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, 2018.

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	**36-3898269**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2 Gansevoort St., 9th Floor **New York, New York**	**10014**
(Address of principal executive offices)	(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	The Nasdaq Capital Market
(Title of Class)	(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, if any, every Interactive Data File required to be submitted 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 ☐	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 $917,401,544 as of June 30, 2018, based on the closing sale price of such stock as reported on the NASDAQ Capital Market.

There were 83,870,546 shares of the registrant's common stock, $0.001 par value, outstanding as of February 15, 2019.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2019 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, 2018

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This Annual Report on Form 10-K contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would" or the negative of these words or other comparable terminology, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- The initiation, timing, progress and results of our pre-clinical studies and clinic trials, including, without limitation, our on-going UNITY-CLL Phase 3 clinical trial, ULTIMATE MS I and II Phase 3 clinical trial and UNITY-NHL Phase 2b clinical trial
- Our ability to advance drug candidates into, and successfully complete, clinical trials
- the timing or likelihood of regulatory filings and approvals
- the commercialization of our drug candidates, if approved
- the pricing and reimbursement of our drug candidates, if approved
- the implementation of our business model, strategic plans for our business, drug candidates and technology
- the scope of protection we are able to establish and maintain for intellectual property rights covering our drug candidates and technologies
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing
- our ability to maintain and establish collaborations and enter into strategic arrangements, if desired
- our financial performance and cash burn management
- developments relating to our competitors and our industry

Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or enter into.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the captions "Business" and "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. In some cases, you can identify forward-looking statements by words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "seek," "should," "target," "will," "would" or the negative of these words or other comparable terminology, although not all forward-looking statements contain these identifying words.. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety 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.

- 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.

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. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make or enter into.

You should read this Annual Report on Form 10-K and the documents that we have filed as exhibits to this Annual Report on Form 10-K completely and with the understanding that our actual future results, performance or achievements may be materially different from what we expect. Any forward-looking statements in this Annual Report on Form 10-K reflect our current views with respect to future events or to our future financial performance and involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. 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 obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

This Annual Report on Form 10-K also contains estimates, projections and other information concerning our industry, our business and the markets for certain diseases, including data regarding the estimated size of those markets, and the incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources.

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 dedicated to developing and delivering medicines for patients with B-cell mediated diseases, including Chronic Lymphocytic Leukemia (CLL), non-Hodgkin's Lymphoma (NHL) and Multiple Sclerosis (MS). We have developed a robust B-cell directed research and development (R&D) platform for identification of key B-cell pathways of interest and rapid clinical testing. Currently, we have five B-cell targeted drug candidates in clinical development, with the lead two therapies, ublituximab (TG-1101) and umbralisib (TGR-1202), in pivotal trials for CLL, NHL and MS. Ublituximab is a novel anti-CD20 monoclonal antibody (mAb) that has been glycoengineered for enhanced potency over first generation antibodies. Umbralisib is an oral, once daily inhibitor of PI3K delta. Umbralisib also uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K delta inhibitors. When used together in combination therapy, ublituximab and umbralisib are referred to as ("U2"), or "1303". Additionally, in early clinical development we have an anti-PD-L1 monoclonal antibody referred to as TG-1501, an oral Bruton's Tyrosine Kinase ("BTK") inhibitor referred to as TG-1701, and an anti-CD47/CD19 bispecific antibody referred to as TG-1801.

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.

Current Phase 3 or Registration Directed Clinical Trial Highlights:

- **Umbralisib Single Agent Cohorts of UNITY-NHL Phase 2b Trial:** UNITY-NHL is a Phase 2b registration-directed clinical trial evaluating umbralisib monotherapy and the U2 combination in previously treated patients with NHL. Currently the follicular lymphoma (FL)/ small lymphocytic leukemia (SLL) and marginal zone lymphoma (MZL) single agent umbralisib cohorts of this trial have been fully enrolled. In February 2019, we announced that the MZL cohort met the primary endpoint of Overall Response Rate (ORR) as determined by Independent Review Committee (IRC) for all treated patients (n=69). The results met the Company's target guidance of 40-50% ORR. Interim safety and efficacy data from the MZL cohort will be presented in an oral presentation at the upcoming American Association for Cancer Research (AACR) annual meeting on April 1, 2019. Previously, in January 2019, the U.S. Food and Drug Administration (FDA) granted Breakthrough Therapy Designation for umbralisib for the treatment of adult patients with MZL who have received at least one prior anti-CD20 regimen, the same population currently being evaluated in the UNITY-NHL MZL cohort. We plan to discuss the results with the FDA regarding a potential new drug application (NDA) filing for accelerated approval. For the FL/SLL cohort, we are targeting topline data readout in second half-2019.

- **Umbralisib plus Ublituximab UNITY-CLL Phase 3 Trial:** UNITY-CLL is a global Phase 3 randomized controlled clinical trial comparing the U2 combination, to an active control arm of obinutuzumab plus chlorambucil in patients with both treatment naïve and relapsed or refractory CLL. The primary endpoint for this study is to demonstrate superiority in Progression Free Survival (PFS) for the U2 combination over the control arm to support the submission for full approval of the U2 combination in CLL. We cannot predict precisely when the PFS readout will occur, however our current estimate is PFS readout may be available by year-end 2019 or first half 2020. This trial is being conducted under Special Protocol Assessment (SPA) with FDA.

- **Ublituximab Single Agent ULTIMATE I & II Trials:** ULTIMATE I and ULTIMATE II are two independent Phase 3 trials. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing ublituximab to teriflunomide in subjects with relapsing forms of Multiple Sclerosis (RMS). The primary endpoint for each study is Annualized Relapse Rate (ARR) following 96 weeks of treatment over the control arm to support the submission for full approval of ublituximab in RMS. We are targeting topline data from this trial in mid-2020. These trials are being conducted under an SPA with the FDA.

CORPORATE INFORMATION

We were incorporated in Delaware in 1993. Our executive offices are located at 2 Gansevoort Street, 9th Floor, New York, New York 10014. Our telephone number is 1-212-554-4484, and our e-mail address is info@tgtxinc.com.

We maintain a website with the address www.tgtherapeutics.com and maintain a twitter account. We make available free of charge through our corporate website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, as well as 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 or our twitter account as a part of, nor incorporating either 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 corporate 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.

STRATEGY

Our Strategy

Our goal is to become a fully-integrated, B-cell targeted biopharmaceutical company capable of delivering multi-drug combination treatments for patients with diseases resulting from cancerous or aberrant B-cells. The key tenets of our strategy include the following:

- Successfully completing our current Phase 3 and registration-directed trials for umbralisib and ublituximab, including, UNITY-CLL, UNITY-NHL, and the ULTIMATE Phase 3 Program in MS;
- Rapidly gaining regulatory approval for umbralisib in NHL, umbralisib plus ublituximab ("U2") in CLL, and ublituximab in MS;
- Efficiently and effectively prepare for commercial launch and build commercial capability to ensure, when approved, broad access to patients for the approved indications for umbralisib and ublituximab;
- Rapidly add ublituximab to umbralisib in NHL to advance U2 in NHL;
- Advance TG-1501, TG-1701, and TG-1801 through clinical development and define potential regulatory paths for these drug candidates both as single agents and in combination with umbralisib, ublituximab, and/or U2;
- Build upon the MS program to expand ublituximab into additional MS indications and other autoimmune diseases;
- Continue to expand our pipeline with mechanisms of importance to B-cell mediated diseases;
- Evaluate potential strategic collaborations to maximize the value of our programs and B-cell directed platform; and
- Maintain our "patient first" culture as we grow our business.

Our Approach and Platform

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

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

- An internal team with a deep understanding of B-cell diseases and the treatment of patients; and
- An external clinical trials network composed of over 200 community and academic clinical trial sites globally, specializing in B-cell diseases.

B-CELL DISEASES OVERVIEW

B-cell mediated diseases comprise a constellation of disorders that result from cancerous B-cells or aberrant B-cells. In the case of cancerous B-cells, the most common forms of B-cell cancers or B-cell malignancies are non-Hodgkin's Lymphoma (NHL) and Chronic Lymphocytic Leukemia (CLL). In the case of aberrant B-cells, many autoimmune diseases are believed to result from aberrant B-cell activity, including, Multiple Sclerosis (MS), Rheumatoid Arthritis (RA), and Lupus.

The Company's current clinical programs are focused on CLL, MZL, FL, and RMS.

Marginal Zone Lymphoma Overview

MZL comprises a group of indolent (slow growing) B-cell non-Hodgkin lymphomas (NHLs) that begin forming in the marginal zone of lymphoid tissue. With an annual incidence of approximately 7,500 newly diagnosed patients in the United States, MZL is the third most common B-cell NHL, accounting for approximately eight percent of all NHL cases. MZL consists of three different subtypes: extranodal MZL of the mucosal-associated lymphoid tissue (MALT), nodal marginal zone lymphoma (NMZL), and splenic marginal zone lymphoma (SMZL).

Follicular Lymphoma Overview

FL is typically a slow-growing or indolent form of NHL which accounts for 20 to 30 percent of all NHL cases, with a prevalence of approximately 245,000 and an incidence of approximately 31,000 in the US, Japan, and 5 major EU markets. FL is usually not considered to be curable, but more of a chronic disease, with patients living for many years.

Chronic Lymphocytic Leukemia Overview

CLL is the most common type of adult leukemia, and in 2019, it is estimated there will be more than 20,000 new cases of CLL diagnosed in the United States. Although signs of CLL may disappear for a period of time after initial treatment, the disease is considered incurable and many people will require additional treatment due to the return of cancerous cells.

Relapsing Forms of Multiple Sclerosis Overview

Relapsing forms of multiple sclerosis (RMS), a chronic demyelinating disease of the central nervous system (CNS) include people with relapsing-remitting multiple sclerosis (RRMS) and people with secondary progressive multiple sclerosis (SPMS) who continue to experience relapses. RRMS is the most common form of multiple sclerosis (MS) and is characterized by episodes of new or worsening signs or symptoms (relapses) followed by periods of recovery. It is estimated that nearly 1,000,000 people are living with MS in the United States and approximately 85 percent are initially diagnosed with RRMS. The majority of people who are diagnosed with RRMS will eventually transition to SPMS, in which they experience steadily worsening disability over time.

OUR PRODUCTS UNDER DEVELOPMENT

We have leveraged our B-cell platform to develop a robust drug pipeline of both targeted orally available, potent and selective small molecule kinase inhibitors and intravenously delivered "off-the-shelf" immunotherapies that leverage the patient's own immune system to fight cancer. We currently own worldwide development and commercial rights, subject to certain limited geographical restrictions, to all of our pre-clinical and clinical programs. The following table summarizes our most advanced drug candidates as of February 28, 2019.

Clinical Drug Candidate (molecular target)	Initial Target Disease	Stage of Development (pivotal study)
Ublituximab (anti-CD20/mAb)	Chronic Lymphocytic Leukemia	Phase 3 trial (UNITY-CLL)
	Multiple Sclerosis	Phase 3 trials (ULTIMATE I and II)
Umbralisib (PI3K delta inhibitor)	Chronic Lymphocytic Leukemia	Phase 3 trial (UNITY-CLL)
	Marginal Zone Lymphoma	Phase 2b trial (UNITY-NHL)
	Follicular Lymphoma	Phase 2b trial (UNITY-NHL)
TG-1501 (anti-PDL1)	B-cell Cancers	Phase 1 trial
TG-1701 (BTK inhibitor)	B-cell Cancers	Phase 1 trial
TG-1801 (anti-CD47/CD19)	B-cell Cancers	Phase 1 trial

Ublituximab Overview

Ublituximab (also referred to as TG-1101) is a glycoengineered anti-CD20 monoclonal antibody that targets a unique epitope on the CD20 antigen found on the surface of B-lymphocytes. We hold exclusive worldwide rights to develop and commercialize ublituximab for all indications, except for the territories of France and Belgium for which an option to commercialize has been retained by LFB Biotechnologies, and South Korea and Southeast Asia which were licensed by us to Ildong Pharmaceutical Ltd 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). Ublituximab 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 rituximab the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2018 of approximately $7 billion.

ADCC is a mechanism that is dependent on interactions between the Fc region of the antibody and the FccR receptors on immune system effector cells, most notably the Fc−gammaR (CD16) receptor found on NK cells. These interactions trigger cells to release cytotoxic molecules and proteases resulting in B-cell death. Ublituximab is a next generation, type I chimeric IgG1 monoclonal antibody with a glycoengineered Fc region designed specifically to induce higher ADCC activity in comparison to rituximab. In pre-clinical (non-human) experiments, ublituximab has demonstrated an ability to enhance ADCC by >50x over rituximab, resulting in enhanced potency.

Umbralisib Overview

Umbralisib (also referred to as TGR-1202) is an oral, once daily inhibitor of PI3K delta inhibitor with nanomolar potency to the delta isoform and high selectivity over the alpha, beta, and gamma isoforms. Umbralisib also uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K-delta inhibitors. Umbralisib has demonstrated activity in preclinical models of hematologic malignancies and *in vitro* on primary cells from patients with hematologic malignancies. 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 isoform is strongly expressed in cells of hematopoietic origin, and often implicated in B-cell related lymphomas.

Additionally, 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 umbralisib with the proteasome inhibitor carfilzomib and the unique effects of the combination to silence c-Myc in various preclinical lymphoma and myeloma models. Importantly, the manuscript for the first time reports on umbralisib's unique complimentary mechanism of inhibiting the protein kinase casein kinase-1 epsilon (CK1e), which may contribute to what we believe is a differentiated safety profile of umbralisib over first generation PI3K delta inhibitors by supporting T regulatory cells, a part of the immune system necessary to protect against autoimmune mediated toxicities.

Early Clinical Development of Ublituximab and Umbralisib

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

Two single-agent, dose-escalation, Phase I studies were undertaken with ublituximab to establish an optimal dose in patients with NHL and CLL. The first was a two part first-in-human Phase I clinical trial completed in France in which ublituximab was evaluated in relapsed or refractory CLL. In 2012 a second single-agent Phase I study was undertaken in the US 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." In July 2014, this trial completed enrollment of 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 rituximab or a rituximab 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. In both Phase 1 studies, single agent ublituximab was deemed well tolerated by treating investigators and displayed promising clinical activity in relapsed and refractory patients.

Single Agent Ublituximab (TG-1101) in Relapsing Forms of Multiple Sclerosis

In May 2016, we commenced our first study of ublituximab in patients with relapsing forms of multiple sclerosis (RMS), 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," was led by Edward Fox, MD, PhD, Director of the Multiple Sclerosis Clinic of Central Texas and Clinical Associate Professor at the University of Texas Dell Medical School in Austin, TX. The primary objective of the study was to determine the optimal dosing regimen for ublituximab 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 were also evaluated.

In October 2018, final data from this Phase 2 study were presented at the 34th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) meeting in Berlin, Germany. The presentation included final data on all 48 patients enrolled in the study through 48 weeks of treatment. Ublituximab was well tolerated across all patients including those receiving rapid infusions, as low as a one hour for the 450mg dose currently being studied in the Phase 3 ULTIMATE program and no study drug related discontinuations occurred. Median B cell depletion was >99% at the primary analysis point of Week 4 (n=48) and maintained at Week 24 and Week 48. Ublituximab also completely eliminated all (100%) T1 Gd-enhancing lesions at Week 24 and maintained complete elimination at Week 48 (n=46) and an Annualized Relapse Rate (ARR) of 0.07 was observed with 93% of subjects relapse free at Week 48.

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

In January 2013, we initiated a Phase I, open label, multi-center, first-in-human clinical trial of umbralisib in patients with hematologic malignancies. The study entitled "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 was open to patients with relapsed or refractory NHL, CLL, and other select hematologic malignancies. As of February 2016, this study closed to enrollment.

In February 2018, data from this first-in-human Phase 1 clinical trial of umbralisib was published in The Lancet Oncology. The manuscript was titled, "Umbralisib, a novel PI3K and casein kinase-1 epsilon inhibitor, in relapsed or refractory chronic lymphocytic leukemia 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 umbralisib. In this study, the data showed that umbralisib was well tolerated with a favorable safety profile distinct from prior generation PI3K delta inhibitors.

Additional Early Studies with Ublituximab (TG-1101) and/or Umbralisib (TGR-1202)

In addition to the above Phase 1 trials for ublituximab and umbralisib, the following Phase 1 and Phase 2 studies, as well as an integrated analysis were conducted:

- **Ublituximab in Combination with Umbralisib 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 ublituximab and umbralisib, (U2), for patients with relapsed and/or refractory CLL and NHL. The MD Anderson Cancer Center was the lead center for this clinical trial. Additional cohorts were added to this study to explore the triple therapy combination of U2 plus ibrutinib and the triple therapy combination of U2 plus bendamustine. Both U2 and the triplet combinations demonstrated acceptable levels of tolerability with promising activity. Enrollment in all cohorts is now closed and patients continued to be followed for safety and efficacy. Data highlights from each cohort include the following:

  - U2: In December 2015 we presented the results from the U2 portion of this trial at the 57th American Society of Hematology (ASH) annual meeting, Abstract Number 1538. The presentation included data from patients with relapsed and refractory NHL and CLL treated with U2. The combination was well tolerated in the 71 patients evaluable for safety at all dose levels up through 1200mg. This was a heavily pretreated population with high-risk features, including 58% refractory to last treatment with multiple previous lines of rituximab-based therapy. Notably, the only Grade 3/4 adverse event occurring in > 5% of patients was neutropenia and of the 71 patients available for safety, only 6 patients (8%) discontinued due to an umbralisib related event. Additionally, 26 patients had been on U2 for 6+ months, with no events of colitis reported as of the date of publication.

  - Efficacy data was presented on patients treated at the higher doses of umbralisib (1200mg of the original formulation and 600mg or greater of the micronized formulation). 80% (8 of 10) ORR was observed in patients with CLL/SLL, including 1 complete response (CR) and 7 partial responses (PRs). Notably, 75% of CLL patients had high-risk cytogenetics (17p and/or 11q del). 71% (12 of 17) ORR was observed in heavily pretreated patients with indolent NHL (FL & MZL), including 4 CRs (24%) and 8 PRs, with 4 of the remaining 5 patients achieving stable disease.

  - U2 plus Bendamustine: In December 2018, updated data for the U2 plus bendamustine cohort was presented at the 60th ASH Annual Meeting. Overall, the U2 plus bendamustine combination was well tolerated and highly active in patients with advanced indolent and aggressive NHL, including those not eligible for HD/SCT or CD19 CART therapy. Efficacy highlights from this poster included an 85% (11 of 13) ORR including a 54% CR rate in patients with relapsed or refractory FL.

  - U2 plus Ibrutinib: In January 2019, we announced the publication of results from the U2 plus ibrutinib cohort in The Lancet Haematology. Safety data was available from 46 patients and the triple combination of ublituximab, umbralisib, and ibrutinib was well tolerated with a manageable adverse event profile, and no maximum tolerated dose achieved for the combination. Efficacy data was available from 44 patients and showed the U2 plus ibrutinib combination to be highly active. The ORR amongst all evaluable patients was 84%, with 100% (22 of 22) of patients with CLL/SLL achieving a response, including 36% achieving a CR. Among patients with NHL, 68% (15 of 22) achieved a response, including a 71% ORR in FL (n=7), a 100% ORR in MZL (n=3), and a 100% ORR in MCL (n=6).

