUFACTURING

We have limited experience in manufacturing products for clinical or commercial purposes. We currently do not have any manufacturing capabilities. We have established contract manufacturing relationships for the supply of TG-1101 as part of our license agreement with LFB Biotechnologies and also with a U.S. based contract manufacturer. We have also established contract manufacturing relationships for the supply of TGR-1202 as part of our licensing agreement with Rhizen. As with any supply program, obtaining pre-clinical and clinical materials of sufficient quality and quantity to meet the requirements of our development programs cannot be guaranteed and we cannot ensure that we will be successful in this endeavor. In addition, we anticipate the need for the current scale of production for each of our products to be significantly expanded as we enter later stages of development. There can be no assurance given that such scale-up will be successful in providing pharmaceutical product that is of sufficient quantity, or of a quality that is consistent with our previously established specifications, or that meets the requirements set by regulatory agencies under which we may seek approval of our product candidates.

At the time of commercial sale, to the extent possible and commercially practicable, we would seek to engage a back-up supplier for each of our product candidates. Until such time, we expect that we will rely on a single contract manufacturer to produce each of our product candidates under current Good Manufacturing Practice, or cGMP, regulations. Our third-party manufacturers have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration and corresponding state agencies to ensure strict compliance with cGMP and other state and federal regulations. Our contractors outside of the United States face similar challenges from the numerous local and regional agencies and authorized bodies. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations. If they are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

GOVERNMENT AND INDUSTRY REGULATION

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our drug candidates, as well as our ongoing research and development activities. None of our drug candidates have been approved for sale in any market in which we have marketing rights. Before marketing in the U.S., any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the new drug application, or NDA. To receive Fast Track designation, an applicant must demonstrate:

- that the drug is intended to treat a serious or life-threatening condition;
- that the drug is intended to treat a serious aspect of the condition; and
- that the drug has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

The FDA must respond to a request for fast track designation within 60 calendar days of receipt of the request. Over the course of drug development, a product in a fast track development program must continue to meet the criteria for fast track designation. Sponsors of products in fast track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in fast track drug development programs ordinarily are eligible for priority review of a completed application in six months or less and also may be permitted to submit portions of a New Drug Application (“NDA”) to the FDA for review before the complete application is submitted.

Sponsors of drugs designated as fast track also may seek approval under the FDA’s accelerated approval regulations. Under this authority, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval will be subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. Post-marketing studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing studies with due diligence. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all, and, therefore, could not submit the NDA to the FDA or foreign regulatory authorities for marketing approval.

In addition, sponsors may also apply to the FDA for Breakthrough Therapy Designation. The Breakthrough Therapy Designation is intended to expedite the development and review of a potential new drug for serious or life-threatening diseases where “preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development.” The designation of a drug as a Breakthrough Therapy was enacted as part of the 2012 Food and Drug Administration Safety and Innovation Act.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

- *Phase 1* : The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.
- *Phase 2* : Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.
- *Phase 3* : Studies establish safety and efficacy in an expanded patient population.
- *Phase 4* : The FDA may require Phase 4 post-marketing studies to find out more about the drug’s long-term risks, benefits, and optimal use, or to test the drug in different populations.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

- slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;
- longer treatment time required to demonstrate efficacy or determine the appropriate product dose;
- insufficient supply of the drug candidates;
- adverse medical events or side effects in treated patients; and
- ineffectiveness of the drug candidates.

In addition, the FDA, equivalent foreign regulatory authority, or a data safety monitoring committee for a trial may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk, or for futility. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Sponsors of drugs may apply for an SPA from the FDA. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. However, final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA or BLA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA/BLA for filing if certain content criteria are not met and, even after accepting an NDA/BLA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy, or REMS, as part of a NDA/BLA. The REMS plan contains post-market obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and conduct sufficient Phase 4 follow-up studies and registries to ensure the continued safe use of the drug.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those disease states, conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA/BLA. Certain changes to an approved NDA/BLA, including, with certain exceptions, any significant changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will generally be limited to those specified in FDA approved labeling, and the advertising of our products will be subject to comprehensive monitoring and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding those contained in approved labeling will constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, warning letters, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Should we wish to market our products outside the U.S., we must receive marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies are typically required to apply for foreign marketing authorizations at a national level. However, within the European Union, registration procedures are available to companies wishing to market a product in more than one European Union member state. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

EMPLOYEES

As of March 1, 2018, we had 75 full and part-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced a work stoppage. We consider our relations with our employees to be good.

ITEM 1A. RISK FACTORS.

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition or operating results could be materially harmed. An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. You should carefully consider the following risk factors and the other information contained elsewhere in this Annual Report before making an investment in our securities.

Risks Related to Our Business and Industry

Because we have in-licensed our product candidates from third parties, any dispute with or non-performance by our licensors will adversely affect our ability to develop and commercialize the applicable product candidates.

Because we license our foundational intellectual property from third parties and we expect to continue to in-license additional intellectual property rights, if there is any dispute between us and our licensor regarding our rights under a license agreement, our ability to develop and commercialize our product candidates may be adversely affected. Disputes may arise with the third parties from whom we license our intellectual property rights from for a variety of reasons, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships and obligations associated with sublicensing;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations, or may conflict in such a way that puts us in breach of one or more agreements, which would make us susceptible to lengthy and expensive disputes with one or more of our licensing partners. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

We do not have full internal development capabilities, and are thus reliant upon our partners and third parties to generate clinical, preclinical and quality data necessary to support the regulatory applications needed to conduct clinical trials and file for marketing approval.

In order to submit and maintain an IND, Biologics License Application (“BLA”), or New Drug Application (“NDA”) to the FDA, it is necessary to submit all information on the clinical, non-clinical, chemistry, manufacturing, controls and quality aspects of the product candidate. We rely on our third party contractors and our licensing partners to provide a significant portion of this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs. Additionally, an IND must be active in each division in which we intend to conduct clinical trials. Currently we do not have an active IND for any of the IRAK4, BTK, or BET inhibitors, nor for our anti-GITR antibody. Additionally, there can be no assurance given that any of the molecules under development in our IRAK4, BTK, or BET inhibitor program or in our anti-GITR antibody research program will demonstrate sufficient pharmacologic properties during pre-clinical evaluation to advance to IND enabling studies, or that such IND enabling studies, if any are conducted, will provide data sufficient to support the filing of an IND, or that such IND, if filed, would be accepted by any FDA division under which we would seek to develop any product candidate. While we maintain an active IND for TG-1101 and TGR-1202 enabling the conduct of studies in the FDA’s Division of Hematology and Oncology, and an active IND for TG-1101 under the FDA’s Division of Neurology, there can be no assurance that we will be successful in obtaining an active IND for these drugs in any other division under whose supervision we may seek to develop our product candidates, or that the FDA will allow us to continue the development of our product candidates in those divisions where we maintain an active IND.

We are highly dependent on the success of our product candidates and cannot give any assurance that these or any future product candidates will be successfully commercialized.

We are a development-stage biopharmaceutical company, and do not currently have any commercial products that generate revenues or any other sources of revenue. We may never be able to successfully develop marketable products. Our pharmaceutical development methods are unproven and may not lead to commercially viable products for any of several reasons.

If we are unable to develop, or receive regulatory approval for or successfully commercialize any of our product candidates, we will not be able to generate product revenues. Even if we are able to develop or receive regulatory approval for or successfully commercialize any of our product candidates, we may not be able to gain market acceptance for our product candidates and future products and may never become profitable.

Because the results of preclinical studies and early clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials, if any, or receive regulatory approval.

Pharmaceutical development has inherent risk. We will be required to demonstrate through adequate and well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in diverse populations for their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, there is typically an extremely high rate of failure of pharmaceutical candidates proceeding through clinical trials.

We plan on conducting additional Phase I, II and III clinical trials for TG-1101 and TGR-1202. Early clinical results seen with TG-1101 and TGR-1202 in a small number of patients may not be reproduced in expanded or larger clinical trials. Additionally, individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. Further, larger scale Phase III studies, which are often conducted internationally, are inherently subject to increased operational risks compared to earlier stage studies, including the risk that the results could vary on a region to region, or country to country basis which could materially adversely affect the study's outcome or the opinion of the validity of the study results by applicable regulatory agencies. Early clinical trial results from interim analysis or from the review of a Data Safety Monitoring Board (DSMB) or similar safety committee may not be reflective of the results of the entire study, when completed. Additionally, many of the results reported in our early clinical trials rely on local investigator assessed safety and efficacy outcomes which may differ from results assessed in a blinded, independent, centrally reviewed manner, often required of adequate and well controlled registration directed clinical trials which may be undertaken at a later date. If the results from expansion cohorts or later trials are different from those found in the earlier studies of TG-1101 and TGR-1202, we may need to terminate or revise our clinical development plan, which could extend the time for conducting our development program and could have a material adverse effect on our business. Our IRAK4, BTK, BET, and anti-GITR programs are all in pre-clinical development and no assurance can be given that they will advance into clinical development. If the results from additional pre-clinical studies or early clinical trials differ from those found in earlier studies, our clinical development plans and timelines for this program could be adversely affected which could have a material adverse effect on our business. Many drugs fail in the early stages of clinical development for safety and tolerability issues, accordingly if our pre-clinical assets advance into clinical development, no assurance can be made that a safe and efficacious dose can be found.

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same diseases that we are studying. Certain clinical trials are designed to continue until a pre-determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates. They may also incur additional costs if enrollment is increased in order to achieve the desired number of events. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials in a cost-effective or timely manner. In addition, conducting multi-national studies adds another level of complexity and risk. We are subject to events affecting countries outside the U.S. Negative or inconclusive results from the clinical trials we conduct or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials.

In September 2015 we announced a Phase 3 clinical trial for the combination of TG-1101 + TGR-1202 for patients with CLL, which is being conducted pursuant to an SPA with the FDA and in August 2017 we announced an SPA for our registration program for TG-1101 in relapsing forms of MS. Many companies which have been granted SPAs and/or the right to utilize the FDA's Fast Track or accelerated approval process have ultimately failed to obtain final approval to market their drugs. Since we are seeking approvals under SPAs for some of our product registration strategies, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Further, any changes or amendments to a protocol that is being conducted under SPA will have to be reviewed and approved by the FDA to verify that the SPA agreement is still valid. Even if the primary endpoint in a Phase 3 clinical trial is achieved, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

The sufficiency of our GENUINE trial results for approval are subject to FDA's discretion .

Obtaining accelerated approval for an agent requires demonstration of meaningful benefit over available therapies. While we believe we have an understanding of what is considered available therapy today, ultimately the determination of what constitutes available therapy is wholly up to the FDA and is subject to change. In October 2017, we announced the outcome of a meeting with the U.S. Food and Drug Administration (FDA) regarding the use of the results from the GENUINE Phase 3 trial to support a Biologics License Application (BLA) filing for accelerated approval of TG-1101 in combination with ibrutinib. As part of the discussion, the FDA also guided that if one or more agents obtained full approval before we could obtain accelerated approval, those agents could be considered available therapy, and we would need to show meaningful benefit over those agents as well. No assurance can be given that other agents will not receive full approval prior to our potential receipt of accelerated approval. If that were to occur, no assurance can be given that we would be successful in proving meaningful benefit over those later approved drugs. If we were unable to prove meaningful benefit over any such agents, we would be effectively blocked from receiving accelerated approval.

While we wait to see if any drugs receive full approval and can evaluate the data associated with any such agents, we are continuing to make preparations for a BLA filing for accelerated approval. Whether or not we ultimately file such application will be subject to multiple factors and no assurance can be given that a filing will be made. If a filing is made, the FDA acceptance of such a filing will depend on the FDA's views on the adequacy of the filing, and further even if the filing is accepted, approval of such a filing is a question wholly within the FDA's discretion to determine. In addition, if we were to receive accelerated approval, we would be required to conduct a post-market confirmatory study, which we may not complete, or if completed, may prove unsuccessful. In such instance, the FDA can remove the product from the market.

The GENUINE study in its final form was not powered for progression-free survival (PFS). There can be no assurance given that we will reach agreement with the FDA on an acceptable use of PFS data from GENUINE to support approval of TG-1101, or even if an agreement is reached, that the PFS results of TG-1101 will be positive and/or sufficient to support a regulatory approval of TG-1101.

Any product candidates we may advance through clinical development are subject to extensive regulation, which can be costly and time consuming, cause unanticipated delays or prevent the receipt of the required approvals or "fast track" or "priority review" status to commercialize our product candidates.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates or any future product candidates are subject to extensive regulation by the FDA in the United States and by comparable health authorities worldwide or in foreign markets. In the United States, we are not permitted to market our product candidates until we receive approval of a BLA or NDA from the FDA. The process of obtaining BLA and NDA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Even with "fast track" or "priority review" status which we intend to seek for our product candidates, where possible, including with regard to TG-1101, such designations do not necessarily mean a faster development process or regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures. In addition, the FDA may require post-approval clinical trials or studies which also may be costly. The FDA approval for a limited indication or approval with required warning language, such as a boxed warning, could significantly impact our ability to successfully market our product candidates. Finally, the FDA may require adoption of a Risk Evaluation and Mitigation Strategy ("REMS") requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed. Assuming successful clinical development, we intend to seek product approvals in countries outside the United States. As a result, we would be subject to regulation by the European Medicines Agency ("EMA"), as well as the other regulatory agencies in many of these countries, and other regulatory agencies around the world.

Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. As in the United States, the regulatory approval process in Europe and in other countries is a lengthy and challenging process. The FDA, and any other regulatory body around the world can delay, limit or deny approval of a product candidate for many reasons, including:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA, NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, recent events raising questions about the safety of certain marketed pharmaceuticals may result in increased cautiousness by the FDA and other regulatory authorities in reviewing new pharmaceuticals based on safety, efficacy or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Regulatory approvals for our product candidates may not be obtained without lengthy delays, if at all. Any delay in obtaining, or inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates.

Any product candidate we advance into clinical trials may cause unacceptable adverse events or have other properties that may delay or prevent their regulatory approval or commercialization or limit their commercial potential.

Unacceptable adverse events caused by any of our product candidates that we take into clinical trials could cause either us or regulatory authorities to interrupt, delay, modify or halt clinical trials and could result in the denial of regulatory approval by the FDA or other regulatory authorities for any or all targeted indications. This, in turn, could prevent us from commercializing the affected product candidate and generating revenues from its sale.

We have not completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of our product candidates. To date, clinical trials using TG-1101 and TGR-1202 have demonstrated a toxicity profile that was deemed acceptable by the investigators performing such studies. Such interpretation may not be shared by future investigators or by the FDA and in the case of TG-1101 and TGR-1202, even if deemed acceptable for oncology applications, it may not be acceptable for diseases outside the oncology setting, and likewise for any other product candidates we may develop. Additionally, the severity, duration and incidence of adverse events may increase in larger study populations. With respect to both TG-1101 and TGR-1202, the toxicity when manufactured under different conditions and in different formulations is not known, and it is possible that additional and/or different adverse events may appear upon the human use of those formulations and those adverse events may arise with greater frequency, intensity and duration than in the current formulation. Should the Company not be able to adequately demonstrate analytical comparability between drug product manufactured under different conditions, the introduction of such new drug product into ongoing trials also has the potential to confound the interpretation of the results or complicate the statistical analysis of such trial. Further, with respect to TGR-1202, although approximately one thousand patients have been dosed amongst all ongoing TGR-1202 studies, the full adverse effect profile of TGR-1202 is not known. It is also unknown as additional patients are exposed for longer durations to TGR-1202, whether greater frequency and/or severity of adverse events are likely to occur. Common toxicities of other drugs in the same class as TGR-1202 include high levels of liver toxicity, infections and colitis, the latter of which notably has presented with later onset, with incidence increasing with duration of exposure. To date, the incidence of these events has been limited for TGR-1202, however no assurance can be given that this safety and tolerability profile will continue to be demonstrated in the future as higher doses, longer durations of exposure, and multiple drug combinations are explored. If any of our product candidates cause unacceptable adverse events in clinical trials, we may not be able to obtain marketing approval and generate revenues from its sale, or even if approved for sale may lack differentiation from competitive products, which could have a material adverse impact on our business and operations.

Additionally, in combination clinical development, there is an inherent risk of drug-drug interactions between combination agents which may affect each component's individual pharmacologic properties and the overall efficacy and safety of the combination regimen. Both TG-1101 and TGR-1202 are being evaluated in combination together, as well as with a variety of other active anti-cancer agents, which may cause unforeseen toxicity, or impact the severity, duration, and incidence of adverse events observed compared to those seen in the single agent studies of these agents. Further, with multi-drug combinations, it is often difficult to interpret or properly assign attribution of an adverse event to any one particular agent, introducing the risk that toxicity caused by a component of a combination regimen could have a material adverse impact on the development of our product candidates. There can be no assurances given that the combination regimens being studied will display tolerability or efficacy suitable to warrant further testing or produce data that is sufficient to obtain marketing approval.

If any of our product candidates receives marketing approval and we, or others, later identify unacceptable adverse events caused by the product, a number of significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the affected product;
- regulatory authorities may require a more significant clinical benefit for approval to offset the risk;
- regulatory authorities may require the addition of labeling statements that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may choose to discontinue sale of the product;
- we could be sued and held liable for harm caused to patients;
- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model; and
- our reputation may suffer.

Any one or a combination of these events could prevent us from obtaining or maintaining regulatory approval and achieving or maintaining market acceptance of the affected product or could substantially increase the costs and expenses of commercializing the affected product, which in turn could delay or prevent us from generating any revenues from the sale of the affected product.

We may experience delays in the commencement of our clinical trials or in the receipt of data from preclinical and clinical trials conducted by third parties, which could result in increased costs and delay our ability to pursue regulatory approval.

Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted by third parties could significantly impact our product development costs. Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing, usually in animals, to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and its proposed clinical trial protocol for our product candidates.

We plan to rely on preclinical and clinical trial data from third parties, if any, for the IND submissions for our product candidates. If receipt of that data is delayed for any reason, including reasons outside of our control, it will delay our plans for IND filings, and clinical trial plans. This, in turn, will delay our ability to make subsequent regulatory filings and ultimately, to commercialize our products if regulatory approval is obtained. If those third parties do not make this data available to us, we will likely, on our own, have to develop all the necessary preclinical and clinical data which will lead to additional delays and increase the costs of our development of our product candidates.

Before we can test any product candidate in human clinical trials the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as in-vitro and animal studies to assess the potential safety and activity of the pharmaceutical product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including good laboratory practices (“GLP”).

We must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the IND on a clinical hold within that 30-day time period. In such a case, we must work with the FDA to resolve any outstanding concerns before the clinical trials can begin. The FDA may also impose clinical holds on a product candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trial.

The FDA may require that we conduct additional preclinical testing for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development.

Even assuming an active IND for a product candidate, we do not know whether our planned clinical trials for any such product candidate will begin on time, or at all. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining institutional review board (“IRB”) or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial;
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues; and
- unexpected safety findings.

Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

Delays in the completion of clinical testing could result in increased costs and delay our ability to generate product revenues.

Once a clinical trial has begun, patient recruitment and enrollment may be slower than we anticipate. Clinical trials may also be delayed as a result of ambiguous or negative interim results. Further, a clinical trial may be suspended or terminated by us, an IRB, an ethics committee or a Data Safety and Monitoring Committee overseeing the clinical trial, any of our clinical trial sites with respect to that site or the FDA or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or clinical trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that the clinical trial presents unacceptable health risks; and
- lack of adequate funding to continue the clinical trial.

Changes in regulatory requirements and guidance also may occur and we may need to amend clinical trial protocols to reflect these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing and successful completion of a clinical trial. If we experience delays in the completion of, or if we must terminate, any clinical trial of any product candidate that we advance into clinical trials, our ability to obtain regulatory approval for that product candidate will be delayed and the commercial prospects, if any, for the product candidate may be harmed. In addition, many of these factors may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we ultimately commercialize any of our product candidates, other therapies for the same indications may have been introduced to the market during the period we have been delayed and such therapies may have established a competitive advantage over our product candidates.

We intend to rely on third parties to help conduct our planned clinical trials. If these third parties do not meet their deadlines or otherwise conduct the trials as required, we may not be able to obtain regulatory approval for or commercialize our product candidates when expected or at all.

We intend to use CROs to assist in the conduct of our planned clinical trials and will rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols. Our future CROs, investigators and other third parties may play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

There is no guarantee that any CROs, investigators and other third parties will devote adequate time and resources to our clinical trials or perform as contractually required. If any third parties upon whom we rely for administration and conduct of our clinical trials fail to meet expected deadlines, fail to adhere to its clinical protocols or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated, and we may not be able to commercialize our product candidates.

If any of our clinical trial sites terminate for any reason, we may experience the loss of follow-up information on patients enrolled in our ongoing clinical trials unless we are able to transfer the care of those patients to another qualified clinical trial site. In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, the integrity of the data generated at the applicable clinical trial site may be jeopardized.

As all of our product candidates are still under development, manufacturing and process improvements implemented in the production of those product candidates may affect their ultimate activity or function.

Our product candidates are in the initial stages of development and are currently manufactured in small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have changed, and process improvements in the future may change, the activity profile of the product candidates, which may affect the safety and efficacy of the products. No assurance can be given that the material manufactured from any of the optimized processes will perform comparably to the product candidates as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing. Additionally, future clinical trial results will be subject to the same level of uncertainty if, following such trials, additional process improvements are made. In addition, we have engaged a secondary manufacturer for TG-1101 to meet our current clinical and future commercial needs and anticipate engaging additional manufacturing sources for TGR-1202 to meet expanded clinical trial and commercial needs. While material produced from this secondary manufacturer for TG-1101 has to date demonstrated acceptable comparability to enable introduction into our clinical trials, no assurance can be given that any additional manufacturers will be successful or that material manufactured by the additional manufacturers will perform comparably to TG-1101 or TGR-1202 as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing, or that the relevant regulatory agencies will agree with our interpretation of comparability. If a secondary manufacturer is not successful in replicating the product or experiences delays, or if regulatory authorities impose unforeseen requirements with respect to product comparability from multiple manufacturing sources, we may experience delays in clinical development.

If we fail to adequately understand and comply with the local laws and customs as we expand into new international markets, these operations may incur losses or otherwise adversely affect our business and results of operations.

We expect to operate a portion of our business in certain countries through subsidiaries or through supply and marketing arrangements. In those countries, where we have limited experience in operating subsidiaries and in reviewing equity investees, we will be subject to additional risks related to complying with a wide variety of national and local laws, including restrictions on the import and export of certain intermediates, drugs, technologies and multiple and possibly overlapping tax structures. In addition, we may face competition in certain countries from companies that may have more experience with operations in such countries or with international operations generally. We may also face difficulties integrating new facilities in different countries into our existing operations, as well as integrating employees hired in different countries into our existing corporate culture. If we do not effectively manage our operations in these subsidiaries and review equity investees effectively, or if we fail to manage our alliances, we may lose money in these countries and it may adversely affect our business and results of our operations. In all interactions with foreign regulatory authorities, the Company is exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

If our competitors develop treatments for the target indications for which any of our product candidates may be approved, and they are approved more quickly, marketed more effectively or demonstrated to be more effective than our product candidates, our commercial opportunity will be reduced or eliminated.

We operate in a highly competitive segment of the biotechnology and biopharmaceutical market. We face competition from numerous sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. Additionally, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We may also compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

The cancer indications for which we are developing our products have a number of established therapies with which we will compete. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new cancer development programs for the treatment of NHL, CLL, and other B-cell proliferative malignancies, including both therapies with traditional, as well as novel, mechanisms of action. Additionally, numerous established therapies exist for the autoimmune disorders for which we are developing TG-1101, including and in particular, multiple sclerosis (MS).

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan® (rituximab) and Gazyva® (obinutuzumab or GA-101), and Novartis' Arzerra® (ofatumumab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing antibodies targeting CD20, CD19, and other B-cell associated targets, chimeric antigen receptor T-cell (CAR-T) immunotherapy, and other B-cell ablative therapy which, if approved, would potentially compete with TG-1101 both in oncology settings as well as in autoimmune disorders. In 2017, the Roche Group's anti-CD20 antibody ocrelizumab was approved for the treatment of MS. Genmab and GSK's (ofatumumab) is also under clinical development for patients with MS. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

With respect to TGR-1202, there are several PI3K delta targeted compounds both approved, such as Gilead's Zydelig® (idelalisib) and Bayer's Aliqopa™ (copanlisib), and in development, including, but not limited to, Verastem's duvelisib which if approved we would expect to compete directly with TGR-1202. In addition, there are numerous other novel therapies targeting similar pathways to TGR-1202 both approved and in development, which could also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (FDA approved for MCL, CLL, Marginal Zone Lymphoma and WM and marketed by AbbVie and Janssen), the BTK inhibitor acalabrutinib (FDA approved for MCL and marketed by AstraZeneca), or the BCL-2 inhibitor venetoclax (FDA approved for CLL and marketed by AbbVie and Roche).

These developments may render our product candidates obsolete or noncompetitive. Compared to us, many of our potential competitors have substantially greater:

- research and development resources, including personnel and technology;
- regulatory experience;
- pharmaceutical development, clinical trial and pharmaceutical commercialization experience;
- experience and expertise in exploitation of intellectual property rights; and
- capital resources.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than us or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop products for the treatment of lymphoma, CLL, or other B-cell and autoimmune related disorders that are more effective, better tolerated, more useful and less costly than ours and may also be more successful in manufacturing and marketing their products. Our competitors may succeed in obtaining approvals from the FDA and foreign regulatory authorities for their product candidates sooner than we do for our products.

We will also face competition from these third parties in recruiting and retaining qualified personnel, establishing clinical trial sites and enrolling patients for clinical trials and in identifying and in-licensing new product candidates.

We rely completely on third parties to manufacture our preclinical and clinical pharmaceutical supplies and we intend to rely on third parties to produce commercial supplies of any approved product candidate, and our commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA, fail to provide us with sufficient quantities of pharmaceutical product or fail to do so at acceptable quality levels or prices.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted only after we submit a BLA or NDA to the FDA, if at all. We do not control the manufacturing process of our product candidates and are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of finished pharmaceutical products (good manufacturing practices, GMP). If our contract manufacturers cannot successfully manufacture material that conforms to our target product specifications, patent specifications, and/or the FDA's strict regulatory requirements of safety, purity and potency, we will not be able to secure and/or maintain FDA approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers cannot meet FDA standards, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. No assurance can be given that a long-term, scalable manufacturer can be identified or that they can make clinical and commercial supplies of our product candidates that meets the product specifications of previously manufactured batches, or is of a sufficient quality, or at an appropriate scale and cost to make it commercially feasible. If they are unable to do so, it could have a material adverse impact on our business.

In addition, we do not have the capability to package finished products for distribution to hospitals and other customers. Prior to commercial launch, we intend to enter into agreements with one or more alternate fill/finish pharmaceutical product suppliers so that we can ensure proper supply chain management once we are authorized to make commercial sales of our product candidates. If we receive marketing approval from the FDA, we intend to sell pharmaceutical product finished and packaged by such suppliers. We have not entered into long-term agreements with our current contract manufacturers or with any fill/finish suppliers, and though we intend to do so prior to commercial launch of our product candidates in order to ensure that we maintain adequate supplies of finished product, we may be unable to enter into such an agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business.

In most cases, our manufacturing partners are single source suppliers. It is expected that our manufacturing partners will be sole source suppliers from single site locations for the foreseeable future. Given this, any disruption of supply from these partners could have a material, long-term impact on our ability to supply products for clinical trials or commercial sale. If our suppliers do not deliver sufficient quantities of our product candidates on a timely basis, or at all, and in accordance with applicable specifications, there could be a significant interruption of our supply, which would adversely affect clinical development and commercialization of our products. In addition, if our current or future supply of any of our product candidates should fail to meet specifications during its stability program there could be a significant interruption of our supply of drug, which would adversely affect the clinical development and commercialization of the product.

Our product candidates may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for redundant supply or a second source for bulk drug substance. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any replacement manufacturers.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any future product candidates or commercialization of our products, producing additional losses and depriving us of potential product revenue.

We currently have no marketing and sales organization and no experience in marketing pharmaceutical products. If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market and sell any products we may develop, we may not be able to effectively market and sell our products and generate product revenue.

We do not currently have the infrastructure for the sales, marketing and distribution of our biotechnology products, and we must build this infrastructure or make arrangements with third parties to perform these functions in order to commercialize our products. We plan to either develop internally or enter into collaborations or other commercial arrangements to develop further, promote and sell all or a portion of our product candidates.

The establishment and development of a sales force, either by us or jointly with a development partner, or the establishment of a contract sales force to market any products we may develop will be expensive and time-consuming and could delay any product launch, and we cannot be certain that we or our development partners would be able to successfully develop this capability. If we or our development partners are unable to establish sales and marketing capability or any other non-technical capabilities necessary to commercialize any products we may develop, we will need to contract with third parties to market and sell such products. We currently possess limited resources and may not be successful in establishing our own internal sales force or in establishing arrangements with third parties on acceptable terms, if at all.

We may seek to establish additional collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

Any future product candidate development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For any current or future product candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any additional collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for any future product candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. If we are unable to negotiate and enter into new collaborations, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or reduce or delay any other future development programs.

If conflicts arise between us and our future collaborators or strategic partners, these parties may act in a manner adverse to us and could limit our ability to implement our strategies.

If conflicts arise between our future corporate or academic collaborators or strategic partners and us, the other party may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators or strategic partners, may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or strategic partners or to which the collaborators or strategic partners have rights, may result in the withdrawal of partner support for any future product candidates. Our current or future collaborators or strategic partners may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely, or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm any future product development efforts.

We will need to obtain FDA approval of any proposed product brand names, and any failure or delay associated with such approval may adversely impact our business.

A pharmaceutical product candidate cannot be marketed in the United States or other countries until we have completed a rigorous and extensive regulatory review processes, including approval of a brand name. Any brand names we intend to use for TG-1101, TGR-1202 or any future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the U.S. Patent and Trademark Office, or USPTO. The FDA typically conducts a review of proposed product brand names, including an evaluation of potential for confusion with other product names. The FDA may also object to a product brand name if it believes the name inappropriately implies medical claims. If the FDA objects to any of our proposed product brand names, we may be required to adopt an alternative brand name for TG-1101, TGR-1202 or any future product candidates. If we adopt an alternative brand name, we would lose the benefit of our existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product brand name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. We may be unable to build a successful brand identity for a new trademark in a timely manner or at all, which would limit our ability to commercialize TG-1101, TGR-1202, or any future product candidates.

If any product candidate that we successfully develop does not achieve broad market acceptance among physicians, patients, healthcare payors, and the medical community, the revenues that we generate from its sales will be limited.

Even if our product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, and the medical community. Coverage and reimbursement of our product candidates by third-party payors, including government payors, generally is also necessary for commercial success. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;
- acceptance by physicians, major operators of cancer clinics and patients of the product as a safe and effective treatment;
- the potential and perceived advantages of product candidates over alternative treatments;
- the safety of product candidates seen in a broader patient group, including its use outside the approved indications;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events; and
- the effectiveness of our sales and marketing efforts.

If any product candidate is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate sufficient revenue from these products and we may not become or remain profitable.

If the market opportunities for our product candidates are smaller than we believe they are, even assuming approval of a drug candidate, our business may suffer.

Our projections of both the number of people who are affected by disease within our target indications, as well as the subset of these people who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, healthcare utilization databases and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Likewise, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials, and will face an even greater risk if we sell our product candidates commercially. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates or limit commercialization of any approved products. An individual may bring a liability claim against us if one of our product candidates causes, or merely appears to have caused, an injury. If we cannot successfully defend our self against product liability claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates;
- impairment to our business reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- loss of revenues.

We believe that we have obtained sufficient product liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the sale of commercial products if marketing approval is obtained for any of our product candidates. However, we may be unable to obtain this product liability insurance on commercially reasonable terms and with insurance coverage that will be adequate to satisfy any liability that may arise. On occasion, large judgments have been awarded in class action or individual lawsuits relating to marketed pharmaceuticals. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

Reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

We intend to seek approval to market our future products in both the United States and in countries and territories outside the United States. If we obtain approval in one or more foreign countries, we will be subject to rules and regulations in those countries relating to our product. In some foreign countries, particularly in the European Union, the pricing of prescription pharmaceuticals and biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for any of our product candidates and may be affected by existing and future healthcare reform measures.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which pharmaceuticals they will pay for and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Additionally, while we may seek approval of our products in combination with each other, there can be no guarantee that we will obtain coverage and reimbursement for any of our products together, or that such reimbursement will incentivize the use of our products in combination with each other as opposed to in combination with other agents which may be priced more favorably to the medical community.

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. Since 2003, there have been a number of other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals.

Most recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the “ACA,” was enacted. The ACA and any revisions or replacements of that Act, any substitute legislation, and other changes in the law or regulatory framework could have a material adverse effect on our business.

Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- expansion of healthcare fraud and abuse laws, including the federal False Claims Act and the federal Anti-Kickback Statute, new government investigative powers and enhanced penalties for non-compliance;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for a manufacturer’s outpatient drugs to be covered under Medicare Part D;
- extension of a manufacturer’s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for certain individuals with income at or below 138% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;
- expansion of the entities eligible for discounts under the 340B Drug Pricing Program;
- the new requirements under the federal Open Payments program and its implementing regulations;
- a new requirement to annually report drug samples that manufacturers and distributors provide to physicians;
- a new regulatory pathway for the approval of biosimilar biological products, all of which will impact existing government healthcare programs and will result in the development of new programs; and
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015. Any remaining legal challenges to the ACA are viewed generally as not significantly impacting the implementation of the law if the plaintiffs prevail.

President Trump ran for office on a platform that supported the repeal of the ACA, and one of his first actions after his inauguration was to sign an Executive Order instructing federal agencies to waive or delay requirements of the ACA that impose economic or regulatory burdens on states, families, the health-care industry and others. Modifications to or repeal of all or certain provisions of the ACA have been attempted in Congress as a result of the outcome of the recent presidential and congressional elections, consistent with statements made by the incoming administration and members of Congress during the presidential and congressional campaigns and following the election. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the ACA. The Budget Resolution is not a law. However, it is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the ACA. In March 2017, following the passage of the budget resolution for fiscal year 2017, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017, which, if enacted, would amend or repeal significant portions of the ACA. Attempts in the Senate in 2017 to pass ACA repeal legislation, including the Better Care Reconciliation Act of 2017, so far have been unsuccessful.

There have been, and likely will continue to be, legislative and regulatory proposals at the federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare products and services. We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any products for which we may obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to generate revenues and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

In addition, governments may impose price controls, which may adversely affect our future profitability.

We will need to increase the size of our organization and the scope of our outside vendor relationships, and we may experience difficulties in managing this growth.

As of March 1, 2018, we had 75 full and part time employees. Over time, we will need to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue research and development activities, and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth, and various projects requires that we:

- manage our clinical trials effectively;
- manage our internal development efforts effectively while carrying out our contractual obligations to licensors, contractors and other third parties;
- continue to improve our operational, financial and management controls and reporting systems and procedures; and
- attract and retain sufficient numbers of talented employees.

We may utilize the services of outside vendors or consultants to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development, chemistry, manufacturing, controls, and other pharmaceutical development functions. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on a substantial number of consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates or otherwise advance its business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may be unable to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

The success of our business depends upon our ability to identify, develop and commercialize product candidates based on our programs. If we do not successfully develop and eventually commercialize products, we will face difficulty in obtaining product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new product candidates require substantial technical, financial and human resources.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for a product candidate could be inaccurate, and our spending on current and future research and development programs may not yield any commercially viable products. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail to attract and keep key management and clinical development personnel, we may be unable to successfully develop or commercialize our product candidates.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts for our product candidates and future product candidates. We are highly dependent on the development, regulatory, commercial and financial expertise of the members of our senior management. The loss of the services of any of our senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. We do not maintain “key man” insurance policies on the lives of these individuals. We will need to hire additional personnel as we continue to expand our manufacturing, research and development activities.

Our success depends on our continued ability to attract, retain and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to the intense competition for qualified personnel among biotechnology, pharmaceutical and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will impede significantly the achievement of our development objectives, our ability to raise additional capital, and our ability to implement our business strategy.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

In addition to FDA restrictions on the marketing of pharmaceutical and biotechnology products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries, as well as consulting or other service agreements with physicians or other potential referral sources and regulate the use and disclosure of identifiable patient information. These laws include anti-kickback statutes and false claims statutes that prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or, in return for, purchasing, leasing, ordering, recommending or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally-financed healthcare programs, and knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and any practices we adopt may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer’s products from reimbursement under government programs, criminal fines and imprisonment. Any challenge to its business practices under these laws could have a material adverse effect on our business, financial condition, and results of operations. Finally, the Health Insurance Portability and Accountability Act (HIPAA), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, their respective implementing regulations and similar state laws and regulations, impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In the event our operations result in our receiving such information, we could become subject to the requirements of these laws and regulations, including potential civil and criminal penalties.

Our employees, consultants, or third party partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees, consultants, or third party partners could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee, consultant, or third party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. The precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions.

We use biological and hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly.

We use hazardous materials, including chemicals and biological agents and compounds, which could be dangerous to human health and safety or the environment. Our operations also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our pharmaceutical development efforts.

In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. If one of our employees was accidentally injured from the use, storage, handling or disposal of these materials or wastes, the medical costs related to his or her treatment would be covered by our workers' compensation insurance policy. However, we do not carry specific biological or hazardous waste insurance coverage and our property and casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, or operations otherwise affected.

All product candidate development timelines and projections in this report are based on the assumption of further financing.

The timelines and projections in this report are predicated upon the assumption that we will raise additional financing in the future to continue the development of our product candidates. In the event we do not successfully raise subsequent financing, our product development activities will necessarily be curtailed commensurate with the magnitude of the shortfall. If our product development activities are slowed or stopped, we would be unable to meet the timelines and projections outlined in this filing. Failure to progress our product candidates as anticipated will have a negative effect on our business, future prospects, and ability to obtain further financing on acceptable terms (if at all), and the value of the enterprise.

We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance initiatives.

As a public company, we incur significant legal, accounting and other expenses under the Sarbanes-Oxley Act of 2002, as well as rules subsequently implemented by the Securities and Exchange Commission, or SEC, and the rules of any stock exchange on which we may become listed. These rules impose various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and appropriate corporate governance practices. Our team has devoted and will continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified persons to serve on our Board of Directors, our Board committees or as executive officers.

The Sarbanes-Oxley Act of 2002 requires, among other things, that we maintain effective internal control over financial reporting and disclosure controls and procedures. As a result, we are required to periodically perform an evaluation of our internal control over financial reporting to allow management to report on the effectiveness of those controls, as required by Section 404 of the Sarbanes-Oxley Act. Additionally, our independent auditors are required to perform a similar evaluation and report on the effectiveness of our internal control over financial reporting. These efforts to comply with Section 404 will require the commitment of significant financial and managerial resources. While we anticipate maintaining the integrity of our internal control over financial reporting and all other aspects of Section 404, we cannot be certain that a material weakness will not be identified when we test the effectiveness of our control systems in the future. If a material weakness is identified, we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources, costly litigation or a loss of public confidence in our internal controls, which could have an adverse effect on the market price of our stock.

Risks Relating to Acquisitions

Acquisitions, investments and strategic alliances that we may make in the future may use significant resources, result in disruptions to our business or distractions of our management, may not proceed as planned, and could expose us to unforeseen liabilities.

We may seek to expand our business through the acquisition of, investments in and strategic alliances with companies, technologies, products, and services. Acquisitions, investments and strategic alliances involve a number of special problems and risks, including, but not limited to:

- difficulty integrating acquired technologies, products, services, operations and personnel with the existing businesses;
- diversion of management's attention in connection with both negotiating the acquisitions and integrating the businesses;
- strain on managerial and operational resources as management tries to oversee larger operations;
- difficulty implementing and maintaining effective internal control over financial reporting at businesses that we acquire, particularly if they are not located near our existing operations;
- exposure to unforeseen liabilities of acquired companies;
- potential costly and time-consuming litigation, including stockholder lawsuits;
- potential issuance of securities to equity holders of the company being acquired with rights that are superior to the rights of holders of our common stock or which may have a dilutive effect on our stockholders;
- risk of loss of invested capital;
- the need to incur additional debt or use cash; and
- the requirement to record potentially significant additional future operating costs for the amortization of intangible assets.

As a result of these or other problems and risks, businesses we acquire may not produce the revenues, earnings, or business synergies that we anticipated, and acquired products, services, or technologies might not perform as we expected. As a result, we may incur higher costs and realize lower revenues than we had anticipated. We may not be able to successfully address these problems and we cannot assure you that the acquisitions will be successfully identified and completed or that, if acquisitions are completed, the acquired businesses, products, services, or technologies will generate sufficient revenue to offset the associated costs or other negative effects on our business.

Any of these risks can be greater if an acquisition is large relative to our size. Failure to effectively manage our growth through acquisitions could adversely affect our growth prospects, business, results of operations, financial condition and cash flows.

Risks Relating to Our Intellectual Property

Our success depends upon our ability to protect our intellectual property and proprietary technologies, and the intellectual property protection for our product candidates depends significantly on third parties.

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection in the US and other countries with respect to our product candidates or any future product candidate that we may license or acquire, their formulations and uses and the methods we use to manufacture them, as well as successfully defending these patents against third-party challenges. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates, and by maintenance of our trade secrets through proper procedures. We will only be able to protect our technologies from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them in the market they are being used or developed. If any of our licensors or partners fails to appropriately prosecute and maintain patent protection for these product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

Currently, the composition of matter patent and several method of use patents for TG-1101 and TGR-1202 in various indications and settings have been applied for but have not yet been issued, or have been issued in certain territories but not under all jurisdictions in which such applications have been filed. While composition of matter patents have been granted in the US for TG-1101 and TGR-1202, no patents to date have been issued for our IRAK4 inhibitor, BET inhibitor, BTK inhibitor and anti-PD-L1 and anti-GITR programs. There can be no guarantee that any of these patents for which an application has already been filed, nor any patents filed in the future for our product candidates will be granted in any or all jurisdictions in which there were filed, or that all claims initially included in such patent applications will be allowed in the final patent that is issued. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents.

These risks and uncertainties include the following:

- the patent applications that we or our partners file may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked or circumvented, or otherwise may not provide any competitive advantage;
- as of March 16, 2013, the U.S. converted from a “first to invent” to a “first to file” system. If we do not win the filing race, we will not be entitled to inventive priority;
- our competitors, many of which have substantially greater resources than we do, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate its ability to make, use, and sell our potential products either in the United States or in international markets;
- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

If patents are not issued that protect our product candidates, it could have a material adverse effect on our financial condition and results of operations. The patent prosecution process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify any patentable aspects of our research and development output and methodology, and, even if we do, an opportunity to obtain patent protection may have passed. Given the uncertain and time-consuming process of filing patent applications and prosecuting them, it is possible that our product(s) or process(es) originally covered by the scope of the patent application may have changed or been modified, leaving our product(s) or process(es) without patent protection. If our licensors or we fail to obtain or maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, third parties may be able to leverage our proprietary information and products without risk of infringement, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability. Moreover, should we enter into other collaborations we may be required to consult with or cede control to collaborators regarding the prosecution, maintenance and enforcement of licensed patents. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has in recent years been the subject of much litigation. In addition, no consistent policy regarding the breadth of claims allowed in pharmaceutical or biotechnology patents has emerged to date in the US. The patent situation outside the US is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the US, and we may fail to seek or obtain patent protection in all major markets. For example, European patent law restricts the patentability of methods of treatment of the human body more than US law does. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the US and other countries may diminish the value of our patents or narrow the scope of our patent protection. For example, the federal courts of the US have taken an increasingly dim view of the patent eligibility of certain subject matter, such as naturally occurring nucleic acid sequences, amino acid sequences and certain methods of utilizing same, which include their detection in a biological sample and diagnostic conclusions arising from their detection. Such subject matter, which had long been a staple of the biotechnology and biopharmaceutical industry to protect their discoveries, is now considered, with few exceptions, ineligible in the first instance for protection under the patent laws of the US. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in those licensed from a third-party.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include changes to transition from a “first-to-invent” system to a “first-to-file” system and to the way issued patents are challenged. The formation of the Patent Trial and Appeal Board now provides a quicker and less expensive process for challenging issued patents. The PTO recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first inventor-to-file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the PTO, or become involved in opposition, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. The costs of these proceedings could be substantial and it is possible that our efforts to establish priority of invention would be unsuccessful, resulting in a material adverse effect on our US patent position. An adverse determination in any such submission, patent office trial, proceeding or litigation could reduce the scope of, render unenforceable, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent does not foreclose challenges to its inventorship, scope, validity or enforceability. Therefore, our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how, technology and other proprietary information, to maintain our competitive position, particularly where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect its rights. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed.

Patent protection and other intellectual property protection are crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate.

If we or our partners are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. For example, Roche has the Cabilly patents in the U.S. that block the commercialization of antibody products derived from a single cell line, like TG-1101. Also, Roche, Biogen Idec, and Genentech hold patents for the use of anti-CD20 antibodies utilized in the treatment of CLL in the U.S. While these patents have been challenged, to the best of our knowledge, those matters were settled in a way that permitted additional anti-CD20 antibodies to be marketed for CLL. If those patents are still enforced at the time we are intending to launch TG-1101, then we will need to either prevail in a litigation to challenge those patents or negotiate a settlement agreement with the patent holders. If we are unable to do so we may be forced to delay the launch of TG-1101 or launch at the risk of litigation for patent infringement, which may have a material adverse effect on our business and results of operations.

In addition, because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the US and other jurisdictions are typically not published until 18 months after a first filing, or in some cases not at all. Therefore, we cannot know with certainty whether we or our licensors were the first to make the inventions claimed in patents or pending patent applications that we own or licensed, or that we or our licensors were the first to file for patent protection of such inventions.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and biopharmaceutical industries generally. If a third party claims that we or any collaborators of ours infringe their intellectual property rights, we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign its products or processes to avoid infringement;
- pay substantial damages, including treble damages and attorneys' fees, which we may have to pay if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

No assurance can be given that patents issued to third parties do not exist, have not been filed, or could not be filed or issued, which contain claims covering its products, technology or methods that may encompass all or a portion of our products and methods. Given the number of patents issued and patent applications filed in our technical areas or fields, we believe there is a risk that third parties may allege they have patent rights encompassing our products or methods.

Other product candidates that we may in-license or acquire could be subject to similar risks and uncertainties.

We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms.

A third party may hold intellectual property, including patent rights that are important or necessary to the development and commercialization of our products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties, whom may or may not be interested in granting such a license, on commercially reasonable terms, or our business could be harmed, possibly materially.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which typically are very expensive, time-consuming and disruptive of day-to-day business operations. Any claims we assert against accused infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents; or provoke those parties to petition the PTO to institute inter parties review against the asserted patents, which may lead to a finding that all or some of the claims of the patent are invalid. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Furthermore, adverse results on US patents may affect related patents in our global portfolio. The adverse result could also put related patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office (“PTO”) may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. The costs of these proceedings could be substantial. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

We may be subject to claims that our consultants or independent contractors have wrongfully used or disclosed alleged trade secrets of their other clients or former employers to it.

As is common in the biotechnology and pharmaceutical industry, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants were previously employed at, may have previously been, or are currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these consultants or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers or their former or current customers. Even if frivolous or unsubstantiated in nature, litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, day-to-day business operations, and the implicated employee(s).

Risks Relating to Our Finances and Capital Requirements

We will need to raise additional capital to continue to operate our business.

As of December 31, 2017, we had approximately \$84.8 million in cash and cash equivalents, which in addition to the capital raised during the first quarter of 2018, we believe will be sufficient to fund the Company’s planned operations into the second quarter of 2019. As a result, we will need additional capital to continue our operations beyond that time. Required additional sources of financing to continue our operations in the future might not be available on favorable terms, if at all. If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned preclinical and clinical trials or obtain approval of any of our product candidates from the FDA or any foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which would have a dilutive effect to stockholders.

Currently, none of our product candidates have been approved by the FDA or any foreign regulatory authority for sale. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from cash on hand and amounts raised in future offerings or financings.

We have a history of operating losses, expect to continue to incur losses, and are unable to predict the extent of future losses or when we will become profitable, if ever.

We have not yet applied for or demonstrated an ability to obtain regulatory approval for or commercialize a product candidate. Our short operating history makes it difficult to evaluate our business prospects and consequently, any predictions about our future performance may not be as accurate as they could be if we had a history of successfully developing and commercializing pharmaceutical or biotechnology products. Our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in the early stages of operations and the competitive environment in which we operate.

We have never been profitable and, as of December 31, 2017, we had an accumulated deficit of \$354.9 million. We have generated operating losses in all periods since we were incorporated. We expect to make substantial expenditures resulting in increased operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial efforts for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

We have not generated any revenue from our product candidates and may never become profitable.

Our ability to become profitable depends upon our ability to generate significant continuing revenues. To obtain significant continuing revenues, we must succeed, either alone or with others, in developing, obtaining regulatory approval for and manufacturing and marketing our product candidates (or utilize early access programs to generate such revenue). To date, our product candidates have not generated any revenues, and we do not know when, or if, we will generate any revenue. Our ability to generate revenue depends on a number of factors, including, but not limited to:

- successful completion of preclinical studies of our product candidates;
- successful commencement and completion of clinical trials of our product candidates and any future product candidates we advance into clinical trials;
- achievement of regulatory approval for our product candidates and any future product candidates we advance into clinical trials (unless we successfully utilize early access programs which allow for revenue generation prior to approval);
- manufacturing commercial quantities of our products at acceptable cost levels if regulatory approvals are obtained;
- successful sales, distribution and marketing of our future products, if any; and
- our entry into collaborative arrangements or co-promotion agreements to market and sell our products.

If we are unable to generate significant continuing revenues, we will not become profitable and we may be unable to continue our operations without continued funding.

We will need substantial additional funding and may be unable to raise capital when needed, which would force us to delay, reduce or eliminate our development programs or commercialization efforts.

We expect to spend substantial amounts on development, including significant amounts on conducting clinical trials for our product candidates, manufacturing clinical supplies and expanding our pharmaceutical development programs. We expect that our monthly cash used by operations will continue to increase for the next several years. We anticipate that we will continue to incur operating losses for the foreseeable future.

We will require substantial additional funds to support our continued research and development activities, as well as the anticipated costs of preclinical studies and clinical trials, regulatory approvals, and eventual commercialization. We anticipate that we will incur operating losses for the foreseeable future. We have based these estimates, however, on assumptions that may prove to be wrong, and we could expend our available financial resources much faster than we currently expect. Further, we will need to raise additional capital to fund our operations and continue to conduct clinical trials to support potential regulatory approval of marketing applications. Future capital requirements will also depend on the extent to which we acquire or in-license additional product candidates. We currently have no commitments or agreements relating to any of these types of transactions.

The amount and timing of our future funding requirements will depend on many factors, including, but not limited to, the following:

- the progress of our clinical trials, including expenses to support the trials and milestone payments that may become payable under our license agreements;
- the costs and timing of regulatory approvals;
- the costs and timing of clinical and commercial manufacturing supply arrangements for each product candidate;
- the costs of establishing sales or distribution capabilities;
- the success of the commercialization of our products;
- our ability to establish and maintain strategic collaborations, including licensing and other arrangements;
- the costs involved in enforcing or defending patent claims or other intellectual property rights; and
- the extent to which we in-license or invest in other indications or product candidates.

Until we can generate a sufficient amount of product revenue and achieve profitability, we expect to finance future cash needs through public or private equity offerings, debt financings or corporate collaboration and licensing arrangements, as well as through interest income earned on cash balances. If we were to be unable to raise additional capital, we would have to significantly delay, scale back or discontinue one or more of our pharmaceutical development programs. We also may be required to relinquish, license or otherwise dispose of rights to product candidates or products that it would otherwise seek to develop or commercialize itself on terms that are less favorable than might otherwise be available.

Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.

We may raise additional funds through public or private equity offerings, debt financings or licensing arrangements. To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing we enter into may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions.

In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. If adequate funds are not available, our ability to achieve profitability or to respond to competitive pressures would be significantly limited and we may be required to delay, significantly curtail or eliminate the development of one or more of our product candidates.

Our tax position could be affected by recent changes in U.S. federal income tax laws.

On December 22, 2017, legislation commonly referred to as the “Tax Cuts and Jobs Act” was signed into law and is generally effective after December 31, 2017. The Tax Cuts and Jobs Act makes significant changes to the U.S. federal income tax rules for taxation of individuals and business entities. Most of the changes applicable to individuals are temporary and apply only to taxable years beginning after December 31, 2017 and before January 1, 2026. For corporations, the Tax Cuts and Jobs Act reduces the top corporate income tax rate to 21% and repeals the corporate alternative minimum tax, limits the deduction for net interest expense, limits the deduction for net operating losses and eliminates net operating loss carrybacks, modifies or repeals many business deductions and credits, shifts the United States toward a more territorial tax system, and imposes new taxes to combat erosion of the U.S. federal income tax base. The Tax Cuts and Jobs Act makes numerous other large and small changes to the federal income tax rules that may affect potential investors and may directly or indirectly affect us. We continue to examine the impact this tax reform legislation may have on our business. However, the effect of the Tax Cuts and Jobs Act on us and our affiliates, whether adverse or favorable, is uncertain, and may not become evident for some period of time. This document does not discuss such legislation or the manner in which it might affect us or purchasers of our common stock. Prospective investors are urged to consult with their legal and tax advisors with respect to the Tax Cuts and Jobs Act and any other regulatory or administrative developments and proposals, and their potential effects on them based on their unique circumstances.

Risks Related to Our Common Stock

We are controlled by current officers, directors and principal stockholders.

Our directors, executive officers, their affiliates, and our principal stockholders beneficially own approximately 39% of our outstanding voting stock, including shares underlying outstanding options and warrants. Our directors, officers and principal stockholders, taken as a whole, have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

Our stock price is, and we expect it to remain, volatile, which could limit investors' ability to sell stock at a profit.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- publicity regarding actual or potential clinical results relating to products under development by our competitors or us;
- delay or failure in initiating, completing or analyzing nonclinical or clinical trials or the unsatisfactory design or results of these trials;
- achievement or rejection of regulatory approvals by our competitors or us;
- announcements of technological innovations or new commercial products by our competitors or us;
- developments concerning proprietary rights, including patents;
- developments concerning our collaborations;
- regulatory developments in the United States and foreign countries;
- economic or other crises and other external factors;
- period-to-period fluctuations in our revenues and other results of operations;
- changes in financial estimates by securities analysts; and
- sales of our common stock.

We will not be able to control many of these factors, and we believe that period-to-period comparisons of our financial results will not necessarily be indicative of our future performance.

In addition, the stock market in general, and the market for biotechnology companies in particular, has experienced extreme price and volume fluctuations that may have been unrelated or disproportionate to the operating performance of individual companies. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our operating performance.

We have not paid dividends in the past and do not expect to pay dividends in the future, and any return on investment may be limited to the value of your stock.

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our stock if you require dividend income. Further, you will only realize income on an investment in our stock in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.

Provisions in our amended and restated certificate of incorporation and restated bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock without the approval of our stockholders. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

On July 18, 2014, the Board of Directors declared a distribution of one right for each outstanding share of common stock. The rights may have certain anti-takeover effects. The rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by the Board of Directors unless the offer is conditioned on a substantial number of rights being acquired. However, the rights should not interfere with any merger, statutory share exchange or other business combination approved by the Board of Directors since the rights may be terminated by us upon resolution of the Board of Directors. Thus, the rights are intended to encourage persons who may seek to acquire control of the Company to initiate such an acquisition through negotiations with the Board of Directors. However, the effect of the rights may be to discourage a third party from making a partial tender offer or otherwise attempting to obtain a substantial equity position in the equity securities of, or seeking to obtain control of, the Company. To the extent any potential acquirers are deterred by the rights, the rights may have the effect of preserving incumbent management in office.

We may become involved in securities class action litigation that could divert management's attention and harm our business.

The stock markets have from time to time experienced significant price and volume fluctuations that have affected the market prices for the common stock of biotechnology and pharmaceutical companies. These broad market fluctuations may cause the market price of our stock to decline. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. We may become involved in this type of litigation in the future. Litigation often is expensive and diverts management's attention and resources, which could adversely affect our business.

ITEM 2. PROPERTIES.

Our corporate and executive office is located in New York, New York. Our New York facility consists of leased office space at 2 Gansevoort Street, 9 th Floor, New York, New York 10014. We are also currently leasing small office spaces in Cary, North Carolina and Kingsport, Tennessee to accommodate our clinical operations groups. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

ITEM 3. LEGAL PROCEEDINGS.

On January 6, 2017, a purported securities class action complaint was filed in New York federal court against the Company and certain of its directors, officers or consultants on behalf of all shareholders who purchased or otherwise acquired TG Therapeutics common stock between September 15, 2014 and October 12, 2016 (the "Class Period"). The case was captioned *John Lyon v. TG Therapeutics, Michael S. Weiss, Sean A. Power and Robert Niecestro*, Case No. 1:17-cv-00112-VM (S.D.N.Y.). The complaint alleged that, throughout the Class Period various statements made by the Company regarding its GENUINE Phase 3 trial were materially false or misleading when made in violation of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. On January 24, 2017, a second purported class action complaint was filed in New York federal court against the Company and certain of its directors, officers or consultants on behalf of all shareholders who purchased or otherwise acquired TG Therapeutics common stock between September 15, 2014 and October 12, 2016. The case was captioned *Kenneth C. Wyzgoski v. TG Therapeutics, Michael S. Weiss, Sean A. Power and Robert Niecestro*, Case No. 1:17-cv-00508-VM (S.D.N.Y.). The claims and allegations in the Wyzgoski complaint were substantially identical to those in the Lyon case. By order dated March 23, 2017, the court consolidated the Lyon and Wyzgoski cases into one action, captioned *In re TG Therapeutics Securities Litigation*, Case No. 1:17-cv-00112-VM (S.D.N.Y.), appointed lead plaintiffs in the case, and approved lead plaintiffs' selection of lead counsel. On April 5, 2017 the Court so ordered a stipulation pursuant to which lead plaintiffs voluntarily dismissed the consolidated action in its entirety without prejudice. The Company denies the allegations and claims made in the above-referenced actions and no consideration was given by the Company in connection with lead plaintiffs' voluntary dismissal of the consolidated action.

ITEM 4. MINE SAFETY DISCLOSURES

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is listed on the Nasdaq Capital Market and trades under the symbol "TGTX".

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

	<u>High</u>	<u>Low</u>
Fiscal Year Ended December 31, 2017		
Fourth Quarter	\$ 12.30	\$ 7.35
Third Quarter	\$ 12.70	\$ 10.00
Second Quarter	\$ 13.85	\$ 9.90
First Quarter	\$ 14.45	\$ 4.20
	<u>High</u>	<u>Low</u>
Fiscal Year Ended December 31, 2016		
Fourth Quarter	\$ 9.33	\$ 4.65
Third Quarter	\$ 7.98	\$ 5.49
Second Quarter	\$ 10.23	\$ 5.97
First Quarter	\$ 11.41	\$ 7.83

Holders

The number of record holders of our common stock as of March 1, 2018 was 271.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2017, regarding the securities authorized for issuance under our equity compensation plan, the TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan.