- **Umbralisib as a single agent in CLL patients who are intolerant to prior BTK inhibitor or PI3K delta inhibitor therapy—** In June 2018, at the 23rd Congress of the European Hematology Association (EHA), data was presented from 47 patients with CLL who were intolerant to prior BTK or PI3K delta inhibitor therapy who were then treated with single agent umbralisib. Umbralisib demonstrated a favorable safety profile with only 13% of patients discontinuing due to an adverse event, of which only one patient discontinued due to a recurrent adverse event (AE) also experienced with prior kinase inhibitor therapy. As of the data presentation, nearly half of the patients enrolled had been on umbralisib for a duration longer than their prior kinase inhibitor. The median progression free survival (PFS) and overall survival (OS) has not been reached with a median follow-up of 9.5 months. Enrollment is now closed with patients continuing to be followed.

- **Umbralisib Long-term Follow-up Integrated Analysis in Patients with Relapsed/Refractory Hematologic Malignancies—** In December 2017, at the 59th ASH Annual Meeting, the Company presented integrated long-term follow-up data from 347 patients exposed to umbralisib 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. In June 2018, an update on the data was presented at the 23rd Congress of the European Hematology Association (EHA). The presentation included data pooled from 4 completed or ongoing Phase 1 or 2 studies containing umbralisib, focusing on 177 patients who have been on daily umbralisib for a minimum of 6 months. Patients were heavily pretreated, with 45% of patients having seen 3 or more prior lines of therapy. Umbralisib continued to exhibit a differentiated safety profile compared to prior generation PI3K delta inhibitors. Serious adverse events occurring in >1% of patients after 6 months on therapy were limited to pneumonia (3%), diarrhea (2%), and cellulitis (2%) with only 2% of patients discontinuing umbralisib as a result of diarrhea/colitis after being on umbralisib for more than 6 months.

- **Phase 2 trial of Ublituximab plus Ibrutinib in patients with relapsed or refractory CLL and Mantle Cell Lymphoma (MCL)**— In December 2013, we initiated a multi-center Phase 2 clinical trial to evaluate the safety and efficacy of the combination of ublituximab and ibrutinib for patients with CLL and MCL. Jeff P. Sharman, MD, Medical Director, 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 ASH meeting held in December 2015, with data from the CLL cohort published in the *British Journal of Haematology* in December 2016. 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 evaluating ublituximab plus ibrutinib in CLL patients with high-risk cytogenetics.

- **Phase 2 trial of Umbralisib plus Ibrutinib in patients with relapsed or refractory CLL and MCL**— In December 2018, we announced the publication of results from the multicenter Phase 1/1b trial of umbralisib in combination with ibrutinib, the oral Bruton's tyrosine kinase (BTK) inhibitor, in Lancet Haematology. This investigator-initiated trial was conducted at Dana-Farber Cancer Institute and four additional centers across the USA in collaboration with the Leukemia and Lymphoma Society, Blood Cancer Research Partnership with funding by TG Therapeutics. The publication includes safety and efficacy information from a total of 42 relapsed or refractory patients, 21 with CLL and 21 with MCL. In this study, the combination of umbralisib and ibrutinib was well tolerated and consistent with the additive toxicity profile of the two drugs individually. No dose-limiting toxicities were observed, and the maximum-tolerated dose of umbralisib when combined with ibrutinib was not reached. The recommended phase 2 dose of umbralisib when given in combination with ibrutinib was 800 mg once daily. Importantly, serious immune-mediated toxicities were not observed with this combination, as had previously been reported with combinations of different agents targeting this pathway, with only one case of transient Grade 3 transaminitis and no Grade 3/4 colitis or pneumonitis. The combination of umbralisib and ibrutinib was also clinically active, with 90% of relapsed/refractory CLL patients achieving an overall response (n=19), of which 62% (n=13) achieved a partial response or partial response with lymphocytosis, and 29% (n=6) achieved a complete response. Of the 21 patients treated with MCL, 67% (n=14) achieved an overall response, of which 48% (n=10) achieved a partial response and 19% (n=4) achieved a complete response.

- **Additional early combination studies utilizing umbralisib with approved agents**— Umbralisib has been evaluated in combination with the anti-CD30 antibody drug conjugate, brentuximab vedotin, in patients with relapsed or refractory Hodgkin's lymphoma 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 umbralisib and or the U2 combination with other approved agents for the treatment of B-cell malignancies.

Phase 3 and Registration-Directed Clinical Trials for Ublituximab and Umbralisib

The company has initiated and enrolled several Phase 3 and registration-directed Phase 2b clinical trials (ie, clinical trials that may support a marketing application for approval). The following are the current Phase 3 trials and registration-directed Phase 2b clinical trials in the order of expected top-line data:

The UNITY-NHL Trial—Marginal Zone Lymphoma (MZL) and Follicular Lymphoma (FL)/Small Lymphocytic Lymphoma (SLL) Cohorts (Umbralisib single agent)

The UNITY-NHL study is a broad Phase 2b multiple cohort trial designed to evaluate the efficacy and safety of umbralisib monotherapy and in combination with ublituximab in previously treated subjects with NHL. In 2017, the UNITY-NHL study began enrolling a cohort of patients with FL/SLL and an additional cohort of patients with MZL. These cohorts of the trial are being led by Nathan H. Fowler, MD, Associate Professor, Department of Lymphoma/Myeloma at the University of Texas MD Anderson Cancer Center. The primary objective of these cohorts of the study are to assess the efficacy of umbralisib single agent as measured by ORR.

For the FL/SLL cohort, adult patients were enrolled who had two prior lines of therapy that included an anti-CD20 monoclonal antibody and an alkylating agent. This cohort is fully enrolled with approximately 125 patients and top-line data are expected in second half 2019.

For the MZL cohort, adult patients were enrolled who had one prior line of therapy that included an anti-CD20 monoclonal antibody. On February 28, 2019 we announced that the MZL cohort of the UNITY-NHL Phase 2b pivotal trial evaluating umbralisib monotherapy met the primary endpoint of Overall Response Rate (ORR) as determined by Independent Review Committee (IRC) for all treated patients (n=69). The results met the Company's target guidance of 40-50% ORR. Interim safety and efficacy data from this study will be presented in an oral presentation at the upcoming American Association of Cancer Research (AACR) annual meeting on April 1, 2019 and full data from this study are expected to be presented at a medical meeting later this year. We plan to discuss the results with the U.S. Food and Drug Administration (FDA) regarding a potential new drug application (NDA) filing for accelerated approval.

The multicenter, open-label, UNITY-NHL Phase 2b study - MZL cohort was designed to evaluate the safety and efficacy of single agent umbralisib in patients with MZL who have received at least one prior anti-CD20 regimen. The primary endpoint is ORR as determined by IRC assessment. The primary analysis of ORR will be conducted once all treated patients have had at least 9 cycles (Cycle = 28 days) of follow-up. Secondary endpoints include safety, duration of response, and progression-free survival (PFS).

The positive ORR outcome announced in February 2019 was based on all 69 enrolled and treated patients, however at the time all patients had not yet been followed for a minimum of 9 cycles as required for the primary analysis of ORR. Accordingly, the study is on-going and patients with benefit on therapy (stable disease or in response) remain on study. Safety data are currently being analyzed.

In January 2019, the FDA granted Breakthrough Therapy Designation (BTD) for umbralisib for the treatment of adult patients with MZL who have received at least one prior anti-CD20 regimen. The BTD was based on interim data from the MZL cohort of the UNITY-NHL trial.

There are additional exploratory cohorts of the UNITY-NHL trial focused on Diffuse Large B-Cell Lymphoma (DLBCL) and Mantle Cell Lymphoma (MCL). Each cohort of the UNITY-NHL trial including, MZL, FL/SLL, DLBCL, and MCL, is enrolled to and evaluated independently.

The UNITY-CLL Trial—Combination of Ublituximab (TG-1101) plus Umbralisib (TGR-1202) in patients with Front-line or Relapsed/Refractory Chronic Lymphocytic Leukemia

In September 2015, we reached an agreement with the FDA regarding a Special Protocol Assessment (SPA) on the design, endpoints and statistical analysis approach of a Phase 3 clinical trial, UNITY-CLL, for the proprietary combination of ublituximab plus umbralisib, 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 ublituximab and umbralisib 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 ublituximab plus umbralisib regimen (the combination sometimes referred to as "U2"), and second, to demonstrate superiority in PFS over the standard of care to support the submission for full approval of the combination. The study randomized patients into four treatment arms: ublituximab plus umbralisib, ublituximab alone, umbralisib alone, and an active control arm of obinutuzumab + chlorambucil. The UNITY-CLL trial is being led by John Gribben, MD, professor of Medical Oncology, Barts Cancer Institute, United Kingdom. The study enrolled over 600 patients across the four treatment arms with approximately 420 patients in the U2 and the active control arm combined. Enrollment completed in October 2017.

In May 2017, an early interim analysis was conducted to assess contribution of each single agent in the ublituximab plus umbralisib combination regimen, which allowed for the early termination of both single agent arms. A second interim analysis was planned to evaluate ORR to support accelerated approval when all patients in the U2 arm and the active control arm had at least 6 months of follow-up. In September 2018, we announced that the independent Data Safety Monitoring Board (“DSMB”) reviewed ongoing data from the trial and advised us that the second interim analysis of ORR could not be conducted at that time as the data were not sufficiently mature to conduct the analysis. Given the uncertainty surrounding the timing and outcome of the ORR analysis, as well as the significant regulatory hurdles associated with accelerated approval in CLL, we are no longer planning to seek accelerated approval for U2 in CLL based on ORR. The Company remains blinded to all efficacy data and the trial continues to be conducted under SPA agreement with the FDA. We await the results for the primary endpoint for the study, PFS, to seek full approval for U2 in patients with CLL, if the study is positive. Importantly, an application based on PFS is expected to support full approval versus accelerated approval, which is a conditional approval.

Additionally, in September 2018, the DSMB reviewed safety data from over 600 patients, including over 300 patients treated with umbralisib either alone or in combination with ublituximab, of which approximately 60% were treatment naïve. After review of the data, the DSMB identified no safety concerns and recommended the trial continue without modification.

The GENUINE Trial— Ublituximab + Ibrutinib in patients with high risk Chronic Lymphocytic Leukemia

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 ublituximab plus ibrutinib or ibrutinib alone. Due to enrollment challenges associated with this study, 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 an SPA with the FDA, and was designed to enroll approximately 330 patients, with a two-part analysis of both ORR and PFS. The trial as amended in October 2016 removed PFS as a co-primary endpoint leaving ORR as the sole primary endpoint. The target number of patients was also reduced to 120 patients. The SPA was terminated at the time the changes were implemented.

In March 2017, we reported positive top-line data from the GENUINE study and in June 2017, the results were presented by Dr. Jeff P. 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. We had hoped to use the ORR results from the GENUINE trial to file for accelerated approval for the combination of ublituximab plus ibrutinib. In October of 2017, we announced the results of a meeting with the FDA related to the potential accelerated approval application. The FDA had expressed concern that an intervening approval for the treatment of relapsed or refractory CLL could, as available therapy, have the effect of blocking our accelerated approval application. In June 2018, venetoclax received full approval for the treatment of relapsed or refractory CLL, the same indication for which we planned to file accelerated approval. While we do believe under the FDA guidance related to accelerated approval that there are benefits of ublituximab plus ibrutinib over presently available therapies that could support approval, we have decided at this time to not pursue the filing of the results from the GENUINE trial to support accelerated approval. We continue to follow patients in the GENUINE study for safety and efficacy including Overall Response Rate, Minimal Residual Disease (MRD) and PFS.

The ULTIMATE I and ULTIMATE II Phase 3 Clinical Trials—Single Agent Ublituximab in relapsing forms of Multiple Sclerosis

In August 2017, we reached an agreement with the FDA regarding an SPA on the design of two Phase 3 clinical trials for ublituximab, referred to as the ULTIMATE I and ULTIMATE II trials, 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 ublituximab in RMS. Each trial is a global, randomized, multi-center, double-blinded, double-dummy, active-controlled study comparing 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 was designed to enroll approximately 440 subjects, randomized in a 1:1 ratio. This trial is being led by Lawrence Steinman, MD, George A. Zimmermann Professor and Professor of Pediatrics, Neurology and Neurological Sciences at Stanford University.

In August 2018, we announced that target enrollment into the ULTIMATE I and II trials had been achieved, and that enrollment would continue into September 2018 to allow identified patients to participate in the study. At completion of full enrollment in October of 2018, approximately 1,100 subjects were enrolled in both studies combined.

TG-1501 (anti-PD-L1 monoclonal antibody) Overview

TG-1501 is a fully human monoclonal antibody of IgG1 subtype that binds to Programmed Death-Ligand 1 (PD-L1) and blocks its interactions with PD-1 and B7.1 receptors. Cancer cells elude anti-tumor immunity through multiple mechanisms, including upregulated expression of ligands for inhibitory immune checkpoint receptors. Signals from PD-L1 on tumor cells and in the tumor microenvironment help those tumors avoid immune attack and elimination by preventing activation of tumor specific effector T-cells. Anti-PD-L1 antibodies are designed to block that signal, permitting effector T-cells to attack the cancer. Clinical studies have shown that blockade of the PD-1/PD-L1 pathway by monoclonal antibodies can enhance the immune response and result in anti-tumor activity.

Preclinically, it has been shown that the effects of anti-PD-L1 intervention can be enhanced by utilizing other mechanisms targeting the tumor microenvironment. Combining immunotherapies like anti-PD-L1, that counters the tumor's immune-evading defense system with other anti-cancer agents such as ublituximab or umbralisib may better engage the body's own immune system to help fight cancer.

A comprehensive array of in vitro biochemical and cellular assays was established to characterize the binding and the functional activities of TG-1501. The in vitro data demonstrated that the affinity, PD-L1 binding capability, relative ability to inhibit PD-1/PDL-1 interactions, and functional activity of TG-1501 in cellular assays are comparable to those of atezolizumab, durvalumab and avelumab - the currently approved products sharing the same mechanism of action.

TG-1501 is currently being evaluated in an ongoing study (Study CK-301-101: NCT03212404), enrolling patients with select solid tumors, being conducted by our licensor. In the dose escalation portion of this trial, doses ranging from 200mg to 800mg were tested with no dose-limiting toxicities observed and no maximum tolerated dose (MTD) was achieved; therefore, a fixed dose of 800 mg was the selected starting dose of TG-1501 for patients with hematologic malignancies.

In December 2018, the FDA approved an IND for TG-1501 and a Phase 1 study in subjects with select subtypes of lymphoma is expected to commence in Q1 2019. After characterizing the safety profile of TG-1501 as monotherapy in hematological malignancies, the study may evaluate TG-1501 in combination with other therapies, including ublituximab and/or umbralisib. Based on our rapidly evolving understanding of the pathobiology of lymphoma subtypes, we envision further combinations with other immunotherapies in the future.

TG-1701 (BTK inhibitor) Overview

TG-1701 is a novel, orally available and covalently-bound Bruton’s tyrosine kinase (BTK) inhibitor that exhibits superior selectivity to BTK compared to ibrutinib in *in vitro* kinase screening.

B-cell receptor (BCR) signaling is crucial for normal B-cell development and supports the survival and growth of malignant B-cells in patients with B-cell leukemias or lymphomas. Targeting BTK, an essential element of BCR signaling pathway which regulates the survival, activation, proliferation, and differentiation of B lymphocytes, has shown remarkable efficacy with an acceptable safety profile in B-cell malignancies.

In June 2018, pre-clinical data for TG-1701 demonstrating favorable pharmacologic properties was presented at the 23rd Congress of the European Hematology Association (EHA) in Stockholm, Sweden. *In vitro* pharmacology studies have revealed that TG-1701 inhibited BTK with greater than 10-fold selectivity as measured by IC50 on the kinase activities of EGFR, ITK, TXK, JAK3, HER2 and HER4. *In vivo* pharmacology studies showed that TG-1701 significantly inhibited the growth of xenograft lymphoid tumors including OCI-LY-10 and DOHH-2 in nude mice.

We are currently evaluating TG-1701 in a Phase 1, multi-center, dose-escalation clinical trial in patients with B-cell malignancies. This trial is designed to evaluate the safety and tolerability of TG-1701 in adults with B-cell malignancies and determine the recommended Phase 2 dose. Key secondary objectives include evaluation of pharmacokinetics (PK), pharmacodynamics, and preliminary anticancer activity.

TG-1801 (anti-CD47/anti-CD19 bispecific monoclonal antibody) Overview

TG-1801 is a first-in-class, bispecific CD47 and CD19 antibody. It is the first therapy to target both CD19, a B-cell specific market widely express across B-cell malignancies, and CD47, the "don't eat me" signal used by both healthy and tumor cells to evade macrophage mediated phagocytosis. CD47 is expressed ubiquitously on normal cells, including red blood cells and platelets. CD19 is a specific B-cell marker, expressed early during pre-B cell ontogeny and until terminal differentiation into early plasma cells. The majority of B-cell lineage malignancies (more than 90%) express CD19, including NHL, CLL and acute lymphoblastic leukemia (ALL). Tumor B-cells that have lost the expression of CD20 after anti-CD20 mAb therapy, have been found to maintain the expression of CD19, making CD19 an attractive target in the treatment of B cell malignancies. By co-targeting both CD47 and CD19, TG-1801 has the potential to overcome the limitations of existing CD47 targeted therapies by avoiding the side effects caused by indiscriminate blockade of CD47 on healthy cells. In addition to potentially enhancing tolerability, the co-targeting of CD19 by TG-1801 may provide a secondary mechanism of direct anti-tumor activity through the engagement of effector cells and induction of antibody dependent cellular cytotoxicity (ADCC).

TG-1801 binds to human CD19 with significantly higher affinity than towards CD47. This difference between its affinity to CD19 and CD47 allows TG-1801 to bind and selectively block CD47 on $CD19^+$ B-cells but not on $CD19^-$ red blood cells or platelets in human peripheral blood.

In *in vitro* assays, TG-1801 induces antibody-dependent cellular phagocytosis (ADCP) and antibody-dependent cellular cytotoxicity (ADCC) of malignant tumor B-cell lines and primary tumor B-cells from patients with B-cell acute lymphoblastic leukemia (B-ALL), B-cell chronic lymphocytic leukemia (B-CLL) and numerous subtypes of NHL.

In *in vivo* mouse tumor models, treatment with TG-1801 inhibited tumor growth in Raji cell subcutaneous xenograft model, NALM-6 cell disseminated tumor model, and patient-derived xenograft models, including primary tumor cells from patients with diffuse large B-cell lymphoma (DLBCL) and B-ALL. In addition, the combination of rituximab and TG-1801 demonstrated enhanced activity over TG-1801 monotherapy.

In summary, TG-1801 demonstrates anti-tumor activity in both *in vitro* assays (ADCP and ADCC) and *in vivo* animal tumor models.