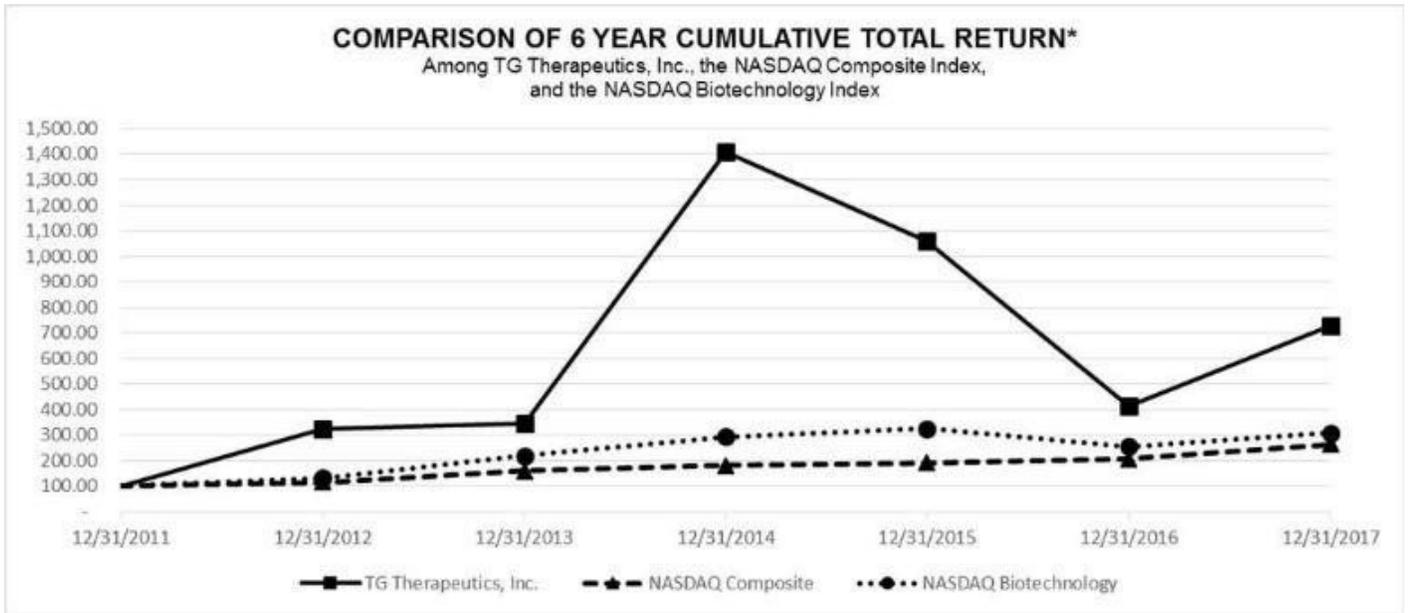
Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column 1)
Equity compensation plans approved by security holders	--	\$ --	504,128
Equity compensation plans not approved by security holders	<u>--</u>	<u>--</u>	<u>--</u>
Total	<u><u>--</u></u>	<u><u>\$ --</u></u>	<u><u>504,128</u></u>

For information about all of our equity compensation plans see Note 5 to our Consolidated Financial Statements included in this report.

COMMON STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return on our common stock for the period from December 31, 2011 **(1)** through December 31, 2017, with the cumulative total return over such period on (i) the U.S. Index of The Nasdaq Stock Market and (ii) the Biotechnology Index of The Nasdaq Stock Market. The graph assumes an investment of \$100 on December 31, 2011, in our common stock (at the adjusted closing market price) and in each of the indices listed above, and assumes the reinvestment of all dividends. Measurement points are December 31 of each year.



(1) In connection with the Company having entered into and consummated an exchange transaction agreement (the “Exchange Transaction”) with Opus Point Partners, LLC (“Opus”) and TG Biologics, Inc. (formerly known as TG Therapeutics, Inc.) (“TG Bio”), we used the start date of December 31, 2011 to be in agreement with this transaction.

* \$100 invested on 12/31/11 in stock or index, including reinvestment of dividends. Fiscal Years ending December 31.

ITEM 6. SELECTED FINANCIAL DATA

The following Statement of Operations Data for the years ended December 31, 2017, 2016, 2015, 2014 and 2013, and Balance Sheet Data as of December 31, 2017, 2016, 2015, 2014 and 2013, as set forth below are derived from our audited consolidated financial statements. This financial data should be read in conjunction with “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Item 8. Financial Statements and Supplementary Data.”

	<u>Years ended December 31,</u>				
	<u>2017</u>	<u>2016</u>	<u>2015</u>	<u>2014</u>	<u>2013</u>
License revenue	<u>\$ 152,381</u>	<u>\$ 152,381</u>	<u>\$ 152,381</u>	<u>\$ 152,381</u>	<u>\$ 152,381</u>
Costs and expenses:					
Research and development:					
Noncash stock expense associated with in-licensing agreements	--	--	--	5,350,094	--
Noncash compensation	5,646,716	2,742,354	4,261,406	8,731,566	1,041,519
Other research and development	<u>96,886,134</u>	<u>66,489,820</u>	<u>43,445,817</u>	<u>26,004,687</u>	<u>12,621,161</u>
Total research and development	<u>102,532,850</u>	<u>69,232,174</u>	<u>47,707,223</u>	<u>40,086,347</u>	<u>13,662,680</u>
General and administrative:					
Noncash compensation	10,298,568	4,767,645	11,435,686	12,373,726	4,161,629
Other general and administrative	<u>6,032,714</u>	<u>5,121,690</u>	<u>4,189,488</u>	<u>3,413,400</u>	<u>2,496,461</u>
Total general and administrative	<u>16,331,282</u>	<u>9,889,335</u>	<u>15,625,174</u>	<u>15,787,126</u>	<u>6,658,090</u>
Impairment of in-process research and development	--	--	--	--	<u>2,797,600</u>
Total costs and expenses	<u>118,864,132</u>	<u>79,121,509</u>	<u>63,332,397</u>	<u>55,873,473</u>	<u>23,118,370</u>
Operating loss	<u>(118,711,751)</u>	<u>(78,969,128)</u>	<u>(63,180,016)</u>	<u>(55,721,092)</u>	<u>(22,965,989)</u>
Other (income) expense:					
Interest income	(294,478)	(323,032)	(174,653)	(55,049)	(30,822)
Other (income) expense	<u>58,739</u>	<u>(393,202)</u>	<u>(56,717)</u>	<u>115,234</u>	<u>(2,456,957)</u>
Total other (income) expense, net	<u>(235,739)</u>	<u>(716,234)</u>	<u>(231,370)</u>	<u>60,185</u>	<u>(2,487,779)</u>
	<u>\$ (118,476,012)</u>	<u>\$ (78,252,894)</u>	<u>\$ (62,948,646)</u>	<u>\$ (55,781,277)</u>	<u>\$ (20,478,210)</u>

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Item 1A. Risk Factors." See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with "Item 8. Financial Statements and Supplementary Data," and our consolidated financial statements beginning on page F-1 of this report.

Overview

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, the Company is developing two therapies targeting hematological malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202, an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202 are in clinical development for patients with hematologic malignancies. We also have pre-clinical programs seeking to develop IRAK4 (interleukin-1 receptor-associated kinase 4) inhibitors, BET (Bromodomain and Extra Terminal) inhibitors, and anti-PD-L1 and anti-GITR antibodies.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

Our license revenues currently consist of license fees arising from our agreement with Ildong. We recognize upfront license fee revenues ratably over the estimated period in which we will have certain significant ongoing responsibilities under the sublicense agreement, with unamortized amounts recorded as deferred revenue.

We have not earned any revenues from the commercial sale of any of our drug candidates.

Our research and development expenses consist primarily of expenses related to in-licensing of new product candidates, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, manufacture, testing and enhancement of our drug candidates and technologies. We expense our research and development costs as they are incurred. Research and development expenses for the years ended December 31, 2017, 2016 and 2015 were approximately \$96.9 million, \$66.5 million and \$43.4 million, respectively, excluding non-cash compensation expenses related to research and development.

The following table sets forth the research and development expenses per project, exclusive of non-cash compensation expenses, for the periods presented.

	<u>2017</u>	<u>2016</u>	<u>2015</u>
TG-1101	\$ 62,441,133	\$ 40,839,899	\$ 29,816,042
TGR-1202	31,963,775	21,394,427	11,671,889
Pre-clinical assets / Other	<u>2,481,226</u>	<u>4,255,494</u>	<u>1,957,886</u>
Total	<u>\$ 96,886,134</u>	<u>\$ 66,489,820</u>	<u>\$ 43,445,817</u>

Our general and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities and facilities-related expenses such as rent expense and amortization of leasehold interest.

Our results of operations include non-cash compensation expenses as a result of the grants of stock options and restricted stock. Compensation expense for awards of options and restricted stock granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual awards. The expense is included in the respective categories of expense in the consolidated statements of operations. We expect to continue to incur significant non-cash compensation expenses.

For awards of options and restricted stock to consultants and other third-parties, compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

In addition, certain restricted stock issued to employees vests upon the achievement of certain milestones; therefore, the total expense is uncertain until the milestone is probable.

Our clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we may need to establish the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA, which would result in us incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

RESULTS OF OPERATIONS

Years Ended December 31, 2017, 2016 and 2015

	Years Ended December 31,		
	2017	2016	2015
License revenue	\$ 152,381	\$ 152,381	\$ 152,381
Costs and expenses:			
Research and development:			
Noncash compensation	5,646,716	2,742,354	4,261,406
Other research and development	<u>96,886,134</u>	<u>66,489,820</u>	<u>43,445,817</u>
Total research and development	<u>102,532,850</u>	<u>69,232,174</u>	<u>47,707,223</u>
General and administrative:			
Noncash compensation	10,298,568	4,767,645	11,435,686
Other general and administrative	<u>6,032,714</u>	<u>5,121,690</u>	<u>4,189,488</u>
Total general and administrative	<u>16,331,282</u>	<u>9,889,335</u>	<u>15,625,174</u>
Total costs and expenses	<u>118,864,132</u>	<u>79,121,509</u>	<u>63,332,397</u>
Operating loss	(118,711,751))	(78,969,128))	(63,180,016))
Other income, net	<u>(235,739)</u>)	<u>(716,234)</u>)	<u>(231,370)</u>)
Net loss	<u>\$ (118,476,012)</u>)	<u>\$ (78,252,894)</u>)	<u>\$ (62,948,646)</u>)

Years Ended December 31, 2017 and 2016

License Revenue. License revenue was approximately \$152,000 for each of the years ended December 31, 2017 and 2016. License revenue is related to the amortization of an upfront payment of \$2.0 million associated with our license agreement with Ildong. The upfront payment from Ildong will be recognized as license revenue on a straight-line basis through December 2025, which represents the estimated period over which the Company will have certain ongoing responsibilities under the sublicense agreement.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled \$5.6 million for the year ended December 31, 2017, as compared to \$2.7 million during the comparable period in 2016. The increase in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to personnel and an increase in the measurement date fair value of certain consultant restricted stock during the year ended December 31, 2017.

Other Research and Development Expenses . Other research and development expenses increased by \$30.4 million from \$66.5 million for the year ended December 31, 2016 to \$96.9 million for the year ended December 31, 2017. The increase in other research and development expenses was due primarily to new and ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the year ended December 31, 2017. We expect our other research and development costs to remain relatively consistent during 2018 as our UNITY-CLL program winds down and our MS Phase 3 program ramps up.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants increased by \$5.5 million from \$4.8 million for the year ended December 31, 2016 to \$10.3 million during the year ended December 31, 2017. The increase in noncash compensation expense was primarily related to greater compensation expense during the year ended December 31, 2017 related to restricted stock granted to executive personnel.

Other General and Administrative Expenses . Other general and administrative expenses increased by \$0.9 million from \$5.1 million for the year ended December 31, 2016 to \$6.0 million for the year ended December 31, 2017. The increase was due primarily to rent related expenses of our office space, as well as increased personnel and other general and administrative costs. We expect our other general and administrative expenses to increase modestly during 2018.

Other Expense (Income), Net . Other income decreased by \$0.5 million from \$0.7 million for the year ended December 31, 2016 to \$0.2 million for the year ended December 31, 2017. The decrease is mainly due a decrease in interest income during 2017, as well as to the receipt of a New York City biotechnology tax credit of approximately \$0.3 million for the year ended December 31, 2016.

Years Ended December 31, 2016 and 2015

License Revenue. License revenue was approximately \$152,000 for each of the years ended December 31, 2016 and 2015. License revenue is related to the amortization of an upfront payment of \$2.0 million associated with our license agreement with Ildong. The upfront payment from Ildong will be recognized as license revenue on a straight-line basis through December 2025, which represents the estimated period over which the Company will have certain ongoing responsibilities under the sublicense agreement.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants totaled \$2.7 million for the year ended December 31, 2016, as compared to \$4.3 million during the comparable period in 2015. The decrease in noncash compensation expense was primarily related to milestone-based vesting of restricted stock grants to non-executive personnel during the year ended December 31, 2015, and a decrease in the measurement date fair value of certain consultant restricted stock during the year ended December 31, 2016.

Other Research and Development Expenses . Other research and development expenses increased by \$23.1 million from \$43.4 million for the year ended December 31, 2015 to \$66.5 million for the year ended December 31, 2016. The increase in other research and development expenses was due primarily to a \$1.0 million licensing fee for the Jubilant sub-license agreement, as well as the ongoing clinical development programs and related manufacturing costs for TG-1101 and TGR-1202 during the year ended December 31, 2016. We expect our other research and development costs to increase modestly during 2017 as enrollment of additional patients in our Phase 3 clinical trials increases and we prepare for a commercial launch.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants decreased by \$6.6 million from \$11.4 million for the year ended December 31, 2015 to \$4.8 million during the year ended December 31, 2016. The decrease in noncash compensation expense was primarily related to greater measurement date fair values of certain consultant restricted stock during the year ended December 31, 2015.

Other General and Administrative Expenses . Other general and administrative expenses increased by \$0.9 million from \$4.2 million for the year ended December 31, 2015 to \$5.1 million for the year ended December 31, 2016. The increase was due primarily to the straight-line rent expense of our new office space, as well as increased personnel and other general and administrative costs. We expect our other general and administrative expenses to increase modestly during 2017.

Other Expense (Income), Net . Other income increased by \$0.5 million from \$0.2 million for the year ended December 31, 2015 to \$0.7 million for the year ended December 31, 2016. The increase is mainly due to the receipt of a New York City biotechnology tax credit of approximately \$0.3 million and an increase in interest income for the year ended December 31, 2016.

LIQUIDITY AND CAPITAL RESOURCES

Our primary sources of cash have been from the sale of equity securities, the upfront payment from our Sublicense Agreement with Ildong, and warrant and option exercises. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of December 31, 2017, we had \$84.8 million in cash and cash equivalents, investment securities, and interest receivable. Subsequent to the year ended December 31, 2017, we sold a total of approximately 2.9 million shares of common stock under the 2017 At-the-Market Issuance Sales Agreement (the “2017 ATM”) for aggregate net proceeds of approximately \$35.3 million.

We anticipate that our cash and cash equivalents as of December 31, 2017 combined with the additional capital raised in the first quarter of 2018 will be sufficient to fund the Company’s planned operations into the second quarter of 2019. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

Cash used in operating activities for the year ended December 31, 2017 was \$93.8 million as compared to \$61.6 million for the year ended December 31, 2016. The increase in cash used in operating activities was due primarily to increased expenditures associated with our clinical development programs for TG-1101 and TGR-1202.

For the year ended December 31, 2017, net cash used in investing activities was \$8.2 million as compared to cash provided by investing activities of \$26.5 million for the year ended December 31, 2016. The decrease in net cash provided by investing activities was primarily due to investments in short-term securities during the year ended December 31, 2017.

For the year ended December 31, 2017, net cash provided by financing activities of \$133.7 million related to proceeds from our March 2017 offering and our program under an At-the-Market Issuance Sales Agreement (the “ATM Program”), as well as proceeds from the exercise of warrants. For the year ended December 31, 2016, net cash provided by financing activities of \$5.0 million related to our program under the ATM Program”, as well as proceeds from the exercise of warrants.

ATM Program

On June 21, 2013, we entered into an At-the-Market Issuance Sales Agreement (the "2013 ATM") with MLV & Co. LLC ("MLV") under which we could issue and sell shares of our common stock, having aggregate offering proceeds of up to \$50.0 million, from time to time through MLV, acting as the sales agent. Under the agreement we would pay MLV a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock sold through MLV.

During the year ended December 31, 2014, we sold a total of 4,850,055 shares of common stock under this arrangement for aggregate total gross proceeds of approximately \$50.0 million at an average selling price of \$10.31 per share. Net proceeds were approximately \$48.8 million after deducting commissions and other transaction costs. We have fully utilized the capacity under the 2013 ATM and, accordingly, no further sales can be made under the 2013 ATM.

In December 2014, we filed a shelf registration statement on Form S-3 (the "2015 S-3"), which was declared effective in January 2015. Under the 2015 S-3, the Company may sell up to a total of \$250 million of its securities. In connection with the 2015 S-3, we amended our 2013 At-the-Market Issuance Sales Agreement with MLV (the "2015 ATM") such that we may issue and sell additional shares of our common stock, having an aggregate offering price of up to \$175.0 million, from time to time through MLV and FBR Capital Markets & Co. ("FBR", each of MLV and FBR individually an "Agent" and collectively the "Agents"), acting as the sales agents. Under the 2015 ATM we pay the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock sold through the Agents.

During the year ended December 31, 2015, we sold a total of 4,094,498 shares of common stock under the 2015 ATM for aggregate total gross proceeds of approximately \$68.2 million at an average selling price of \$16.66 per share, resulting in net proceeds of approximately \$67.0 million after deducting commissions and other transaction costs.

During the year ended December 31, 2016, we sold a total of 570,366 shares of common stock under the 2015 ATM for aggregate total gross proceeds of approximately \$4.5 million at an average selling price of \$7.88 per share, resulting in net proceeds of approximately \$4.4 million after deducting commissions and other transaction costs.

During the year ended December 31, 2017, we sold a total of 3,104,253 shares of common stock under the 2015 ATM for aggregate total gross proceeds of approximately \$31.6 million at an average selling price of \$10.18 per share, resulting in net proceeds of approximately \$31.0 million after deducting commissions and other transaction costs.

In May 2017, we filed a shelf registration statement on Form S-3 (the "2017 S-3"), which was declared effective in June 2017, replacing the 2015 S-3. Under the 2017 S-3, the Company may sell up to a total of \$300 million of its securities. In connection with the 2017 S-3, we entered into an At-the-Market Issuance Sales Agreement (the "2017 ATM") with Jefferies LLC, Cantor Fitzgerald & Co., FBR Capital Markets & Co., SunTrust Robinson Humphrey, Inc., Raymond James & Associates, Inc., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each a "2017 Agent" and collectively, the "2017 Agents"), relating to the sale of shares of our common stock. Under the 2017 ATM we pay the 2017 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the year ended December 31, 2017, we sold a total of 4,689,418 shares of common stock under the 2017 ATM for aggregate total gross proceeds of approximately \$47.7 million at an average selling price of \$10.18 per share, resulting in net proceeds of approximately \$46.9 million after deducting commissions and other transactions costs.

Subsequent to December 31, 2017, we sold an aggregate of 2,889,344 shares of common stock pursuant to the 2017 ATM for total gross proceeds of approximately \$35.9 million at an average selling price of \$12.42 per share, resulting in net proceeds of approximately \$35.3 million after deducting commissions and other transactions costs.

Equity Financings

In March 2017, we completed an underwritten public offering of 5,128,206 shares of our common stock (plus a 30-day underwriter overallotment option to purchase up to an additional 769,230 shares of common stock, which was exercised) at a price of \$9.75 per share. Net proceeds from this offering, including the overallotment option, were approximately \$54 million, net of underwriting discounts and offering expenses of approximately \$3.6 million.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

OBLIGATIONS AND COMMITMENTS

As of December 31, 2017, we have known contractual obligations, commitments and contingencies of \$15.6 million related to our operating lease obligations.

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual obligations					
Operating leases	<u>\$ 15,592,733</u>	<u>\$ 1,081,927</u>	<u>\$ 2,084,258</u>	<u>\$ 2,154,566</u>	<u>\$ 10,271,981</u>
Total	<u><u>\$ 15,592,733</u></u>	<u><u>\$ 1,081,927</u></u>	<u><u>\$ 2,084,258</u></u>	<u><u>\$ 2,154,566</u></u>	<u><u>\$ 10,271,981</u></u>

Leases

In October 2014, we entered into an agreement (the "Office Agreement") with FBIO, to occupy approximately 45% of the 24,000 square feet of New York City office space leased by FBIO, which is now our corporate headquarters. The Office Agreement requires us to pay our respective share of the average annual rent and other costs of the 15-year lease. We approximate an average annual rental obligation of \$1.1 million under the Office Agreement. We began to occupy this new space in April 2016, with rental payments beginning in the third quarter of 2016. During the years ended December 31, 2017 and 2016, we recorded rent expense of approximately \$1.2 million and \$1.4 million, respectively, and at December 31, 2017, have deferred rent of approximately \$1.4 million. Mr. Weiss, our Executive Chairman and CEO, is also Executive Vice Chairman of FBIO.

During the year ended December 31, 2017, we agreed to pay FBIO \$2.8 million for our portion of the build out costs, which have been allocated to us at the 45% rate mentioned above. The allocated build-out costs have been recorded in leasehold interest and will be amortized over the 15-year term of the Office Agreement. After an initial commitment period of the 45% rate for a period of three (3) years, we and FBIO will determine actual office space utilization annually and if our utilization differs from the amount we have been billed, we will either receive credits or be assessed incremental utilization charges. Also in connection with this lease, in October 2014 we pledged \$0.6 million to secure a line of credit as a security deposit for the Office Agreement, which has been recorded as restricted cash in the accompanying consolidated balance sheets.

Total rental expense was approximately \$1.4 million, \$1.6 million and \$0.3 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Future minimum lease commitments as of December 31, 2017 total, in the aggregate, approximately \$15.6 million through December 31, 2031. The preceding table shows future minimum lease commitments, which include our office leases in New York, North Carolina and Tennessee, by period as of December 31, 2017.

CRITICAL ACCOUNTING POLICIES

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

Revenue Recognition . We recognize license revenue in accordance with the revenue recognition guidance of the Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”), or Codification. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

Stock Compensation . We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. For employee and director grants, the value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of our stock, the risk-free interest rate, the estimated life of the option, the closing market price of our stock and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock and our assessment of future volatility; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options and warrants. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those equity awards expected to vest. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the options, restricted stock and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain. Compensation expense for such awards that vest upon the achievement of milestones is recognized when the achievement of such milestone becomes probable.

Total compensation expense for options and restricted stock issued to consultants is determined at the “measurement date.” The expense is recognized over the vesting period for the options and restricted stock. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record stock-based compensation expense based on the fair value of the equity awards at the reporting date. These equity awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

In-process Research and Development . All acquired research and development projects are recorded at their fair value as of the date acquisition. The fair values are assessed as of the balance sheet date to ascertain if there has been any impairment of the recorded value. If there is an impairment the asset is written down to its current fair value by the recording of an expense.

Accruals for Clinical Research Organization and Clinical Site Costs. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Accounting Related to Goodwill. As of December 31, 2017 and 2016, there was \$799,391 of goodwill on our consolidated balance sheets. Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

We are required to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition that were used to determine the valuation of goodwill and intangibles. In future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment indicators.

Accounting For Income Taxes . In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statements of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in maintaining the valuation allowance.

Fair Value of 5% Notes Payable. We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of three categories.

We elected the fair value option for valuing the 5% Notes. We elected the fair value option in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-09, "Scope of Modification Accounting" ("ASU 2017-09"). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all the following are met:

- The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.
- The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.
- The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

ASU 2017-09 is effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted for public business entities for reporting periods for which financial statements have not yet been issued, and all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. adopted ASU 2017-09 on January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on our consolidated financial statements as of December 31, 2017.

In January 2017, the FASB issued ASU No. 2017-04, “Simplifying the Test for Goodwill Impairment” (“ASU 2017-04”). ASU 2017-04 removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit’s fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, ASU 2017-04:

- Clarifies the requirements for excluding and allocating foreign currency translation adjustments to reporting units in connection with an entity’s testing of reporting units for goodwill impairment.
- Clarifies that an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.
- Makes minor changes to the overview and background sections of certain Accounting Standards Codification (“ASC” or “Codification”) subtopics and topics as part of the Board’s initiative to unify and improve those sections throughout the Codification.

ASU 2017-04 is effective prospectively for annual and interim periods beginning on or after December 15, 2019, and early adoption is permitted on testing dates after January 1, 2017. The Company does not expect the adoption of ASU 2017-04 to have a material impact on the Company’s condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, “FASB Clarifies the Definition of a Business” (“ASU 2017-01”). ASU 2017-01 clarifies the definition of a business in ASC 805. The amendments in ASU 2017-01 are intended to make application of the guidance more consistent and cost-efficient. The amendments in ASU 2017-01:

- Provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated.
- Provide that if the screen is not met, (1) to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. The framework includes two sets of criteria to consider that depend on whether a set has outputs. Although outputs are not required for a set to be a business, outputs generally are a key element of a business; therefore, the Board has developed more stringent criteria for sets without outputs.
- Narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606.

ASU 2017-01 is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company adopted ASU 2017-01 on January 1, 2018. The adoption of ASU 2017-01 did not have a material effect on our consolidated financial statements as of December 31, 2017.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" (Topic 606) ("ASU 2014-09"), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU 2014-09 provides a single set of criteria for revenue recognition among all industries. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services.

ASU 2014-09 includes guidance for determining whether a license transfers to a customer at a point in time or over time based on the nature of the entity's promise to the customer. To determine whether the entity's promise is to provide a right to access its intellectual property or a right to use its intellectual property, the entity should consider the nature of the intellectual property to which the customer will have rights.

ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company adopted ASU 2014-09 on January 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material effect on our consolidated financial statements as of December 31, 2017.

Other pronouncements issued by the FASB or other authoritative accounting standards group with future effective dates are either not applicable or not significant to our consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We currently invest in government and investment-grade corporate debt in accordance with our investment policy, which we may change from time to time. The securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. As of December 31, 2017, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including government debt and money market funds. The average duration of all of our held-to-maturity investments held as of December 31, 2017, was less than 12 months. Due to the relative short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements and the notes thereto, included in Part IV, Item 15(a), part 1, are incorporated by reference into this Item 8.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURES.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2017, management carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and our Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive and Chief Financial Officers concluded that, as of December 31, 2017, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. In making this assessment, our management used the criteria established in Internal Control – Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO Framework. Our management has concluded that, as of December 31, 2017, our internal control over financial reporting was effective based on these criteria.

The effectiveness of our internal control over financial reporting as of December 31, 2017 was audited by CohnReznick LLP, our independent registered public accounting firm, as stated in their report appearing below, which expressed an unqualified opinion on the effectiveness of our internal control over financial reporting as of December 31, 2017.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our Company have been detected.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and
Stockholders of TG Therapeutics, Inc.

Opinion on Internal Control over Financial Reporting

We have audited TG Therapeutics, Inc. (the Company's) internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework (2013) issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets and the related consolidated statements of operations, stockholders' equity and cash flows of the Company and our report dated March 15, 2018, expressed an unqualified opinion.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ CohnReznick LLP

New York, New York
March 15, 2018

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2018 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES.

1. Consolidated Financial Statements

The following consolidated financial statements of TG Therapeutics, Inc. are filed as part of this report.

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2. Consolidated Financial Statement Schedules

All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

3. Exhibits

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of TG Therapeutics, Inc. dated April 26, 2012 (incorporated by reference to Exhibit 3.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2012).
3.2	Certificate of Amendment to Amended and Restated Certificate of Incorporation of TG Therapeutics, Inc. dated June 9, 2014 (incorporated by reference to Exhibit 3.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2014).
3.3	Amended and Restated Bylaws of TG Therapeutics, Inc. dated July 18, 2014 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on July 21, 2014).
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K for the year ended December 31, 2011).
4.2	Form of warrant to purchase common stock of TG Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on November 13, 2012).
4.3	Form of Warrant issued to stockholders (incorporated by reference to Exhibit 10.34 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011).
4.4	Stockholder Protection Rights Agreement, dated July 18, 2014 between TG Therapeutics, Inc. and American Stock Transfer & Trust Company, LLC, as Rights Agent (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on July 21, 2014).
10.1	Amended and Restated Convertible Promissory Note, dated March 1, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on March 7, 2011).

- [10.2](#) Employment Agreement, effective December 29, 2011, between the Registrant and Michael Weiss (incorporated by reference to Exhibit 10.30 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). †
- [10.3](#) Restricted Stock Subscription Agreement, effective December 29, 2011, between the Registrant and Michael Weiss (incorporated by reference to Exhibit 10.31 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). †
- [10.4](#) Amendment to Restricted Stock Agreement, dated July 12, 2013, by and between TG Therapeutics, Inc. and Michael S. Weiss (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on July 16, 2013). †
- [10.5](#) Amendment to Restricted Stock Agreements, dated December 31, 2014, by and between TG Therapeutics, Inc. and Michael S. Weiss (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 7, 2015). †
- [10.6](#) Employment Agreement, effective December 29, 2011, between the Registrant and Sean Power (incorporated by reference to Exhibit 10.32 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). †
- [10.7](#) Restricted Stock Subscription Agreement, effective December 29, 2011 between the Registrant and Sean Power (incorporated by reference to Exhibit 10.33 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). †
- [10.8](#) Amendment to Restricted Stock Agreement, dated July 12, 2013, by and between TG Therapeutics, Inc. and Sean A. Power (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on July 16, 2013). †
- [10.9](#) Amendment to Restricted Stock Agreements, dated December 31, 2014, by and between TG Therapeutics, Inc. and Sean A. Power (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on January 7, 2015). †
- [10.10](#) License Agreement, dated January 30, 2012, by and among the Registrant, GTC Biotherapeutics, Inc., LFB Biotechnologies S.A.S. and LFB/GTC LLC (incorporated by reference to Exhibit 10.35 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011). *
- [10.11](#) TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan, dated May 14, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q/A for the quarter ended March 31, 2012).
- [10.12](#) First Amendment to TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan, filed with the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders on June 4, 2015, filed on April 24, 2015, and incorporated herein by reference.
- [10.13](#) Sublicense Agreement between TG Therapeutics, Inc. and Ildong Pharmaceutical Co. Ltd., dated November 13, 2012 (incorporated by reference to Exhibit 10.37 to the Registrant's Form 10-K for the fiscal year ended December 31, 2012). *
- [10.14](#) License Agreement between TG Therapeutics, Inc. and Ligand Pharmaceuticals Incorporated, dated June 23, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended June 30, 2014).*
- [10.15](#) Licensing Agreement between TG Therapeutics, Inc. and Rhizen Pharmaceuticals SA, dated September 22, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 20, 2015). *

10.16	Collaboration Agreement between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated March 3, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant’s Form 10-Q for the quarter ended March 31, 2015). *
10.17	Sublicense Agreement between TG Therapeutics, Inc. and Checkpoint Therapeutics, Inc., dated May 27, 2016, (incorporated by reference to Exhibit 10.1 to the Registrant’s Form 10-Q for the quarter ended June 30, 2016). *
10.18	Amendment to Employment Agreement, effective January 1, 2017, between TG Therapeutics, Inc. and Michael S. Weiss (incorporated by reference to Exhibit 10.18 to the Registrant’s Form 10-K/A for the year ended December 31, 2016). †
10.19	Advisory Agreement, effective January 1, 2017, between TG Therapeutics, Inc. and Caribe BioAdvisors, LLC (incorporated by reference to Exhibit 10.19 to the Registrant’s Form 10-K/A for the year ended December 31, 2016).
10.20	License Agreement between TG Therapeutics, Inc. and Jiangsu Hengrui Medicine Co., dated January 8, 2018. * #
21.1	Subsidiaries of TG Therapeutics, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Principal Executive Officer
31.2	Certification of Principal Financial Officer
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following financial information from TG Therapeutics, Inc.’s Annual Report on Form 10-K for the year ended December 31, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders’ Equity, (iv) Consolidated Statements of Cash Flows, (v) the Notes to Consolidated Financial Statements.

Filed Herewith.

† Indicates management contract or compensatory plan or arrangement.

* Confidential treatment has been requested with respect to omitted portions of this exhibit.

TG Therapeutics, Inc.
Consolidated Financial Statements

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders
TG Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of TG Therapeutics, Inc. (the “Company”) as of December 31, 2017 and 2016, and the related consolidated statements of operations, stockholders’ equity and cash flows for each of the three years in the period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and 2016, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company’s internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 15, 2018, expressed an unqualified opinion.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ CohnReznick LLP

We have served as the Company’s auditor since 2003.

New York, New York
March 15, 2018

TG Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets as of December 31

	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 56,717,847	\$ 25,031,280
Short-term investment securities	27,998,810	19,853,860
Interest receivable	108,468	83,852
Prepaid research and development	8,055,486	5,678,755
Other current assets	436,789	216,397
Total current assets	93,317,400	50,864,144
Restricted cash	587,291	583,208
Leasehold interest, net	2,429,434	2,042,281
Equipment, net	248,020	328,148
Goodwill	799,391	799,391
Other assets	--	164,375
Total assets	\$ 97,381,536	\$ 54,781,547
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	\$ 25,877,218	\$ 15,267,668
Accrued compensation	1,800,000	1,389,516
Current portion of deferred revenue	152,381	152,381
Notes payable	127,614	68,875
Total current liabilities	27,957,213	16,878,440
Deferred rent	1,364,601	816,257
Deferred revenue, net of current portion	1,066,667	1,219,048
Total liabilities	30,388,481	18,913,745
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value per share (10,000,000 shares authorized, none issued and outstanding as of December 31, 2017 and 2016)	--	--
Common stock, \$0.001 par value per share (150,000,000 shares authorized, 73,181,750 and 56,820,422 shares issued, 73,140,441 and 56,779,113 shares outstanding at December 31, 2017 and 2016, respectively)	73,182	56,820
Additional paid-in capital	422,017,042	272,432,139
	(234,337)	(234,337)

Treasury stock, at cost, 41,309 shares at December 31, 2017 and 2016))
		<u>(354,862,832)</u> <u>(236,386,820)</u>
Accumulated deficit))
		<u>66,993,055</u> <u>35,867,802</u>
Total stockholders' equity		<u>\$ 97,381,536</u> <u>\$ 54,781,547</u>
Total liabilities and stockholders' equity		

The accompanying notes are an integral part of the consolidated financial statements.

TG Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Operations for the Years Ended December 31

	<u>2017</u>	<u>2016</u>	<u>2015</u>
License revenue	\$ 152,381	\$ 152,381	\$ 152,381
Costs and expenses:			
Research and development:			
Noncash compensation	5,646,716	2,742,354	4,261,406
Other research and development	- 96,886,134	- 66,489,820	- 43,445,817
Total research and development	- 102,532,850	- 69,232,174	- 47,707,223
General and administrative:			
Noncash compensation	10,298,568	4,767,645	11,435,686
Other general and administrative	- 6,032,714	- 5,121,690	- 4,189,488
Total general and administrative	- 16,331,282	- 9,889,335	- 15,625,174
Total costs and expenses	- 118,864,132	- 79,121,509	- 63,332,397
Operating loss) - (118,711,751)) - (78,969,128)) - (63,180,016)
Other (income) expense:			
Interest income) (294,478)) (323,032)) (174,653)
Other (income) expense	- 58,739	- (393,202)	- (56,717)
Total other income, net) - (235,739)) - (716,234)) - (231,370)
Net loss) = <u>\$ (118,476,012)</u>) = <u>\$ (78,252,894)</u>) = <u>\$ (62,948,646)</u>
Basic and diluted net loss per common share) = <u>\$ (1.91)</u>) = <u>\$ (1.60)</u>) = <u>\$ (1.38)</u>
Weighted average shares used in computing basic and diluted net loss per common share	= <u>62,069,570</u>	= <u>49,041,354</u>	= <u>45,646,414</u>

The accompanying notes are an integral part of the consolidated financial statements.

TG Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity for the Years Ended December 31, 2017, 2016 and 2015

	Common Stock		Contingently issuable	Additional Paid-in	Treasury Stock		Accumulated	Total
	Shares	Amount			Shares	Capital		
Balance at January 1, 2015	44,974,248	\$ 44,974	\$ 6	\$ 175,476,521	41,309	\$ (234,337)	\$ (95,185,280)	\$ 80,101,884
Issuance of common stock in connection with exercise of warrants	2,946,703	2,946		1,064,393				1,067,339
Issuance of common stock in connection with cashless exercise of warrants	2,915	3		(3)				--
Issuance of common stock in connection with conversion of notes payable	522	1		6,924				6,925
Issuance of restricted stock	1,992,535	1,993		(1,993)				--
Forfeiture of restricted stock	(31,166)	(31)		31				--
Issuance of common stock to related party for cash (See Note 9)	114,855	115		749,890				750,005
Issuance of common stock in At-the-Market offering (net of offering costs of \$1,310,591)	4,094,498	4,094		66,894,609				66,898,703
Compensation in respect of restricted stock granted to employees, directors and consultants				15,697,092				15,697,092
Net loss							(62,948,646)	(62,948,646)
Balance at December 31, 2015	54,095,110	54,095	6	259,887,464	41,309	(234,337)	(158,133,926)	101,573,302
Issuance of common stock in connection with exercise of warrants	273,370	273		617,969				618,242
Issuance of common stock in connection with conversion of notes payable	3,710	4		33,013				33,017
Issuance of restricted stock	1,924,639	1,925		(1,925)				--
Forfeiture of restricted stock	(46,773)	(47)		47				--
Issuance of common stock in At-the-Market offering (net of offering costs of \$108,185)	570,366	570		4,385,566				4,386,136
Compensation in respect of restricted stock granted to employees, directors and consultants				7,509,999				7,509,999
Adjustment to contingently issuable shares			(6)	6				--
Net loss							(78,252,894)	(78,252,894)
Balance at December 31, 2016	56,820,422	56,820	--	272,432,139	41,309	(234,337)	(236,386,820)	35,867,802
Issuance of common stock in connection with exercise of warrants	887,585	888		2,142,197				2,143,085
Issuance of restricted stock	1,836,511	1,837		(1,837)				--
Forfeiture of restricted stock	(53,875)	(54)		54				--
Issuance of common stock in public offering (net of offering costs of \$3.6 million)	5,897,436	5,897		53,634,115				53,640,012
Issuance of common stock in At-the-Market offering (net of offering costs of \$1.1 million)	7,793,671	7,794		77,865,090				77,872,884
Compensation in respect of restricted stock granted to employees, directors and consultants				15,945,284				15,945,284
Net loss							(118,476,012)	(118,476,012)
Balance at December 31, 2017	<u>73,181,750</u>	<u>\$ 73,182</u>	<u>\$ --</u>	<u>\$ 422,017,042</u>	<u>41,309</u>	<u>\$ (234,337)</u>	<u>\$ (354,862,832)</u>	<u>\$ 66,993,055</u>

The accompanying notes are an integral part of the consolidated financial statements.

TG Therapeutics, Inc. and Subsidiaries
Consolidated Statements of Cash Flows for the Years Ended December 31

	<u>2017</u>	<u>2016</u>	<u>2015</u>
CASH FLOWS FROM OPERATING ACTIVITIES			
Consolidated net loss	\$ (118,476,012)	\$ (78,252,894)	\$ (62,948,646)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:			
Gain on sale of long-term securities	--)	(33,042)	--)
Noncash stock compensation expense	15,945,284	7,509,999	15,697,092
Depreciation and amortization	82,355	62,960	15,452
Amortization of premium on investment securities	61,320	459,429	536,142
Change in fair value of notes payable and accrued interest	58,739)	(109,657)	(56,717)
Changes in assets and liabilities:			
Increase in restricted cash	(4,083)	(4,065)	(4,131)
(Increase) decrease in other current assets	(2,665,222)	3,564,316)	(3,105,771)
Decrease (increase) in leasehold interest	124,947)	(2,042,281)	--)
(Increase) decrease in accrued interest receivable	(24,616)	102,169)	(100,505)
Decrease (increase) in other assets	161,730)	(4,784)	(41,722)
Increase in accounts payable and accrued expenses	11,020,034	6,492,644	5,470,915
Increase in deferred rent	104,343	816,257	--
Decrease in deferred revenue	(152,381)	(152,381)	(152,381)
Net cash used in operating activities	(93,763,562)	(61,591,330)	(44,690,272)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of equipment	(2,227)	(343,985)	(42,217)
Investment in held-to-maturity securities	(28,006,270)	(15,199,922)	(48,993,652)
Proceeds from maturity of short-term securities	19,800,000	29,500,000	24,350,000
Proceeds from the sale of long-term securities	--	12,589,219	--
Net cash (used in) provided by investing activities	(8,208,497)	26,545,312)	(24,685,869)
CASH FLOWS FROM FINANCING ACTIVITIES			
	2,143,085	618,242	1,067,339

Proceeds from the exercise of warrants	131,515,541	4,411,233	67,760,517
Proceeds from sale of common stock, net	-	(13,506)	(104,170)
Deferred financing costs paid	-	-	-
Net cash provided by financing activities	<u>133,658,626</u>	<u>5,015,969</u>	<u>68,723,686</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	31,686,567	(30,030,049)	(652,455)
Cash and cash equivalents at beginning of year	<u>25,031,280</u>	<u>55,061,329</u>	<u>55,713,784</u>
CASH AND CASH EQUIVALENTS AT END OF YEAR	<u>\$ 56,717,847</u>	<u>\$ 25,031,280</u>	<u>\$ 55,061,329</u>
NONCASH TRANSACTIONS			
Reclassification of deferred financing costs to additional paid-in capital	\$ (2,645)	\$ (25,097)	\$ (111,810)
Conversion of convertible notes payable to common stock	--	\$ 33,017	\$ 6,924

The accompanying notes are an integral part of the consolidated financial statements.

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Unless the context requires otherwise, references in this report to "TG," "Company," "we," "us" and "our" refer to TG Therapeutics, Inc. and our subsidiaries.

NOTE 1 - ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

DESCRIPTION OF BUSINESS

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel treatments for B-cell malignancies and autoimmune diseases. Currently, we are developing two therapies targeting hematologic malignancies. TG-1101 (ublituximab) is a novel, glycoengineered monoclonal antibody that targets a unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202 (umbralisib), an orally available PI3K delta inhibitor. The delta isoform of PI3K is strongly expressed in cells of hematopoietic origin and is believed to be important in the proliferation and survival of B-lymphocytes. Both TG-1101 and TGR-1202, or the combination of which is referred to as "U2," are in Phase 3 clinical development for patients with hematologic malignancies, with TG-1101 also in Phase 3 clinical development for Multiple Sclerosis. Additionally, the Company has recently brought its anti-PD-L1 monoclonal antibody into Phase 1 development and aims to bring additional pipeline assets into the clinic in the future.

We also actively evaluate complementary products, technologies and companies for in-licensing, partnership, acquisition and/or investment opportunities. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates.

LIQUIDITY AND CAPITAL RESOURCES

We have incurred operating losses since our inception, and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of December 31, 2017, we have an accumulated deficit of \$354.9 million.

Our major sources of cash have been proceeds from the private placement and public offering of equity securities. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on many factors, including our ability to obtain regulatory approval for our drug candidates; successfully complete any post-approval regulatory obligations; and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

As of December 31, 2017, we had \$84.8 million in cash and cash equivalents, investment securities, and interest receivable. The Company believes its cash, cash equivalents, investment securities, and interest receivable on hand as of December 31, 2017 combined with the additional capital raised in the first quarter of 2018 (see Note 13) will be sufficient to fund the Company's planned operations into the second quarter of 2019. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidates. We are dependent upon significant future financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

Our common stock is quoted on the Nasdaq Capital Market and trades under the symbol "TGTX."

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RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2017-09, "Scope of Modification Accounting" ("ASU 2017-09"). ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting. An entity should account for the effects of a modification unless all the following are met:

- The fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the modified award is the same as the fair value (or calculated value or intrinsic value, if such an alternative measurement method is used) of the original award immediately before the original award is modified. If the modification does not affect any of the inputs to the valuation technique that the entity uses to value the award, the entity is not required to estimate the value immediately before and after the modification.
- The vesting conditions of the modified award are the same as the vesting conditions of the original award immediately before the original award is modified.
- The classification of the modified award as an equity instrument or a liability instrument is the same as the classification of the original award immediately before the original award is modified.

ASU 2017-09 is effective for annual and interim periods beginning on or after December 15, 2017. Early adoption is permitted for public business entities for reporting periods for which financial statements have not yet been issued, and all other entities for reporting periods for which financial statements have not yet been made available for issuance. The amendments should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 on January 1, 2018. The adoption of ASU 2017-09 did not have a material effect on our consolidated financial statements as of December 31, 2017.

In January 2017, the FASB issued ASU No. 2017-04, "Simplifying the Test for Goodwill Impairment" ("ASU 2017-04"). ASU 2017-04 removes the requirement to compare the implied fair value of goodwill with its carrying amount as part of step 2 of the goodwill impairment test. As a result, under ASU 2017-04, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount and should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. In addition, ASU 2017-04:

- Clarifies the requirements for excluding and allocating foreign currency translation adjustments to reporting units in connection with an entity's testing of reporting units for goodwill impairment.
- Clarifies that an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss, if applicable.
- Makes minor changes to the overview and background sections of certain Accounting Standards Codification ("ASC" or "Codification") subtopics and topics as part of the Board's initiative to unify and improve those sections throughout the Codification.

ASU 2017-04 is effective prospectively for annual and interim periods beginning on or after December 15, 2019, and early adoption is permitted on testing dates after January 1, 2017. The Company does not expect the adoption of ASU 2017-04 to have a material impact on the Company's condensed consolidated financial statements.

In January 2017, the FASB issued ASU No. 2017-01, "FASB Clarifies the Definition of a Business" ("ASU 2017-01"). ASU 2017-01 clarifies the definition of a business in ASC 805. The amendments in ASU 2017-01 are intended to make application of the guidance more consistent and cost-efficient. The amendments in ASU 2017-01:

- Provide a screen to determine when a set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. This screen reduces the number of transactions that need to be further evaluated.
- Provide that if the screen is not met, (1) to be considered a business, a set must include, at a minimum, an input and a substantive process that together significantly contribute to the ability to create output and (2) remove the evaluation of whether a market participant could replace missing elements. The amendments provide a framework to assist entities in evaluating whether both an input and a substantive process are present. The framework includes two sets of criteria to consider that depend on whether a set has outputs. Although outputs are not required for a set to be a business, outputs generally are a key element of a business; therefore, the Board has developed more stringent criteria for sets without outputs.
- Narrow the definition of the term output so that the term is consistent with how outputs are described in Topic 606.

ASU 2017-01 is effective for annual and interim periods beginning after December 15, 2017, with early adoption permitted for transactions that occurred before the issuance date or effective date of the standard if the transactions were not reported in financial statements that have been issued or made available for issuance. The Company adopted ASU 2017-01 on January 1, 2018. The adoption of ASU 2017-01 did not have a material effect on our consolidated financial statements as of December 31, 2017.

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In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" (Topic 606) ("ASU 2014-09"), which supersedes all existing revenue recognition requirements, including most industry-specific guidance. ASU 2014-09 provides a single set of criteria for revenue recognition among all industries. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the Company expects to receive for those goods or services.

ASU 2014-09 includes guidance for determining whether a license transfers to a customer at a point in time or over time based on the nature of the entity's promise to the customer. To determine whether the entity's promise is to provide a right to access its intellectual property or a right to use its intellectual property, the entity should consider the nature of the intellectual property to which the customer will have rights.

ASU 2014-09 is effective for interim and annual periods beginning after December 15, 2017. The standard allows for two transition methods - full retrospective, in which the standard is applied to each prior reporting period presented, or modified retrospective, in which the cumulative effect of initially applying the standard is recognized at the date of initial adoption. The Company adopted ASU 2014-09 on January 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material effect on our consolidated financial statements as of December 31, 2017.

Other pronouncements issued by the FASB or other authoritative accounting standards with future effective dates are either not applicable or not significant to our condensed consolidated financial statements.

USE OF ESTIMATES

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. Actual results could differ from those estimates. Such differences could be material to the financial statements.

CASH AND CASH EQUIVALENTS

We treat liquid investments with original maturities of less than three months when purchased as cash and cash equivalents.

RESTRICTED CASH

We record cash pledged or held in trust as restricted cash. As of December 31, 2017, we have approximately \$0.6 million of restricted cash pledged to secure a line of credit as a security deposit for an Office Agreement (see Note 9).

INVESTMENT SECURITIES

Investment securities at both December 31, 2017 and 2016 consist of short-term government securities. We classify these securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method.

A decline in the market value of any investment security below cost, that is deemed to be other than temporary, results in a reduction in the carrying amount to fair value. The impairment is charged to operations and a new cost basis for the security is established. Other-than-temporary impairment charges are included in interest and other income (expense), net. Unrealized gains, if determined to be temporary, are included in accumulated other comprehensive income in equity. Dividend and interest income are recognized when earned.

CREDIT RISK

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company maintains its cash and cash equivalents with high-credit quality financial institutions. At times, such amounts may exceed federally-insured limits.

REVENUE RECOGNITION

We recognize license revenue in accordance with the revenue recognition guidance of the FASB Accounting Standards Codification, or Codification. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

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RESEARCH AND DEVELOPMENT COSTS

Generally, research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Prepaid research and development in our consolidated balance sheets includes, among other things, certain fees related to development and manufacturing services. These development and manufacturing agreements often require payments in advance of services performed or goods received. Accordingly, as of December 31, 2017 and 2016, we recorded approximately \$8.1 million and \$5.7 million, respectively, in prepaid research and development related to such advance agreements.

INCOME TAXES

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. If the likelihood of realizing the deferred tax assets or liability is less than “more likely than not,” a valuation allowance is then created.

We, and our subsidiaries, file income tax returns in the U.S. Federal jurisdiction and in various states. We have tax net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they were generated for tax purposes. Since a portion of these net operating loss carryforwards may be utilized in the future, many of these net operating loss carryforwards will remain subject to examination. We recognize interest and penalties related to uncertain income tax positions in income tax expense. Refer to Note 7 for further information for impact of tax reform.

STOCK-BASED COMPENSATION

We recognize all share-based payments to employees and non-employee directors (as compensation for service) as noncash compensation expense in the consolidated financial statements based on the fair values of such payments. Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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For share-based payments to consultants and other third-parties (including related parties), noncash compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties (including related parties) are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date.

In addition, because some of the options, restricted stock and warrants issued to employees, consultants and other third-parties vest upon achievement of certain milestones, the total expense is uncertain. Compensation expense for such awards that vest upon the achievement of milestones is recognized when the achievement of such milestone becomes probable.

BASIC AND DILUTED NET LOSS PER COMMON SHARE

Basic net loss per common share is calculated by dividing net loss applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net loss per common share, since potentially dilutive securities from stock options, stock warrants and convertible notes would have an antidilutive effect either because the Company incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 4,835,706, 8,033,779 and 7,064,396 at December 31, 2017, 2016 and 2015, respectively. During the years ended December 31, 2017, 2016 and 2015 the Company incurred a net loss, therefore, all of the securities are antidilutive and excluded from the computation of diluted loss per share.

	December 31,		
	2017	2016	2015
Unvested restricted stock	4,820,143	7,142,055	5,859,914
Shares issuable upon note conversion	15,563	14,812	17,733
Warrants	--	876,912	1,186,749
Total	4,835,706	8,033,779	7,064,396

LONG-LIVED ASSETS AND GOODWILL

Long-lived assets are reviewed for an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management’s policy in determining whether an impairment indicator, a triggering event, exists comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, we make certain assumptions in determining the impairment amount. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized.

Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit’s carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit’s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit’s goodwill is compared with the carrying amount of the unit’s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. We will continue to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

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NOTE 2 – CASH AND CASH EQUIVALENTS

The following tables summarize our cash and cash equivalents at December 31, 2017 and 2016:

	<u>December 31, 2017</u>	<u>December 31, 2016</u>
Checking and bank deposits	\$ 55,681,820	\$ 4,052,333
Money market funds	1,036,027	20,978,947
Total	\$ 56,717,847	\$ 25,031,280

NOTE 3 – INVESTMENT SECURITIES

Our investments as of December 31, 2017 and 2016 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost. During the year ended December 31, 2016, we liquidated our long-term investment securities with a net carrying amount of approximately \$12.6 million, realizing a gain of approximately \$33,000 on the sale. The decision to sell our long-term securities was made due to market rate conditions on long-term securities coupled with the recognized gain we were able to yield on the sale of the securities.

The following tables summarize our investment securities at December 31, 2017 and 2016:

	<u>December 31, 2017</u>			
	<u>Amortized cost, as adjusted</u>	<u>Gross unrealized holding gains</u>	<u>Gross unrealized holding losses</u>	<u>Estimated fair value</u>
Short-term investments:				
Obligations of domestic governmental agencies (maturing between January 2018 and November 2018) (held-to-maturity)	\$ 27,998,810	\$ --	\$ 35,235	\$ 27,963,575
Total short-term investment securities	\$ 27,998,810	\$ --	\$ 35,235	\$ 27,963,575
	<u>December 31, 2016</u>			
	<u>Amortized cost, as adjusted</u>	<u>Gross unrealized holding gains</u>	<u>Gross unrealized holding losses</u>	<u>Estimated fair value</u>
Short-term investments:				
Obligations of domestic governmental agencies (maturing between February 2017 and September 2017) (held-to-maturity)	\$ 19,853,860	\$ 3,270	\$ 2,492	\$ 19,854,638
Total short-term investment securities	\$ 19,853,860	\$ 3,270	\$ 2,492	\$ 19,854,638

NOTE 4 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The fair value hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1 – quoted prices in active markets for identical assets and liabilities;
- Level 2 – inputs other than Level 1 quoted prices that are directly or indirectly observable; and

- Level 3 – unobservable inputs that are not corroborated by market data.

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As of December 31, 2017 and 2016, the fair values of cash and cash equivalents, restricted cash, and notes and interest payable approximate their carrying value.

At the time of our merger (we were then known as Manhattan Pharmaceuticals, Inc. (“Manhattan”)) with Ariston Pharmaceuticals, Inc. (“Ariston”) in March 2010, Ariston issued \$15.5 million of five-year 5% notes payable (the “5% Notes”) in satisfaction of several note payable issuances. The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into common stock at the conversion price of \$1,125 per share. Ariston agreed to make quarterly payments on the 5% Notes equal to 50% of the net product cash flow received from the exploitation or commercialization of Ariston’s product candidates, AST-726 and AST-915. We have no obligations under the 5% Notes aside from a) 50% of the net product cash flows from Ariston’s product candidates, if any, payable to noteholders; and b) the conversion feature, discussed above.

The cumulative liability including accrued and unpaid interest of the 5% Notes was approximately \$17.5 million at December 31, 2017 and \$16.7 million at December 31, 2016. No payments have been made on the 5% Notes as of December 31, 2017.

In December 2011, we elected the fair value option for valuing the 5% Notes. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

As of December 31, 2013, as a result of expiring intellectual property rights and other factors, it was determined that net product cash flows from AST-726 were unlikely. As we have no other obligations under the 5% Notes aside from the net product cash flows and the conversion feature, the conversion feature was used to estimate the 5% Notes’ fair value as of December 31, 2017 and 2016. The assumptions, assessments and projections of future revenues are subject to uncertainties, difficult to predict, and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value and the differences could be material to our consolidated financial statements.

The following tables provide the fair value measurements of applicable financial liabilities as of December 31, 2017 and 2016:

Financial liabilities at fair value as of December 31, 2017				
	Level 1	Level 2	Level 3	Total
5% Notes	\$ --	\$ --	\$ 127,614	\$ 127,614
Totals	\$ --	\$ --	\$ 127,614	\$ 127,614

Financial liabilities at fair value as of December 31, 2016				
	Level 1	Level 2	Level 3	Total
5% Notes	\$ --	\$ --	\$ 68,875	\$ 68,875
Totals	\$ --	\$ --	\$ 68,875	\$ 68,875

The Level 3 amounts above represent the fair value of the 5% Notes and related accrued interest.

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The following table summarizes the changes in Level 3 instruments for the years ended December 31, 2016 and 2017:

		\$ 211,549
Balance at January 1, 2016		
Interest accrued on face value of 5% Notes		886,084
Conversion of 5% Notes)	(33,017)
Change in fair value of Level 3 liabilities)	(995,741)
Balance at December 31, 2016		68,875
Interest accrued on face value of 5% Notes		844,797
Conversion of 5% Notes		--
Change in fair value of Level 3 liabilities)	(786,058)
Balance at December 31, 2017		\$ <u><u>127,614</u></u>

The change in the fair value of the Level 3 liabilities is reported in other (income) expense in the accompanying consolidated statements of operations.

NOTE 5 – STOCKHOLDERS’ EQUITY

Preferred Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, \$0.001 par value, with rights senior to those of our common stock, issuable in one or more series. Upon issuance, the Company can determine the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of common stock.

Stockholder Rights Plan

On July 18, 2014, we adopted a stockholder rights plan. The stockholder rights plan is embodied in the Stockholder Protection Rights Agreement dated as of July 18, 2014 (the "Rights Agreement"), between us and American Stock Transfer & Trust Company, LLC, as rights agent (the "Rights Agent").

Accordingly, the Board of Directors declared a distribution of one right (a "Right") for each outstanding share of common stock, to stockholders of record at the close of business on July 28, 2014, for each share of common stock issued (including shares distributed from treasury) by us thereafter and prior to the Separation Time (as defined in the Rights Agreement), and for certain shares of common stock issued after the Separation Time. Following the Separation Time, each Right entitles the registered holder to purchase from us one one-thousandth (1/1,000) of a share of Series A Junior Participating Preferred Stock, par value \$0.001 per share (the "Preferred Stock"), at a purchase price of \$100.00 (the "Exercise Price"), subject to adjustment. The description and terms of the Rights are set forth in the Rights Agreement. Each one one-thousandth of a share of Preferred Stock has substantially the same rights as one share of common stock. Subject to the terms and conditions of the Rights Agreement, Rights become exercisable ten days after the public announcement that a "Person" has become an "Acquiring Person" (as each such term is defined in the Rights Agreement). Any Rights held by an Acquiring Person are void and may not be exercised.

If a Person becomes an Acquiring Person, all holders of Rights, except the Acquiring Person, may purchase at the Right's then-current exercise price, common stock having a market value equal to twice the exercise price. Moreover, at any time after a Person becomes an Acquiring Person (unless such Person acquires 50 percent or more of our common stock then outstanding, as more fully described in the Rights Agreement), the Board of Directors may exchange all (but not less than all) of the then outstanding Rights (other than rights owned by such Person, which would have become void) for shares of common stock at an exchange ratio of one share of common stock per Right, appropriately adjusted in order to protect the interests of holders of Rights.

The Rights Agreement was approved by our Board of Directors on July 18, 2014. The Rights will expire at the close of business on its ten year anniversary, unless earlier exchanged or terminated by us.

Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 150,000,000 shares of \$0.001 par value common stock.

On June 21, 2013, we entered into an At-the-Market Issuance Sales Agreement (the "2013 ATM") with MLV & Co. LLC ("MLV") under which we could issue and sell shares of our common stock, having an aggregate offering price of up to \$50.0 million, from time to time through MLV, acting as the sales agent. Under the agreement we would pay MLV a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock sold through MLV.

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During the year ended December 31, 2014, we sold a total of 4,850,055 shares of common stock under the 2013 ATM for aggregate total gross proceeds of approximately \$50.0 million at an average selling price of \$10.31 per share. Net proceeds were approximately \$48.9 million after deducting commissions and other transactions costs.

In December 2014, we filed a shelf registration statement on Form S-3 (the "2015 S-3"), which was declared effective in January 2015. Under the 2015 S-3, the Company may sell up to a total of \$250 million of its securities. In connection with the 2015 S-3, we amended our 2013 At-the-Market Issuance Sales Agreement with MLV (the "2015 ATM") such that we may issue and sell additional shares of our common stock, having an aggregate offering price of up to \$175.0 million, from time to time through MLV and FBR Capital Markets & Co. ("FBR", each of MLV and FBR individually an "Agent" and collectively the "Agents"), acting as the sales agents. Under the 2015 ATM we pay the Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock sold through the Agents.

During the year ended December 31, 2017, we sold a total of 3,104,253 shares of common stock under the 2015 ATM for aggregate total gross proceeds of approximately \$31.6 million at an average selling price of \$10.18 per share, resulting in net proceeds of approximately \$31.0 million after deducting commissions and other transaction costs. During the year ended December 31, 2016, we sold a total of 570,366 shares of common stock under the 2015 ATM for aggregate total gross proceeds of approximately \$4.5 million at an average selling price of \$7.88 per share, resulting in net proceeds of approximately \$4.4 million after deducting commissions and other transaction costs.

In March 2017, we completed an underwritten public offering of 5,128,206 shares of our common stock (plus a 30-day underwriter overallotment option to purchase up to an additional 769,230 shares of common stock, which was exercised) at a price of \$9.75 per share. Net proceeds from this offering, including the overallotment option, were approximately \$54 million, net of underwriting discounts and offering expenses of approximately \$3.6 million.

In May 2017, we filed a shelf registration statement on Form S-3 (the "2017 S-3"), which was declared effective in June 2017, replacing the 2015 S-3. Under the 2017 S-3, the Company may sell up to a total of \$300 million of its securities. In connection with the 2017 S-3, we entered into an At-the-Market Issuance Sales Agreement (the "2017 ATM") with Jefferies LLC, Cantor Fitzgerald & Co., FBR Capital Markets & Co., SunTrust Robinson Humphrey, Inc., Raymond James & Associates, Inc., Ladenburg Thalmann & Co. Inc. and H.C. Wainwright & Co., LLC (each a "2017 Agent" and collectively, the "2017 Agents"), relating to the sale of shares of our common stock. Under the 2017 ATM we pay the 2017 Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of common stock.