In the first quarter of 2019 we commenced, a Phase 1 first-in-human, dose-escalation study of TG-1801. This study will evaluate escalating doses of TG-1801 in patients with B-Cell lymphoma. The primary objective of the study is to determine the recommended Phase 2 dose and to characterize the safety profile of TG-1801. Key secondary objectives are to evaluate the pharmacokinetics of TG-1801 and its preliminary anticancer activity.

Preclinical Programs

In addition to our clinical programs, we currently have licensed preclinical programs for BET (TG-1601), IRAK4, and GITR.

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
Ublituximab & Umbralisib	CLL patients	Phase III	2019	Approximately $5 million
Umbralisib +/-Ublituximab	Relapsed/refractory NHL patients	Phase IIb	2019*	Approximately $5 million
Ublituximab	In Relapsing forms of Multiple Sclerosis (RMS)	Phase III	2020	Approximately $35 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, trade secrets, proprietary information 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.

We file patent applications directed to our drug candidates in an effort to establish intellectual property positions regarding these new chemical entities as well as uses of these new chemical entities in the treatment of diseases. We also file patent applications directed to novel combinations of our drugs together and with drugs developed by others. The intellectual property portfolios for our most advanced drug candidates as of February 28, 2018 are summarized below. Each of these portfolios contain pending patent applications covering our drug candidates and uses and combinations of the drug candidates, prosecution has just begun or is in progress. Prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the USPTO often significantly narrowed by the time they issue, if they issue at all. We expect this to be the case with respect to our pending patent applications referred to below.

Additionally, 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.

Ublituximab

Pursuant to our license for 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 ublituximab as well as method of use patents which cover use of ublituximab in combination with various agents and for various therapeutic indications.

The composition of matter patent for ublituximab has been issued in the U.S. and Europe, which affords patent protection until 2029 in the U.S. and 2025 in Europe, exclusive of patent term extensions. We also have a method of use patent on the combination of umbralisib and ublituximab which has been issued in the U.S., EU, and Japan, and is pending in other territories globally. Additionally, we have numerous granted patents and pending patent applications outside the U.S. which include claims directed to the composition of matter and methods of treatment with ublituximab in various settings.

Umbralisib

Pursuant to our license for umbralisib 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 umbralisib as well as method of use patents which cover use of umbralisib in combination with various agents and for various therapeutic indications. Our composition of matter patent for umbralisib has been issued in the U.S. 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 umbralisib and ublituximab which has been issued in the U.S., EU, and Japan, and is pending in other territories globally. All other patent applications currently filed for umbralisib 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.

TG-1501 (anti-PDL1 monoclonal antibody)

Pursuant to our Global Collaboration with Checkpoint Therapeutics, we have the exclusive commercial rights in the treatment of hematological cancers and autoimmune diseases to a series of 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.

TG-1701 (BTK inhibitor)

Pursuant to our license agreement with Jiangsu Hengrui, 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. Any patents maturing from these pending applications will expire no sooner than October 2034.

TG-1801 (anti-CD47/anti-CD19 bispecific antibody)

Pursuant to our joint venture and license option agreement with Novimmune, we have the exclusive commercial rights to a series of global patent applications, all of which are currently pending. Any patents maturing from these pending applications will expire no sooner than December 2032.

Limitations on Patent Rights and Trade Secrets

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.*" In addition, the limited patent protection 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.

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, while we have and plan to continue to enter into confidentiality agreements designed to protect our trade secrets, know-how and proprietary information and to grant us ownership of inventions that are developed by individuals in connection with their relationship with us, these agreements may not, however, provide protection for our trade secrets, know-how and proprietary information in the event of unauthorized disclosure of such information.

Orphan Drug Designation

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, ublituximab has received Orphan Drug Designation from the FDA for the treatment of MZL (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 umbralisib 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 ublituximab and umbralisib for the treatment of patients with CLL and DLBCL. We believe that ublituximab and umbralisib, as well as our other pipeline products may be eligible for additional Orphan Drug Designations; however, we cannot assure you that ublituximab, umbralisib, or any other drug candidates we may acquire or in-license, will obtain such Orphan Drug Designations or that we will be the first to receive FDA approval for any drug candidates that do obtain Orphan Drug Designation so as to be eligible for market exclusivity protection.

U.S. Patent Term Restoration and Marketing Exclusivity

Depending upon the timing, duration and specifics of the FDA approval of our drug candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of an NDA plus the time between the submission date of an NDA and the approval of that application. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. The USPTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we intend to apply for restoration of patent term for one of our currently owned or licensed patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant NDA.

Marketing exclusivity provisions under the FDCA can also delay the submission or the approval of certain marketing applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovator drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder. The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the pre-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness. Orphan drug exclusivity, as described below, may offer a seven-year period of marketing exclusivity, except in certain circumstances. Pediatric exclusivity is another type of regulatory market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric trial in accordance with an FDA-issued "Written Request" for such a trial.

Upon FDA approval, we believe that ublituximab and umbralisib each would qualify as a New Chemical Entity, or NCE, which provides for five years of exclusivity following approval as discussed above.

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.

Ublituximab

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 ublituximab. Under the license agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of ublituximab. To date, we have made no payments to LFB Group under the license agreement, excluding an upfront equity payment. 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 ublituximab 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.

Ildong Pharmaceutical Co. Ltd.

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong relating to the development and commercialization of ublituximab 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 ublituximab 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 ublituximab 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.

Umbralisib

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

Under the terms of the Umbralisib 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 umbralisib, 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 umbralisib 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 umbralisib 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 umbralisib, 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.

TG-1501 (anti-PD-L1 monoclonal antibody)

In March 2015, we entered into a Global Collaboration (the "Collaboration") with Checkpoint Therapeutics, Inc. ("Checkpoint") for the development and commercialization of Checkpoint's anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies with an option to acquire rights in autoimmune diseases. These antibodies were generated at Dana-Farber Cancer Institute (Dana-Farber). 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. We are currently renegotiating certain terms of the Collaboration agreement with Checkpoint and may incur additional upfront payments when a definitive agreement is reached.

TG-1701 (BTK inhibitor)

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co., (Hengrui), 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 Hengrui'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) for hematologic malignancies. Pursuant to the agreement, we paid Hengrui an upfront fee of $1.0 million in our common stock. Hengrui 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 within China, we must notify Hengrui, giving Hengrui the right of first offer. The agreement allows combinations of TG-1701 or TG-1702 with umbralisib, ublituximab, or U2. Additional combinations may be undertaken under the agreement subject to additional pre-specified payments to Hengrui.

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 Hengrui 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.

TG-1801 (anti-CD47/anti-CD19 bispecific antibody)

In June 2018, we entered into a Joint Venture and License Option Agreement with Novimmune SA (Novimmune) to collaborate on the development and commercialization of Novimmune's novel first-in-class anti-CD47/anti-CD19 bispecific antibody known as TG-1801 (previously NI-1701). The companies will jointly develop the product on a worldwide basis, focusing on indications in the area of hematologic B-cell malignancies. We serve as the primary responsible party for the development, manufacturing and commercialization of the product. Pursuant to the agreement, in June 2018 we paid Novimmune an upfront payment of $3.0 million in our common stock. Further milestone payments will be paid based on early clinical development, and the Company will be responsible for the costs of clinical development of the product through the end of the Phase 2 clinical trials, after which the Company and Novimmune will be jointly responsible for all development and commercialization costs. The Company and Novimmune will each maintain an exclusive option, exercisable at specific times during development, for the Company to license the rights to TG-1801, in which case Novimmune is eligible to receive additional milestone payments totaling approximately $185 million as well as tiered royalties on net sales in the high single to low double digits upon and subject to the achievement of certain milestones.

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.

TG-1601 (BET inhibitor)

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.

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. The resulting changes in standard of care can impact the likelihood of regulatory accelerated approval opportunities for our drug candidates.

For the cancer indications for which we are developing our products there are a number of established therapies with which we will compete:

- For the treatment of Chronic Lymphocytic Leukemia, if U2 is approved, we expect U2 to compete with recently approved drugs such as ibrutinib (AbbVie and Janssen), venetoclax (AbbVie and Roche), obinutuzumab (Roche), idelalisib (Gilead) and duvelisib (Verastem), and established treatments such as rituximab (Roche), and several generically available chemotherapies. Additionally, there are two second generation BTK inhibitors similar to ibrutinib in late-stage clinical testing for CLL that could enter the market in the next 12-36 months. Each of these agents can be used as monotherapy or in combination with one or more of the other agents.

- For the treatment of Marginal Zone Lymphoma, if approved, we expect umbralisib to compete with ibrutinib (AbbVie and Janssen) and established treatments such as rituximab and several generically available chemotherapies. Additionally, the combination of rituximab and lenalidomide (Celgene) has been studied in MZL and may be approved.

- For the treatment of Follicular Lymphoma, if approved, we expect umbralisib to compete with recently approved drugs such as obinutuzumab (Roche), idelalisib (Gilead), copanlisib (Bayer), and duvelisib (Verastem), and established treatments such as rituximab (Roche), and several generically available chemotherapies. Each of these agents can be used as monotherapy or in combination with one or more of the other agents. The combination of rituximab and lenalidomide (Celgene) has also been studied in FL and may be approved. There are also several PI3K delta inhibitors in earlier stages of development.

- In addition, a number of pharmaceutical companies are developing antibodies and bispecific antibodies targeting CD20, CD19, CD47 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 U2 and umbralisib.

For Multiple Sclerosis for which we are developing ublituximab there are a number of established therapies with which we will compete:

- If ublituximab is approved, we expect ublituximab will primarily compete against other CD20 targeted agents, while the group of CD20 targeted agents will also compete broadly against a number of already approved MS therapies. Currently, there is one anti-CD20 monoclonal antibody approved, ocrelizumab (Roche), and another in Phase 3 development, ofatumumab (Novartis), which is expected to enter the market in the next 12-24 months.

TG-1501, TG-1701 and TG-1801 if approved will also face competition from drugs on the market and under development that have the same mechanism of action as each of those drugs.

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 of our own. We have established contract manufacturing relationships for the supply of ublituximab. We have also established contract manufacturing relationships for the supply of umbralisib 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, as we move closer to commercialization for ublituximab and umbralisib we will need to scale-up production to ensure adequate commercial supply, complete validation batches and complete pre-approval inspection batches. We are currently in the process of scaling up ublituximab and completing validation and pre-approval inspection batches for both ublituximab and umbralisib. This is an expensive process which will require significant investment on our part over the next 24 months and there can be no assurance given that such scale-up and process validation 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.

Process improvements are common during clinical development to accommodate raw material and component variability, enhance productivity and/or accommodate different or larger equipment utilized during the scale-up process required for commercial manufacture. These types of incremental process changes have been made during clinical development for both TG's small and large molecule programs. For example, our UNITY-CLL Phase 3 clinical trial contains ublituximab produced from both a pre-commercial process and the current commercial process. While there are some analytical differences between the two materials, we do not expect those differences to have an effect on the clinical performance of ublituximab. The primary difference is that the commercial process has resulted in further enhancement to the ADCC effect, potentially enhancing potency. We will analyze the Phase 3 data to ensure that the materials are substantially similar in performance. If there are material differences in safety or efficacy, we may need to adjust our statistical analysis of the Phase 3 study, which could impact the approvability of the U2 combination in CLL.

At the time of commercial sale, to the extent possible and commercially practicable, we would seek to engage back-up suppliers for raw materials, manufacturing and testing services 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.

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. 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.

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.

For clinical trials that are intended to form the basis of a new drug or biologics license application for approval, sponsors of drugs may apply for an SPA from the FDA, by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols. While obtaining an SPA provides some assurance the design of a trial should be sufficient for approval, the 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.

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, referred to as the UNITY-CLL trial, for the proprietary combination of ublituximab and umbralisib, 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 ublituximab and umbralisib in combination. Additionally, in August 2017, we reached an agreement with the FDA regarding an SPA on the design of two Phase 3 clinical trials for ublituximab, referred to as the ULTIMATE I and ULTIMATE II Phase 3 clinical trials, 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 ublituximab. Despite obtaining an SPA the trials may not be positive and even if positive may not support FDA approval.

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 nonclinical or clinical data demonstrate the potential to address an unmet medical need

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.

In addition, sponsors may also apply to the FDA for Breakthrough Therapy Designation ("BTD"). The procedures and requirements for BTD are similar to those required for fast track such that the Breakthrough Therapy Designation is intended to expedite the development and review of a potential new drug for serious or life-threatening diseases however with BTD, there is a further requirement that the sponsor present "preliminary clinical evidence" which "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.

In January 2019, we announced that the FDA granted Breakthrough Therapy Designation for umbralisib for the treatment of adult patients with marginal zone lymphoma (MZL) who have received at least one prior anti-CD20 regimen based on interim results from a subset of patients from the MZL cohort of the UNITY-NHL clinical trial.

Sponsors of drugs designated as fast track and as breakthrough therapy 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. To obtain accelerated approval you have to be the first company to have a treatment that successfully addresses a certain unmet medical need or you need to clearly be better than all other treatments for that medical need, subject to certain qualifications. Many companies have filed for accelerated approval and have subsequently failed to obtain such approval for a variety of reasons, including not being first or not being best. To the extent a product does obtain an accelerated approval, such approval will be subject to the requirement that the applicant study the drug further in a post-marketing confirmation clinical trial 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. Accelerated approval is sometimes referred to as conditional approval because if the results of these confirmation clinical trials are not successful, the FDA has the right to remove the drug from the market and has done so in the past. Post-marketing confirmation studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing confirmation studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing confirmation studies with due diligence.

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 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. Many drug approvals have been delayed due to issues at contract manufacturing facilities. If we were to experience any such delay that would negatively impact our business and timeline to commercialization of any of our drug candidates affected by such manufacturing issue.

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 continued 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 requirements 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. Importantly, the level of evidence of efficacy and safety necessary to apply for marketing authorization for a drug candidate differs from country to country. In particular, clinical trial endpoints, and the level of clinical evidence that may support an accelerated approval filing with the US FDA, such as the ORR data we intend to use as the basis for a filing for umbralisib in MZL, may be insufficient to file for marketing application outside of the US. 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.

Coverage and Reimbursement

Sales of our drugs will depend, in part, on the extent to which our drugs will be covered by third-party payors, such as government health programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly reducing reimbursements for medical drugs and services. In addition, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third-party reimbursement for our drug candidates, if approved, or a decision by a third-party payor to not cover our drug candidates could reduce physician usage of such drugs and have a material adverse effect on our sales, results of operations and financial condition.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs. Unlike Medicare Part A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs, and each drug plan can develop its own drug formulary that identifies which drugs it will cover and at what tier or level. However, Part D prescription drug formularies must include drugs within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs may increase demand for drugs for which we receive marketing approval. However, any negotiated prices for our drugs covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

The American Recovery and Reinvestment Act of 2009 provides funding for the federal government to compare the effectiveness of different treatments for the same illness. The plan for the research was published in 2012 by the Department of Health and Human Services, the Agency for Healthcare Research and Quality and the National Institutes for Health, and periodic reports on the status of the research and related expenditures will be made to Congress. Although the results of the comparative effectiveness studies are not intended to mandate coverage policies for public or private payors, it is not clear what effect, if any, the research will have on the sales of our drug candidates, if any such drug or the condition that they are intended to treat is the subject of a trial. It is also possible that comparative effectiveness research demonstrating benefits in a competitor's drug could adversely affect the sales of our drug candidate. If third-party payors do not consider our drugs to be cost-effective compared to other available therapies, they may not cover our drugs after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow us to sell our drugs on a profitable basis.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, enacted in March 2010, has had a significant impact on the health care industry. The Affordable Care Act expanded coverage for the uninsured while at the same time containing overall healthcare costs. With regard to pharmaceutical products, the Affordable Care Act, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and 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 the manufacturer's outpatient drugs to be covered under Medicare Part D.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, started in April 2013, and, due to subsequent legislative amendments, will stay in effect through 2025 unless additional Congressional action is taken. On January 2, 2013, then President Obama signed into law the American Taxpayer Relief Act of 2012, or the ATRA, which among other things, also reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. We expect that additional federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare drugs and services, and in turn could significantly reduce the projected value of certain development projects and reduce our profitability. In January 2017, Congress voted to adopt a budget resolution for fiscal year 2017, that while not a law, is widely viewed as the first step toward the passage of legislation that would repeal certain aspects of the Affordable Care Act. The 2017 Tax Cuts and Jobs Act, or TJCA, includes a provision repealing the individual mandate, effective January 1, 2019. Further, on January 20, 2017, U.S. President Donald Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. Several state Attorneys General filed suit to stop the administration from terminating these subsidies, but on October 25, 2017, a federal judge in California denied their request for a restraining order. In addition, CMS has recently proposed regulations that would give states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the health benefits required under the Affordable Care Act for plans sold through these marketplaces. There may be further action to repeal, replace or modify the Affordable Care Act. While any legislative and regulatory changes will likely take time to develop, and may or may not have an impact on the regulatory regime to which we are subject, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, in some foreign countries, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal drugs for which their national health insurance systems provide reimbursement and to control the prices of medicinal drugs for human use. A member state may approve a specific price for the medicinal drug or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal drug on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical drugs will allow favorable reimbursement and pricing arrangements for any of our drugs. Historically, drugs launched in the European Union do not follow price structures of the United States and generally tend to be significantly lower.

Other Healthcare Laws

We may also be subject to healthcare regulation and enforcement by the federal government and the states and foreign governments where we may market our product candidates, if approved. These laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security and physician sunshine laws and regulations.

The federal Anti-Kickback Statute prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or paying remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs. The government has enforced the Anti-Kickback Statute to reach large settlements with healthcare companies based on sham consulting and other financial arrangements with physicians. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

In addition, the civil False Claims Act prohibits, among other things, knowingly presenting or causing the presentation of a false, fictitious or fraudulent claim for payment to the U.S. government. Actions under the False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. The federal government is using the False Claims Act, and the accompanying threat of significant liability, in its investigation and prosecution of pharmaceutical and biotechnology companies throughout the U.S., for example, in connection with the promotion of products for unapproved uses and other sales and marketing practices. The government has obtained multi-million and multi-billion dollar settlements under the False Claims Act in addition to individual criminal convictions under applicable criminal statutes. Given the significant size of actual and potential settlements, it is expected that the government will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, also created new federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

There has also been a recent trend of increased federal and state regulation of payments made to physicians and other healthcare providers. The Affordable Care Act, among other things, imposes new reporting requirements on drug manufacturers for payments made by them to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit required information may result in civil monetary penalties of up to an aggregate of $150,000 per year (or up to an aggregate of $1 million per year for "knowing failures"), for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an annual submission. Drug manufacturers are required to submit annual reports to the Centers for Medicare & Medicaid Services, which publicly posts the data on its website. Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology and Clinical Health Act, or HITECH, and their respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, we may be subject to state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways, thus complicating compliance efforts.

EMPLOYEES

As of February 20, 2019, we had 105 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 Financial Position and Need for Additional Capital

We are a biopharmaceutical company with a limited operating history and have not generated any revenue from drug sales. We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

We are a biopharmaceutical company with a limited operating history on which investors can base an investment decision. Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We commenced operations in January 2012. Our operations to date have been limited primarily to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential drug candidates and undertaking pre-clinical studies and commencing clinical trials and conducting Phase 3 and registration directed clinical trials for our most advanced drug candidates, ublituximab and umbralisib. We have never generated any revenue from drug sales. We have not obtained regulatory approvals for any of our drug candidates.