During the year ended December 31, 2017, we sold a total of 4,689,418 shares of common stock under the 2017 ATM for aggregate total gross proceeds of approximately \$47.7 million at an average selling price of \$10.18 per share, resulting in net proceeds of approximately \$46.9 million after deducting commissions and other transactions costs.

Subsequent to December 31, 2017, we sold an aggregate of 2,889,344 shares of common stock pursuant to the 2017 ATM for total gross proceeds of approximately \$35.9 million at an average selling price of \$12.42 per share, resulting in net proceeds of approximately \$35.3 million after deducting commissions and other transactions costs.

The 2017 S-3 is currently our only active shelf registration statement. After deducting shares already sold, there is approximately \$252.3 million and \$216.4 million of common stock that remains available for sale under the 2017 S-3 at December 31, 2017 and post year-end December 31, 2017, respectively. We may offer the securities under the 2017 S-3 from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interests of our stockholders. We believe that the 2017 S-3 provides us with the flexibility to raise additional capital to finance our operations as needed.

Treasury Stock

As of December 31, 2017 and 2016, 41,309 shares of common stock are being held in Treasury, at a cost of approximately \$234,000, representing the fair market value on the date the shares were surrendered to the Company to satisfy employee tax obligations.

Equity Incentive Plans

The TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan ("2012 Incentive Plan") was approved by stockholders in June 2015. As of December 31, 2017 and 2016, no options were outstanding and up to an additional 504,128 shares may be issued under the 2012 Incentive Plan .

Effective as of January 1, 2017, we entered into an amendment (the "Amendment") to the employment agreement entered into as of December 15, 2011 (together with the Amendment, the "Employment Agreement") with Michael S. Weiss, our Executive Chairman and Chief Executive Officer and President. Under the Amendment, Mr. Weiss will remain as Chief Executive Officer and President, removing the interim status. Simultaneously, we entered into a Strategic Advisory Agreement (the "Advisory Agreement") with Caribe BioAdvisors, LLC (the "Advisor") owned by Mr. Weiss to provide the services of Mr. Weiss as Chairman of the Board and as Executive Chairman. As part of the Amendment, Mr. Weiss also agreed to forfeit 3,381,866 restricted shares previously granted under the Employment Agreement that were predominantly subject to time-based vesting over the next three years. Simultaneously, (i) Mr. Weiss was issued 418,371 restricted shares under the Employment Agreement that vest in 2018 and 2019 and (ii) the Advisor was issued 2,960,000 restricted shares under the Advisory Agreement that vested on market capitalization thresholds ranging from \$375 million to \$750 million. In accordance with GAAP, there was no incremental stock compensation expense recognition as a result of the modification.

TG Therapeutics, Inc. and Subsidiaries
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Stock Options

The following table summarizes stock option activity for the years ended December 31, 2017, 2016 and 2015:

	Number of shares	Weighted- average exercise price	Weighted- average contractual term (in years)	Aggregate intrinsic value
Outstanding at January 1, 2015	194	971.70	3.50	\$ --
Granted	--	--		
Exercised	--	--		
Forfeited	(152)	463.32		
Expired	(42)	2,811.53		
Outstanding at December 31, 2015	--	--	--	\$ --
Granted	--	--		
Exercised	--	--		
Forfeited	--	--	--	
Expired	--	--		
Outstanding at December 31, 2016	--	--	--	\$ --
Granted	--	--		
Exercised	--	--		
Forfeited	--	--		
Expired	--	--		
Outstanding at December 31, 2017	--	\$ --	--	\$ --
Exercisable at December 31, 2017	--	\$ --	--	\$ --

As of December 31, 2017, there are no unvested option awards and no unrecognized compensation cost related to option awards.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock. The restricted stock vesting consists of milestone and time-based vesting. The following table summarizes restricted share activity for the years ended December 31, 2017, 2016 and 2015:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2015	6,400,001	5.86
	1,992,535	12.89

Granted			
Vested)	(1,001,455	5.04
Forfeited)	<u>(31,166</u>	16.76
Outstanding at December 31, 2015		7,359,915	7.83
Granted		1,924,639	4.99
Vested)	(595,726	7.38
Forfeited)	<u>(46,773</u>	10.34
Outstanding at December 31, 2016		8,642,055	\$ 7.20
Granted		1,836,511	6.40
Vested)	(4,103,048	5.24
Forfeited)	<u>(53,875</u>	8.47
Outstanding at December 31, 2017		<u>6,321,643</u>	<u>\$ 7.17</u>

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Total compensation expense associated with restricted stock grants was \$15,945,284, \$7,509,999 and \$15,697,092 during the years ended December 31, 2017, 2016 and 2015, respectively. As of December 31, 2017, there was approximately \$14.8 million of total unrecognized compensation expense related to unvested time-based restricted stock, which is expected to be recognized over a weighted-average period of 1.0 year. This amount does not include, as of December 31, 2017, 242,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,413,917 shares of restricted stock outstanding issued to non-employees. Milestone-based non-cash compensation expense will be measured and recorded if and when a milestone becomes probable. The expense for non-employee shares is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date.

Warrants

The following table summarizes warrant activity for the years ended December 31, 2017, 2016 and 2015:

	<u>Warrants</u>	<u>Weighted- average exercise price</u>	<u>Aggregate intrinsic value</u>
Outstanding at January 1, 2015	4,148,228	0.94	\$ <u><u>61,792,184</u></u>
Issued	--	--	
Exercised	(2,950,115)	0.36	
Expired	<u>(11,364)</u>	2.25	
Outstanding at December 31, 2015	1,186,749	2.37	\$ <u><u>11,341,452</u></u>
Issued	--	--	
Exercised	(273,370)	2.26	
Expired	<u>--</u>	2.25	
Outstanding at December 31, 2016	913,379	\$ 2.41	\$ <u><u>1,961,403</u></u>
Issued	--	--	
Exercised	(887,585)	2.41	
Expired	<u>(25,794)</u>	--	
Outstanding at December 31, 2017	<u><u>--</u></u>	<u><u>\$ --</u></u>	<u><u>\$ --</u></u>

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

NOTE 6 – NOTES PAYABLE

The following is a summary of notes payable:

	December 31, 2017			December 31, 2016		
	Current portion, net	Non- current portion, net	Total	Current portion, net	Non- current portion, net	Total
Convertible 5% Notes Payable	\$ 127,614	\$ --	\$ 127,614	\$ 68,875	\$ --	\$ 68,875
Totals	<u>\$ 127,614</u>	<u>\$ --</u>	<u>\$ 127,614</u>	<u>\$ 68,875</u>	<u>\$ --</u>	<u>\$ 68,875</u>

Convertible 5% Notes Payable

The 5% Notes and accrued and unpaid interest thereon are convertible at the option of the holder into common stock at the conversion price of \$1,125 per share. We have no obligation under the 5% Notes aside from (a) 50% of the net product cash flows from Ariston’s product candidates, if any, payable to noteholders; and (b) the conversion feature, discussed above. Interest accrues monthly, is added to principal on an annual basis, every March 8, and is payable at maturity, which was March 8, 2015 (see Note 4 for further details).

The cumulative liability including accrued and unpaid interest of these notes was approximately \$17.5 million at December 31, 2017 and \$16.7 million at December 31, 2016. No payments have been made on the 5% Notes as of December 31, 2017.

In December 2011, we elected the fair value option for valuing the 5% Notes. The fair value option was elected in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments (see Note 4 for further details).

NOTE 7 – INCOME TAXES

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. In determining the need for a valuation allowance, management reviews both positive and negative evidence, including current and historical results of operations, future income projections and the overall prospects of our business. Based upon management's assessment of all available evidence, we believe that it is more-likely-than-not that the deferred tax assets will not be realizable, and therefore, a valuation allowance has been established. The valuation allowance for deferred tax assets was approximately \$99,713,000 and \$116,172,000 as of December 31, 2017 and 2016, respectively.

On December 22, 2017, H.R.1, commonly known as the Tax Cuts and Jobs Act (the “Act”) was signed into law. Among other things, the Act reduces our corporate federal tax rate from 34% to 21% effective January 1, 2018. As a result, we are required to re-measure, through income tax expense, our deferred tax assets and liabilities using the enacted rate at which we expect them to be recovered or settled. The re-measurement of our net deferred tax asset would have resulted in additional income tax expense of \$51,767,584; however, with full valuation allowance in place, the expense is reversed through a corresponding adjustment to the valuation allowance, resulting in no impact on income tax expense.

As of December 31, 2017, we have U.S. net operating loss carryforwards (“NOLs”) of approximately \$375,475,000 and research and development credit carryforwards (“R&D credits”) of approximately \$10,491,000. For income tax purposes, these NOLs and R&D credits will expire in various amounts through 2037. The Tax Reform Act of 1986 contains provisions which limit the ability to utilize net operating loss carryforwards and R&D credit carryforwards in the case of certain events including significant changes in ownership interests. The Exchange Transaction with TG Bio may have resulted in a “change in ownership” as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended. Additionally, stock issuance activities may have resulted in a “change in ownership” as defined by IRC Section 382 of the Internal Revenue Code of 1986, as amended. Accordingly, a substantial portion of the Company’s NOLs above may be subject to annual limitations in reducing any future year’s taxable income, and a substantial portion of the R&D Credit carryforwards may be subject to annual limitations in reducing any future year’s tax.

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Notes to Consolidated Financial Statements

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2017 and 2016 are presented below.

	2017	2016
Deferred tax assets (liabilities):		
Net operating loss carryforwards	\$ 83,655,879	\$ 95,329,928
Research and development credit	10,490,793	7,326,715
Noncash compensation	4,933,807	12,915,672
Other	- 632,274	- 599,514
Deferred tax asset, excluding valuation allowance	99,712,753	116,171,829
	- (99,712,753)	- (116,171,829)
Less valuation allowance))))
Net deferred tax assets	= \$ --	= \$ --

There was no current or deferred income tax expense for the year ended December 31, 2017. Income tax expense differed from amounts computed by applying the US Federal income tax rate of 34% to pretax loss as follows:

	For the year ended December 31,		
	2017	2016	2015
Loss before income taxes, as reported in the consolidated statements of operations	\$ (118,476,012)	\$ (78,252,894)	\$ (62,948,646)
)))
Computed "expected" tax benefit	\$ (40,281,844)	\$ (26,605,984)	\$ (21,402,540)
)))
Increase (decrease) in income taxes resulting from:			
Expected benefit from state and local taxes	(1,105,708)	(835,072)	(672,306)
)))
Research and development credits	(3,697,258)	(2,364,417)	(1,603,364)
)))
Other	1,563,114	(7,506)	566,310
)))
Impact of change in state tax rates on deferred taxes	--	--	5,836,819
Stock awards	8,213,188		
Effects of federal tax reform rate changes	51,767,584		
Change in the balance of the valuation allowance for deferred tax assets	- (16,459,076)	29,812,979	17,275,081
	= \$ --	= \$ --	= \$ --

We file income tax returns in the U.S Federal and various state and local jurisdictions. With certain exceptions, the Company is no longer subject to U.S. Federal and state income tax examinations by tax authorities for years prior to 2014. However, NOLs and tax credits generated from those prior years could still be adjusted upon audit.

The Company would recognize interest and penalties, if any, to uncertain tax position in income tax expense in the statement of operations. There was no accrual for interest and penalties related to uncertain tax positions for 2017. We do not believe that there will be a material change in our unrecognized tax positions over the next twelve months. All of the unrecognized tax benefits, if recognized, would be offset by the valuation allowance.

NOTE 8 – LICENSE AGREEMENTS

BET

In May 2016, as part of a broader agreement with Jubilant Biosys (“Jubilant”), an India-based biotechnology company, we entered into a sub-license agreement (“JBET Agreement”) with Checkpoint Therapeutics, Inc. (“Checkpoint”) (see Note 9), for the development and commercialization of Jubilant’s novel BET inhibitor program in the field of hematological malignancies.

TG Therapeutics, Inc. and Subsidiaries
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Under the terms of the agreement, we paid Checkpoint an up-front licensing fee of \$1.0 million and will make additional payments contingent on certain preclinical, clinical, and regulatory milestones, including commercial milestones totaling up to approximately \$177 million and a single-digit royalty on net sales. TG will also provide funding to support certain targeted research efforts at Jubilant.

Anti-PD-L1 and anti-GITR

On March 3, 2015, we entered into a Global Collaboration Agreement (the "Collaboration") with Checkpoint, a subsidiary of Fortress Biotech, Inc. ("FBIO"), a related party, for the development and commercialization of Checkpoint's anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. Checkpoint retains the rights to develop and commercialize these antibodies in solid tumors.

Under the terms of the Collaboration, we made an up-front payment of \$0.5 million, will make development and sales-based milestone payments up to an aggregate of \$164 million, and will pay a tiered single digit royalty on net sales. The royalty term will terminate on a country by country basis upon the later of (i) ten years after the first commercial sale of any applicable licensed product in such country, or (ii) the expiration of the last-to-expire patent held by the Dana Farber Cancer Institute containing a valid claim to any licensed product in such country.

Michael Weiss, our Executive Chairman, CEO and President is also the Executive Vice Chairman of FBIO and the Executive Chairman of Checkpoint (see Note 9).

TGR-1202

On September 22, 2014, we exercised our option to license the global rights to TGR-1202, thereby entering into an exclusive licensing agreement (the "TGR-1202 License") with Rhizen Pharmaceuticals, SA ("Rhizen") for the development and commercialization of TGR-1202. Prior to this, we had been jointly developing TGR-1202 in a 50:50 joint venture with Rhizen.

Under the terms of the TGR-1202 License, Rhizen received a \$4.0 million cash payment and 371,530 shares of our common stock as an upfront license fee. With respect to TGR-1202, Rhizen will be eligible to receive regulatory filing, approval and sales-based milestone payments in the aggregate of approximately \$175 million, a small portion of which will be payable on the first New Drug Application (NDA) filing and the remainder on approval in multiple jurisdictions for up to two oncology indications and one non-oncology indication and attaining certain sales milestones. In addition, if TGR-1202 is co-formulated with another drug to create a new product (a "New Product"), Rhizen will be eligible to receive similar regulatory approval and sales-based milestone payments for such New Product. Additionally, Rhizen will be entitled to tiered royalties on our future net sales of TGR-1202 and any New Product. In lieu of sales milestones and royalties on net sales, Rhizen shall also be eligible to participate in sublicensing revenue, if any, based on a percentage that decreases as a function of the number of patients treated in clinical trials following the exercise of the license option. Rhizen will retain global manufacturing rights to TGR-1202, provided that they are price competitive with alternative manufacturers.

IRAK4

On June 23, 2014, we entered into an exclusive licensing agreement with Ligand Pharmaceuticals Incorporated ("Ligand") for the development and commercialization of Ligand's interleukin-1 receptor associated kinase-4 ("IRAK4") inhibitor technology, which currently is in preclinical development for potential use against certain cancers and autoimmune diseases. IRAK4 is a serine/threonine protein kinase that is a key downstream signaling component of the interleukin-1 receptor and multiple toll-like receptors.

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Under the terms of the license agreement, Ligand received 125,000 shares of our common stock as an upfront license fee. Ligand will also be eligible to receive maximum potential milestone payments of approximately \$207 million upon the achievement of specific clinical, regulatory and commercial milestone events. Additionally, Ligand will be entitled to royalties on our future net sales of licensed products containing IRAK4 inhibitors. The basic royalty rate for licensed products covered by Ligand's issued patents will be 6% for annual sales of up to \$1 billion and 9.5% for annual sales in excess of that threshold.

Additionally, Opus Point Partners, LLC, who identified the opportunity and advised us on the transaction, will also be entitled to receive a 1% royalty for annual sales of up to \$1 billion. Michael S. Weiss, our Executive Chairman and Chief Executive Officer, is a Managing Member of Opus Point Partners, LLC.

TG-1101

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong relating to the development and commercialization of TG-1101 in South Korea and Southeast Asia. Under the terms of the sublicense agreement, Ildong has been granted a royalty bearing, exclusive right, including the right to grant sublicenses, to develop and commercialize TG-1101 in South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar.

An upfront payment of \$2.0 million, which was received in December 2012, net of \$0.3 million of income tax withholdings, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last licensed patent right or 15 years after the first commercial sale of a product in such country, unless the agreement is earlier terminated, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. We recorded license revenue of approximately \$152,000 for each of the years ended December 31, 2017, 2016 and 2015, and, at December 31, 2017, 2016 and 2015, have deferred revenue of approximately \$1,219,000, \$1,371,000 and \$1,524,000, respectively, associated with this \$2,000,000 payment (approximately \$152,000 of which has been classified in current liabilities at December 31, 2017).

We may receive up to an additional \$5.0 million in payments upon the achievement of pre-specified milestones. In addition, upon commercialization, Ildong will make royalty payments to us on net sales of TG-1101 in the sublicense territory.

NOTE 9 – RELATED PARTY TRANSACTIONS

LFB Biotechnologies

On January 30, 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublituximab (the "LFB License Agreement"). In connection with the LFB License Agreement, LFB Group was issued 5,000,000 shares of common stock, and a warrant to purchase 2,500,000 shares of common stock at a purchase price of \$0.001 per share. In addition, on November 9, 2012, we nominated Dr. Yann Echelard to our Board of Directors as LFB Group's nominee. LFB Group maintains the right to nominate a board member until such time as LFB Group owns less than 10% of the outstanding common stock.

In connection with the LFB License Agreement, LFB Group maintained the right to purchase at least \$750,000 in additional shares of common stock at a purchase price per share as defined in a November 2012 securities exchange agreement. Accordingly, in February 2015, LFB Group purchased 114,855 shares of our common stock at a price of \$6.53 per share for net proceeds of \$750,000. In May 2015, LFB Group exercised its warrant to purchase 2,500,000 shares of common stock at a purchase price of \$0.001 per share.

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

Under the terms of the LFB License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred approximately \$2.3 million, \$8.1 million and \$9.3 million in expenses for such services during the years ended December 31, 2017, 2016 and 2015, respectively, which have been included in other research and development expenses in the accompanying consolidated statements of operations. As of December 31, 2017, and 2016, we had zero and approximately \$0.4 million, respectively, recorded in accounts payable related to the LFB License Agreement. In conjunction with the development and manufacturing services discussed above, certain agreements between us and LFB Group require payments in advance of services performed or goods delivered. Accordingly, as of December 31, 2017 and 2016, we recorded zero and approximately \$1.3 million, respectively, in prepaid research and development for such advance payments.

Other Parties

In March 2014, we entered into a shared services agreement (the “Opus Shared Services Agreement”) with Opus Point Partners Management, LLC (“Opus”) in which the parties agreed to share a rented facility and costs for certain other services. Michael S. Weiss, our Executive Chairman and CEO, is a Managing Member of Opus. During the years ended December 31, 2017 and 2016, we incurred expenses of zero and approximately \$0.3 million, respectively, principally for rent, related to this Opus Shared Services Agreement. As of December 31, 2017 and 2016, we had zero accounts payable related to this Opus Shared Services Agreement. The Opus Shared Services Agreement is no longer in effect as we began occupying new space in April 2016.

In October 2014, we entered into an agreement (the “Office Agreement”) with FBIO to occupy approximately 45% of the 24,000 square feet of New York City office space leased by FBIO, which is now our corporate headquarters. The Office Agreement requires us to pay our respective share of the average annual rent and other costs of the 15-year lease. We approximate an average annual rental obligation of \$1.1 million under the Office Agreement. We began to occupy this new space in April 2016, with rental payments beginning in the third quarter of 2016. During the years ended December 31, 2017 and 2016, we recorded rent expense of approximately \$1.2 million and \$1.4 million, and at December 31, 2017, have deferred rent of approximately \$1.4 million. Mr. Weiss, our Executive Chairman and CEO, is also Executive Vice Chairman of FBIO.

During the year ended December 31, 2017, we agreed to pay FBIO \$2.8 million for our portion of the build-out costs, which have been allocated to us at the 45% rate mentioned above. The allocated build-out costs have been recorded in Leasehold Interest on the Company’s consolidated balance sheet and will be amortized over the 15-year term of the Office Agreement. After an initial commitment period of the 45% rate for a period of three (3) years, we and FBIO will determine actual office space utilization annually and if our utilization differs from the amount we have been billed, we will either receive credits or be assessed incremental utilization charges. Also in connection with this lease, in October 2014 we pledged \$0.6 million to secure a line of credit as a security deposit for the Office Agreement, which has been recorded as restricted cash in the accompanying consolidated balance sheets.

In July 2015, we entered into a Shared Services Agreement (the “Shared Services Agreement”) with FBIO to share the cost of certain services such as facilities use, personnel costs and other overhead and administrative costs. This Shared Services Agreement requires us to pay our respective share of services utilized. In connection with the Shared Services Agreement, we incurred expenses of approximately \$1.2 million and \$0.8 million for shared services for the years ended December 31, 2017 and 2016, primarily related to shared personnel.

In May 2016, as part of a broader agreement with Jubilant, an India-based biotechnology company, we entered into the JBET Agreement with Checkpoint, a subsidiary of FBIO, for the development and commercialization of Jubilant’s novel BET inhibitor program in the field of hematological malignancies. We paid Checkpoint an up-front licensing fee of \$1.0 million in July 2016 and incurred expenses of \$0.2 million in March 2017 for the first milestone achievement as part of the JBET Agreement recorded in other research and development in the accompanying consolidated statement of operations. As of December 31, 2017 and 2016, we had approximately \$0.3 million and \$0.8 million, respectively, recorded in accounts payable, related mostly to the JBET Agreement. Mr. Weiss is also the Executive Chairman of Checkpoint.

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

NOTE 10 – COMMITMENTS AND CONTINGENCIES

As of December 31, 2017, we have known contractual obligations, commitments and contingencies of approximately \$15.6 million related to our operating lease obligations.

	Payment due by period				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual obligations					
Operating leases	<u>\$ 15,592,733</u>	<u>\$ 1,081,927</u>	<u>\$ 2,084,258</u>	<u>\$ 2,154,566</u>	<u>\$ 10,271,981</u>
Total	<u><u>\$ 15,592,733</u></u>	<u><u>\$ 1,081,927</u></u>	<u><u>\$ 2,084,258</u></u>	<u><u>\$ 2,154,566</u></u>	<u><u>\$ 10,271,981</u></u>

Leases

See Note 9 for a detailed description of our lease arrangement in New York. Total rental expense was approximately \$1.4 million, \$1.6 million and \$0.3 million for the years ended December 31, 2017, 2016 and 2015, respectively.

Future minimum lease commitments as of December 31, 2017, in the aggregate total approximately \$15.6 million through December 31, 2031. The preceding table shows future minimum lease commitments, which include our office leases in New York, North Carolina and Tennessee, by year as of December 31, 2017.

TG Therapeutics, Inc. and Subsidiaries
Notes to Consolidated Financial Statements

NOTE 11 – QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

	3 Months Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
License revenue	<u>\$ 38,095</u>	<u>\$ 38,095</u>	<u>\$ 38,096</u>	<u>\$ 38,095</u>
Total costs and expenses	<u>27,704,517</u>	<u>28,463,466</u>	<u>31,623,323</u>	<u>31,072,826</u>
Net loss	<u>\$ (27,727,509)</u>	<u>\$ (28,353,084)</u>	<u>\$ (31,535,652)</u>	<u>\$ (30,859,767)</u>
Basic and diluted net loss per common share	<u>\$ (0.52)</u>	<u>\$ (0.45)</u>	<u>\$ (0.48)</u>	<u>\$ (0.46)</u>

	3 Months Ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
License revenue	<u>\$ 38,095</u>	<u>\$ 38,095</u>	<u>\$ 38,096</u>	<u>\$ 38,095</u>
Total costs and expenses	<u>14,030,251</u>	<u>16,061,538</u>	<u>24,963,567</u>	<u>24,066,153</u>
Net loss	<u>\$ (13,848,662)</u>	<u>\$ (15,899,062)</u>	<u>\$ (24,831,027)</u>	<u>\$ (23,674,143)</u>
Basic and diluted net loss per common share	<u>\$ (0.28)</u>	<u>\$ (0.33)</u>	<u>\$ (0.50)</u>	<u>\$ (0.48)</u>

NOTE 12 – LITIGATION

On January 6, 2017, a purported securities class action complaint was filed in New York federal court against the Company and certain of its directors, officers or consultants on behalf of all shareholders who purchased or otherwise acquired TG Therapeutics common stock between September 15, 2014 and October 12, 2016 (the “Class Period”). The case was captioned *John Lyon v. TG Therapeutics, Michael S. Weiss, Sean A. Power and Robert Niecestro*, Case No. 1:17-cv-00112-VM (S.D.N.Y.). The complaint alleged that, throughout the Class Period various statements made by the Company regarding its GENUINE Phase 3 trial were materially false or misleading when made in violation of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. On January 24, 2017, a second purported class action complaint was filed in New York federal court against the Company and certain of its directors, officers or consultants on behalf of all shareholders who purchased or otherwise acquired TG Therapeutics common stock between September 15, 2014 and October 12, 2016. The case was captioned *Kenneth C. Wyzgoski v. TG Therapeutics, Michael S. Weiss, Sean A. Power and Robert Niecestro*, Case No. 1:17-cv-00508-VM (S.D.N.Y.). The claims and allegations in the Wyzgoski complaint were substantially identical to those in the Lyon case. By order dated March 23, 2017, the court consolidated the Lyon and Wyzgoski cases into one action, captioned *In re TG Therapeutics Securities Litigation*, Case No. 1:17-cv-00112-VM (S.D.N.Y.), appointed lead plaintiffs in the case, and approved lead plaintiffs’ selection of lead counsel. On April 5, 2017 the Court so ordered a stipulation pursuant to which lead plaintiffs voluntarily dismissed the consolidated action in its entirety without prejudice. The Company denies the allegations and claims made in the above-referenced actions and no consideration was given by the Company in connection with lead plaintiffs’ voluntary dismissal of the consolidated action.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

TG THERAPEUTICS, INC.

Date: March 15, 2018

By: /s/ Michael S. Weiss
Michael S. Weiss
Executive Chairman,
Chief Executive Officer and President

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Michael S. Weiss and Sean A. Power, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 15, 2018, and in the capacities indicated:

Signatures	Title
<u>/s/ Michael S. Weiss</u> Michael S. Weiss	Executive Chairman, Chief Executive Officer and President (principal executive officer)
<u>/s/ Sean A. Power</u> Sean A. Power	Chief Financial Officer (principal financial and accounting officer)
<u>/s/ Laurence N. Charney</u> Laurence N. Charney	Director
<u>/s/ Yann Echelard</u> Yann Echelard	Director
<u>/s/ Kenneth Hoberman</u> Kenneth Hoberman	Director
<u>/s/ Daniel Hume</u> Daniel Hume	Director
<u>/s/ William J. Kennedy</u> William J. Kennedy	Director
<u>/s/ Mark Schoenebaum, M.D.</u> Mark Schoenebaum, M.D.	Director

EXHIBIT INDEX

Exhibit Number	Exhibit Description
21.1	Subsidiaries of TG Therapeutics, Inc.
23.1	Consent of Independent Registered Public Accounting Firm
31.1	Certification of Principal Executive Officer
31.2	Certification of Principal Financial Officer
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002

Subsidiaries of TG Therapeutics, Inc.

Ariston Pharmaceuticals, Inc.

TG Biologics, Inc.

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in registration statement Nos. 333-181439 and 333-210227 on Form S-8 and registration statement No. 333- 218293 on Form S-3 of TG Therapeutics, Inc. of our report dated March 15, 2018 on our audits of the consolidated financial statements of TG Therapeutics, Inc. and Subsidiaries as of December 31, 2017 and 2016, and for each of the three years in the period ended December 31, 2017, and our report on our audit of internal control over financial reporting of TG Therapeutics, Inc. and Subsidiaries as of December 31, 2017, dated March 15, 2018, included in this Annual Report on Form 10-K of TG Therapeutics, Inc. and Subsidiaries for the year ended December 31, 2017.

/s/ CohnReznick LLP

New York, New York
March 15, 2018

**CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Michael S. Weiss, certify that:

1. I have reviewed this annual report on Form 10-K of TG Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have :
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2018

/s/ Michael S. Weiss

Michael S. Weiss

Executive Chairman, Chief Executive Officer and President
Principal Executive Officer

**CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Sean A. Power, certify that:

1. I have reviewed this annual report on Form 10-K of TG Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 15, 2018

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

**STATEMENT OF CHIEF EXECUTIVE OFFICER OF
TG THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of TG Therapeutics, Inc. (the “Company”) on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (the “Report”), I, Michael S. Weiss, Executive Chairman, Chief Executive Officer and President of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge :

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2018

/s/ Michael S. Weiss

Michael S. Weiss

Executive Chairman, Chief Executive Officer and President

Principal Executive Officer

**STATEMENT OF CHIEF FINANCIAL OFFICER OF
TG THERAPEUTICS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report of TG Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Sean A. Power, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 15, 2018

/s/ Sean A. Power

Sean A. Power

Chief Financial Officer

Principal Financial and Accounting Officer

LICENSE AGREEMENT
BY AND BETWEEN
Jiangsu Hengrui Medicine Co.
AND
TG Therapeutics, Inc.

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the “**Agreement**”) is dated as of January 8, 2018 (the “**Effective Date**”) by and between Jiangsu Hengrui Medicine Co., a Chinese corporation having its place of business at No.7 Kunlunshan Road, Lianyungang Eco & Tech Development Zone, Jiangsu Province, China 222047 (including its successors and permitted assigns, “**Licensor**”), and TG Therapeutics, Inc., a Delaware corporation with its place of business at 2 Gansevoort St., New York, New York 10014 (including its successors and permitted assigns, “**TGTX**”). TGTX, on the one hand, and Licensor, on the other hand, shall each be referred to herein as a “**Party**” or, collectively, as the “**Parties**.”

RECITALS:

WHEREAS, TGTX is engaged in the research, development, manufacturing and commercialization of pharmaceutical products, and TGTX is interested in developing and commercializing products containing or comprising the Compounds; and

WHEREAS, TGTX desires to license from Licensor and Licensor wishes to license to TGTX, on an exclusive basis, the right to use, develop and commercialize Licensor Technology in and for a defined field of use.

NOW, THEREFORE, in consideration of the foregoing and of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE I.

DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

1.1. “**Adverse Event**” means any untoward medical occurrence associated with the use of a Licensed Product in a human clinical trial subject or in a patient, whether or not considered related to the Licensed Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease, as defined more fully in 21 CFR §312.32.

1.2. “**Affiliate**” means, with respect to either Party, a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.2, the word “**control**” (including, with correlative meaning, the terms “**controlled by**” or “**under common control with**”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person by the ownership of at least fifty percent (50%) of the voting securities of such Person.

1.3. “**Calendar Quarter**” means each three month period commencing January 1, April 1, July 1 or October 1, provided however that (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter, and (b) the last Calendar Quarter of the Term shall end upon the termination or expiration of this Agreement.

1.4. “**Calendar Year**” means the period beginning on the 1st of January and ending on the 31st of December of the same year, provided however that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same calendar year as the Effective Date, and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.

1.5. “**Change of Control**” means, with respect to a Party, (a) a merger or consolidation of such Party with a Third Party that results in the voting securities of such Party outstanding immediately prior thereto, or any securities into which such voting securities have been converted or exchanged, ceasing to represent more than 50% of the combined voting power of the surviving entity or the parent of the surviving entity immediately after such merger or consolidation, or (b) a transaction or series of related transactions in which a Third Party, together with its Affiliates, becomes the beneficial owner of more than 50% of the combined voting power of the outstanding securities of such Party, or (c) the sale or other transfer to a Third Party of all or substantially all of such Party’s business to which the subject matter of this Agreement relates .

1.6. “*****” means the * of * and its possessions.

1.7. “**Combination Product**” means a product (a) containing a Licensed Product together with one or more other active ingredients, or (b) with one or more products, devices, pieces of equipment or components, but sold for an integrated price (e.g., with the purchase of one product the customer gets a coupon for the other) or for a single price.

1.8. **“Commercialization”** or **“Commercialize”** means any and all activities undertaken at any time for a particular Licensed Product and that relate to the manufacturing, marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of the Licensed Product, and interacting with Regulatory Authorities regarding the foregoing.

1.9. **“Commercially Reasonable Efforts”** means, with respect to the efforts to be expended by a Party or such Party’s applicable Affiliate with respect to any objective, such reasonable, diligent, and good faith efforts normally used to accomplish a similar objective under similar circumstances by a similarly-situated company. Commercially Reasonable Efforts will not mean that a Party commits that it or such Party’s applicable Affiliate will actually accomplish the applicable task.

1.10. **“Compounds”** means Licensor’s proprietary Bruton’s Tyrosine Kinase (BTK) inhibitors set forth on Schedule 1 and any other *, *, *, *, *, * and *.

1.11. **“Control”** means, with respect to (a) Patent Rights, (b) Know-How or (c) biological, chemical or physical material, that a Party or one of its Affiliates owns or has a license or sublicense to such Patent Rights, Know-How or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such Patent Rights, Know-How or material as provided for in this Agreement without violating the terms of any agreement or other arrangement with any Third Party. Notwithstanding anything in this Agreement to the contrary, a Party will be deemed to not Control any Patents, Know-How or material that are owned or controlled by a Third Party described in the definition of “Change of Control,” or such Third Party’s Affiliates (other than an Affiliate of such Party prior to the Change of Control), (a) prior to the closing of such Change of Control, except to the extent that any such Patents or Know-How were developed prior to such Change of Control through the use of such Party’s technology, or (b) after such Change of Control to the extent that such Patents or Know-How are developed or conceived by such Third Party or its Affiliates (other than such Party) after such Change of Control without using or incorporating such Party’s technology.

1.12. **“Covered”** means, with respect to a Licensed Product, that the manufacturing, importing, using, selling, or offering for sale of such Licensed Product would, but for ownership of or a license granted hereunder under Licensor Patents, infringe a Valid Claim of Licensor Patents in the country in which the activity occurs.

1.13. **“Development”** or **“Develop”** means, with respect to a Licensed Product, the performance of all preclinical and clinical development (including, without limitation, toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), clinical trials, and manufacturing and regulatory activities that are required to obtain Regulatory Approval of such Licensed Product.

1.14. **“EMA”** means the European Medicines Agency or any successor agency.

1.15. **“European Commission”** means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.

1.16. **“FDA”** means the United States Food and Drug Administration, or a successor federal agency thereto.

1.17. **“Field”** means prophylactic, palliative, therapeutic or diagnostic uses of a Licensed Product as monotherapy or in combination with ublituximab (TG-1101, an anti-CD20 mAb), in combination with umbralisib (TGR-1202, a PI3Kd inhibitor), or in combination with ublituximab (TG-1101) and umbralisib (TGR-1202) in connection with Hematologic Malignancies. “Hematologic Malignancies” are forms of cancer that begin in the cells of blood-forming tissue, such as the bone marrow, or in the cells of the immune system. Non-limiting examples of such malignancies include acute and chronic leukemias, such as Chronic Lymphocytic leukemia (“CLL”), Small Lymphocytic lymphoma (“SLL”), Mantle Cell lymphoma (“MCL”), Multiple myeloma (“MM”), Myelodysplastic syndromes (“MS”); Hodgkin lymphoma (“HL”), including classical Hodgkin lymphoma (cHL) and Nodular lymphocyte-predominant Hodgkin lymphoma (NLPHL); Non-Hodgkin lymphomas (NHL) including B-cell lymphoma and NK/T-cell lymphoma; precursor B/T lymphoblastic lymphoma; and Waldenstrom macroglobulinemia (WM), in all cases, in humans or animals.

1.18. **“First Commercial Sale”** means, with respect to a Licensed Product in any country, the first commercial transfer or disposition for value of such Licensed Product in such country to a Third Party by TGTX, an Affiliate of TGTX or a Sublicensee after Regulatory Approval has been obtained in such country.

1.19. **“GAAP”** means United States generally accepted accounting principles.

1.20. **“Governmental Body”** means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity, or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

1.21. **“Know-How”** means any scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including, without limitation, discoveries, inventions, trade secrets, databases, practices, protocols, regulatory filings, methods, processes, techniques, software, works of authorship, plans, concepts, ideas, biological and other materials, reagents, specifications, formulations, formulae, data (including, but not limited to, pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, the FDA or other Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or pending patent application. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. “Know-How” includes any rights including copyright, moral, trade-secret, database or design rights protecting such Know-How. “Know-How” excludes Patent Rights.

1.22. **“Indication”** means a generally acknowledged disease or condition, a significant manifestation of a disease or condition, or symptoms associated with a disease or condition or a risk for a disease or condition, which a Licensed Product is intended to address.

1.23. **“Law” or “Laws”** means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.

1.24. **“Licensed Product”** means any pharmaceutical product, in any dosage form, preparation, composition, formulation, presentation or package configuration, that is Commercialized or undergoing research or preclinical or clinical Development that contains or comprises, in part or in whole, a Compound. For clarity: if a product is described by the foregoing sentence it is a “Licensed Product” for all purposes hereof whether or not it is Covered and whether or not the manufacturing, importing, using, selling, or offering for sale of such product would, but for a license granted under this Agreement under the Licensor Technology, infringe any Licensor Patents in the country in which the activity occurs.

1.25. **“Licensor Know-How”** means any and all Know-How that (a) is Controlled by Licensor or any of its Affiliates as of the Effective Date or at any time thereafter during the Term and (b) pertains directly and particularly to the Compounds and (c) is from time to time expressly identified in writing by Licensor to TGTX as constituting Licensor Know-How. The Licensor Know-How shall include, but not be limited to, the Know-How listed on Schedule 2 hereto.

1.26. **“Licensor Patents”** means all Patent Rights that are Controlled by Licensor or any of its Affiliates as of the Effective Date or at any time thereafter during the Term and that pertain directly and particularly to the Compounds, which are set forth on Schedule 3 hereto, as updated from time to time.

1.27. **“Licensor Technology”** means the Licensor Patents and the Licensor Know-How.

1.28. **“Major Market”** means any of the (a) *, (b) the *, or (c) *.

1.29. **“NDA”** means a New Drug Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 314.3 et seq., a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. CFR § 601, and any equivalent application submitted in any country, including a European Marketing Authorization Application, together, in each case, with all additions, deletions or supplements thereto.

1.30. **“NDA Approval”** means the receipt of notice from the relevant US Regulatory Authority that an NDA for a Licensed Product has met all the criteria for marketing approval.

1.31. **“Net Sales”** means the gross amount invoiced or otherwise charged by TGTX, its Affiliates and Sublicensees to Third Parties for a Licensed Product, less:

- (a) Normal and customary trade, quantity, cash and discounts and credits allowed and taken;
- (b) Discounts, refunds, rebates, chargebacks, retroactive price adjustments, and any other allowances given and taken which effectively reduce the net selling price (other than such which have already diminished the gross amount invoiced such as those outlined in Section 1.29(a) above), including, without limitation, Medicaid rebates, institutional rebates or volume discounts;
- (c) Product returns and allowances;
- (d) Administrative fees paid to government related group purchasing organizations (e.g., Medicare) and government-mandated rebates;
- (e) Shipping, handling, freight, postage, insurance and transportation charges, but all only to the extent included as a separate line item in the gross amount invoiced;
- (f) Any tax, tariff or duties imposed on the production, sale, delivery or use of the Licensed Product, including, without limitation, sales, use, excise or value added taxes and customs and duties, but all only to the extent included as a separate line item (e.g., “taxes”) in the gross amount invoiced; and
- (g) Bad debt actually written off during the accounting period (provided, that any bad debt write-off so taken which is later reversed shall be added back to Net Sales in the accounting period in which the reversal occurs).

Notwithstanding the foregoing, amounts invoiced by TGTX and its Affiliates and Sublicensees for sales of Licensed Products among TGTX and its Sublicensees and their respective Affiliates for resale shall not be included in the computation of Net Sales.

For purposes of determining royalties and sales milestones payable on Combination Products, Net Sales will be calculated as follows, in each calendar quarter:

(i) If all therapeutically active pharmaceutical ingredients comprising the Combination Product are marketed and sold separately in commercially relevant quantities in a calendar quarter and the Net Selling Price (as defined below) for each such therapeutically active pharmaceutical ingredients can be separately determined for such quarter, Net Sales of each Combination Product for determining the royalty payment and sales milestones payable with respect to such Combination Product shall be calculated by $\frac{\text{Net Selling Price of Combination Product}}{\text{Net Selling Price of Single Therapeutically Active Pharmaceutical Ingredient}} \times \text{Net Sales of Single Therapeutically Active Pharmaceutical Ingredient}$, in which $\text{Net Selling Price of Combination Product}$ is the Net Selling Price of the single therapeutically active pharmaceutical ingredient in the Licensed Product contained in the Combination Product sold during the relevant payment period and $\text{Net Selling Price of Single Therapeutically Active Pharmaceutical Ingredient}$ is the Net Selling Price of the other single therapeutically active pharmaceutical ingredient contained in the Combination Product sold during such payment period. “Net Selling Price” means the gross price at which a product is sold to a third party after discounts, deductions, credits, taxes and allowances

(ii) If: (a) neither of the therapeutically active pharmaceutical ingredients of a Combination Product are sold separately in commercially relevant quantities during a particular payment period, or (b) a Combination Product has ≥ 2 or more therapeutically active pharmaceutical ingredients in addition to the Licensed Product, then, in any such case, the Parties will meet and negotiate an appropriate method for determining the Net Sales resulting from sales of such Combination Product, taking into account the contribution each therapeutically active pharmaceutical ingredient makes to the total selling price of such Combination Product, based on the principle behind the formulas above and with reference to a mutually agreed sampled median of comparable branded, non-generic or non-biosimilar products comprised of BTK (e.g., $\frac{\text{Net Sales of Combination Product}}{\text{Net Sales of Single Therapeutically Active Pharmaceutical Ingredient}}$), $\frac{\text{Net Sales of Combination Product}}{\text{Net Sales of Single Therapeutically Active Pharmaceutical Ingredient}}$ and $\frac{\text{Net Sales of Combination Product}}{\text{Net Sales of Single Therapeutically Active Pharmaceutical Ingredient}}$, or $\frac{\text{Net Sales of Combination Product}}{\text{Net Sales of Single Therapeutically Active Pharmaceutical Ingredient}}$ agent as a monotherapy for use in the Field.

1.32. **“Non-Hematology Malignancy Indications”** means any Indication that is not covered in the Field.

1.33. **“Patent Right”** means: (a) an issued or granted patent, including any extension, supplemental protection certificate, registration, confirmation, reissue, reexamination, extension or renewal thereof; (b) a pending patent application, including any continuation, divisional, continuation-in-part, substitute or provisional application thereof; and (c) all counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction; provided, however, that, with respect to items (b) and (c), no patent application shall be considered pending after a period of seven years from its effective filing date.

1.34. **“Person”** means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.

1.35. **“Pivotal Trial”** means any clinical trial designed and executed to obtain statistically significant evidence that the Licensed Product is safe and efficacious and is intended to be or is in fact used as one of the, or the sole, adequate and well-controlled trial(s) for registration in any jurisdiction.

1.36. **“Phase 2 Clinical Trial”** means any human clinical trial conducted in patients that is intended to provide preliminary evidence suggesting effectiveness of the drug, including clinical trials described in 21 C.F.R. §312.21(b), or, with respect to a jurisdiction other than the United States, a similar clinical trial.

1.37. **“Regulatory Authority”** means (a) the FDA, (b) the EMA or the European Commission, or (c) any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products in any other jurisdiction anywhere in the world.

1.38. **“Regulatory Approval”** means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority, necessary for the Development, manufacture, use, storage, import, transport and Commercialization of a given Licensed Product in a particular country or jurisdiction. For the avoidance of doubt, Regulatory Approval outside of the United States shall include any pricing or marketing approval needed prior to the sale of a Licensed Product in the Field.

1.39. **“Royalty Term”** means, on a Licensed Product-by-Licensed Product and country-by-country basis, the period from the First Commercial Sale of a given Licensed Product in such country until the later of (1) expiry of the * containing a Valid Claim that Covers such Licensed Product in such country or (2) * (*) years from such First Commercial Sale of such Licensed Product in such country.

1.40. **“ Serious Adverse Event ”** means any untoward medical occurrence that, at any dose, results in death, is life-threatening, requires inpatient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect, as more fully defined in 21 CFR § 312.32.

1.41. **“ Share Value ”** as of a particular date means the closing sale price of the Shares on the Share’s principal United States securities exchange on such date , or other major securities exchange where TGTX is listed for trading.

1.42. **“ Shares ”** means shares of TGTX’s common stock, par value \$0.001 per share, as constituted on the Effective Date; the meaning of such term shall be adjusted appropriately to reflect the occurrence of any stock split, reverse stock split, recapitalization, reorganization or other such event.

1.43. **“Sublicensee”** means a Person, other than TGTX or its Affiliate, to which TGTX or its Affiliate has, pursuant to Section 2.2, granted a license, sublicense, or other similar rights via sale or divestment, to Develop and/or Commercialize Licensed Products under any of the license rights granted under Section 2.1. **“ Sublicense ”** shall be construed accordingly.

1.44. **“Sublicense Income”** shall mean all upfront, realized contingent, and milestone payments received by TGTX or its Affiliate from Sublicensees, excluding:

(a) the portion of amounts received by TGTX or its Affiliate from such Sublicensee as the purchase price for TGTX's or its Affiliate's debt or equity securities; provided that any amount paid above the fair market value for such securities (which shall be the Share Value, if applicable, but calculated as a * -day volume weighted average price following an announcement of the securities purchase) shall be part of Sublicense Income, and

(b) the portion of amounts received by TGTX or its Affiliate to fund the direct cost of research or development activities to be performed in connection with the relevant Sublicense, or services or goods obtained for use in connection with the relevant Sublicense.

For sake of clarity, Sublicense Income shall exclude any royalty payments made by a Sublicensee to TGTX or its Affiliate, a portion of which will be payable to Licensor as provided in Section 5.4.

1.45. **“Third Party”** means any Person other than Licensor, TGTX or Affiliates of either of them, or any Sublicensees.

1.46. **“Third Party Action”** means any claim or action made by a Third Party against a Party that claims that a Licensed Product, or its use, Development, manufacture or sale infringes such Third Party’s intellectual property rights.

1.47. **“United States”** or **“US”** means the United States of America and its territories and possessions.

1.48. **“ Valid Claim ”** means a claim of an issued and unexpired patent which has not lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise.

1.49. The definition of each of the following terms is set forth in the section of the Agreement indicated below:

“**Action**” has the meaning set forth in Section 6.5(b).

“**BTK Inhibitor Program**” has the meaning set forth in Section 8.2(f).

“**Claim**” has the meaning set forth in Section 9.1.

“**Confidential Information**” has the meaning set forth in Section 7.1.

“**Controlling Party**” has the meaning set forth in Section 6.6(c).

“**Development Program**” has the meaning set forth in Section 3.1.

“**Disclosing Party**” has the meaning set forth in Section 7.1.

“**Indemnified Party**” has the meaning set forth in Section 9.4.

“**Indemnifying Party**” has the meaning set forth in Section 9.4.

“**Licensor Indemnitees**” has the meaning set forth in Section 9.1.

“**Receiving Party**” has the meaning set forth in Section 7.1.

“**Superiority**” has the meaning set forth in Section 5.2(a).

“**Term**” has the meaning set forth in Section 10.1.

“**TGTX Indemnitees**” has the meaning set forth in Section 9.2.

ARTICLE II.

LICENSES AND OTHER RIGHTS

2.1. **Grant of License to TGTX** . Subject to the terms and conditions of this Agreement, Licensor hereby grants to TGTX, and TGTX hereby accepts, an exclusive (even as to Licensor, except as provided in Section 2.3), royalty-bearing right and license (with the right to sublicense, and to further sublicense, subject to the provisions of Section 2.2) under the Licensor Technology to research, Develop, manufacture, have manufactured, use, import and Commercialize and have Commercialized the Licensed Products, in all cases, solely in and for the Field and in and for all the countries of the world, except for those listed on Exhibit A (the “**Territory**”). Licensor and its Affiliates grant no licenses or rights to use other than as expressly set forth herein.

2.2. **Grant of Sublicenses by TGTX** . TGTX shall have the right, in its sole discretion, to grant Sublicenses, in whole or in part, under the license granted in Section 2.1 to any of its Affiliates or Third Parties, excluding biotech or pharmaceutical companies that are headquartered, or have their principal operations, in * ; provided, however, that (1) the granting by TGTX of a Sublicense shall not relieve TGTX of any of its obligations hereunder;(2) TGTX’s right to grant a Person a Sublicense shall be subject to TGTX including within such Sublicense express provisions binding the Sublicensee to all of the duties, obligations, restrictions and acknowledgements hereunder of TGTX (with Licensor being an express third-party beneficiary thereof), and stating that the Sublicense shall (except as otherwise expressly provided in Section 10.3 or 10.4(c)) automatically terminate upon the expiration or earlier termination of this Agreement; (3) TGTX, within * (*) days of the granting of each Sublicense, shall notify Licensor of such grant and the name and address of each such Sublicensee; and (4) the Sublicense shall be at * . Notwithstanding the foregoing sentence, it is not required that a Sublicense include provisions for the Sublicensee to pay Royalties or make milestone payments directly to Licensor or to provide royalty reports directly to Licensor. TGTX shall ensure that all of its Sublicensees shall comply with the terms and conditions of this Agreement (as applicable to them) and TGTX shall be and remain fully responsible for the compliance by such Sublicensees with the terms and conditions of this Agreement (as applicable to them) as if such Sublicensees were TGTX hereunder. Except for Sublicenses as expressly allowed herein, TGTX acknowledges that it has no right to, and agrees not to purport to, grant to anyone a sublicense under the Licensor Technology.

2.3. **Retained Rights; No Implied Licenses** . Licensor hereby retains the right to use, itself and with or through its Affiliates and Third Parties, the Licensor Technology for: (A)(i) any and all uses outside of the Field throughout the world and (ii) for any and all uses within the Field outside of the Territory and (B) to manufacture and conduct development (including, but subject to TGTX’s consent, clinical development) of the Licensed Product within the Territory. Except as expressly set forth herein, no rights are granted by Licensor to TGTX hereunder, whether by necessity, implication or otherwise. Notwithstanding any of the foregoing, Licensor is obliged to give TGTX * (*) days advance written notice prior to engaging in activities falling within the scope of this clause (B) above.

2.4. **Right of First Offer for Uses outside the Field** . Prior to agreeing to a license, sale or other disposition of the right to commercialize the Licensed Product for uses outside of the Field and within the Territory, Licensor shall notify TGTX in writing of such pending agreement. For clarity, Licensor reserves the right to enter into such an agreement with a Licensor Affiliate or a Third Party on any terms that Licensor determines to be acceptable.

2.5. **Right of First Refusal for Combination Development**. Prior to undertaking any Hematologic Malignancy combination clinical trial with a Licensed Product in the Territory and outside the Field, Licensor shall (i) notify TGTX in writing of its intent to undertake such combination and (ii) for a period of * (*) days after TGTX’s receipt of such notice, TGTX shall have the right to pursue such combination subject to the terms of Section 5.2(b) . If TGTX fails to notify Licensor of its intent to pursue such combination and make the appropriate milestone payment as specified in Section 5.2(b) within such *day period, Licensor shall be free to pursue such combination at its sole expense. For sake of clarity, in the event that TGTX makes any payment under Section 5.2(b) for combination of a Licensed Product with any specific agent, then any combination with that class of agent will be added to the Field, and Licensor shall no longer have the right to pursue combinations of any Licensed Product with that class of agents in the Territory. Further, in the event that TGTX makes the All Combinations Payment (as defined in Section 5.2(b)), the Field will be expanded to encompass all combinations within Hematologic Malignancy Indications and Licensor may not undertake any combination clinical trial within the Territory and within the Field.

2.6. **Exclusivity** . During the Term, neither Party shall Develop beyond Phase 2 or Commercialize a product comprising a BTK inhibitor for use in the Field and in the Territory other than the Licensed Product (a “**Distracting Product**”); provided, however, that nothing in this Agreement shall in anyway prevent, impact, or otherwise affect either Party’s right to conduct clinical trials with any agents owned by third parties and to seek approval for combinations with approved agents, including approved BTK inhibitor .

2.7. **Acquisition of Distracting Product** . Notwithstanding the provisions of Section 2.6, if a Party or any of its Affiliates (such Party, the “**Distracted Party**”) acquires rights to Develop or Commercialize a Distracting Product in the Field and in the Territory as the result of a merger, acquisition (including by license) or combination with or of a Third Party other than a Change of Control (each, an “**Acquisition Transaction**”) and, on the date of the completion of such Acquisition Transaction, such Distracting Product is being researched, developed or commercialized and such activities would, but for the provisions of this Section 2.7, constitute a breach of Section 2.6, then the Distracted Party or such Affiliate will, within * (*) days after the completion of such Acquisition Transaction notify the other Party of such acquisition and either:

- (a) request that such Distracting Product be included in this Agreement on terms to be negotiated, in which case, the Parties will discuss the matter in good faith for a period of no less than * (*) days (or such longer period as may be agreed to by the Parties) and, if unable to reach agreement on the terms on which such Distracting Product would be included hereunder within such period, the Distracted Party will elect to take the action specified in either clause (b) or (c) below; *provided* that the time periods specified in such clauses will be tolled for so long as the Parties are engaged in discussion under this clause (a);
- (b) notify the other Party that the Distracted Party or its Affiliate will Divest its rights to such Distracting Product, in which case, within * (*) days after the completion of the Acquisition Transaction, the Distracted Party or its Affiliate will divest such Distracting Product; or
- (c) notify the other Party in writing that it is ceasing all such research, development and commercialization activities with respect to the Distracting Product, in which case, within * (*) days thereafter the Distracted Party and its Affiliates will cease all such activities.

During the discussion period under clause (a), prior to the time of divestiture pursuant to clause (b) or prior to the termination of activities pursuant to clause (c), as applicable, the Distracted Party and its Affiliates will use Commercially Reasonable Efforts to segregate all Development and Commercialization activities relating to the Distracting Product from Development and Commercialization with respect to the Licensed Product, including using Commercially Reasonable Efforts to ensure that (i) no personnel involved in performing the research, development or commercialization of such Distracting Product have access to non-public plans or information relating to the Development or Commercialization of the Licensed Product and (ii) no personnel involved in performing the Development or Commercialization of the Licensed Product have access to non-public plans or information relating to the Development or Commercialization of such Distracting Product.

2.8. **Change of Control** . If there is a Change of Control involving a Party (where such Party is the acquired entity), the obligations of Section 2.6 will not apply to any program or product that exists prior to the closing of such Change of Control and that is Controlled by the relevant acquirer or its Affiliates; *provided* that, at the acquired Party’s election to be made in writing prior to the closing of such Change of Control either (A) the license and rights granted to TGTX within this agreement will terminate effective upon the closing of such Change of Control and, to the extent requested by Licensor, TGTX will transfer and assign to the Licensor all clinical data, filings, contacts, including sublicense agreements, and regulatory approvals associated with the Licensed Product and Compound within a * (*) days or (B)(i) the acquired Party and the acquirer and its Affiliates will fulfill TGTX obligations under Diligence by TGTX of Section 3.1, (ii) the acquirer and its Affiliates establish and enforce internal processes, policies, procedures and systems to segregate information relating to any such program or product from any Confidential Information related to the Licensed Product, (iii) the acquirer and its Affiliates will not use, directly or indirectly, any Patent Rights, Know-How or Confidential Information of the acquired Party (including any Patent Rights, Know-How or Confidential Information licensed or acquired from the other Party under this Agreement) in connection with such program or product, and (iv) no personnel who were employees or consultants of the acquired Party or its Affiliates at the closing of such Change of Control will participate in the development or commercialization of such program.

2.9. **Grantback of Rights**. Subject to the terms and conditions of this Agreement, during the Term of this Agreement, TGTX hereby grants to Licensor, and Licensor hereby accepts, a non-exclusive, royalty-free license (with the right to sublicense through multiple tiers) under any intellectual property rights owned or controlled by TGTX, which relate specifically to improvements to Licensed Product (e.g., formulation, process optimization) solely as, and only to an extent that, such intellectual property rights are used by TGTX to Develop a Licensed Product in the Territory, for use by Licensor solely to research, Develop, manufacture, have manufactured, use, import and Commercialize and have Commercialized the Licensed Product, in all cases, solely outside the Territory. TGTX and its Affiliates grant no licenses or rights to use other than as expressly set forth herein. Likewise, if in the course of Licensor’s Development activities, Licensor creates intellectual property rights, which relate specifically to improvements to Licensed Product (e.g., formulation, process optimization), such intellectual property rights shall automatically be included under Licensor Technology and become subject to the rights and license granted to TGTX under the terms of this Agreement.

2.10. **Licensor Right of First Offer for Ublituximab * Rights** . Prior to agreeing to a license, sale or other disposition of the right to develop and commercialize ublituximab (TG-1101, an anti-CD20 mAb) within * , TGTX shall notify Licensor in writing of such pending agreement. For clarity, TGTX reserves the right to enter into such an agreement with an Affiliate of TGTX or a Third Party on any terms that TGTX determines to be acceptable.

ARTICLE III.

DEVELOPMENT, MANUFACTURE AND COMMERCIALIZATION

3.1. **Diligence by TGTX.** TGTX shall use Commercially Reasonable Efforts to Develop and to Commercialize at least one Licensed Product in the Territory and for the Field in each Major Market. In connection therewith, TGTX shall formulate and execute a development program to Develop one or more Licensed Products in the Territory and for the Field in each Major Market (the “**Development Program**”). TGTX shall deliver to Licensor a development plan (Development Plan) within * (*) days of the Effective Date detailing the actions to be undertaken by TGTX for such Development Program. In particular, under Commercially Reasonable Efforts and good faith, TGTX shall:

- a) File IND in the US by the end of *
- b) Initiate a * in the US by the end of *

TGTX may accomplish such milestones itself or through its Affiliate or Sublicensees. TGTX or its Affiliate shall have an option of satisfying its diligence obligations hereunder in * , * , or both, at its sole discretion, by (i) initiating discussions with one or more potential Sublicensees in either or both of those Major Market by the end of 2019, or (ii) pursuing a Development Program in the US, which is sufficient to satisfy regulatory requirements in * , * , or both.

3.2. **No Guaranty of Favorable Results .** Licensor does not warrant that the Development Program, TGTX’s other preclinical studies and evaluation (if any) and/or TGTX’s clinical studies (if any) will produce any particular results or any favorable results.

3.3. **TGTX Responsibility and Authority for Development .** TGTX shall have the exclusive right, and sole responsibility and decision-making authority, to research and Develop any Licensed Products in the Territory and for the Field and to conduct (either itself or through its Affiliate, agents, subcontractors and/or Sublicensees) all clinical trials and non-clinical studies TGTX believes appropriate to obtain Regulatory Approval for Licensed Products in the Territory and for the Field.

3.4. **Commercialization .** Subject to the terms of this Agreement, TGTX shall have the exclusive right, and sole responsibility and decision-making authority, to Commercialize any Licensed Products in the Territory and for the Field itself, through its Affiliate, or through one or more Sublicensees or other Third Parties selected by TGTX and shall have the sole decision-making authority and responsibility in all matters relating to the Commercialization of Licensed Products.

3.5. **Manufacturing .** TGTX shall have the exclusive right, and sole responsibility and decision-making authority, to manufacture, at the clinical and/or commercial stage, any Licensed Product itself or through one or more Sublicensees or vendors selected by TGTX.

3.6. **Reporting to Licensor .** TGTX shall, at least * , participate in a telephone or video conference with Licensor to provide to Licensor an oral update report (followed by transmittal to Licensor of written minutes) regarding the progress of all research and Development efforts toward Licensed Products and regarding the progress of Commercialization of Licensed Products. Additionally, TGTX shall share with Licensor a confidential copy of TGTX’s annual report to the FDA of its clinical development efforts in connection with Licensed Products.

3.7. **Right to Subcontract of TGTX .** Subject to any required compliance with Section 2.2, TGTX may exercise any of the rights or obligations that TGTX may have under this Agreement (including, without limitation, any of the rights licensed in Section 2.1 hereof) by Sublicensing, but any Sublicense granted or entered into by TGTX as contemplated by this Section 3.7 or any Sublicensee’s exercise or performance of all or any portion of the rights or obligations that TGTX may have under this Agreement shall not relieve TGTX from any of its obligations under this Agreement.

3.8. **Compliance with Law .** TGTX undertakes and agrees that the conduct of the Development of Licensed Products hereunder, the use of the Licensor Technology, and all Development, manufacture and Commercialization of Licensed Products by it and its Affiliates and Sublicensees shall comply in all material respects with all applicable international, federal, state and local laws, rules and regulations, including, but not limited to, environmental, occupational safety/health, safety and import/export restrictions, laws, rules and regulations.