We have not yet demonstrated our ability to successfully complete large-scale, pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale drug, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Typically, it takes many years to develop one new drug from the time it is discovered to when it is available for treating patients. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. We will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

Since inception, we have focused substantially all of our efforts and financial resources on clinical trials and manufacturing of our drug candidates. To date, we have financed our operations primarily through public offerings of our common stock and a debt financing. Through March 1, 2019, we have received an aggregate of approximately $450 million from such transactions, including approximately $420 million in aggregate gross proceeds from the sale of common stock in one or more offerings and through the use of our ATM from January 2012 through December 2018 but excluding $30.0 million in gross proceeds from the debt financing in February 2019.

Since inception, we have incurred significant operating losses. As of December 31, 2018, we had an accumulated deficit of $528.3 million. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur significant expenses and operating losses for the foreseeable future. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital. We expect our research and development expenses to significantly increase in connection with continuing our existing clinical trials and beginning additional clinical trials. In addition, if we obtain marketing approval for our drug candidates, we will incur significant sales, marketing and outsourced-manufacturing expenses. We have incurred and will continue to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing pharmaceuticals, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our ability to become profitable depends upon our ability to generate revenue.

To date, we have not generated any significant revenue from our drug candidates and we do not expect to generate any revenue from the sale of drugs in the near future. 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. Accordingly, we do not expect to generate significant and sustained revenue unless and until we obtain marketing approval of, and begin to sell umbralisib, ublituximab and/or one of our other product candidates. Our ability to generate revenue depends on a number of factors, including, but not limited to, our ability to:

- Successfully complete clinical trials that meet their clinical endpoints;
- Initiate and successfully complete all safety, pharmacokinetic, biodistribution, non-clinical studies required to obtain US and Foreign marketing approval for our drug candidates;
- Obtain approval from the US FDA and Foreign equivalent to market and sell our drug candidates;
- Establish commercial manufacturing capabilities alone and/or with third parties that are satisfactory to the regulatory authorities, cost effective, and that are capable of providing commercial supply of our drug candidates
- Establish a commercial infrastructure to commercialize our drug candidates, if approved, by developing a sales force and/or entering into collaborations with third parties; and
- achieve market acceptance of our drug candidates in the medical community and with third-party payors.

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 to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some of our drug development programs or commercialization efforts.

The development of pharmaceuticals is capital-intensive. We are currently advancing our most advanced drug candidates, umbralisib, ublituximab, TG-1501, TG-1701 and TG-1801 through clinical development. While we may experience short-term decreases in clinical trial expenses as our larger phase 3 clinical trials complete and before our Phase 1 and 2 programs can advance into Phase 2 and 3, we do expect over time our overall expenses will increase in connection with our ongoing activities, particularly as we continue the research and development of, initiate or continue clinical trials of, and seek marketing approval for, our drug candidates. In addition, depending on the status of regulatory approval or, if we obtain marketing approval for any of our drug candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Moreover, in anticipation of filing for regulatory approvals for umbralisib and ublituximab we will need to expend substantial resources on manufacturing and new drug application (NDA)/ new biologics license application (BLA) preparation over the next 12-24+ months, which could exceed any cost savings associated with lower clinical trial expenses during the same period.

While this timing is our current estimate, 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.

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, marketing and medical educational efforts that are required for a successful launch of umbralisib and/or ublituximab or any of our product candidates and otherwise 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. Accordingly, 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.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or drug candidates and occupy valuable management time and resources.

Until such time, if ever, as we can generate substantial drug revenues, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds, other than funds already borrowed under the loan and security agreement that we entered into with Hercules in February 2019 (See Note 14 for more information). To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect the rights of our common stockholders. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include restrictive covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, acquiring, selling or licensing intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through collaborations, strategic alliances or licensing arrangements with third parties at a time that is not desirable to us and we may be required to relinquish valuable rights to some intellectual property, future revenue streams, research programs or drug candidates or to grant licenses on terms that may not be favorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example, see our risk factors under the heading "Risks Related to Our Indebtedness."

Additionally, fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our drug candidates. Dislocations in the financial markets have generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders.

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.

Due to limited resources we 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.

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.

Risks Related to our Indebtedness

Our level of indebtedness and debt service obligations could adversely affect our financial condition, and may make it more difficult for us to fund our operations.

In February 2019, we entered into a Loan and Security Agreement (the "Loan Agreement"), with Hercules Capital, Inc., a Maryland corporation ("Hercules") (See Note 14 for more information) . Under the Loan Agreement, Hercules will provide access to term loans with an aggregate principal amount of up to $60.0 million (the Term Loan). Concurrently with the closing of the Loan Agreement, we borrowed an initial tranche of $30.0 million. In addition, we have incurred long term liabilities of approximately $18.0 million with a contract manufacturing organization (CMO) for the scale-up, tech-transfer, and long-term supply of one of our drug candidates. This is an expensive and lengthy process and we expect to incur additional obligations associated with these ongoing manufacturing activities over the course of the next 24 months, and potentially longer. To date, this CMO has provided payment terms which we believe are reasonable, however no assurance can be given that such terms will continue to be available to us in the future. No assurances can be made that the obligations associated with the Loan Agreement and the CMO will not have a material adverse impact on our financial condition.

All obligations under the Loan Agreement are secured by substantially all of our existing property and assets, excluding intellectual property. This indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing its outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including:

- We will need to repay the indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations, our research and development efforts and other general corporate activities; and
- our failure to comply with the restrictive covenants in the Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Hercules could seek to enforce its security interest in the assets securing such indebtedness.

To the extent additional debt is added to our current debt levels, the risks described above could increase.

We may not have cash available in an amount sufficient to enable it to make interest or principal payments on its indebtedness when due.

Failure to satisfy our current and future debt obligations under the Loan Agreement, or breaching any of its covenants under the Loan Agreement, subject to specified cure periods with respect to certain breaches, could result in an event of default and, as a result, Hercules could accelerate all of the amounts due. In the event of an acceleration of amounts due under the Loan Agreement as a result of an event of default, we may not have enough available cash or be able to raise additional funds through equity or debt financings to repay such indebtedness at the time of such acceleration. In that case, we may be required to delay, limit, reduce or terminate our product candidate development or commercialization efforts or grant to others rights to develop and market product candidates that we would otherwise prefer to develop and market our self. Hercules could also exercise its rights as collateral agent to take possession and dispose of the collateral securing the term loans for its benefit, which collateral includes substantially all of our property other than intellectual property. Our business, financial condition and results of operations could be materially adversely affected as a result of any of these events. We are subject to certain restrictive covenants which, if breached, could have a material adverse effect on our business and prospects.

The Loan Agreement imposes operating and other restrictions on the Company. Such restrictions will affect, and in many respects limit or prohibit, our ability and the ability of any future subsidiary to, among other things:

- dispose of certain assets;
- change its lines of business;
- engage in mergers, acquisitions or consolidations;
- incur additional indebtedness;
- create liens on assets;
- pay dividends and make contributions or repurchase our capital stock; and
- engage in certain transactions with affiliates.

Risks Related to Drug Development and Regulatory Approval

If we are unable to obtain regulatory approval for our most advanced drug candidates or other drug candidates and ultimately commercialize our most advanced drug candidates or other drug candidates, or experience significant delays in doing so, our business will be materially harmed.

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 a variety of reasons. We have invested substantially all of our efforts and financial resources in the identification, pre-clinical and clinical development of our drug candidates, including ublituximab, umbralisib, TG-1501, TG-1701 and TG-1801. Our ability to generate drug revenues, which we do not expect will occur for a number of years, if ever, will depend heavily on the successful completion of our current and future Phase 3 and registration-directed clinical trials and eventual commercialization of our drug candidates, which may never occur. We currently generate no revenues from sales of any drugs, and we may never be able to develop or commercialize a marketable drug. Each of our drug candidates will require additional pre-clinical or clinical development, management of clinical, pre-clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from drug sales. The success of our most advanced drug candidates and other drug candidates will depend on several factors, including the following:

- Successful completion of our UNITY-NHL trial, UNITY-CLL trial and our ULTIMATE I and II trials;
- Receipt of regulatory approvals from applicable regulatory authorities for our drug candidates;
- Establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- Obtaining and maintaining patent and trade secret protection or regulatory exclusivity for our drug candidates;
- Launching commercial sales of our drug candidates, if and when approved, whether alone or in collaboration with others;
- Acceptance of the drug candidates, if and when approved, by patients, the medical community and third-party payors;
- Effectively differentiating and competing with other therapies;
- Obtaining and maintaining healthcare coverage and adequate reimbursement;
- Enforcing and defending intellectual property rights and claims; and
- Maintaining an acceptable safety profile of the drug candidates following approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our drug candidates, which would materially harm our business.

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 and we may not be able to continue our operations. 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 risks. The outcome of pre-clinical development testing and early clinical trials may not be predictive of the outcome of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drug candidates. Once a drug candidate has displayed sufficient pre-clinical data to warrant clinical investigation, 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 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 experience 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.

For instance, early clinical results seen with ublituximab (TG-1101) and umbralisib (TGR-1202) in a small number of patients may not be reproduced in expanded or larger clinical trials such as in our UNITY-CLL, UNITY-NHL and ULTIMATE I and II programs. 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 3 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. In addition, 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. Clinical trial results can change over time as additional patients are accrued to a study or as additional follow-up is conducted, which may result in a material negative impact on the preliminary results. For instance, we recently announced that the MZL cohort of the UNITY-NHL study met the primary endpoint of ORR, falling within our target range which was between 40%-50%, and while we believe that the ORR results have the potential to increase over time within this range, or beyond, as patients continue to be followed, no assurance can be given that that will be the case, and the results may ultimately fall at the lower end of the range. Further, time to event based endpoints such as duration of response (DOR) and progression-free survival (PFS) have the potential to change, sometimes drastically, with longer follow-up. No assurance can be provided that the ORR, DOR and PFS data from the MZL cohort of the UNITY-NHL study will be supportive of an FDA approval or will support broad market uptake based on the profile of competitor drugs which may be available. Additionally, while the MZL cohort of the UNITY-NHL study met its primary endpoint, each cohort of this study is operated and analyzed independently, and no assurance can be given that other cohorts from the UNITY-NHL study, including the FL/SLL cohort and the DLBCL cohort, will meet their primary endpoint, have a positive outcome, or will be supportive of an FDA filing.

All of our Phase 3 and registration directed clinical trials such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II utilize international clinical research sites, including sites in eastern European countries. The Company works with what we believe are reputable Clinical Research Organization's ("CRO") and clinical research sites in conducting our studies internationally. Nevertheless, the risk of fraud, incompetence, unexpected patient variability and other issues affecting the quality and the outcome of our Phase 3 and registration directed studies could arise from US or international sites. If that were to occur, the study could be negatively impacted, potentially even preventing it from being useful for regulatory approval. If such event were to occur, it would have a substantial negative impact on the Company.

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. All of our current Phase 3 and registration directed studies such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II trials utilize blinded, independent, centrally review to assess the primary endpoint of such studies. If the results from interim analysis are not consistent with final results or results from our registration directed trials are different from the results found in the earlier studies of ublituximab and umbralisib, 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. For example, we recently presented to the FDA, interim results from the Marginal Zone Lymphoma ("MZL") cohort of our UNITY-NHL trial that supported the granting of BTD. These interim results were also accepted for presentation at the 2019 American Association of Cancer Research (AACR) annual meeting. No assurance can be given that the final results from that cohort will reflect the activity seen in these interim results, or that the final results will be sufficient to file for accelerated approval for umbralisib for the treatment of MZL, and if filed that umbralisib will receive accelerated approval. Similarly, while early Phase 1 data for umbralisib and ublituximab alone and together looked promising there is no assurance that the UNITY-CLL trial will be positive. Moreover, while we believe one of the key differentiators for umbralisib is its tolerability and side effect profile compared to other drugs in the same class, no assurance can be given that a differentiated safety and tolerability profile will be realized in our Phase 3 or registration directed trials such as UNITY-CLL or UNITY-NHL. Specifically, we have not yet analyzed the safety data from the MZL cohort of the UNITY-NHL study, therefore there can be no assurance given that the safety data, once analyzed, will be consistent with prior safety data presented on umbralisib, will be differentiated from other similar agents in the same class, or that it will be favorable enough to support an FDA filing. In addition, no assurance can be given that new toxicities, or an increase in the severity or frequency of previously seen toxicities, will not be observed, which could have a material negative impact on the approvability or marketability of umbralisib or any of our product candidates. Finally, while the Phase 2 data for ublituximab in MS looked promising, no assurance can be given that the profile will carry into Phase 3 and that the ULTIMATE I and II clinical trials will be positive.

In addition to umbralisib and ublituximab, we have a number of compounds in early clinical development, such as TG-1501, TG-1701 and TG-1801. Many drugs fail in the early stages of clinical development for safety and tolerability issues, despite promising pre-clinical results. Accordingly, no assurance can be made that a safe and efficacious dose can be found for these compounds or that they will ever enter into advanced clinical trials alone or in combination with umbralisib and/or ublituximab.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our drug candidates.

Our drug candidates umbralisib and ublituximab are in several Phase 3 and registration directed clinical trials such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II. As with all clinical trials, the risk of failure for our drug candidates is high. It is impossible to predict when or if any of our drug candidates will prove effective and safe in humans or will receive regulatory approval. Before obtaining marketing approval from regulatory authorities for the sale of any drug candidate, we must complete pre-clinical studies and then conduct extensive clinical trials to demonstrate the safety and efficacy of our drug candidates in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. A failure of one or more clinical trials can occur at any stage of testing. Accordingly, our current Phase 3 and registration directed trials, such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II and future clinical trials may not be successful.

Successful completion of our clinical trials is a prerequisite to submitting NDA, a BLA to the U.S. FDA and a Marketing Authorization Application ("MAA"), in the European Union for each drug candidate and, consequently, the ultimate approval and commercial marketing of our drug candidates. We do not know whether any of our clinical trials for our drug candidates will be completed on schedule, if at all.

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 research/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. We may experience numerous unforeseen events during, or as a result of, any current or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our drug candidates, including:

- the FDA or other regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial;
- health authorities or institutional review boards ("IRBs"), or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site or country;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trials of our drug candidates may produce negative or inconclusive results, and we may decide, or health authorities may require us, to conduct additional pre-clinical studies or clinical trials or we may decide to abandon drug development programs;
- the number of patients required for clinical trials of our drug candidates may be larger than we anticipate, and enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors, including our clinical trial sites, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or health authorities or IRBs or ethics committees may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our drug candidates may be greater than we anticipate;
- the supply or quality of our drug candidates or other materials necessary to conduct clinical trials of our drug candidates may be insufficient or inadequate; and
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, health authorities, IRBs or ethics committees to suspend or terminate the trials, or reports may arise from pre-clinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our drug candidates.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the DSMB for such trial or by the FDA or other regulatory authorities. Such health authorities may impose a suspension or termination due to a number offactors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the impositionof a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Many of thefactors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our drug candidates. Further, the FDA may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our clinical trials. This could happen even for a protocol that has received an SPA. In September 2015, we announced a Phase 3 clinical trial for the combination of ublituximab plus umbralisib for patients with CLL, which is being conducted pursuant to a SPA with the FDA and in August 2017 we announced an SPA for our registration program for ublituximab in RMS. Many companies which have been granted SPAs 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 study design or 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.

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. If we are required to repeat or conduct additional clinical trials or other testing of our drug candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our drug candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our drug candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- be subject to post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Our drug development costs will also increase if we experience delays in testing or regulatory approvals. We may also incur additional costs if enrollment is increased. All our current Phase 3 and registration-directed clinical trials, such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II enrolled larger number of patients than our initial projections, adding significant costs to those studies over and above what had been projected. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. 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. UNITY-CLL is an event-driven study, which means the study can only end when a certain pre-specified number of events have occurred. In the case of UNITY-CLL, an event is defined as disease progression or death. Given that these events cannot be predicted with certainty, predicting accurately when this study will reach a sufficient number of events to be complete is impossible. We have stated we believe the number of events can be reached by YE19 or in 2020 but there can be no assurance that that will occur and timelines for the completion of this study should not be relied on given the inherent uncertainty. Delays beyond early 2020 could have a material and adverse impact on the Company. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our drug candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our drug candidates. Any delays in our pre-clinical or future clinical development programs may harm our business, financial condition and prospects significantly.

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

We have and will continue to explore strategies for ublituximab and/or umbralisib that involve use of the FDA's accelerated approval pathway. Obtaining accelerated approval for an agent requires demonstration of meaningful benefit over all available therapies for a serious condition. 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. 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. We are currently awaiting final results from our UNITY-NHL trial, in particular the MZL cohort, which we are hoping will be useful for accelerated approval if positive. Even if the results are positive, no assurance can be given that umbralisib will obtain accelerated approval for a variety of reasons, including if a new treatment receives full approval prior to our potential receipt of accelerated approval. Previously, we were hopeful to utilize the results from our GENUINE study for accelerated approval but the intervening full approval of a drug called venetoclax for relapsed/refractory CLL has made that potential application more challenging. While no final decision has been made as to the filing of the GENUINE study for accelerated approval, the Company has no plans to pursue that filing at this time. No assurance can be given that a filing based on the GENUINE results will ever be made.

Finally, if any of our drugs were ever 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.

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, or FDA's willingness to accept such data, may be jeopardized.

Our drug candidates may cause undesirable side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

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

As is the case with all drugs, it is likely that there will be side effects associated with the use of our drug candidates. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our drug candidates for any or all targeted indications. The drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Many compounds that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the compound. Further, early clinical trials by their nature utilize a small sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our drug candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate in Phase 3 or registration directed trials and on the market.

We are currently running our Phase 3 and registration-directed trials, such as UNITY-CLL, UNITY-NHL and ULTIMATE I and II and 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 the adverse events, if any, will be observed in patients who receive any of our product candidates. To date, clinical trials using ublituximab and umbralisib 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 health authorities and in the case of ublituximab and umbralisib, even if deemed acceptable for oncology and/or autoimmune indications, it may not be acceptable for diseases outside the oncology and autoimmune settings, 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 such as found in our on-going Phase 3 and registration-directed trials. Particularly, with respect to umbralisib, although over 1,000 patients to date have been dosed amongst all ongoing umbralisib studies, the full adverse effect profile of umbralisib is not known. It is also unknown as additional patients are exposed for longer durations to umbralisib, whether greater frequency and/or severity of adverse events are likely to occur. Common toxicities of other drugs in the same class as umbralisib 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. No assurance can be given that an acceptable safety and tolerability profile for umbralisib will continue to be demonstrated in the future with longer durations of exposure, at the fixed 800mg dose being evaluated in our registration-directed trials and in multiple drug combinations. 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 drug-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 ublituximab and umbralisib are being evaluated in combination with each other, 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. We also intend to explore multiple combination studies involving TG-1501, TG-1701, and TG-1801. 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 drug candidates receive marketing approval and we or others later identify undesirable or unacceptable side effects caused by such drug candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such drug candidates;
- regulatory authorities may require a more significant clinical benefit for approval to offset the risk;
- regulatory authorities may require the addition of labeling statements, including warnings, contra-indications, or precautions, that could diminish the usage of the product or otherwise limit the commercial success of the affected product;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way such drug candidates are distributed or administered, conduct additional clinical trials;
- regulatory authorities may require a Risk Evaluation and Mitigation Strategy ("REMS"), plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such drug candidates from the marketplace;
- we may not be able to enter into collaboration agreements on acceptable terms and execute on our business model;
- we could be sued and held liable for injury caused to individuals exposed to or taking our drug candidates; 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 significantly impact our ability to successfully commercialize our drug candidates and generate revenues.