3.9. **Costs and Expenses .** As between Licensor and TGTX, * shall be solely responsible for all costs and expenses related to Development, manufacture and Commercialization of the Licensed Products for the Field in the Territory, including without limitation costs and expenses associated with all preclinical activities and clinical trials, and all regulatory filings and proceedings relating to Licensed Product for the Field and in the Territory.

3.10. **Patent Marking .** TGTX agrees that with respect to each unit or package of Licensed Products sold in a given country, TGTX shall comply with the customary patent marking laws and practices of such country as to the applicable Licensor Patents.

3.11. **Trademarks .** As between Licensor and TGTX, * shall have the sole authority to select trademarks for Licensed Products and shall own all such trademarks in the Territory for the Field. Licensor does not grant TGTX the right to use any trademarks of Licensor or its Affiliates.

ARTICLE IV.

REGULATORY MATTERS

4.1. **Regulatory Filings.** TGTX (or its applicable Affiliate) shall (a) have the sole right and responsibility, at its sole cost and expense, for preparing and filing all Regulatory Approval applications required to Develop Licensed Products and Commercialize Licensed Products in the Territory in the Field in its own name; (b) all Regulatory Approvals for Licensed Products shall be solely owned by TGTX; and (c) TGTX shall have the sole right and responsibility for (i) maintaining all Regulatory Approvals and (ii) reporting to any Regulatory Authority within the Territory all Adverse Events and Serious Adverse Events related to any Licensed Product if and to the extent required by applicable Laws. To maximize market protection of any Licensed Product, TGTX may file for any orphan drug designations within the Field as appropriate within requisite timeframes prior to the submission of any Regulatory Approval application.

4.2. **Right of Reference.** Each Party hereby grants to the other Party, and at the request of the other Party will grant to the other Party's Sublicensees, a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous Law recognized outside of the United States), to, and a right to copy, access, and otherwise use, all information and data (including all chemistry, manufacturing and controls information as well as data made, collected or otherwise generated in the conduct of any clinical studies for Licensed Products) included in or used in support of any regulatory filing, Regulatory Approval, drug master file or other regulatory documentation (including orphan drug applications and designations) owned or controlled by such Party, and such Party shall provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) (or any successor or analogous Law outside of the United States). In addition, upon request of either Party (on behalf of itself or a Sublicensee), the other Party shall obtain and provide to the requesting Party certificates or other formal or official attestations concerning the regulatory status of the Licensed Products (*e.g.* , Certificates of Free Sale, Certificates for Export, Certificates to Foreign Governments). Notwithstanding anything to the contrary in this Agreement, neither Party shall withdraw or inactivate any regulatory filing that the other Party references or otherwise uses pursuant to this Section 4.2

4.3. **Communications with Authorities.** TGTX (or one of its Affiliates or Sublicensees) shall be responsible for and act as the sole point of contact for communications with Regulatory Authorities in the Territory in connection with the Development, Commercialization, and manufacturing of Licensed Products for uses in the Field. At the request of TGTX, Licensor shall make available to TGTX, free of charge, a qualified representative or representatives who shall, together with the representatives of TGTX, prepare for and/or participate in and contribute to meetings with the Regulatory Authorities with respect to regulatory matters relating solely to the Licensor Technology. TGTX shall pay for any out-of-pocket expenses incurred by Licensor in assisting TGTX under this Section 4.2.

4.4. **Adverse Event Reporting.** TGTX agrees to comply with any and all Laws that are applicable to it as of the Effective Date and thereafter during the Term in connection with Licensed Product safety data collection and reporting (and, if applicable, recalls). The Parties hereby agree to report to each other all Adverse Events and/or Serious Adverse Events with respect to the Licensed Product (whether occurring in any Clinical Trial conducted with regard to the Licensed Product or in connection with the Commercialization of the Licensed Product in any country), within timeframes consistent with its reporting obligations under applicable Laws and in any event, if either Party is actively conducting a Clinical Trial under its own IND or Commercializing the Licensed Product under its own Regulatory Approval, then the other Party shall report such events no later than * (*) business days for a Serious Adverse Event, and quarterly for Adverse Events, which report shall, in each case, include the circumstances and nature of such Serious Adverse Event or Adverse Event as required for reporting under applicable Laws. In addition, to the extent requested by either Party, the other Party shall promptly provide to the requesting Party any other information or materials that the requesting Party may require to provide to any Regulatory Authority with respect to any such Adverse Event or Serious Adverse Event. All disclosures made under this Section 4.3 shall be deemed Confidential Information of the disclosing Party; provided, that, the Party receiving such disclosures may, upon written notice to the disclosing Party, report the occurrence, circumstances and nature of such Adverse Event and/or Serious Adverse Event to any Regulatory Authority solely insofar as such reporting is required to comply with applicable Laws.

4.5. **Clinical Development Coordination and Governance.** In the spirit of a productive, mutually beneficial alliance management, TGTX and Hengrui agree to share their clinical development plans and results related to hematology malignancy within their respective territories with each other at least * via a Joint Steering Committee (“**JSC**”). The Parties shall establish the JSC within * (*) calendar days after the Effective Date. The JSC shall perform the following functions:

(a) Review and discuss the overall strategy for developing, manufacturing and commercializing the Licensed Products in the Territory. For clarity, * shall have final authority over clinical development to be conducted by it or its Sublicensee(s) within the Field and in the Territory;

(b) Review and discuss any proposed hematology malignancy studies to be conducted with the Licensed Products to prevent or manage logistical confusion or conflict and potential adverse impact on the other Parties’ efforts to Develop and Commercialize the Licensed Products in its territory. For clarity, * shall have final authority over clinical development in its territories;

(c) Facilitate the exchange of information between the Parties under this Agreement regarding the development, manufacturing and commercialization of the Licensed Products and establishing procedures for the efficient sharing of information and materials and Know-How reasonably necessary or useful for the development, manufacture or commercialization of the Licensed Products;

(d) Review and discuss the contents of all submissions to regulatory authorities and governmental authorities relating to the use of the Licensed Products within the Field;

(e) Resolve any disputes or other matters referred to the JSC **JSC** . TGTX and Hengrui shall each designate * (*) representatives of appropriate seniority and experience to serve on the JSC by written notice to the other party. Replacements and substitutes should be specified by written notice. The JSC should be chaired by a representative of *, who is responsible for (i) calling meetings, (ii) preparing and issuing minutes within * weeks thereafter, and (iii) preparing and circulating an agenda for the upcoming meeting, provided that the chairperson shall consider including any agenda items proposed by either TGTX or Hengrui no less than * prior to the next scheduled JSC meeting. Meeting can take the form of in-person meeting or teleconference.

4.6. **Ex-Territory Sales.** Subject to applicable Law, _neither Party shall engage in any advertising or promotional activities relating to any Licensed Product directed primarily to customers or other buyers or users of such Licensed Product located outside its territory or accept orders for Licensed Products from or sell Licensed Products into such other Party’s territory for its own account, and if a Party receives any order for any Licensed Product in the other Party’s territory, it shall refer such orders to the other Party.

4.7. **Export Monitoring.** Each Party and its Sublicensees will use Commercially Reasonable Efforts to monitor and prevent exports of Licensed Products from its own territory for Commercialization in the other Party’s territory using methods permitted under applicable Law that are commonly used in the industry for such purpose (if any), and shall promptly inform the other Party of any such exports of Licensed Products from its territory, and any actions taken to prevent such exports. Each Party agrees to take reasonable actions requested in writing by the other Party that are consistent with Law to prevent exports of Licensed Products from its territory for Commercialization in the other Party’s territory.

ARTICLE V.

Financial Provisions

5.1. Upfront Fee . TGTX becomes obligated on the Effective Date to pay Licensor a one-time, non-refundable payment of * dollars (\$ *) in partial consideration of the rights granted to TGTX under this Agreement. Such payment shall be payable in * (*) equal installments of * dollars (\$ *), the first of which is due within * (*) business days of the Effective Date, and the second of which is due * (*) days after the Effective Date. TGTX shall have the right to elect to pay such payments up to * % in Shares, with any remainder of such milestone payment not paid in Shares payable in cash. The number of Shares payable shall be equal to a fraction where the numerator is the amount of such milestone elected to be paid in Shares and the denominator is the Share Value calculated as * volume weighted average price (VWAP) prior to the Effective Date for both the first and the second installments. For payment made in Shares, TGTX shall deliver to Licensor a stock certificate representing the portion of such payment elected to be paid in Shares. Such stock certificate shall be unlegended except for a standard securities-law restrictive legend. For clarity, non-publicly traded Shares cannot be used hereunder for payment of the upfront fee, or milestone or royalty payments.

5.2. Development and Commercial Milestone Payments. As further partial consideration for Licensor’s grant of the rights and licenses to TGTX hereunder, TGTX shall pay to Licensor the following one-time, non-refundable milestone payments (a) with regard to each Licensed Product to achieve the respective milestone events in Section 5.2(a), assuming that both * and * move forward in development, and (b) upon achievement of each respective approval and sales milestone event in Section 5.2(b) by TGTX or its Affiliates or Sublicensees. TGTX shall promptly, but in no event later than * (*) days following TGTX or its Affiliate’s receipt of actual knowledge of each achievement of a milestone event, notify Licensor in writing of the achievement of such milestone event and, unless otherwise specified, shall pay the relevant milestone payment within * (*) days thereafter. TGTX shall have the right to elect to pay all clinical development milestones payments in this Section 5.2 up to * % in Shares, with the remainder of such milestone payment to be paid in cash. The number of Shares payable shall be equal to a fraction where the numerator is the amount of such milestone elected to be paid in Shares and the denominator is the Share Value calculated as * (*) day VWAP prior to the date such milestone is achieved. For payments made in Shares, TGTX shall deliver to Licensor a stock certificate representing the Shares on the date such notice of achievement is delivered or within * (*) business days thereafter; such stock certificate shall be unlegended except for a standard securities-law restrictive legend.

(a) Clinical Development Payments .

Table with 2 columns: Milestone Event, Milestone Payment. It contains four rows of placeholder text for milestones, each with a dollar sign and asterisks.

For the purposes of this provision, “ Superiority ” will have been demonstrated if, *. TGTX shall have the right to elect to pay all milestones payments in this section 5.2(a) up to * % in Shares, with the remainder of such milestone payment to be paid in cash. The number of Shares payable shall be equal to a fraction where the numerator is the amount of such milestone elected to be paid in Shares and the denominator is the Share Value calculated as * (*) day VWAP prior to the date such notice of achievement is delivered. For payments made in Shares, TGTX shall deliver to Licensor a stock certificate representing the Shares on the date such notice of achievement is delivered or within * (*) business days thereafter; such stock certificate shall be unlegended except for a standard securities-law restrictive legend.

(b) Combination Development Payments. As further partial consideration for Licensor’s grant of the rights and licenses to TGTX hereunder, TGTX shall pay to Licensor a one-time, non-refundable milestone payment of * dollars (\$ *) * or *, in the case that a * is unnecessary, evaluating the combination of a Licensed Product with any and each molecule other than ublituximab (TG-1101) and/or umbralisib (TGR-1202). For sake of clarity, a milestone payment will be payable only once for each new agent evaluated in combination with a * provided such combination is evaluated in a * or *, in the case that a * is unnecessary. Further, at any time prior to the initiation of the first * for a *, TGTX may elect to pay to Licensor a one-time, non-refundable milestone payment of * (\$ *) (the “ All Combinations Payment”) to expand the Field in the Territory to include the use of the Licensed Products to treat all hematologic malignancy indications in the Territory. In the event TGTX elects to make the All Combinations Payment, TGTX will owe no further payments under this Section 5.2(b) for any combination Clinical Trial undertaken of any Phase with any agent. Hengrui shall have the right to elect to receive all milestones payments in this Section 5.2(b) up to * % in Shares, with the remainder of such milestone payment to be paid in cash. The number of Shares payable shall be equal to a fraction where the numerator is the amount of such milestone elected to be paid in Shares and the denominator is the Share Value calculated as * VWAP of the date such notice of achievement is delivered. For payments made in Shares, TGTX shall deliver to Licensor a stock certificate representing the Shares on the date such notice of achievement is delivered or within * (*) business days thereafter; such stock certificate shall be unlegended except for a standard securities-law restrictive legend.

hereunder an amount equal to * percent (* %) of any royalty paid by TGTX to such Third Party.

(e) The royalty rates specified in Section 5.4(a) shall be reduced to * percent (* %) on a country-by-country basis if and when one or more Generic Products achieve * percent market share (by prescription units) in such country, relative to all approved monotherapy products containing Compound indicated for hematologic malignancy. For purposes of this Section, "Generic Product" means a pharmaceutical product that contains the Compound as monotherapy and that is sold in the same country as a Licensed Product by a Third Party that is not a Sublicensee, one of TGTX's Affiliates, or a Third Party that is otherwise acting on TGTX's behalf in conducting such sales.

(f) The deduction in the foregoing clause (d) shall be limited in its cumulative application so that no royalty payment hereunder shall be reduced by more than * percent (* %) .

5.5. **Timing of Payment.** Royalties/payments in the nature of royalties payable under Section 5.4 shall be payable on actual Net Sales and shall accrue at the time provided therefor by US GAAP. Royalty/payment in the nature of royalties obligations that have accrued during a particular Calendar Quarter shall be paid, on a Calendar Quarter basis, within * (*) days after the end of each Calendar Quarter during which the royalty/payment in the nature of royalties obligation accrued; provided that within * (*) days after the conclusion of each Calendar Year TGTX shall provide notice to Licensor of any adjustments necessary to account for any royalties/payment in the nature of royalties which were overpaid or underpaid for such prior Calendar Year's Calendar Quarters, and the Parties shall promptly true-up based on such adjustments, provided however, the lapse of such * -day period shall not impact the right of TGTX to credit any over-payments discovered during an audit against future royalties due under Section 5.7 hereof.

5.6. **Royalty (Etc.) Reports and Records Retention.** Within * (*) days after the end of each Calendar Quarter during which Licensed Products have been sold, TGTX shall deliver to Licensor, together with the applicable royalty/payment in the nature of royalties payment due, a written report, on a Licensed Product-by-Licensed Product and country-by-country basis, of (a) gross invoiced (or otherwise charged) amounts of sales, by TGTX and its Affiliates and Sublicensees, of Licensed Products subject to royalty payments for such Calendar Quarter, (b) amounts deducted by category (following the definition of Net Sales) from such gross invoiced amounts to calculate Net Sales, (c) Net Sales subject to royalty or royalty/payment in the nature of royalties payments for such Calendar Quarter and Calendar Year to date and (d) the corresponding royalty or royalty/payment in the nature of royalties. Such report shall be deemed "Confidential Information" of TGTX subject to the obligations of Article VII of this Agreement. For * years after each sale of a Licensed Product (whether Covered or not), TGTX shall keep (and shall ensure that its Affiliates and Sublicensees shall keep) complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty or royalty/payment in the nature of royalties calculations hereunder.

5.7. **Audits .**

(a) From the First Commercial Sale (of the first Licensed Product to have a First Commercial Sale) until * Calendar Year after the conclusion of the final Royalty Term, upon the written request of Licensor, and not more than * in each * , TGTX shall permit, and shall cause its Affiliates and Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by Licensor (who has not been engaged by Licensor to provide services in any other capacity at any time during the * period before such selection), and reasonably acceptable to TGTX or such Affiliate or Sublicensee, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of TGTX and its Affiliates or Sublicensees to verify the accuracy of the royalty and payment in the nature of royalties reports and payments under this Article V. Such review may cover: (i) the records for sales made in any Calendar Year ending not more than * (*) years before the date of such request, and (ii) only those periods that have not been subject to a prior audit.

(b) If such accounting firm concludes that additional royalties and/or royalties/payment in the nature of royalties were owed during such period, TGTX shall pay the additional royalties and/or royalties/payment in the nature of royalties within * (*) days after the date such public accounting firm delivers to TGTX such accounting firm's written report. If such accounting firm concludes that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods or at TGTX's request, shall be reimbursed to TGTX within * (*) days after the date such public accounting firm delivers such report to TGTX. If TGTX disagrees with such calculation, TGTX may contest such calculation in writing – at which point the parties will work in good faith to submit the matter to a mediator for resolution. If the parties are unable to reach an agreement via mediation, then TGTX or Licensor may initiate a court action to seek to recover the additional payment or to increase the amount of credit or reimbursement. Licensor shall pay for the cost of any audit by Licensor, unless TGTX has underpaid Licensor by five percent (* %) or more for a specific royalty period, in which case TGTX shall pay for the reasonable costs of audit.

(c) Each Party shall treat all information that it receives under this Section 5.7 in accordance with the confidentiality provisions of Article VII of this Agreement, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the audited Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for a Party to enforce its rights under the Agreement.

5.8. **Mode of Payment and Currency .** All payments to Licensor under this Agreement, except for payments made in Shares, whether or not in respect of Net Sales or milestone events, shall be made by deposit of US Dollars in the requisite amount to such bank account as Licensor may from time to time designate by advance written notice to TGTX. Conversion of sales or expenses recorded in local currencies to Dollars will be performed in a manner consistent with TGTX's normal practices used to prepare its audited financial statements for external reporting purposes, provided that such practices use a widely accepted source of published exchange rates. Based on the resulting Net Sales in US Dollars, the then applicable royalties/payment in the nature of royalties shall be calculated.

5.9. **Late Payments .** If a Party does not receive payment of any sum due to it on or before the due date therefor, simple interest shall thereafter accrue on the sum due to such Party from the due date until the date of payment at a rate equal to the lesser of (a) US dollar one-month LIBOR, or its official successor, plus * basis points, or (b) the maximum rate permissible under applicable Law. Accrual and payment of interest shall not be deemed to excuse or cure breaches of contract arising from late payment or nonpayment.

5.10. **Taxes.** All amounts due hereunder exclude all applicable sales, use, and other taxes and duties, and TGTX shall be responsible for payment of all such taxes (other than taxes based on Licensor's income) and duties and any related penalties and interest, arising from the payment of amounts due under this Agreement. The Parties agree to cooperate with one another and use Commercially Reasonable Efforts to avoid or reduce tax withholding or similar obligations in respect of royalties, payments in the nature of royalties, milestone payments, and other payments made by TGTX to Licensor under this Agreement. To the extent TGTX is required to withhold taxes on any payment to Licensor, TGTX shall pay the amounts of such taxes to the proper governmental authority in a timely manner and promptly transmit to Licensor official receipts issued by the appropriate taxing authority and/or an official tax certificate, or such other evidence as Licensor may reasonably request, to establish that such taxes have been paid. Licensor shall provide TGTX any tax forms that may be reasonably necessary in order for TGTX to not withhold tax or to withhold tax at a reduced rate under an applicable bilateral income tax treaty. Licensor shall use Commercially Reasonable Efforts to provide any such tax forms to TGTX at least * (*) days before the due date for any payment for which Licensor desires that TGTX apply a reduced withholding rate. Each Party shall provide the others with reasonable assistance to enable the recovery, as permitted by applicable law, of withholding taxes, value added taxes, or similar obligations resulting from payments made under this Agreement, such recovery to be for the benefit of the Party bearing such withholding tax or value added tax. Licensor shall indemnify and hold TGTX harmless from and against any penalties, interest or other tax liability arising from any failure by TGTX (at the express request of Licensor) to withhold or by reduction (at the express request of Licensor) in its withholding.

ARTICLE VI.

Inventions and Patents

6.1. Patent Prosecution and Maintenance.

(a) **Licensor Patents** . Licensor shall have the first right to file, prosecute and maintain Licensor Patents in Licensor's name and at Licensor's expense. TGTX and Licensor agree to consult on a reasonable list of countries in which Licensor shall file, prosecute and maintain Licensor Patents.

(b) **Liaising.** Licensor shall keep TGTX promptly and regularly informed of the course of the filing and prosecution of Licensor Patents or related proceedings (e.g. interferences, oppositions, reexaminations, reissues, revocations or nullifications) in a timely manner, and to take into consideration the advice and recommendations of TGTX, however, Licensor shall make all decisions relating thereto.

(c) **Election Not to File/Prosecute/Maintain Licensor Patents** . TGTX acknowledges and agrees that Licensor shall not be required to file, prosecute or maintain Patent Rights for the Licensor Patents, provided, however, if Licensor decides to not pursue or maintain any such Patent Rights then Licensor shall provide TGTX with at least * (*) days' notice before discontinuing the filing, prosecution or maintenance of such Patent Rights so that TGTX may assume responsibility for such activities in Licensor's name but at TGTX's expense. In such event, TGTX will no longer owe any royalty obligation on account of such (country-level) Patent Rights assumed by TGTX.

6.2. **Certification under Drug Price Competition and Patent Restoration Act.** Each of Licensor and TGTX shall immediately give written notice to the other of any certification of which they become aware filed pursuant to 21 U.S.C. Section 355(b)(2)(A) (or any amendment or successor statute thereto) claiming that any Licensor Patents covering a Compound or a Licensed Product, or the manufacture or use of each of the foregoing, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale in the US of a Licensed Product by a Third Party.

6.3. **Listing of Patents.** TGTX shall have the sole right to determine which of the Licensor Patents, if any, shall be listed for inclusion in the Approved Drug Products with Therapeutic Equivalence Evaluations publication pursuant to 21 U.S.C. Section 355, or any successor Law in the United States, together with any comparable Laws in any other country in the Territory and pertaining to uses within the Field. Licensor will co-operate with TGTX to list any of said Licensor Patents.

6.4. Enforcement of Patents.

(a) **Notice.** If either Licensor or TGTX believes that a Licensor Patent is being infringed in the Field, or that Licensor Know-How has been misappropriated in the Field, by a Third Party or if a Third Party claims that any Licensor Patent is invalid or unenforceable, the Party possessing such knowledge or belief shall notify the other and provide it with details of such infringement, misappropriation or claim that are known by such Party.

(b) **Right to Bring an Action for Licensor's Patents.** If such infringement, misappropriation or claim is in one or more of the Major Markets in respect of Licensor Patents, Licensor shall have the right to attempt to resolve such infringement, misappropriation or claim, including by filing an infringement suit, defending against or bringing a declaratory judgment action as to such claim or taking other similar action (each, "initiation" of an "Action") and (subject to Section 6.5(e)) to compromise or settle such infringement or claim. * may, in its sole discretion and at its expense, join in any such Action and in such case shall reasonably cooperate with Licensor. If Licensor does not intend to initiate an Action, Licensor shall promptly inform TGTX. If Licensor does not initiate an Action with respect to such an infringement or claim within * (*) days following notice thereof, * shall have the right to attempt to resolve such infringement, misappropriation or claim, including by initiating an Action, and (subject to Section 6.5(e)) to compromise or settle such infringement, misappropriation or claim. At TGTX's request, Licensor shall immediately provide TGTX with all relevant documentation (as may be requested by TGTX) evidencing that TGTX is validly empowered by the Licensor to initiate an Action. Licensor shall be under the obligation to join TGTX in its Action if TGTX determines that this is necessary to demonstrate "standing to sue." The Party initiating such Action shall have the sole and exclusive right to select counsel for any suit initiated by it pursuant to this Section 6.5. If a Party initiates an Action but then elects not to pursue the Action, the other Party shall have the right (but not the obligation) to take over the Action, in which case the second Party shall be deemed to have been the initiating Party.

(c) **Costs of an Action.** Subject to the respective indemnity obligations of the Parties set forth in Article IX and subject to Section 6.5(f), each Party involved in an Action under Section 6.5(b) shall pay its own costs and expenses incurred in connection with such Action.

(d) **Settlement.** No Party shall settle or otherwise compromise (or resolve by consent to the entry of judgment upon) any Action by admitting that any Licensor Patent is to any extent invalid or unenforceable, or that any Licensor Know-How is not protected or has not been misappropriated, without the other Party's prior written consent, and, in the case of Licensor, Licensor may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) an Action in a way that adversely affects or would be reasonably expected to adversely affect any of TGTX's rights or benefits hereunder with respect to any Licensor Technology or any Licensed Product, without TGTX's prior written consent.

(e) **Reasonable Assistance.** Each Party (if it is not the Party enforcing or defending Licensor's Patent Rights) shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees and consultants available, subject to the other Party's reimbursement of any reasonable out-of-pocket expenses incurred on an on-going basis by the non-enforcing or non-defending Party in providing such assistance.

(f) **Distribution of Amounts Recovered.** Any amounts recovered by the Party initiating an Action pursuant to this Section 6.5, whether by settlement or judgment, shall be allocated in the following order: (i) to reimburse the Party initiating such Action for any costs incurred; (ii) to reimburse the Party not initiating such Action for its costs incurred in such Action, if it joins (as opposed to taking over) such Action; and (iii) the remaining amount of such recovery shall (A) if Licensor initiated the Action, the remainder shall be allocated to TGTX and the portion thereof attributable to "lost sales" shall be deemed to be Net Sales for the Calendar Quarter in which the amount is actually received by TGTX and TGTX shall pay to Licensor a royalty on such portion based on the royalty rates set forth in Section 5.4(a), and the portion thereof not attributable to "lost sales" shall be allocated to * % to Licensor and * % to TGTX (B) if Licensor failed to initiate and TGTX initiated the Action, the remainder shall be allocated to TGTX and the portion thereof attributable to "lost sales" shall be deemed to be Net Sales for the Calendar Quarter in which the amount is actually received by TGTX and TGTX shall pay to Licensor a royalty on such portion based on the royalty rates set forth in Section 5.4(a), and the portion thereof not attributable to "lost sales" shall be allocated to TGTX.

6.5. Third Party Actions Claiming Infringement .

(a) **Notice.** If either Licensor or TGTX becomes aware of any Third Party Action, such Party shall promptly notify the other of all details regarding such claim or action that is reasonably available to such Party.

(b) **Right to Defend.** TGTX shall have the right, at its sole expense, but not the obligation, to defend a Third Party Action described in Section 6.6(a) and (subject to Section 6.6(f)) to compromise or settle such Third Party Action. If TGTX declines or fails to assert its intention to defend such Third Party Action within * (*) days of receipt/sending of notice under Section 6.6(a), then Licensor shall have the right, at its sole expense, to defend such Third Party Action and (subject to Section 6.6(f)) to compromise or settle such Third Party Action. The Party defending such Third Party Action shall have the sole and exclusive right to select counsel for such Third Party Action.

(c) **Consultation.** The Party defending a Third Party Action pursuant to Section 6.6(b) shall be the "Controlling Party". The Controlling Party shall consult with the non-Controlling Party, pursuant to an appropriate joint defense or common interest agreement, on all material aspects of the defense. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. The non-Controlling Party will be entitled to join the Third Party Action and be represented by independent counsel of its own choice at its own expense.

(d) **Appeal** . In the event that a judgment in a Third Party Action is entered against either Party and an appeal is available, the Controlling Party shall have the first right, but not the obligation, to file such appeal. In the event the Controlling Party does not desire to file such an appeal, it will promptly, in a reasonable time period (i.e., with sufficient time for the non-Controlling Party to take whatever action may be necessary) before the date on which such right to appeal will lapse or otherwise diminish, permit the non-Controlling Party to pursue such appeal at such non-Controlling Party's own cost and expense. If applicable Law requires the other Party's involvement in an appeal, the other Party shall be a nominal party in the appeal and shall provide reasonable cooperation to such Party at such Party's expense.

(e) **Costs of an Action** . Subject to the respective indemnity obligations of the Parties set forth in Article IX, the Controlling Party shall pay all costs and expenses associated with such Third Party Action other than the expenses of the other Party if the other Party elects to join such Third Party Action (as provided in the last sentence of Section 6.6(c)).

(f) **No Settlement without Consent**. Neither Licensor or TGTX shall settle or otherwise compromise (or resolve by consent to the entry of judgment upon) any Third Party Action by admitting that any Licensor Patent is to any extent invalid or unenforceable or that any Licensed Product, or its use, Development, importation, manufacture or sale infringes such Third Party's intellectual property rights, in each case without the other Party's prior written consent, and, in the case of Licensor, Licensor may not settle or otherwise compromise (or resolve by consent to the entry of judgment upon) a Third Party Action in a way that adversely affects or would be reasonably expected to adversely affect TGTX's rights and benefits hereunder with respect to any Licensor Technology or any Licensed Product, without TGTX's prior written consent.

ARTICLE VII.

CONFIDENTIALITY

7.1. **Definitions** . The Parties recognize that disclosures of Confidential Information between them before the Effective Date were subject to the Confidential Disclosure Agreement between them dated February 22, 2016. TGTX and Licensor each recognizes that during the Term, it may be necessary for a Party (the "**Disclosing Party**") to provide Confidential Information (as defined herein) to another Party (the "**Receiving Party**") that is highly valuable, the disclosure of which would be highly prejudicial to such Party. The disclosure and use of Confidential Information shall be governed by the provisions of this Article VII. Neither TGTX nor Licensor shall use the other's Confidential Information except as expressly permitted in this Agreement. For purposes of this Agreement, "**Confidential Information**" means all information (including information relating to the business, operations and products of a Party or any of its Affiliates) disclosed by the Disclosing Party to the Receiving Party and which reasonably ought to have been understood to be confidential and/or non-public information at the time disclosed to the Receiving Party, or which is designated in writing by the Disclosing Party as "Confidential" (or equivalent), or which when disclosed orally to the Receiving Party is declared to be confidential by the Disclosing Party and is so confirmed in a writing delivered to the Receiving Party within * (*) days after such oral disclosure, including but not limited to any technical information, Know-How, trade secrets, or inventions (whether patentable or not), that such Party discloses to another Party under this Agreement, or otherwise becomes known to another Party by virtue of or that relates to this Agreement.