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.

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. In the United States, we are not permitted to market a product candidate 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. 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 REMS requiring prescriber training, post-market registries, or otherwise restricting the marketing and dissemination of these products. Despite the time and expense invested in the 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 these countries.

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 an indication;
- the FDA may not accept clinical data from trials 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 not approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators currently contract for clinical supplies and plan to contract for 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, raising questions about the safety of 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.

A breakthrough therapy designation by the FDA for our drug candidates, including umbralisib for the treatment of adult patients with relapsed or refractory Marginal Zone Lymphoma (MZL) who have received at least one prior treatment including an anti-CD20 monoclonal antibody, may not lead to a faster development or regulatory review or approval process, and it does not ensure that our drug candidates will receive marketing approval.

In January 2019, the FDA granted breakthrough therapy designation to umbralisib for the treatment of adult patients with relapsed or refractory MZL who have received at least one prior treatment including an anti-CD20 monoclonal antibody. We may also seek breakthrough therapy designation for some of our other drug candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and 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. Our breakthrough therapy designation was based on interim data from the MZL cohort of the UNITY-NHL clinical trial. No assurance can be given that the full results from the MZL cohort of the UNITY-NHL clinical trial will be positive and support a filing for accelerated approval.

For drugs that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval. Designation as a breakthrough therapy is wholly within the discretion of the FDA. Accordingly, even if we believe one of our drug candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to grant such designation to the drug candidate. In any event, the receipt of a breakthrough therapy designation for a drug candidate may not result in a faster development process, review or approval compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our drug candidates qualify as breakthrough therapies, the FDA may later decide that the drugs no longer meet the conditions for qualification and rescind the designation.

A fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We may seek fast track designation for some of our other drug candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for fast track designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular drug candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we receive fast track designation for our other drug candidates, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program.

While we have received orphan drug designation for umbralisib and ublituximab for specified indications, we may seek additional orphan drug designation for those and some of our other drug candidates. However, we may be unsuccessful in obtaining or may be unable to maintain the benefits associated with orphan drug designation, including the potential for market exclusivity.

Ublituximab 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 EMA for the treatment of CLL in November of 2009. We also obtained orphan drug designation for umbralisib 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 ublituximab and umbralisib for the treatment of patients with CLL and DLBCL. As part of our business strategy, we may seek orphan drug designation for our other drug candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers.

Even if we obtain orphan drug exclusivity for a drug, that exclusivity may not effectively protect the designated drug from competition because different drugs can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we intend to seek additional orphan drug designation for our other drug candidates, we may never receive such designations. Even if we receive orphan drug designation for any of our drug candidates, there is no guarantee that we will enjoy the benefits of those designations.

As all of our product candidates are still under development, manufacturing site additions, scale-up 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 relatively 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/ and analytical profile of the product candidates, which may affect the safety and efficacy of the products. For instance, the manufacturing process for ublituximab has undergone several process improvements during the clinical trial process which have resulted in analytical differences between the materials. Such process improvements continued during the conduct of Phase 3 and material from more than one manufacturing process were utilized in the Phase 3 UNITY-CLL trial. While analytical differences exist between those materials, we do not believe the differences will alter the safety or efficacy profile of ublituximab. However, it is possible that additional and/or different adverse events may appear among patients exposed to drug product manufactured under one process compared to the other, or that adverse events may arise with greater frequency, intensity and duration among patients exposed to drug product manufactured under one process compared to the other. Additionally, the efficacy of ublituximab also can be negatively impacted by such process changes. Given the uncertainty of the impact on product specifications, quality and performance, process improvements made during Phase 3 development carry a higher level of risk then those made prior to Phase 3 development. If there are significant differences in product attributes between the two materials, we may need to adjust our statistical analysis plans of the Phase 3 study to confirm that there is no difference in safety or efficacy between product made by each process in order to and allow us to utilize data from all enrolled patients, as well as be able to integrate clinical safety and/or efficacy results across studies to support any potential marketing application. There can be no assurance given that such analyses will be successful in demonstrating no clinical differences between these drug products, which could substantially impact the approvability of the U2 combination based on the results of the UNITY-CLL study. In such circumstances, that would have a material adverse effect on the Company.

Further, no assurance can be given that the material manufactured from any future optimized processes, if any, for ublituximab or any of our product candidates will perform comparably to the product candidates as manufactured to date which could result in an unexpected safety or efficacy outcome as compared to the data published or presented to date. Similarly, following each round of process improvements, if any, for any of our drug candidates, future clinical trial results conducted with the new material will be subject to uncertainty related to the effects, if any, of those additional process improvements that were made.

In addition, we have engaged a secondary manufacturer for ublituximab to meet our current clinical and future commercial needs and anticipate engaging additional manufacturing sources for umbralisib to meet expanded clinical trial and commercial needs. 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. No assurance can be given that any additional manufacturers will be successful or that material manufactured by the additional manufacturers will perform comparably to ublituximab or umbralisib as manufactured to date and used in currently available pre-clinical data and or in early clinical trials presented publicly or reported in this or any previous filing, or that the relevant regulatory agencies will agree with our interpretation of comparability.

In addition, as we move closer to commercialization for ublituximab and umbralisib we will need to scale-up production to ensure adequate commercial supply. We are currently in the process of scaling up ublituximab. This is an expensive process and 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. If scale-up were not to succeed our ability to supply our anticipated market at a reasonable cost of goods would be negatively impacted. In such event, that would have a material adverse effect on the Company. Scale up could also require additional process improvement that might be required to accommodate new and larger equipment utilized in the scaled-up process. If that were to occur and we could not demonstrate to the FDA that the materials were analytically substantially similar, we might be required to run additional clinical testing to demonstrate that they are substantially similar. That would entail a significant delay and significant increase in total cost, all of which would have a material adverse effect on the Company.

Risks Related to Commercialization

The incidence and prevalence for target patient populations of our drug candidates have not been established with precision. If the market opportunities for our drug candidates are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the patient population, our revenue and ability to achieve profitability will be adversely affected, possibly materially.

The precise incidence and/or prevalence of CLL, relapsed/refractory MZL, relapsed/refractory FL and MS are unknown. 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. Our beliefs are typically based on one on one and group interactions with target physicians and our 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 total addressable market opportunity for umbralisib and ublituximab for the treatment of patients with CLL, MZL, FL and MS will ultimately depend upon, among other things, the final label indication, approved for sale for these indications, acceptance by the medical community, patient access, drug pricing and reimbursement. The number of patients in major markets, including the number of addressable patients in those markets, may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our drugs, new patients may become increasingly difficult to identify or gain access to, or patients and physicians may choose to utilize competitive products, all of which would adversely affect our results of operations and our business.

We face substantial competition for treatments for our target indications, which may result in others commercializing drugs before or more successfully than we do resulting in the reduction or elimination of our commercial opportunity.

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.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we or our collaborators may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we or our collaborators are able to enter the market. The key competitive factors affecting the success of all of our drug candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of any related companion diagnostic tests, the level of generic competition and the availability of reimbursement from government and other third-party payors.

For the cancer indications for which we are developing our products there are a number of established therapies with which we will compete:

- For the treatment of CLL, if U2 is approved, we expect U2 to compete with recently approved drugs such as ibrutinib (AbbVie and Janssen), venetoclax (AbbVie and Roche), obinutuzumab (Roche), idelalisib (Gilead) and duvelisib (Verastem), and established treatments such as rituximab (Roche), and several generically available chemotherapies. Additionally, there are two second generation BTK inhibitors similar to ibrutinib in late-stage clinical testing for CLL that could enter the market in the next 12-36 months. Each of these agents can be used as monotherapy or in combination with one or more of the other agents.

- For the treatment of Marginal Zone Lymphoma, if approved, we expect umbralisib to compete with ibrutinib (AbbVie and Janssen) and established treatments such as rituximab and several generically available chemotherapies. Additionally, the combination of rituximab and lenalidomide (Celgene) has been studied in MZL and may be approved.

- For the treatment of Follicular Lymphoma, if approved, we expect umbralisib to compete with recently approved drugs such as obinutuzumab (Roche), idelalisib (Gilead), copanlisib (Bayer), and duvelisib (Verastem), and established treatments such as rituximab (Roche), and several generically available chemotherapies. Each of these agents can be used as monotherapy or in combination with one or more of the other agents. The combination of rituximab and lenalidomide (Celgene) has also been studied in FL and may be approved. There are also several PI3K delta inhibitors in earlier stages of development.

- In addition, a number of pharmaceutical companies are developing antibodies and bispecific antibodies targeting CD20, CD19, CD47 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 U2 and umbralisib.

For Multiple Sclerosis for which we are developing ublituximab there are a number of established therapies with which we will compete:

- If ublituximab is approved, we expect ublituximab will primarily compete against other CD20 targeted agents, while the group of CD20 targeted agents will also compete broadly against a number of already approved MS therapies. Currently, there is one anti-CD20 monoclonal antibody approved, ocrelizumab (Roche), and another in Phase 3 development, ofatumumab (Novartis), which is expected to enter the market in the next 12-24 months.

TG-1501, TG-1701 and TG-1801 if approved will also face competition from drugs on the market and under development that have the same mechanism of action as each of those drugs.

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. 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.

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

Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any drug candidates that we may develop.

We will face an inherent risk of product liability exposure related to the testing of our drug candidates in human clinical trials and use of our drug candidates through compassionate use programs, and we will face an even greater risk if we commercially sell any drug candidates that we may develop. If we cannot successfully defend ourselves against claims that our drug candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any drug candidates that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue; and
- the inability to commercialize any drug candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage if we successfully commercialize any drug candidate. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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 would also be necessary for commercial success. The degree of market acceptance of any approved product would depend on a number of factors, including:

- the efficacy and safety as demonstrated in clinical trials;
- the timing of market introduction of such product candidate as well as competitive products;
- 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 the product candidate over alternative treatments;
- the safety of the product candidate in a broader patient group;
- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- changes in regulatory requirements by government authorities for the product candidate;
- relative convenience and ease of administration;
- the prevalence and severity of side effects and adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

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.

Even if we are able to commercialize any drug candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a drug candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the drug candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the drug candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more drug candidates, even if our drug candidates obtain marketing approval.

Our ability to commercialize any drug candidates successfully also will depend in part on the extent to which coverage and reimbursement for these drug candidates and related treatments will be available from government authorities, private health insurers and other organizations. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. We cannot be sure that coverage will be available for any drug candidate that we commercialize and, if coverage is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any drug candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any drug candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower-cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

We are subject to new legislation, regulatory proposals and managed care initiatives that may increase our costs of compliance and adversely affect our ability to market our products, obtain collaborators and raise capital.

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.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "ACA," was enacted in 2010 and made significant changes to the United States' healthcare system. 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, those 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.

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 United States 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. At the end of 2017, Congress passed the Tax Cuts and Jobs Act, which repealed the penalty for individuals who fail to maintain minimum essential health coverage as required by the ACA. Following this legislation, Texas and 19 other states filed a lawsuit alleging that the ACA is unconstitutional as the individual mandate was repealed, undermining the legal basis for the Supreme Court's prior decision. On December 14, 2018, Texas federal district court judge Reed O'Connor issued a ruling declaring that the ACA in it is entirety is unconstitutional. While this decision has no immediate legal effect on the ACA and its provisions, this lawsuit is ongoing and the outcome through the appeals process may have a significant impact on our business.

Most recently, the Bipartisan Budget Act of 2018, the "BBA," which set government spending levels for Fiscal Years 2018 and 2019, revised certain provisions of the ACA. Specifically, beginning in 2019, the BBA increased manufacturer point-of-sale discounts off negotiated prices of applicable brand drugs in the Medicare Part D coverage gap from 50% to 70%, ultimately increasing the liability for brand drug manufacturers. Further, this mandatory manufacturer discount applies to biosimilars beginning in 2019.

The Trump Administration has also taken several regulatory steps to redirect ACA implementation. The Department of Health and Human Services ("HHS") finalized Medicare fee-for-service hospital payment reductions for Part B drugs acquired through the 340B Drug Pricing Program, which has been overturned by the courts. HHS also has signaled its intent to continue to pursue reimbursement policy changes for Medicare Part B drugs as a whole that likely would reduce hospital and physician reimbursement for these drugs.

HHS has made numerous other proposals aimed at lowering drug prices for Medicare beneficiaries and increasing price transparency. These proposals include giving Medicare Advantage and Part D plans flexibility in the availability of drugs in "protected classes," more transparency in the cost of drugs, including the beneficiary's financial liability, and less costly alternatives and permitting the use of step therapy as a means of prior authorization. HHS has also proposed requiring pharmaceutical manufacturers disclose the prices of certain drugs in direct-to-consumer television advertisements.

HHS also has taken steps to increase the availability of cheaper health insurance options, typically with fewer benefits and less generous. The Administration has also signaled its intention to address drug prices and to increase competition, including by increasing the availability of biosimilars and generic drugs. As these are regulatory actions, a new administration could undo or modify these efforts.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. Any reduction in reimbursement from Medicare or other government healthcare programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the US Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

There 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:

- our ability to generate revenues and achieve or maintain profitability;
- 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;
- 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 cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

We cannot predict the likelihood, nature or extent of how government regulation that may arise from future legislation or administrative or executive action taken by the U.S. presidential administration may impact our business and industry. In particular, the U.S. President has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. Notably, on January 23, 2017, President Trump ordered a civilian hiring freeze for all executive departments and agencies, including the FDA, which prohibits the FDA from filling employee vacancies or creating new positions. Under the terms of the order, the freeze was to remain in effect until implementation of a plan to be recommended by the Director for the Office of Management and Budget ("OMB") in consultation with the Director of the Office of Personnel Management, to reduce the size of the federal workforce through attrition. An under-staffed FDA could result in delays in FDA's responsiveness or in its ability to review submissions or applications, issue regulations or guidance or implement or enforce regulatory requirements in a timely fashion or at all. This hiring freeze was lifted later in 2017. Moreover, on January 30, 2017, President Trump issued an Executive Order, applicable to all executive agencies, including the FDA, which requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

If, in the future, we are unable to establish sales and marketing capabilities or enter into agreements with third parties to sell and market our drug candidates, we may not be successful in commercializing our drug candidates if and when they are approved, and we may not be able to generate any revenue.

We do not currently have a sales or marketing infrastructure and have limited experience in the sale, marketing or distribution of drugs. To achieve commercial success for any approved drug candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. In the future, we may choose to build a focused sales and marketing infrastructure to sell, or participate in sales activities with our collaborators for, some of our drug candidates if and when they are approved.

In advance of FDA approval of our first product, we will need to make significant investments to build a commercial organization and infrastructure. We will need to hire a sales force and commercial support personnel, in order to build processes and systems to support a commercial launch prior to knowing whether our product will receive FDA approval. It is possible that the FDA approval is unexpectedly delayed or our product is not approved at all. In either case we will incur delays that may impede or significantly delay our ability to generate revenue and at the same time will incur significant expenses. If this were to occur, it would have a material adverse effect on the Company.

There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time-consuming and could delay any drug launch. If the commercial launch of a drug candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our drug candidates on our own include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future drugs;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, our drug revenues or the profitability of these drug revenues to us are likely to be lower than if we were to market and sell any drug candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our drug candidates or may be unable to do so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drug candidates effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our drug candidates. Further, our business, results of operations, financial condition and prospects will be materially adversely affected.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, once we begin commercializing our drug candidates, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors play a primary role in the recommendation and prescription of any drug candidates for which we obtain marketing approval. Our future arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our drug candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the Affordable Care Act require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Department of Health and Human Services information related to physician payments and other transfers of value and the ownership and investment interests of such physicians and their immediate family members;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

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 laws. 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, we are exposed to liability risks under the Foreign Corrupt Practices Act or similar anti-bribery laws.

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Any product for which we obtain marketing approval could be subject to restrictions or withdrawal from the market and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with products.

Any product for which we obtain marketing approval, along with the manufacturing processes and facilities, post-approval clinical data, labeling, advertising and promotional activities for such product, will be subject to continual requirements of, and review by, the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration requirements, current Good Manufacturing Practice ("CGMP") requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping, and requirements regarding company presentations and interactions with healthcare professionals. Even if we obtain regulatory approval of a product, the approval may be subject to limitations on the indicated uses for which the product may be marketed, be subject to conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety and/or efficacy of the product. We also may be subject to state laws and registration requirements covering the distribution of drug products. Later discovery of previously unknown problems with products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on product manufacturing, distribution or use;
- restrictions on the labeling or marketing of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we or our subsidiaries submit;
- recalls;
- fines;
- suspension or withdrawal of marketing or regulatory approvals;
- refusal to permit the import or export of products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; and
- adverse publicity.

If we, or our respective suppliers, third-party contractors, clinical investigators or collaborators are slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or adoption of new regulatory requirements or policies, we, our subsidiaries, or our respective collaborators may be subject to the actions listed above, including losing marketing approval for products, resulting in decreased revenue from milestones, product sales or royalties.

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 ublituximab, umbralisib or any future product candidates will require approval from the FDA regardless of whether we have secured a formal trademark registration from the United States Patent and Trademark Office ("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 ublituximab, umbralisib 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 ublituximab, umbralisib, or any future product candidates. We do not currently have an agreed upon brand name for umbralisib, and no assurance can be given that we will obtain one in a timely fashion. Any delay in obtaining a brand name for umbralisib or any other of our drug candidates could delay approval and/or commercialization and have a negative impact on our launch and future prospects for umbralisib or any other such drug candidates.

Risks Related to Our Dependence on Third Parties

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

In order to submit and maintain an Investigational New Drug application ("IND"), BLA, or 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 portions 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. While we maintain an active IND for ublituximab and umbralisib enabling the conduct of studies in the FDA's Division of Hematology and Oncology, and an active IND for ublituximab under the FDA's Division of Neurology, there can be no assurance that the FDA will allow us to continue the development of our product candidates in those divisions where we maintain an active IND.