7.2. **Obligation** . Licensor and TGTX agree that they will disclose the other Party's Confidential Information to its own (or its respective Affiliate's, or with respect to TGTX, its Sublicensees') officers, employees, consultants and agents only if and to the extent necessary to carry out their respective responsibilities under this Agreement or in accordance with the exercise of their rights under this Agreement, and such disclosure shall be limited to the maximum extent possible consistent with such responsibilities and rights. Except as set forth in the foregoing sentence, no Party shall disclose Confidential Information of the other to any Third Party without the other's prior written consent. In all events, however, any and all disclosure to a Third Party (or to any such Affiliate or Sublicensee) shall be pursuant to the terms of a non-disclosure/nonuse agreement no less restrictive than this Article VII. The Party which disclosed Confidential Information of the other to any Third Party (or to any such Affiliate or Sublicensee) shall be responsible and liable for any disclosure or use by such Third Party, Affiliate or Sublicensee (or its disclosees) which would have violated this Agreement if committed by the Party itself. No Party shall use Confidential Information of the other except as expressly allowed by and for the purposes of this Agreement. Each Party shall take such action to preserve the confidentiality of each other's Confidential Information as it would customarily take to preserve the confidentiality of its own Confidential Information (but in no event less than a reasonable standard of care). Upon expiration or termination of this Agreement, each Party, upon the other's request, shall return or destroy (at Disclosing Party's discretion) all the Confidential Information disclosed to the other Party pursuant to this Agreement, including all copies and extracts of documents, within * (*) days after the request, except for one archival copy (and such electronic copies that exist as part of the Party's computer systems, network storage systems and electronic backup systems) of such materials solely to be able to monitor its obligations that survive under this Agreement.

7.3. **Exceptions** . The non-use and non-disclosure obligations set forth in this Article VII shall not apply to any Confidential Information, or portion thereof, that the Receiving Party can demonstrate by competent evidence:

- (a) at the time of disclosure is in the public domain;
- (b) after disclosure, becomes part of the public domain, by publication or otherwise, through no fault of the Receiving Party or its disclosees;
- (c) is made available to the Receiving Party by an independent Third Party without obligation of confidentiality; provided, however, that to the Receiving Party's knowledge, such information was not obtained by said Third Party, directly or indirectly, from the Disclosing Party hereunder; or

In addition, the Receiving Party may disclose information that is required to be disclosed by law, by a valid order of a court or by order or regulation of a governmental agency including but not limited to, regulations of the SEC or in the course of arbitration or litigation; provided, however, that in all cases the Receiving Party shall give the other party prompt notice of the pending disclosure and make a reasonable effort to obtain, or to assist the Disclosing Party in obtaining, a protective order or confidential-treatment order preventing or limiting (to the greatest possible extent and for the longest possible period) the disclosure and/or requiring that the Confidential Information so disclosed be used only for the purposes for which the law or regulation required, or for which the order was issued.

7.4. **Third Party Information** . The Parties acknowledge that the defined term "Confidential Information" shall include not only a Disclosing Party's own Confidential Information but also Confidential Information of a Third Party which is in the possession of a Disclosing Party. TGTX and Licensor agree not to disclose to the other any Confidential Information of a Third Party which is in the possession of such Party, unless the other has given an express prior written consent (which specifies the owner of such Confidential Information) to receive such particular Confidential Information.

7.5. **Press Releases and Disclosure**. The Parties acknowledge that each Party may desire or be required to issue a press release or to make other public disclosures relating to the execution of this Agreement and its terms. The Parties agree to consult with each other reasonably and in good faith with respect to the text and timing of such a press release or other public disclosure prior to the issuance thereof, provided that a Party may not unreasonably withhold consent to such release, and that either Party may issue such press release as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations. (Provided, that no Party shall use the trademark or logo of the other Party, its Affiliates or their respective employee(s) in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, except as may be required by Law or required by the rules of an applicable * or * national securities exchange or except with the prior express written permission of such other Party, such permission not to be unreasonably withheld.) Notwithstanding the above, once a public disclosure has been made, either Party shall be free to disclose to third parties any information contained in said public disclosure, without further pre-review.

ARTICLE VIII.

REPRESENTATIONS, WARRANTIES AND COVENANTS

8.1. **Representations and Warranties.** (a) TGTX represents and warrants to Licensor, and (b) Licensor represents and warrants to TGTX, in each case as of the Effective Date:

- (a) Such Party is a corporation duly organized and validly existing under the Laws of the jurisdiction of its incorporation;
 - (b) Such Party has all right, power and authority to enter into this Agreement, and to perform its obligations under this Agreement;
 - (c) Such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
 - (d) This Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other Laws relating to or affecting creditors' rights generally and by general equitable principles;
 - (e) To the best of such party's knowledge, the execution, delivery and performance of this Agreement by such Party does not and will not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound;
 - (f) To the best of such party's actual knowledge, all consents, approvals and authorizations from all governmental authorities or other Third Parties required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and the execution, delivery and performance of this Agreement by such Party does not and will not violate any Law of any Governmental Body having authority over such Party;
 - (g) No person or entity has or will have, as a result of the execution and delivery of or as a result of the transactions contemplated by this Agreement, any right, interest or valid claim against or upon such Party for any commission, fee or other compensation as a finder or broker because of any act by such Party or its Affiliates, agents or Sublicensees; and
 - (h) To the best of such party's actual knowledge, no agreement between it and any Third Party is in conflict with the rights granted to any other party pursuant to this Agreement.
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8.2. **Additional Representations and Warranties of Licensor.** Licensor represents and warrants to TGTX as of the Effective Date that:

- (a) No consent by any Third Party or Governmental Body is required with respect to the execution and delivery of this Agreement by Licensor or the consummation by Licensor of the transactions contemplated hereby;
- (b) To the best of Licensor's actual knowledge, no valid claims have been asserted or threatened by any Person (i) challenging the validity, effective status, or ownership of Licensor Technology, and/or (ii) to the effect that the use, reproduction, modification, manufacturing, distribution, licensing, sublicensing, sale or any other exercise of rights in any of Licensor Technology infringes or will infringe on any intellectual property right of any Person; and no such claims have been asserted or are threatened;
- (c) The Licensor Patents are subsisting and are not the subject of any litigation procedure, discovery process, interference, reissue, reexamination, opposition, appeal proceedings or any other legal dispute;
- (d) The Licensor Patents constitute all Patent Rights owned or Controlled by Licensor that pertain directly and particularly to the research, Development, manufacture, use and Commercialization of the Licensed Products in the Field and in the Territory as currently envisioned;
- (e) To the best of Licensor's actual knowledge, no Third Party has filed, pursued or maintained or threatened in writing to file, pursue or maintain any claim, lawsuit, charge, complaint or other action alleging that any Licensor Technology is invalid or unenforceable; and
- (f) Licensor has ceased its research and development activities to discover compounds under a BTK Inhibitor Program (as defined herein) and will not initiate research and development activities aimed at discovering compounds under a BTK Inhibitor Program prior to the * (*) anniversary of the Effective Date. For the purposes of this provision, a " **BTK Inhibitor Program** " is one that seeks to discover a selective compound that *, and which may be suitable for treating hematological malignancies and/or autoimmune indications.

8.3. **Disclaimer** . Notwithstanding the representations and warranties set forth in this Article VIII, TGTX acknowledges and accepts the risks inherent in attempting to Develop and Commercialize any pharmaceutical product. There is no implied representation that the Compounds can be successfully Developed or Commercialized. The representations and warranties set forth in this Article VIII are provided in lieu of, and **EACH PARTY HEREBY DISCLAIMS** , all other warranties, express and implied, relating to the subject matter of this Agreement, the Licensor Technology, the Compounds and/or the Licensed Products, including but not limited to **the implied warranties of merchantability and fitness for a particular purpose, title and non-infringement of Third Party rights** . Each Party's representations and warranties under this Agreement are solely for the benefit of the other Party and may be asserted only by the other Party and not by any Affiliate, Sublicensee or any customer of the other Party, its Affiliates or Sublicensees. Each Party, its Affiliates and Sublicensees shall be solely responsible for all representations and warranties that it, its Affiliates or Sublicensees make to any customer, Affiliates or Sublicensees .

ARTICLE IX.

INDEMNIFICATION; LIMITATION OF LIABILITY; INSURANCE

9.1. **Indemnification by TGTX.** TGTX shall indemnify, defend and hold Licensor and its Affiliates, and each of their respective employees, officers, directors and agents (the " **Licensor Indemnitees** ") harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys' fees and expenses) to the extent arising out of any Third Party claim, demand, action or other proceeding (each, a " **Claim** ") related to (a) TGTX's performance of its obligations or exercise (by it or its Affiliates or Sublicensees) of its rights under this Agreement, including without limitation, product liability claims; or (b) breach by TGTX of its representations and warranties set forth in Article VIII; provided, however, that TGTX's obligations pursuant to this Section 9.1 shall not apply (x) to the extent such claims or suits result from the gross negligence or willful misconduct of any of the Licensor Indemnitees, or (y) with respect to claims or suits arising out of breach by Licensor of this Agreement, including without limitation of its or their representations and warranties set forth in Article VIII.

9.2. **Indemnification by Licensor.** Licensor shall indemnify, defend and hold TGTX and its Affiliates and each of their respective agents, employees, officers and directors (the " **TGTX Indemnitees** ") harmless from and against any and all actions, judgments, settlements, liabilities, damages, penalties, fines, losses, costs and expenses (including reasonable attorneys' fees and expenses) to the extent arising out of any and all Claims related to (a) Licensor's performance of its obligations or exercise (by it or its Affiliates) of its or their rights under this Agreement; or (b) breach by Licensor of its representations and warranties set forth in Article VIII; provided, however, that Licensor's obligations pursuant to this Section 9.2 shall not apply (x) to the extent that such claims or suits result from the gross negligence or willful misconduct of any of the TGTX Indemnitees or (y) with respect to claims or suits arising out of a breach by TGTX of this Agreement, including without limitation its representations and warranties set forth in Article VIII.

9.3. **No Consequential, Etc., Damages** . EXCEPT FOR DAMAGES FOR WHICH A PARTY IS RESPONSIBLE PURSUANT TO ITS INDEMNIFICATION OBLIGATIONS SET FORTH IN ARTICLE IX, EACH PARTY SPECIFICALLY DISCLAIMS ALL LIABILITY FOR AND SHALL IN NO EVENT BE LIABLE TO ANY OTHER PARTY OR TO ANY OTHER PARTY'S AFFILIATES FOR ANY INCIDENTAL, SPECIAL, INDIRECT OR CONSEQUENTIAL DAMAGES, EXPENSES, LOST PROFITS, LOST SAVINGS, INTERRUPTIONS OF BUSINESS OR OTHER DAMAGES OF ANY KIND OR CHARACTER WHATSOEVER ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE DEVELOPMENT PROGRAM OR THE LICENSED TECHNOLOGY OR RESULTING FROM THE MANUFACTURE, HANDLING, MARKETING, SALE, DISTRIBUTION OR USE OF LICENSED PRODUCTS, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY WAS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

9.4. **Procedure** .

(a) The Party or other Person intending to claim indemnification under this Article IX (an "**Indemnified Party**") shall promptly notify the opposed Party (the "**Indemnifying Party**") of any Claim in respect of which the Indemnified Party intends to claim such indemnification (provided, that no delay or deficiency on the part of the Indemnified Party in so notifying the Indemnifying Party will relieve the Indemnifying Party of any liability or obligation under this Agreement except to the extent the Indemnifying Party has suffered actual prejudice directly caused by the delay or other deficiency), and the Indemnifying Party shall assume the defense thereof (with counsel selected by the Indemnifying Party and reasonably satisfactory to the Indemnified Party) whether or not such Claim is rightfully brought; provided, however, that an Indemnified Party shall have the right to retain its own counsel and to participate in the defense thereof, with the fees and expenses to be paid by the Indemnified Party unless the Indemnifying Party does not assume the defense or unless a representation of both the Indemnified Party and the Indemnifying Party by the same counsel would be inappropriate due to the actual or potential differing interests between them, in which case the reasonable fees and expenses of counsel retained by the Indemnified Party shall be paid by the Indemnifying Party. (Provided, that in no event shall the Indemnifying Party be required to pay for more than one separate counsel no matter the number or circumstances of all Indemnified Parties.)

(b) If the Indemnifying Party shall fail to timely assume the defense of and reasonably defend such Claim, the Indemnified Party shall have the right to retain or assume control of such defense and the Indemnifying Party shall pay (as incurred and on demand) the fees and expenses of counsel retained by the Indemnified Party.

(c) The Indemnifying Party shall not be liable for the indemnification of any Claim settled (or resolved by consent to the entry of judgment) without the written consent of the Indemnifying Party. Also, if the Indemnifying Party shall control the defense of any such Claim, the Indemnifying Party shall have the right to settle such Claim; provided, that the Indemnifying Party shall obtain the prior written consent (which shall not be unreasonably withheld or delayed) of the Indemnified Party before entering into any settlement of (or resolving by consent to the entry of judgment upon) such Claim unless (i) there is no finding or admission of any violation of law or any violation of the rights of any person by an Indemnified Party, no requirement that the Indemnified Party admit negligence, fault or culpability, and no adverse effect on any other claims that may be made by or against the Indemnified Party and (ii) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party and such settlement does not require the Indemnified Party to take (or refrain from taking) any action.

(d) The Indemnified Party, and its employees and agents, shall cooperate fully with the Indemnifying Party and its legal representatives in the investigations of any Claim.

(e) Regardless of who controls the defense, each Party hereto shall reasonably cooperate in the defense as may be requested.

9.5. **Expenses** . As the Parties intend complete indemnification, all costs and expenses of enforcing any provision of this Article IX shall also be reimbursed by the Indemnifying Party..

9.6. **Limitation of Liability** . EACH PARTY SHALL HAVE NO REMEDY, AND EACH PARTY SHALL HAVE NO LIABILITY, OTHER THAN AS EXPRESSLY SET FORTH IN THIS AGREEMENT. EXCEPT WITH RESPECT TO THE INDEMNIFICATION SPECIFICALLY PROVIDED IN ARTICLE IX OR CLAIMS FOR NON-PAYMENT. NO ACTION, REGARDLESS OF FORM, ARISING OUT OF OR RELATED TO THIS AGREEMENT MAY BE BROUGHT BY EITHER PARTY MORE THAN * YEARS AFTER SUCH PARTY HAS KNOWLEDGE OF THE OCCURRENCE THAT GAVE RISE TO THE CAUSE OF ACTION OR AFTER EXPIRATION OF THE APPLICABLE STATUTORY LIMITATIONS PERIOD, WHICHEVER IS SOONER.

9.7. **Insurance**. During the Term and for three years thereafter, TGTX shall obtain and maintain, at its own cost and expense, product liability insurance in amounts, that are reasonable and customary in the United States pharmaceutical and biotechnology industry for companies engaged in comparable activities, with Licensor identified as an additional named insured. It is understood and agreed that this insurance shall not be construed to limit TGTX's liability with respect to its indemnification obligations hereunder. TGTX shall upon request provide to Licensor upon request a certificate evidencing the insurance TGTX is required to obtain and keep in force under this Section 9.7.

ARTICLE X.

TERM AND TERMINATION

10.1. **Term and Expiration.** The term of this Agreement shall commence on the Effective Date and, unless earlier terminated as provided in this Article X, shall continue in full force and effect, on a country-by-country and Licensed Product-by-Licensed Product basis until the Royalty Term in such country with respect to such Licensed Product expires, at which time this Agreement shall expire in its entirety with respect to such Licensed Product in such country. (The “**Term**” shall mean the period from the Effective Date until the earlier of termination of this Agreement as provided in this Article X or expiration of this Agreement upon the expiration of the last-to-expire Royalty Term.) The Parties confirm that subject to the foregoing sentence, this Agreement shall not be terminated or invalidated by any future determination that any or all of the Licensor Patents have expired or been invalidated.

10.2. **Termination upon Material Breach.** If a Party breaches any of its material obligations under this Agreement, the Party not in default may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and, if desired, stating its intention to terminate this Agreement if such breach is not cured. If such breach is not capable of being cured, or is capable of being cured but nonetheless has not within * (*) days after the receipt of such notice been cured, then the Party not in default shall (in addition to and not in lieu of all other available rights and remedies) be entitled to at its option either (a) terminate this Agreement immediately by written notice to the other Party, or (b) continue this Agreement in full force and effect and seek any legal or equitable remedies that the non-breaching Party may have. In case of a breach of an obligation to pay money, which obligation to pay is not disputed in good faith, the cure period shall be * (*) days instead of * (*) days. The Parties agree that any failure by TGTX to pay when due * percent (* %) of such portion of any amount of money owing from TGTX to Licensor as is not disputed in good faith by TGTX (subject to the * (*) day cure period) shall conclusively be deemed to constitute a “material” breach. Notwithstanding the foregoing provisions, in the event of a good-faith dispute as to whether any alleged breach is in fact a breach, termination under this Section 10.2 in respect of such alleged breach shall not take effect unless and until (y) such dispute is resolved (according to the procedure described in 11.2) in favor of the Party alleging the breach or (z) the breaching Party’s denial that the alleged breach is in fact a breach ceases to be in good faith.

10.3. **Termination for Bankruptcy.** Licensor may terminate this Agreement immediately upon written notice to TGTX in the event that TGTX has a petition in bankruptcy filed against it that is not dismissed within * (*) days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors. If TGTX has before such filing or such assignment entered into a written Sublicense which complies with Section 2.2, then the Sublicensee thereunder shall have the right to, by but only by delivering to Licensor within * (*) days after such termination a written election to do so and a written assumption of all of TGTX’s past and future obligations, liabilities and duties under this Agreement, convert its Sublicense into a direct of license from Licensor of the same technology, for the same field and for the same territory, as had been provided for in the Sublicense and otherwise on the same terms and conditions as are set forth in this Agreement as if such Sublicensee were TGTX hereunder. TGTX may terminate this Agreement immediately upon written notice to Licensor in the event that Licensor has a petition in bankruptcy filed against it that is not dismissed within * (*) days of such filing, files a petition in bankruptcy, or makes an assignment for the benefit of creditors.

10.4. **TGTX Termination.** TGTX may terminate this Agreement at any time for any reason upon * (*) days’ prior written notice to Licensor, provided that (i) TGTX and Hengrui attempted to resolve any issues in good faith, and (ii) TGTX and Hengrui agree to consult with each other with regard to public communications related to the termination of agreement. If TGTX has the right to terminate this Agreement pursuant to Section 10.2 for an uncured material breach by the Licensor, TGTX shall, within * (*) days after the end of the applicable cure period, elect in writing to either (i) exercise such right of termination with the effects set forth in Section 10.5 or (ii) waive such right of termination and any other right to pursue damages or other remedies in connection with such uncured material breach and maintain this Agreement in full force and effect provided that the then applicable royalty rates specified in Section 5.4, after taking into account all clauses thereunder, shall be and remain reduced by a further * % for the remainder of the term of this Agreement despite the * percent (* %) floor set by clause (f) in Section 5.4.

10.5. **Effects of Termination/Expiration.**

(a) Articles I (Definitions), VII (Confidentiality), IX (Indemnification; Limitation of Liability; Insurance) and XI (Miscellaneous Provisions) and Sections 5.6 (Royalty Reports and Records Retention), 5.7 (Audits), 5.9 (Late Payments), 5.10 (Taxes) and 10.5 (Effects of Termination/Expiration) hereof shall survive the expiration or termination of this Agreement for any reason.

(b) Termination or expiration of this Agreement shall not relieve the Parties of any liability that accrued hereunder before the effective date of such termination or expiration. In addition, termination or expiration of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party’s right to obtain performance of any obligation.

(c) Upon termination of this Agreement pursuant to Section 10.2 for an uncured material breach by TGTX or pursuant to Section 10.3, all licenses granted to TGTX hereunder shall terminate. If TGTX has before termination entered into a written Sublicense which complies with Section 2.2, then, if the Sublicensee thereunder is not then in breach of such Sublicense, the Sublicensee shall have the right to convert its Sublicense into a direct license from Licensor of the same technology, for the same field and for the same territory, as had been provided for in the Sublicense and otherwise on the same terms and conditions as are set forth in this Agreement as if such Sublicensee were TGTX hereunder. Such right of conversion shall be exercisable by Sublicensee by delivering to Licensor within * (*) days after such termination a written election to so convert. In addition, upon any termination of this Agreement pursuant to Section 10.2 for an uncured material breach by TGTX or pursuant to Section 10.3, TGTX and Licensor agree that TGTX shall: (i) assign to Licensor all Regulatory Approvals, applications for Regulatory Approvals and all drug master files and drug dossiers in the Territory, (ii) transfer to Licensor all correspondence and files pertaining to such Regulatory Approvals, applications for Regulatory Approvals and all drug master files and drug dossiers in the Territory, (iii) transfer to Licensor all data generated by TGTX, its Affiliates and Sublicensees in connection with the Development of the Licensed Products (in written or electronic form as Licensor may direct), (iv) grant, and hereby does grant, to Licensor a non-exclusive, fully-paid, perpetual, irrevocable license, with the right to sublicense through multiple tiers, to all intellectual property developed by TGTX, its Affiliates and Sublicensees in connection with the Development of the Licensed Products, and (v) upon the request of Licensor, assign to Licensor any contracts related to the Development, manufacture or Commercialization of the Licensed Products in the Territory under the following scenarios and conditions: (i) if at the time of termination TGTX has met the diligence milestone set forth under Section 3.1(a), the Licensor shall pay TGTX a royalty amounting to * % of Net Sales in the Territory on an annual basis until TGTX recovers * % of the cost of development of the Licensed Products; (ii) if at the time of termination TGTX has met the diligence milestone set forth under Section 3.1(b), the Licensor shall pay TGTX a royalty amounting to * % of * in the Territory on an annual basis until TGTX recovers * % of the cost of development of the Licensed Products; or (iii) if at the time of termination TGTX has dosed at least * in a Phase 3 clinical study or Pivotal Trial, the Licensor shall pay TGTX a royalty amounting to * % of Net Sales in the Territory on an annual basis until TGTX recovers * % of the cost of development of the Licensed Products. The cost of development of the Licensed Products shall include all costs and expenses incurred by TGTX as of the time of termination, as calculated in good faith by TGTX, subject to Licensor's right to an audit. Net Sales shall have the meaning set forth under Section 1.31, except it shall apply to sales of the License Products by Licensor, its Affiliates, or any sublicensees. Licensor can, in its sole discretion, choose not to assume Regulatory Approvals and filings, data, or intellectual property generated by TGTX. In such event, TGTX will not be entitled to any cost of development recovery.

ARTICLE XI.

MISCELLANEOUS PROVISIONS

11.1. **Relationship of the Parties.** Nothing in this Agreement is intended or shall be deemed to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties. No Party shall have any right or authority to commit or legally bind any other Party in any way whatsoever including, without limitation, the making of any agreement, representation or warranty and each Party agrees to not purport to do so.

11.2. **Disputes .**

(a) The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights or obligations hereunder. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Section 11.2 to resolve any controversy or claim arising out of, relating to or in connection with any provision of this Agreement, if and when a dispute arises under this Agreement. With respect to all disputes arising between the Parties, including, without limitation, any alleged failure to perform, or breach, of this Agreement, or any issue relating to the interpretation or application of this Agreement, if the Parties are unable to resolve such dispute within * (*) days after such dispute is first identified by either Party in writing to the other, the Parties shall refer such dispute to the Chief Executive Officers and/or Chairman for each Party for attempted resolution by good faith negotiations within * (*) days after such notice is received. If the senior executive officers designated by the Parties are not able to resolve such dispute within such * (*) day period, either Party may submit such dispute in accordance with Section 11.2(b).

(b) **Arbitration.** Any dispute arising out of or relating to this Agreement, including the breach, termination or validity thereof, which has not been resolved by the executives of the Parties as provided herein will be finally resolved by arbitration in accordance with the CPR Rules for Non-Administered Arbitration then currently in effect, by three arbitrators of whom each party will appoint one in accordance with the 'screened' appointment procedure provided in Rule 5.4, provided, however, that if one party fails to participate in either the negotiation or mediation as agreed herein, the other party can commence arbitration prior to the expiration of the time periods set forth above. The arbitration will be governed by the Federal Arbitration Act, 9 U.S.C. §§1 et seq., and judgment upon the award rendered by the arbitrator(s) may be entered by any court having jurisdiction thereof. The place of arbitration will be New York, NY. The award may be made a judgment by any court of competent jurisdiction pursuant to the New York Convention, 9 U.S.C. § 201 et seq., and for this purpose the Party against whom the award is made will agree to the personal jurisdiction of the court in which recognition is sought and will not raise any argument of forum non conveniens.

(c) Notwithstanding anything to the contrary in this Article 11, either Party may seek injunctive relief in any court in any jurisdiction where appropriate.

11.3. **Assignment.**

(a) Any assignment not in accordance with this Section 11.2 shall be void.

(b) No assignment shall relieve the assigning Party of any of its responsibilities or obligations hereunder.

(c) Neither Party may transfer or assign its rights or licenses or delegate its obligations under this Agreement, in whole or in part, by operation of law or otherwise, to any Third Party without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; *provided that*, notwithstanding the foregoing, either Party may assign its rights or licenses and/or delegate its obligations under this Agreement to an Affiliate or to a successor to all or substantially all of its assets, whether by way of merger, sale of all or substantially all of its assets, sale of stock or otherwise, without the other Party's prior written consent. As a condition to any permitted assignment hereunder, the assignee must expressly assume, in a writing delivered to the other Party (and in a form reasonably acceptable to the other Party) all of such assigning Party's obligations under this Agreement, whether arising before, at or after the assignment.

11.4. **Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

11.5. **Force Majeure.** No Party shall be liable to any other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement (other than obligations for the payment of money) for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other like reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable, and the time for performance shall be extended for a number of days equal to the duration of the force majeure.

11.6. **Entire Agreement of the Parties; Amendments.** This Agreement and the Schedules hereto constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior or contemporaneous negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter (provided, that any and all previous nondisclosure/nonuse obligations are not superseded and remain in full force and effect in addition to the nondisclosure/nonuse provisions hereof). Each Party acknowledges that it has not relied, in deciding whether to enter into this Agreement on this Agreement's expressly stated terms and conditions, on any representations, warranties, agreements, commitments or promises which are not expressly set forth within this Agreement. No modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.

11.7. **Governing Law.** This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, excluding application of any conflict of laws principles.

11.8. **Notices and Deliveries .** Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if and only if delivered in person, by email or by express courier service to the Party to which it is directed at its physical or email address shown below or such other physical or email address as such Party shall have last given by such written notice to the other Party.

If to TGTX, addressed to:

TG Therapeutics, Inc.
2 Gansevoort St., 9th Floor
New York, NY 10014
Attention: Michael S. Weiss, Executive Chairman, and Chief Executive Officer
Email: *

With a copy to:

Foley & Lardner LLP
3000 K St., NW, Suite 600
Washington, DC 20007
U.S.A.
Attention: Ybet Villacorta *

If to Licensor, addressed to:

Jiangsu Hengrui Medicine Co.
No.7 Kunlunshan Road, Lianyungang Eco & Tech Development Zone,
Jiangsu Province, China 222047
Attention: Lianshan Zhang, Ph.D., President of Global R&D
Paul Lu, Ph.D., Global Business Development
Email: *

With a copy to :

Goodwin Procter
100 Northern Avenue
Boston, MA 02210
U.S.A.
Attention : Christopher Denn *

11.9. **Waiver.** No waiver of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of the waiving Party. A waiver by a Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof.

11.10. **Rights and Remedies are Cumulative .** Except to the extent expressly set forth herein, all rights, remedies, undertakings, obligations and agreements contained in or available upon violation of this Agreement shall be cumulative and none of them shall be in limitation of any other remedy or right authorized in law or in equity, or any undertaking, obligation or agreement of the applicable Party.

11.11. **Severability.** This Agreement is severable. When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable Law, but if any provision of this Agreement is held to be to any extent prohibited by or invalid under applicable Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement (or of such provision). The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.

11.12. **Third Party Beneficiaries .** Except for the rights of Indemnified Parties pursuant to Article IX hereof and the rights of Sublicensees set forth in Sections 10.2 and 10.4(c), the terms and provisions of this Agreement are intended solely for the benefit of each Party hereto and their respective successors or permitted assigns and it is not the intention of the Parties to confer third-party beneficiary rights upon any other person, including without limitation Sublicensees. The enforcement of any obligation of Licensor under this Agreement shall only be pursued by TGTX or such Indemnified Party, and not Sublicensees (except as set forth in Sections 10.2 and 10.4(c)).

11.13. **No Implied License.** No right or license is granted to TGTX hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by Licensor or its Affiliates, except by an express license granted hereunder. No right or license is granted to Licensor hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by TGTX or its Affiliates, except by an express license granted hereunder.

11.14. **No Right of Set-Off.** Except as expressly provided in Section 5.7(b) of this Agreement, TGTX shall not have a right to set-off any royalties, milestones or other amount due to Licensor under this Agreement against any damages incurred by TGTX for a breach by Licensor of this Agreement.

11.15. **Equitable Relief .** Each Party recognizes that the covenants and agreements herein and their continued performance as set forth in this Agreement are necessary and critical to protect the legitimate interests of the other Party, that the other Party would not have entered into this Agreement in the absence of such covenants and agreements and the assurance of continued performance as set forth in this Agreement, and that a Party's breach or threatened breach of such covenants and agreements may cause the opposed Party irreparable harm and significant injury, the amount of which will be extremely difficult to estimate and ascertain, thus potentially making any remedy at law or in damages inadequate. Therefore, each Party agrees that an opposed Party shall be entitled to seek specific performance, an order restraining any breach or threatened breach of Article VII and all other provisions of this Agreement, and any other equitable relief (including but not limited to temporary, preliminary and/or permanent injunctive relief). This right shall be in addition to and not exclusive of any other remedy available to such other Party at law or in equity.

11.16. **Interpretation.** The language used in this Agreement is the language chosen by the Parties to express their mutual intent, and no provision of this Agreement shall be interpreted for or against a Party because that Party or its attorney drafted the provision.

11.17. **Use of Name.** Neither Party shall be permitted to use the name, or any proprietary trademarks, trade names, trade dress or logos ("**Marks**") of the other Party, or its Affiliates, or its Sublicensees, in any publicity, promotion, news release or public disclosure relating to this Agreement or its subject matter, without the prior express written permission of the other Party. **Counterparts.** This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (.pdf) copy of this Agreement, including the signature pages, will be deemed an original.

[*the remainder of this page has been left blank intentionally*]

IN WITNESS WHEREOF, the Parties have caused this License Agreement to be executed and delivered by their respective duly authorized officers as of the day and year first above written.

JIANGSU HENGRUI MEDICINE CO.

By: /s/ Piaoyang Sun

Name: Piaoyang Sun

Title: Chairman

TG THERAPEUTICS, INC.

By: /s/ Michael S. Weiss

Name: Michael S. Weiss

Title: Executive Chairman, President and Chief Executive Officer

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

Exhibit A

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Schedule 1

Compounds

* (*)

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* (*)

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CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

Schedule 2

Licensors Know-How includes, but is not limited to, the information disclosed in the documents available in a data room, which is accessible via the following link:

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