Additionally, we use CRO's to assist in the conduct of our current clinical trials and expect to use such services for future clinical trials and we rely upon medical institutions, clinical investigators and contract laboratories to conduct our trials in accordance with our clinical protocols and appropriate regulations. Our current and future CROs, investigators and other third parties play a significant role in the conduct of our 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. In addition to the third parties identified above, we are also heavily reliant on the conduct of our patients enrolled to our studies by our third-party investigators. We rely on our clinical trial sites and investigators to properly identify and screen qualified candidates for our clinical trials, and for them to ensure participants adhere to our clinical protocol requirements. The majority of our clinical trial conduct occurs in the out-patient setting, where patients are expected to continueto adhere to our study protocol specified requirements. The ability of our enrolled patients to properly identify, document, and report adverse events; take protocol specified study drugs at the correct quantity, time, and setting, as applicable; avoid contraindicated medications; and comply with other protocol specified procedures such as returning to the trial site for scheduled laboratory and disease assessments, is wholly out of our control. Deviations from protocol procedures, such as those identified previously, could materially affect the quality of our clinical trial data, and therefore ultimately affect our ability to develop and commercialize our drug candidates. If any of our clinical trial sites terminates for any reason, we may experience theloss 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. If any of our clinical trial sites are required by the FDA or IRB to close down due to data management or patient management or any other issues we may lose patients. In our MS Phase 2 trial, during routine monitoring and site audits, significant Good Clinical Practice (GCP) violations and other noncompliance issues were identified at one of our US-based large academic sites. The investigator left the institution; shortly thereafter the site terminated their participation in our study, before all data could be source document verified. While we do not believe this will have any effect on the overall results of the MS Phase 2 trial, sensitivity analyses excluding data from this site will be performed and no assurance can be given that the results were not affected.

Whether conducted through a CRO or through our internal staff, we are solely responsible for ensuring that each of our clinical trials are conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on CROs will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. We and our CROs are required to comply with regulations, including GCP Guidelines for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP regulations through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that our current or future clinical trials comply with GCPs. In addition, our clinical trials must be conducted with drug candidates produced under cGMPs regulations. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action. We also are required to register most ongoing clinical trials and post the results of completed clinical trials on government-sponsored databases, e.g. ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our drug candidates, CROs play an important role in the conduct of our clinical trials, especially outside of the United States. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct current or future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed; or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, regulatory approval and commercialization of our drug candidates may be delayed, we may not be able to obtain regulatory approval and commercialize our drug candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our drug candidates. As a result, we believe that our financial results and the commercial prospects for our drug candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of our drug candidates for pre-clinical development and clinical trials, and we expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our drug candidates for pre-clinical development and clinical testing, as well as for the commercial manufacture of our drugs if any of our drug candidates receive marketing approval. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates or drugs or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our marketing applications to the FDA. We do not control the manufacturing process of, and will be completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our drug candidates. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved. Further, our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of drug candidates or drugs, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our drug candidates.

We do not have any long-term supply agreements with all our contract manufacturers, and in those instances where we do not, we purchase our required drug supply, including the drug product and drug substance on a purchase order basis. In addition, we may be unable to establish or maintain any agreements with third-party manufacturers or to do so on acceptable terms. 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.

Even if we are able to establish and maintain agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Moreover, our current long-term supply agreements and, we would expect all future long-term supply agreements would, contain certain minimum purchases in what are commonly referred to as “take or pay” provisions. To the extent our demand does not meet the minimum supply required amounts, we would be forced to pay more than desired. This could create a situation where we are spending more than required and could impact our on-going operations and entail curtailing other important research and development or commercialization efforts. All of which could have a material adverse effect on the Company.

Our drug candidates and any drugs that we may develop may compete with other drug candidates and approved drugs 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. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers causing additional costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our drug candidates or drugs could result in significant delays or gaps in availability of such drug candidates or drugs and may adversely affect our future profit margins and our ability to commercialize any drugs 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.

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 fill/finish suppliers, and 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.

The third parties upon whom we rely for the supply of the active pharmaceutical ingredient ("API"), drug product, drug substance and other materials used in our drug candidates are our sole source of supply, and the loss of any of these suppliers could significantly harm our business.

The API, drug product and drug substance used in our drug candidates are currently supplied to us from single-source suppliers. Our ability to successfully develop our drug candidates, supply our drug candidates for clinical trials and to ultimately supply our commercial drugs in quantities sufficient to meet the market demand, depends in part on our ability to obtain the API, drug product and drug substance for these drugs in accordance with regulatory requirements and in sufficient quantities for clinical testing and commercialization. If any of our suppliers ceases its operations for any reason or is unable or unwilling to supply API, drug product, drug substance and other materials in sufficient quantities or on the timelines necessary to meet our needs, it could significantly and adversely affect our business, the supply of our drug candidates and our financial condition.

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. Various raw materials, components, and testing services required for our products may also be single sourced. 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 or 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.

For all of our drug candidates, we plan to identify and qualify additional manufacturers and other suppliers to provide such API, drug product and drug substance prior to or following submission of an NDA to the FDA and/or an MAA to the EMA. We are not certain, however, that our single-source suppliers will be able to meet our demand for their products, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

Establishing additional or replacement suppliers for the API, drug product and drug substance used in our drug candidates, if required, may not be accomplished quickly or at all. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional regulatory approval, which could result in further delay. While we seek to maintain adequate inventory of the API, drug product and drug substance used in our drug candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such API, drug product and drug substance from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

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 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 license 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 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.

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 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.

Our drug development programs and the potential commercialization of our drug candidates will require substantial additional cash to fund expenses. For some of our drug candidates, we may decide to collaborate with additional pharmaceutical and biotechnology companies for the development and potential commercialization of those drug candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration 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 our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject drug candidate, the costs and complexities of manufacturing and delivering such drug 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 drug 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 our drug candidate. The terms of any additional collaborations or other arrangements that we may establish may not be favorable to us.

We may be restricted under our collaboration agreements from entering into future agreements on certain terms with potential collaborators. 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.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the drug candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our drug candidates or bring them to market and generate drug revenue.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable drug candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any termination or expiration of any future collaboration agreement could adversely affect us financially or harm our business reputation.

Risks Relating to Our Intellectual Property

Our success depends upon our ability to obtain and protect our intellectual property and proprietary technologies and if the scope of our patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully commercialize our technology and drugs may be impaired.

Our commercial success in part depends on obtaining and maintaining patent protection and trade secret protection in the United States 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 and intellectual property 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. The degree of patent protection we require to successfully commercialize our drug candidates may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect any of our drug candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States.

Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally twenty years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned patent portfolio may not provide us with adequate and continuing patent protection sufficient to exclude others from commercializing drugs similar or identical to our drug candidates, including generic versions of such drugs.

Currently, the composition of matter patent for ublituximab and umbralisib are granted in both the United States and EU, among other countries. A method of use patent covering the combination of ublituximab and umbralisib has also been granted in the US, EU, Japan, and several other territories. Additionally, several method of use patents for ublituximab and umbralisib in various indications and settings have also 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. No patents to date have been issued for TG-1501, TG-1701 and TG-1801 or for our pre-clinical product candidates. 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, or what the scope of an issued patent may ultimately be.

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 United States 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 file new patent applications or make, use, and sell our potential products either in the United States or in international markets
- there may be significant pressure on the United States 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.

In addition, 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. Further, with respect to some of the pending patent applications covering our drug candidates, prosecution has yet to commence. Patent prosecution is a lengthy process, during which the scope of the claims initially submitted for examination by the U.S. Patent and Trademark Office, or USPTO, have been significantly narrowed by the time they issue, if at all. 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. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our licensors or we fail to appropriately prosecute and maintain patent protection or trade secret protection for one or more product candidates or any future product candidate we may license or acquire, 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 impair our ability to compete in the market and adversely affect our ability to generate revenues and achieve profitability, which would have a material adverse effect on our financial condition and results of operations. Furthermore, should we enter into other collaborations, including out-licensing or partnerships, 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 United States. The patent situation outside the United States is even more uncertain. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States, 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 United States 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 United States 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 United States 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 United States. 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.

In addition, U.S. patent laws may change, which could prevent or limit us or our subsidiaries from filing patent applications or patent claims to protect products and/or technologies or limit the exclusivity periods that are available to patent holders, as well as affect the validity, enforceability, or scope of issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents 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.

We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, reexamination, inter parties 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 United States 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.

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.

Even if our patent applications issue as patents, and they are unchallenged, our issued patents and our pending patents, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our owned or licensed patents by developing similar or alternative technologies or drugs in a non-infringing manner. For example, a third party may develop a competitive drug that provides benefits similar to one or more of our drug candidates but that has a different composition that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our drug candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our drug candidates could be negatively affected, which would harm our business.

In addition, we may in the future be subject to claims by our former employees or consultants asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants and advisors and any other third parties who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. An adverse determination in any such submission or proceeding may result in loss of exclusivity or freedom to operate 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 drugs, without payment to us, or could limit the duration of the patent protection covering our technology and drug candidates. Such challenges may also result in our inability to manufacture or commercialize our drug candidates 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 drug candidates.

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.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In addition, periodic maintenance fees on issued patents often must be paid to the USPTO and foreign patent agencies over the lifetime of the patent. While an unintentional lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our drugs or procedures, we may not be able to stop a competitor from marketing drugs that are the same as or similar to our drug candidates, which would have a material adverse effect on our business.

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 depends upon our ability and the ability of our collaborators to develop, manufacture, market and sell our drug candidates and use our proprietary technologies without infringing the proprietary rights and intellectual property of third parties. The biotechnology and pharmaceutical industries are characterized by extensive and frequent litigation regarding patents and other intellectual property rights. We may in the future become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our drug candidates and technology, including interference proceedings before the USPTO.

Our competitors or other third parties may assert infringement claims against us, alleging that our drugs are covered by their patents. Given the vast number of patents in our field of technology, we cannot be certain that we do not infringe existing patents or that we will not infringe patents that may be granted in the future. 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. 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 United States 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.

We are aware of certain patents that may pose issues for our commercialization of our drug candidates. For example, Roche, Biogen Idec, and Genentech hold patents for the use of anti-CD20 antibodies utilized in the treatment of CLL in the United States which are expected to expire in November of 2019. 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 valid and enforced at the time we are intending to launch ublituximab, 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 decide to initiate proceedings to challenge the validity of these patents in the future, we may be unsuccessful, as courts or patent offices in the United States and abroad could uphold the validity of any such patents. If we were to challenge the validity of any issued United States patent in court, we would need to overcome a statutory presumption of validity that attaches to every United States patent. This means that in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent's claims. If we are unable to do so, we may be forced to delay the launch of ublituximab or launch at the risk of litigation for patent infringement, which may have a material adverse effect on our business and results of operations.

If a third party claims that we or any collaborators of ours infringe their intellectual property rights, we may have to 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. If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our drug candidates and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain such a license, it could be granted on non-exclusive terms, thereby providing our competitors and other third parties access to the same technologies licensed to us. Without such a license, we could be forced, including by court order, to cease developing and commercializing the infringing technology or drug candidates. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed such third-party patent rights. A finding of infringement could prevent us from commercializing our drug candidates or force us to cease some of our business operations, which could materially harm our business.

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. For example, we engage extensively with third parties, including academic institutions, to conduct non-clinical and clinical research on our product candidates. While we seek to ensure all material transfer and service agreements governing this research provide us with favorable terms covering newly generated intellectual property, a general principle under which much of this research with academic institutions is conducted provides third party ownership of newly generated intellectual property, with an exclusive option available for us to obtain a license to such intellectual property. Through the conduct of this research, it is possible that valuable intellectual property could be developed by a third party, which we will then need to license in order to better develop or commercialize our products. No assurance can be given that we will be able to successfully negotiate such a license on commercially reasonable terms, or at all. Further, should we fail to successfully negotiate a license to such intellectual property, most institutions are then free to license such intellectual property to any other third party, including potentially direct competitors of ours. Should we fail to adequately secure a license to any newly generated intellectual property, our ability to successfully develop or commercialize our products may be hindered, 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 invalidity of our or certain of our subsidiaries' patents or that we infringe their patents; or provoke those parties to petition the USPTO 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 pending patents at risk of being invalidated, held unenforceable, or interpreted narrowly.

In patent litigation in the United States, defendant counterclaims challenging the validity, enforceability or scope of asserted patents are commonplace. In addition, third parties may initiate legal proceedings against us to assert such challenges to our intellectual property rights. The outcome of any such proceeding is generally unpredictable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Patents may be unenforceable if someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. It is possible that prior art of which we and the patent examiner were unaware during prosecution exists, which could render our patents invalid. Moreover, it is also possible that prior art may exist that we are aware of but do not believe is relevant to our current or future patents, but that could nevertheless be determined to render our patents invalid.

Competing drugs may also be sold in other countries in which our patent coverage might not exist or be as strong. If we lose a foreign patent lawsuit, alleging our infringement of a competitor's patents, we could be prevented from marketing our drugs in one or more foreign countries. Any of these outcomes would have a materially adverse effect on our business.

In addition, 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. Furthermore, adverse results on United States patents may affect related patents in our global portfolio. The adverse result could also put related pending patent applications at risk of not issuing. Additionally, 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.

Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or pending 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 or any of our respective licensors' 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.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by patents, we rely upon unpatented trade secret protection, unpatented know-how and continuing technological innovation to develop and maintain our competitive position. With respect to the building of our proprietary compound library, we consider trade secrets and know-how to be our primary intellectual property. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our collaborators, scientific advisors, employees and consultants, and invention assignment agreements with our consultants and employees. We may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements, however, despite the existence generally of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

Our trade secrets could otherwise become known or be independently discovered by our competitors. Competitors could purchase our drug candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. 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 our trade secrets are not adequately protected so as to protect our market against competitors' drugs, our competitive position could be adversely affected, as could our business.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed alleged trade secrets of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other proprietary information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. 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 could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our drug candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing our drug candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent sales representatives. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our drug candidates, which would have an adverse effect on our business, results of operations and financial condition.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

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 are highly dependent on the research and development, clinical, business development, financial and legal expertise of our senior management team as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreement with our chief executive officer and employment letters with our senior managers, each of our executive officers may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to continue hiring qualified development personnel. Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will be critical to our success. The loss of the services of our chief executive officer or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified medical and scientific personnel. 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.

We will need to develop and expand our Company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of February 15, 2019, we had 105 full-time employees, and we expect to continue to increase our number of employees and expand the scope of our operations. Our management and medical and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. To accommodate growth, additional physical expansion of our operations in the future may lead to significant costs, including capital expenditures, and may divert financial resources from other projects, such as the development of our drug candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our drug candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Additionally, to help manage the expanding needs, 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.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including, weakened demand for our drug candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services.

Following its June 23, 2016 vote to leave the European Union, on March 29, 2017, the United Kingdom invoked Article 50 of the Lisbon Treaty and formally began the process of exiting the European Union. Although Brexit has already and may continue to adversely affect European and/or worldwide economic or market, political or regulatory conditions and may contribute to instability in the global financial markets, political institutions and regulatory agencies, the resulting immediate changes in foreign currency exchange rates have had a limited overall impact due to natural hedging. The long-term impact of Brexit, including on our business and our industry, will depend on the terms that are negotiated in relation to the United Kingdom's future relationship with the European Union, and we are closely monitoring the Brexit developments in order to determine, quantify and proactively address changes as they become clear. Despite the Brexit developments, we do not expect macroeconomic conditions to have a significant impact on our liquidity needs, financial condition or results of operations.

We or the third parties upon whom we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our drug candidates' development programs.

Despite the implementation of security measures, our internal computer systems and those of our third-party CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs. For example, the loss of clinical trial data for our drug candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology or drug candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our drug candidates could be delayed.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could have a material adverse effect on our business.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties 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, misconduct, 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. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of ethics applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and 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 comply with these laws or regulations. In addition, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may acquire businesses or drugs, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions.

We may acquire additional businesses or drugs, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new drugs resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the IRS and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made and changes are likely to continue to occur in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders', tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

On December 22, 2017, the Tax Cuts and Jobs Act, or TCJA, was enacted. The TCJA significantly reforms the Internal Revenue Code of 1986, as amended. The TCJA, among other things, includes changes to U.S. federal tax rates, imposes significant additional limitations on the deductibility of interest and net operating loss carryforwards and allows for the expensing of capital expenditures. Our net deferred tax assets and liabilities were revalued as of December 31, 2017 at the newly enacted U.S. corporate rate, and the impact was recognized in our tax expense in the year of enactment but was offset by a corresponding reduction to the valuation allowance. We continue to examine the impact this tax reform legislation may have on our business. The impact of this tax reform is uncertain and could be adverse.

Our tax position could be affected by recent changes in United States 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 United States 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 United States 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, 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 and Being a Publicly-Traded Company

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 by us.

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.

Our executive officers, directors, principal stockholders and their affiliates maintain the ability to exercise significant influence over our company and all matters submitted to stockholders for approval.

Our executive officers, directors and stockholders who own more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially own shares of common stock representing a significant percentage of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire. In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be the sole source of gain for our stockholders.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, under the Loan Agreement, we are currently restricted from paying cash dividends, and we expect these restrictions to continue in the future. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future.

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.

An active trading market for our common stock may not be sustained, and investors may not be able to resell their shares at or above the price they paid.

Although we have listed our common stock on The Nasdaq Global Select Market, an active trading market for our shares may not be sustained. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the price at which they acquired their shares or at the time that they would like to sell. An inactive trading market may also impair our ability to raise capital to continue to fund operations by selling shares and may impair our ability to acquire other companies or technologies by using our shares as consideration.

If equity research analysts do not publish research or reports about our business or if they publish negative evaluations of or downgrade our common stock, the price of our common stock could decline.

The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us or our business. We do not control these analysts. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business downgrade their evaluations of our common stock, the price of our common stock could decline. If one or more of these analysts cease to cover our common stock, we could lose visibility in the market for our common stock, which in turn could cause our common stock price to decline.

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 ("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 control, which could have an adverse effect on the market price of our stock.

Volatility in the price of our common stock may subject us to securities litigation, which could cause us to incur substantial costs and divert management's attention, financial resources and other company assets.

In the past, securities class action litigation has often been brought against a company following periods of volatility in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. In addition, we and certain of our executive officers have been named as defendants in a securities class action and derivative lawsuits captioned Randall Reinmann v. TG Therapeutics Inc., and Michael S. Weiss, Case No. 1:18-cv-09104-KPF and Thessalus Capital v. Weiss, et al., 1:18-cv-11918-KPF. These lawsuits and any future lawsuits to which we may become a party are subject to inherent uncertainties and will likely be expensive and time-consuming to investigate, defend and resolve, and will divert our management's attention and financial and other resources. The outcome of litigation is necessarily uncertain, and we could be forced to expend significant resources in the defense of these and other suits, and we may not prevail. Any litigation to which we are a party may result in an onerous or unfavorable judgment that may not be reversed upon appeal or in payments of substantial monetary damages or fines, or we may decide to settle this or other lawsuits on similarly unfavorable terms, which could adversely affect our business, financial condition, results of operations or stock price. See Item 3. “Legal Proceedings” below for additional information regarding the securities class action and derivative lawsuits.

Future sales of our common stock, including by us or our directors and executive officers or shares issued upon the exercise of currently outstanding options, could cause our stock price to decline.

A substantial portion of our outstanding common stock can be traded without restriction at any time. In addition, a portion of our outstanding common stock is currently restricted as a result of federal securities laws, but can be sold at any time subject to applicable volume limitations. As such, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, by us or others, could reduce the market price of our common stock or impair our ability to raise adequate capital through the sale of additional equity securities. In addition, we have a significant number of shares that are subject to outstanding options. The exercise of these options and the subsequent sale of the underlying common stock could cause a further decline in our stock price. These sales also might make it difficult for us to sell equity securities in the future at a time and at a price that we deem appropriate. We cannot predict the number, timing or size of future issuances or the effect, if any, that any future issuances may have on the market price for our common stock.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change” (generally defined as a greater than 50% change (by value) in the ownership of its equity over a three year period), the corporation’s ability to use its pre-change net operating loss carryforwards and certain other pre-change tax attributes to offset its post-change income may be limited. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. As of December 31, 2017, we had federal net operating loss carryforwards of approximately $288.6 million, and our ability to utilize those net operating loss carryforwards could be limited by an “ownership change” as described above, which could result in increased tax liability to us. In addition, pursuant to the TCJA, we may not use net operating loss carry-forwards to reduce our taxable income in any year by more than 80%, and we may not carry back any net operating losses to prior years. These new rules apply regardless of the occurrence of an ownership change.

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, 9th 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.

In October 2018, a purported securities class action complaint was filed in the U.S. District Court for the Southern District of New York (the "Southern District") against the Company and one of its officers on behalf of all shareholders who purchased or otherwise acquired TG Therapeutics common stock between June 4, 2018 and September 25, 2018 (the "Class Period"). The case is captioned Randall Reinmann v. TG Therapeutics Inc., and Michael S. Weiss, Case No. 1:18-cv-09104-KPF. The complaint alleges that, throughout the Class Period, the Company made false and/or misleading statements and/or failed to disclose various facts and circumstances regarding its UNITY-CLL study allegedly in violation of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. In December 2018, the Southern District appointed Co-Lead Plaintiffs to represent the putative class, and approved their selection of Lead Counsel. On March 1, 2019, Co-Lead Plaintiffs filed a notice with the Southern District seeking to voluntarily dismiss the action in its entirety without prejudice.

In addition, on December 18, 2018, a related shareholder derivative litigation was filed in the Southern District against the Company's directors and one of its officers in litigation captioned Thessalus Capital v. Weiss, et al., 1:18-cv-11918-KPF. The Company is named only as a nominal defendant. The suit alleges that the officer and directors breached their fiduciary duties to the Company, wasted corporate assets, and violated the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with the Company's alleged failure to disclose various facts and circumstances regarding its UNITY-CLL study. The plaintiff asserts that the alleged disclosure violations concerning the Company's UNITY-CLL study have caused the Company to incur losses, including defense costs, and further alleges that the named officer and directors received excessive compensation.

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".

Holders

The number of record holders of our common stock as of February 14, 2019 was 239.

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, 2018, regarding the securities authorized for issuance under our equity compensation plan, the TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan.

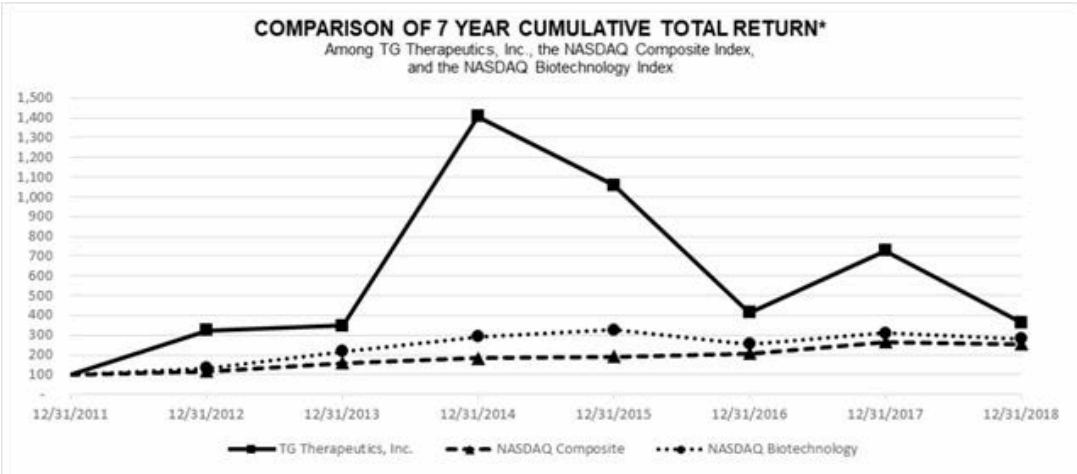
Equity Compensation Plan Information

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	1,916,900	$ 6.50	3,216,213
Equity compensation plans not approved by security holders	--	--	--
Total	1,916,900	$ 6.50	3,216,213

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, 2018, 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 December 31, 2011 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, 2018, 2017, 2016, 2015 and 2014, and Balance Sheet Data as of December 31, 2018, 2017, 2016, 2015 and 2014, 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."

(in thousands)

	Years ended December 31,				
	2018	2017	2016	2015	2014
License revenue	$ 152	$ 152	$ 152	$ 152	$ 152
Costs and expenses:					
Research and development:					
Noncash stock expense associated with in-licensing agreements	4,000	--	--	--	5,350
Noncash compensation	5,598	5,647	2,742	4,261	8,731
Other research and development	149,793	96,886	66,490	43,446	26,005
Total research and development	159,391	102,533	69,232	47,707	40,086
General and administrative:					
Noncash compensation	7,288	10,298	4,767	11,436	12,374
Other general and administrative	7,873	6,033	5,122	4,189	3,413
Total general and administrative	15,161	16,331	9,889	15,625	15,787
Total costs and expenses	174,552	118,864	79,121	63,332	55,873
Operating loss	(174,400)	(118,712)	(78,969)	(63,180)	(55,721)
Other (income) expense:					
Interest income	(857)	(295)	(323)	(174)	(55)
Other (income) expense	(61)	59	(393)	(57)	115
Total other (income) expense, net	(918)	(236)	(716)	(231)	60
Net loss	$ (173,482)	$ (118,476)	$ (78,253)	$ (62,949)	$ (55,781)
Basic and diluted net loss per common share	$ (2.30)	$ (1.91)	$ (1.60)	$ (1.38)	$ (1.64)

Balance Sheet Information:

	December 31,				
(in thousands)	2018	2017	2016	2015	2014
Cash, cash equivalents, investment securities and interest receivable	$ 68,901	$ 84,825	$ 44,969	$ 102,417	$ 78,861
Total assets	83,616	97,381	54,782	113,473	86,747
Accumulated deficit	(528,345)	(354,863)	(236,387)	(158,134)	(95,185)
Total equity	24,036	66,993	35,868	101,573	80,102

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 "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 dedicated to developing and delivering medicines for patients with B-cell mediated diseases, including Chronic Lymphocytic Leukemia (CLL), non-Hodgkin's Lymphoma (NHL) and Multiple Sclerosis (MS). We have developed a robust B-cell directed research and development (R&D) platform for identification of key B-cell pathways of interest and rapid clinical testing. Currently, we have five B-cell targeted drug candidates in clinical development, with the lead two therapies, ublituximab (TG-1101) and umbralisib (TGR-1202), in pivotal trials for CLL, NHL and MS. Ublituximab is a novel anti-CD20 monoclonal antibody (mAb) that has been glycoengineered for enhanced potency over first generation antibodies. Umbralisib is an oral, once daily inhibitor of PI3K delta. Umbralisib also uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K delta inhibitors. When used together in combination therapy, ublituximab and umbralisib are referred to as ("U2"), or "1303". Additionally, in early clinical development we have an anti-PD-L1 monoclonal antibody referred to as TG-1501, an oral Bruton's Tyrosine Kinase ("BTK") inhibitor referred to as TG-1701, and an anti-CD47/CD19 bispecific antibody referred to as TG-1801.

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, 2018, 2017 and 2016 were approximately $153.8 million, $96.9 million and $66.5 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.

(in thousands)	2018	2017	2016
Ublituximab	$ 105,429	$ 62,441	$ 40,840
Umbralisib	42,852	31,964	21,394
Early Clinical Pipeline & Pre-Clinical	5,512	2,481	4,256
Total	$ 153,793	$ 96,886	$ 66,490

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.

Our results of operations include non-cash compensation expenses as a result of the grants of restricted stock. Compensation expense for awards of 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 condensed 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 vest 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, or at all. In addition, we expect losses to continue as we fund in-licensing and development of new drug candidates. As we further our development efforts, we may enter into additional third-party collaborative agreements and incur additional expenses, such as licensing fees and milestone payments. In addition, we may need to establish a commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA or a foreign health authority, which would result in 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, 2018, 2017 and 2016

(in thousands)	Years Ended December 31, 2018	2017	2016
License revenue	$ 152	$ 152	$ 152
Costs and expenses:			
Research and development:			
Non-cash stock expense associated with in-licensing agreements	4,000	--	--
Noncash compensation	5,598	5,647	2,742
Other research and development	149,793	96,886	66,490
Total research and development	159,391	102,533	69,232
General and administrative:			
Noncash compensation	7,288	10,298	4,767
Other general and administrative	7,873	6,033	5,122
Total general and administrative	15,161	16,331	9,889
Total costs and expenses	174,552	118,864	79,121
Operating loss	(174,400)	(118,712)	(78,969)
Other income, net	(918)	(236)	(716)
Net loss	$ (173,482)	$ (118,476)	$ (78,253)

Years Ended December 31, 2018 and 2017

License Revenue. License revenue was approximately $152,000 for each of the years ended December 31, 2018 and 2017. 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 Stock Expense Associated with In-Licensing Agreement (Research and Development). Noncash stock expense associated with in-licensing agreement (research and development) amounted to $4.0 million for the year ended December 31, 2018, as compared to zero during the comparable period in 2017. The expense during the year ended December 31, 2018 was recorded in conjunction with the 333,868 total shares of common stock issued to Novimmune and Jiangsu Hengrui as upfront payments for the licenses to the CD47/CD19 and BTK programs, respectively.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants remained consistent between the two periods totaling $5.6 million for both years ended December 31, 2018 and 2017.

Other Research and Development Expenses. Other research and development expenses increased by $52.9 million from $96.9 million for the year ended December 31, 2017 to $149.8 million for the year ended December 31, 2018. The increase in R&D expense is primarily attributable to ongoing late-stage clinical development programs and related manufacturing costs for ublituximab and umbralisib during the year ended December 31, 2018. We expect our other research and development costs to decrease modestly during 2019.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants decreased by $3.0 million from $10.3 million for the year ended December 31, 2017 to $7.3 million during the year ended December 31, 2018. The decrease in noncash compensation expense was primarily related to a decrease in the measurement date fair value of certain consultant restricted stock during the year ended December 31, 2018 and 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 $1.9 million from $6.0 million for the year ended December 31, 2017 to $7.9 million for the year ended December 31, 2018. The increase was due primarily to increased personnel and other general and administrative costs. We expect our other general and administrative expenses to remain relatively consistent during 2019.

Other Expense (Income), Net. Other income increased by $0.7 million from $0.2 million for the year ended December 31, 2017 to $0.9 million for the year ended December 31, 2018. The increase is mainly due to an increase in interest income during 2018.

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 ublituximab and umbralisib during the year ended December 31, 2017.

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.

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 to 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.

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, 2018, we had $68.9 million in cash and cash equivalents, investment securities, and interest receivable. Subsequent to the year ended December 31, 2018, we entered into a term loan facility of up to $60.0 million (“Term Loan”) with Hercules Capital, Inc., (“Hercules”). The Term Loan is governed by a loan and security agreement, dated February 28, 2019 (the “Loan Agreement”), which provides for up to four separate advances. The first advance of $30.0 million was drawn on the closing date of February 28, 2019 (the “Closing Date”) (see Note 14 to the consolidated financial statemetns and "Debt Financings" for further information). In addition, on March 1, 2019, we announced the pricing of a public offering of 4,100,000 shares of our common stock (plus a 30-day underwriter overallotment option to purchase up to an additional 615,000 shares of common stock), with expected gross proceeds to the Company of $25.2 million, less underwriting discounts and commissions. The offering is expected to close on March 5, 2019.

We anticipate that our cash and cash equivalents as of December 31, 2018 combined with the additional capital being raised in the first quarter of 2019 will be sufficient to fund the Company’s planned operations into mid 2020. 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, 2018 was $128.9 million as compared to $93.8 million for the year ended December 31, 2017. The increase in cash used in operating activities was due primarily to increased expenditures associated with our clinical development programs for ublituximab and umbralisib.

For the year ended December 31, 2018, net cash provided by investing activities was $1.2 million as compared to cash used in investing activities of $8.2 million for the year ended December 31, 2017. The increase in net cash provided by investing activities was primarily due to greater proceeds from the sale of short-term securities during the year ended December 31, 2018.

For the year ended December 31, 2018, net cash provided by financing activities of $113.6 million related primarily to proceeds from the issuance of common stock as part of our ATM program.

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 (the "2015 ATM") with MLV & Co. LLC (“MLV”) 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.

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.

During the year ended December 31, 2018, we sold a total of 9,025,222 shares of common stock under the 2017 ATM for aggregate total gross proceeds of approximately $115.8 million at an average selling price of $12.83 per share, resulting in net proceeds of approximately $113.7 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.

On March 1, 2019, we announced the pricing of a public offering of 4,100,000 shares of our common stock (plus a 30-day underwriter overallotment option to purchase up to an additional 615,000 shares of common stock) with expected gross proceeds to the Company of $25.2 million, less underwriting discounts and commissions. The shares were sold under a shelf registration statement Form S-3 (File No. 333-218293) that was previously filed and declared effective by the SEC in June 2017. The offering is expected to close on March 5, 2019.

Debt Financings

On February 28, 2019 (the "Closing Date"), the Company ("Borrower") entered into a term loan facility of up to $60.0 million ("Term Loan") with Hercules Capital, Inc., ("Hercules"), the proceeds of which will be used for its ongoing research and development programs and for general corporate purposes. The Term Loan is governed by a loan and security agreement, dated February 28, 2019 (the "Loan Agreement"), which provides for up to four separate advances. The first advance of $30.0 million was drawn on the Closing Date. Two additional advances of $10.0 million may be drawn at the Borrower's option but subject to the clinical trial milestones, and the fourth advance of $10.0 million, available in minimum increments of $5.0 million, is available through December 15, 2020 subject to the approval of Hercules' investment committee.

The Term Loan will mature on March 1, 2022 (the "Loan Maturity Date"). Each advance accrues interest at a per annum rate of interest equal to the greater of either (i) the "prime rate" as reported in The Wall Street Journal plus 4.75%, and (ii) 10.25%. The Term Loan provides for interest-only payments until October 1, 2020. The interest-only period may be extended to April 1, 2021 if the Borrower, on or before September 30, 2020, achieves either the third milestone or the Company has raised at least an amount equal to $150.0 million in unrestricted net cash proceeds from one or more equity financings, subordinated indebtedness and/or upfront proceeds from business development transactions permitted under the Loan Agreement, in each case after February 7, 2019, and prior to September 30, 2020. Thereafter, amortization payments will be payable monthly in eighteen installments (or, if the period requiring interest-only payments has been extended to April 1, 2021, in twelve installments) of principal and interest (subject to recalculation upon a change in prime rates). At its option upon seven business days' prior written notice to Hercules, the Company may prepay all or any portion greater than or equal to $5.0 million of the outstanding advances by paying the entire principal balance (or portion thereof), all accrued and unpaid interest, subject to a prepayment charge of 3.0%, if such advance is prepaid in any of the first twelve months following the Closing Date, 1.5%, if such advance is prepaid after twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date, and 0% thereafter. In addition, a final payment equal to 3.5% of the aggregate principal amount of the loan extended by Hercules is due on the maturity date. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 4.0% per annum of the past due amount outstanding.

The Term Loan is secured by a lien on substantially all of the assets of the Borrower, other than intellectual property and contains customary covenants and representations, including a liquidity covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Loan Agreement include, without limitation, and subject to customary grace periods, (1) the Borrower's failure to make any payments of principal or interest under the Loan Agreement, promissory notes or other loan documents, (2) the Borrower's breach or default in the performance of any covenant under the Loan Agreement, (3) the occurrence of a material adverse effect, (4) the Borrower making a false or misleading representation or warranty in any material respect, (5) the Borrower's insolvency or bankruptcy, (6) certain attachments or judgments on the Borrower's assets, or (7) the occurrence of any material default under certain agreements or obligations of the Borrower involving indebtedness in excess of $750,000. If an event of default occurs, Hercules is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Loan Agreement also contains warrant coverage of 2% of the total amount funded. A warrant (the "Warrant") was issued by Borrower to Hercules to purchase 147,058 shares of common stock with an exercise price of $4.08. The Warrant shall be exercisable for seven years from the date of issuance. Hercules may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. The shares will be registered and freely tradeable within six months of issuance.

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, 2018, we have known contractual obligations, commitments and contingencies of $35.4 million related to our long-term liabilities and operating lease obligations.

Payment due by period (in thousands)

	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual obligations					
Operating leases	$ 16,996	$ 1,362	$ 2,701	$ 2,742	$ 10,191
Contract manufacturer	18,350	--	18,350	--	--
Total	$ 35,346	$ 1,362	$ 21,051	$ 2,742	$ 10,191

Contract Manufacturer

In 2018, we entered into an agreement with a contract manufacturer for the clinical and potential commercial supply of one of our product candidates. As part of this agreement, the contract manufacturer has agreed to defer payment of certain costs and expenses under the agreement in exchange for the payment of an administrative fee. As of December 31, 2018, we have incurred costs related to this agreement of approximately $18.4 million. All costs incurred in 2018 are to be billed in 2019 and are due in 2020. We will incur an administrative fee of six percent (6%) per year starting from the date of invoice issuance. No payments have been made to the contract manufacturer as of December 31, 2018 and accordingly the entire amount has been classified as long term liabilities included in our consolidated balance sheet.

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 $1.2 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, 2018 and 2017, we recorded rent expense of approximately $1.4 million and $1.2 million, respectively, and at December 31, 2018, have deferred rent of approximately $1.5 million. Mr. Weiss, our Executive Chairman and CEO, is also Executive Vice Chairman of FBIO.

During the year ended December 31, 2018, we agreed to pay FBIO $0.1 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, we pledged $1.2 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, $1.4 million and $1.6 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Future minimum lease commitments as of December 31, 2018 total, in the aggregate, approximately $17.0 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, 2018.

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. Effective January 1, 2018, the Company began recognizing revenue under Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), using the modified retrospective transition method. The impact of adopting the new revenue standard was not material to our consolidated financial statements and there was no adjustment to beginning retained earnings on January 1, 2018. The core principle of this new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, a company must assess the promised goods or services in the contract and identify each promised good or service that is distinct. A performance obligation meets ASC 606's definition of a "distinct" good or service (or bundle of goods or services) if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct).
- The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The transaction price allocated to each performance obligation is recognized when that performance obligation is satisfied, at a point in time or over time as appropriate.

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 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.

RECENTLY ISSUED ACCOUNTING STANDARDS

In July 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-11, "Leases - Targeted Improvements" ("ASU 2018-11") as an update to ASU 2016-02, Leases ("ASU 2016-02" or "Topic 842") issued on February 25, 2016. ASU 2016-02 is effective for public business entities for fiscal years beginning January 1, 2019. ASU 2016-02 required companies to adopt the new leases standard at the beginning of the earliest period presented in the financial statements, which is January 1, 2017, using a modified retrospective transition method where lessees must recognize lease assets and liabilities for all leases even though those leases may have expired before the effective date of January 1, 2017. Lessees must also provide the new and enhanced disclosures for each period presented, including the comparative periods.

ASU 2018-11 provides an entity with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new lease standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new lease standard will continue to be in accordance with ASC 840, Leases. An entity that elects this additional (and optional) transition method must provide the required ASC 840 disclosures for all periods that continue to be in accordance with ASC 840. The amendments do not change the existing disclosure requirements in ASC 840.

ASU 2018-11 is effective for public business entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with earlier adoption permitted. The Company adopted ASU 2018-11 on January 1, 2019 using a modified retrospective method and will not restate comparative periods. We elected the package of practical expedients permitted under the transition guidance, which allows us to carryforward our historical lease classification and our assessment on whether a contract is or contains a lease. The adoption of this guidance resulted in the addition of material balances of right of use assets and lease liabilities to our consolidated balance sheets at January 1, 2019, primarily relating to our lease of office space (see Note 9). We do not currently expect a material impact to our consolidated statements of operations as a result of this standard.

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting" ("ASU 2018-07"). ASU 2018-07 expands the scope of FASB Topic 718, Compensation – Stock Compensation ("Topic 718") to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date. The entity must not remeasure assets that are completed. Disclosures required at transition include the nature of and reason for the change in accounting principle and, if applicable, quantitative information about the cumulative effect of the change on retained earnings or other components of equity.

ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU 2018-07 on January 1, 2019. The adoption of ASU 2018-07 did not have a material effect on our consolidated financial statements as of January 1, 2019. The adoption of ASU 2018-07 had no impact on nonemployee performance awards as they are measured based on the outcome that is probable.

In May 2017, the FASB issued 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 and for the year ended December 31, 2018.

In November 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows – Restricted Cash" ("ASU 2016-18"). ASU 2016-18 requires that a statement of cash flows explain the change during the period for the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 does not provide a definition of restricted cash or restricted cash equivalents, and does not change the balance sheet presentation for such items. The Company adopted ASU 2016-18 on January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on our consolidated financial statements as of December 31, 2018.

In May 2014, the FASB issued ASU No. 2014-09, "Revenue from Contracts with Customers" (Topic 606) ("ASU 2014-09" or "ASC 606"), 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, 2018.

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, 2018, 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, 2018, 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, 2018, 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, 2018, 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, 2018. 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, 2018, 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, 2018 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, 2018.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2018 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, 2018, 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, 2018, 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 Stated) (PCAOB), the consolidated balance sheets and the related consolidated statements of operations, stockholders' equity and cash flows of the Company as of December 31, 2018 and 2017 and for each of the three years in the period ended December 31, 2018 and our report dated March 1, 2019, 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 1, 2019

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 2019 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 2019 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 2019 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 2019 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2019 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.

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).
4.4	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 (incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K for the year ended December 31, 2017). *
10.21	Joint Venture and License Option Agreement by and between TG Therapeutics, Inc. and Novimmune S.A., dated June 18, 2018 (incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-Q for the quarter ended June 30, 2018). *
10.22	Master Services Agreement, effective February 21, 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, 2018, 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

Report of Independent Registered Public Accounting Firm

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of TG Therapeutics, Inc. (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018, 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, 2018, 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 1, 2019, 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 1, 2019

TG Therapeutics, Inc. and Subsidiaries
Consolidated Balance Sheets as of December 31
(in thousands, except share and per share amounts)

	2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 41,958	$ 56,718
Short-term investment securities	26,848	27,999
Interest receivable	95	108
Prepaid research and development	9,691	8,056
Other current assets	439	437
Total current assets	79,031	93,318
Restricted cash	1,241	587
Leasehold interest, net	2,294	2,429
Equipment, net	251	248
Goodwill	799	799
Total assets	$ 83,616	$ 97,381
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 36,377	$ 25,877
Accrued compensation	2,258	1,800
Current portion of deferred revenue	152	152
Notes payable	67	128
Total current liabilities	38,854	27,957
Deferred rent	1,462	1,364
Deferred revenue, net of current portion	914	1,067
Long-term liabilities	18,350	--
Total liabilities	59,580	30,388
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, 2018 and 2017)	--	--
Common stock, $0.001 par value per share (150,000,000 shares authorized, 83,911,855 and 73,181,750 shares issued, 83,870,546 and 73,140,441 shares outstanding at December 31, 2018 and 2017, respectively)	84	73
Additional paid-in capital	552,531	422,017
Treasury stock, at cost, 41,309 shares at December 31, 2018 and 2017	(234)	(234)
Accumulated deficit	(528,345)	(354,863)
Total stockholders' equity	24,036	66,993
Total liabilities and stockholders' equity	$ 83,616	$ 97,381

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
(in thousands, except share and per share amounts)

	2018	2017	2016
License revenue	$ 152	$ 152	$ 152
Costs and expenses:			
Research and development:			
Non cash stock expense associated with in-licensing agreements	4,000	--	--
Noncash compensation	5,598	5,647	2,742
Other research and development	149,793	96,886	66,490
Total research and development	159,391	102,533	69,232
General and administrative:			
Noncash compensation	7,288	10,298	4,767
Other general and administrative	7,873	6,033	5,122
Total general and administrative	15,161	16,331	9,889
Total costs and expenses	174,552	118,864	79,121
Operating loss	(174,400)	(118,712)	(78,969)
Other (income) expense:			
Interest income	(857)	(295)	(323)
Other (income) expense	(61)	59	(393)
Total other income, net	(918)	(236)	(716)
Net loss	$ (173,482)	$ (118,476)	$ (78,253)
Basic and diluted net loss per common share	$ (2.30)	$ (1.91)	$ (1.60)
Weighted average shares used in computing basic and diluted net loss per common share	75,466,813	62,069,570	49,041,354

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, 2018, 2017 and 2016
(in thousands, except share amounts)

	Common Stock		Contingently issuable	Additional Paid-in	Treasury Stock		Accumulated	
	Shares	Amount	Shares	Capital	Shares	Amount	Deficit	Total
Balance at January 1, 2016	54,095,110	54	6	259,887	41,309	(234)	(158,134)	101,573
Issuance of common stock in connection with exercise of warrants	273,370	*		618				618
Issuance of common stock in connection with conversion of notes payable	3,710	*		33				33
Issuance of restricted stock	1,924,639	2		(2)				--
Forfeiture of restricted stock	(46,773)	*		*				--
Issuance of common stock in At-the-Market offering (net of offering costs of $0.1 million)	570,366	*		4,386				4,386
Compensation in respect of restricted stock granted to employees, directors and consultants				7,510				7,510
Adjustment to contingently issuable shares			(6)	*				--
Net loss							(78,253)	(78,253)
Balance at December 31, 2016	56,820,422	57	--	272,432	41,309	(234)	(236,387)	35,868
Issuance of common stock in connection with exercise of warrants	887,585	*		2,142				2,143
Issuance of restricted stock	1,836,511	2		(2)				--
Forfeiture of restricted stock	(53,875)			*				--
Issuance of common stock in public offering (net of offering costs of $3.6 million)	5,897,436	6		53,634				53,640
Issuance of common stock in At-the-Market offering (net of offering costs of $1.1 million)	7,793,671	8		77,865				77,873
Compensation in respect of restricted stock granted to employees, directors and consultants				15,945				15,945
Net loss							(118,476)	(118,476)
Balance at December 31, 2017	73,181,750	73	--	422,017	41,309	(234)	(354,863)	66,993
Issuance of restricted stock	1,562,211	2		(2)				--
Forfeiture of restricted stock	(191,196)	*		*				--
Issuance of common stock in At-the-Market offerings (net of offering costs of $2.0 million)	9,025,222	9		113,630				113,639
Compensation in respect of restricted stock granted to employees, directors and consultants				12,886				12,886
Shares issued in connection with in-licensing agreements	333,868	*		4,000				4,000
Net loss							(173,482)	(173,482)
Balance at December 31, 2018	83,911,855	$ 84	$ --	$ 552,531	41,309	$ (234)	$ (528,345)	$ 24,036

** Amount less than one thousand dollars.*

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
(in thousands)

	2018	2017	2016
CASH FLOWS FROM OPERATING ACTIVITIES			
Consolidated net loss	$ (173,482)	$ (118,476)	$ (78,253)
Adjustments to reconcile consolidated net loss to net cash used in operating activities:			
Gain on sale of long-term securities	--	--	(33)
Noncash stock compensation expense	12,886	15,945	7,510
Shares issued in connection with in-licensing agreement	4,000	--	--
Depreciation and amortization	88	82	63
Amortization of premium on investment securities	(119)	61	459
Change in fair value of notes payable and accrued interest	(61)	59	(110)
Changes in assets and liabilities:			
(Increase) decrease in other current assets	(1,638)	(2,665)	3,565
Decrease (increase) in leasehold interest	135	125	(2,042)
Decrease (increase) in accrued interest receivable	14	(25)	102
Decrease (increase) in other assets	--	162	(5)
Increase in accounts payable and accrued expenses	10,957	11,020	6,493
Increase in other liabilities	18,350	--	--
Increase in deferred rent	97	104	816
Decrease in deferred revenue	(152)	(152)	(152)
Net cash used in operating activities	(128,925)	(93,760)	(61,587)
CASH FLOWS FROM INVESTING ACTIVITIES			
Proceeds from maturity of short-term securities	32,500	19,800	29,500
Investment in held-to-maturity securities	(31,230)	(28,006)	(15,200)
Purchases of equipment	(90)	(2)	(344)
Proceeds from the sale of long-term securities	--	-	12,589
Net cash provided by (used in) investing activities	1,180	(8,208)	26,545
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from sale of common stock, net	113,639	131,516	4,411
Proceeds from the exercise of warrants	--	2,143	618
Deferred financing costs paid	--	--	(13)
Net cash provided by financing activities	113,639	133,659	5,016
NET (DECREASE) INCREASE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	(14,106)	31,691	(30,026)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF YEAR	57,305	25,614	55,640
CASH, CASH EQUIVALENTS AND RESTRICTED CASH AT END OF YEAR	$ 43,199	$ 57,305	$ 25,614
Reconciliation to amounts on consolidated balance sheets:			
Cash and cash equivalents	$ 41,958	$ 56,718	$ 25,031
Restricted cash	1,241	587	583
Total cash, cash equivalents and restricted cash	$ 43,199	$ 57,305	$ 25,614
NONCASH TRANSACTIONS			
Reclassification of deferred financing costs to additional paid-in capital	$ --	$ (3)	$ (25)
Conversion of convertible notes payable to common stock	$ --	$ --	$ 33

The accompanying notes are an integral part of the 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 dedicated to developing and delivering medicines for patients with B-cell mediated diseases, including Chronic Lymphocytic Leukemia (CLL), non-Hodgkin's Lymphoma (NHL) and Multiple Sclerosis (MS). We have developed a robust B-cell directed research and development (R&D) platform for identification of key B-cell pathways of interest and rapid clinical testing. Currently, we have five B-cell targeted drug candidates in clinical development, with the lead two therapies, ublituximab (TG-1101) and umbralisib (TGR-1202), in pivotal trials for CLL, NHL and MS. Ublituximab is a novel anti-CD20 monoclonal antibody (mAb) that has been glycoengineered for enhanced potency over first generation antibodies. Umbralisib is an oral, once daily inhibitor of PI3K delta. Umbralisib also uniquely inhibits CK1-epsilon, which may allow it to overcome certain tolerability issues associated with first generation PI3K delta inhibitors. When used together in combination therapy, ublituximab and umbralisib are referred to as ("U2"), or "1303". Additionally, in early clinical development we have an anti-PD-L1 monoclonal antibody referred to as TG-1501, an oral Bruton's Tyrosine Kinase ("BTK") inhibitor referred to as TG-1701, and an anti-CD47/CD19 bispecific antibody referred to as TG-1801.

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, 2018, we have an accumulated deficit of $528.3 million.

Our major sources of cash have been proceeds from the private placement and public offering of equity securities, and in 2019 from our loan and security agreement executed with Hercules (See Note 14 for more information). 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, 2018, we had $68.9 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, 2018 combined with the additional capital being raised in the first quarter of 2019 and flexible vendor payment arrangements (see Notes 6 and 14) will be sufficient to fund the Company's planned operations into mid 2020. 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."

RECENTLY ISSUED ACCOUNTING STANDARDS

In July 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2018-11, "Leases - Targeted Improvements" ("ASU 2018-11") as an update to ASU 2016-02, Leases ("ASU 2016-02" or "Topic 842") issued on February 25, 2016. ASU 2016-02 is effective for public business entities for fiscal years beginning January 1, 2019. ASU 2016-02 required companies to adopt the new leases standard at the beginning of the earliest period presented in the financial statements, which is January 1, 2017, using a modified retrospective transition method where lessees must recognize lease assets and liabilities for all leases even though those leases may have expired before the effective date of January 1, 2017. Lessees must also provide the new and enhanced disclosures for each period presented, including the comparative periods.

ASU 2018-11 provides an entity with an additional (and optional) transition method to adopt the new leases standard. Under this new transition method, an entity initially applies the new lease standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Consequently, an entity's reporting for the comparative periods presented in the financial statements in which it adopts the new lease standard will continue to be in accordance with ASC 840, Leases. An entity that elects this additional (and optional) transition method must provide the required ASC 840 disclosures for all periods that continue to be in accordance with ASC 840. The amendments do not change the existing disclosure requirements in ASC 840.

ASU 2018-11 is effective for public business entities for fiscal years beginning after December 15, 2018, and interim periods within those fiscal years, with earlier adoption permitted. The Company adopted ASU 2018-11 on January 1, 2019 using a modified retrospective method and will not restate comparative periods. We elected the package of practical expedients permitted under the transition guidance, which allows us to carryforward our historical lease classification and our assessment on whether a contract is or contains a lease. The adoption of this guidance resulted in the addition of material balances of right of use assets and lease liabilities to our consolidated balance sheets at January 1, 2019, primarily relating to our lease of office space (see Note 9). We do not currently expect a material impact to our consolidated statements of operations as a result of this standard.

In June 2018, the FASB issued ASU No. 2018-07, "Improvements to Nonemployee Share-Based Payment Accounting" ("ASU 2018-07"). ASU 2018-07 expands the scope of FASB Topic 718, Compensation – Stock Compensation ("Topic 718") to include share-based payment transactions for acquiring goods and services from nonemployees. An entity should only remeasure equity-classified awards for which a measurement date has not been established through a cumulative-effect adjustment to retained earnings as of the beginning of the fiscal year of adoption. Upon transition, the entity is required to measure these nonemployee awards at fair value as of the adoption date. The entity must not remeasure assets that are completed. Disclosures required at transition include the nature of and reason for the change in accounting principle and, if applicable, quantitative information about the cumulative effect of the change on retained earnings or other components of equity.

ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted, but no earlier than an entity's adoption date of Topic 606. The Company adopted ASU 2018-07 on January 1, 2019. The adoption of ASU 2018-07 did not have a material effect on our consolidated financial statements as of January 1, 2019. The adoption of ASU 2018-07 had no impact on nonemployee performance awards as they are measured based on the outcome that is probable.

In May 2017, the FASB issued 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 and for the year ended December 31, 2018.

In November 2016, the FASB issued ASU No. 2016-18, "Statement of Cash Flows – Restricted Cash" ("ASU 2016-18"). ASU 2016-18 requires that a statement of cash flows explain the change during the period for the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. ASU 2016-18 does not provide a definition of restricted cash or restricted cash equivalents, and does not change the balance sheet presentation for such items. The Company adopted ASU 2016-18 on January 1, 2018. The adoption of ASU 2016-18 did not have a material effect on our consolidated financial statements as of December 31, 2018.

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, 2018.

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, 2018 and December 31, 2017, we have approximately $1.2 million and $0.6 million, respectively, 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, 2018 and 2017 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 and short-term investments with high-credit quality financial institutions. At times, such amounts may exceed federally-insured limits.

REVENUE RECOGNITION

Effective January 1, 2018, the Company began recognizing revenue under ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), using the modified retrospective transition method. The impact of adopting the new revenue standard was not material to our consolidated financial statements and there was no adjustment to beginning retained earnings on January 1, 2018. The core principle of this new revenue standard is that a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. The following five steps are applied to achieve that core principle:

- Step 1: Identify the contract with the customer
- Step 2: Identify the performance obligations in the contract
- Step 3: Determine the transaction price
- Step 4: Allocate the transaction price to the performance obligations in the contract
- Step 5: Recognize revenue when the company satisfies a performance obligation

In order to identify the performance obligations in a contract with a customer, a company must assess the promised goods or services in the contract and identify each promised good or service that is distinct. A performance obligation meets ASC 606's definition of a "distinct" good or service (or bundle of goods or services) if both of the following criteria are met:

- The customer can benefit from the good or service either on its own or together with other resources that are readily available to the customer (i.e., the good or service is capable of being distinct).
- The entity's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract (i.e., the promise to transfer the good or service is distinct within the context of the contract).

If a good or service is not distinct, the good or service is combined with other promised goods or services until a bundle of goods or services is identified that is distinct.

The transaction price is the amount of consideration to which an entity expects to be entitled in exchange for transferring promised goods or services to a customer, excluding amounts collected on behalf of third parties (for example, some sales taxes). The consideration promised in a contract with a customer may include fixed amounts, variable amounts, or both. Variable consideration is included in the transaction price only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The transaction price is allocated to each performance obligation on a relative standalone selling price basis. The transaction price allocated to each performance obligation is recognized when that performance obligation is satisfied, at a point in time or over time as appropriate.

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, costs related to agreements with CRO's, certain costs to third party service providers related to development and manufacturing services as well as clinical development. These agreements often require payments in advance of services performed or goods received. Accordingly, as of December 31, 2018 and December 31, 2017, we recorded approximately $9.7 million and $8.1 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 condensed 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.

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 restricted stock 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 milestones becomes probable.

BASIC AND DILUTED NET LOSS PER COMMON SHARE

Basic net loss per share of our common stock is calculated by dividing net loss applicable to the common stock by the weighted-average number of our common stock outstanding for the period. Diluted net loss per share of common stock is the same as basic net loss per share of common stock since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because we 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 6,528,932, 4,835,706 and 8,033,779 at December 31, 2018, 2017 and 2016, respectively. During the years ended December 31, 2018, 2017 and 2016 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,		
	2018	2017	2016
Unvested restricted stock	4,595,689	4,820,143	7,142,055
Options	1,916,900	--	--
Shares issuable upon note conversion	16,343	15,563	14,812
Warrants	--	--	876,912
Total	6,528,932	4,835,706	8,033,779

LONG-LIVED ASSETS AND GOODWILL

Long-lived assets are reviewed for potential impairment 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 exists, a triggering event, 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 earlier 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. There was no impairment to goodwill as of December 31, 2018.

NOTE 2 – CASH AND CASH EQUIVALENTS

The following tables summarize our cash and cash equivalents at December 31, 2018 and 2017:

(in thousands)	December 31, 2018	December 31, 2017
Checking and bank deposits	$ 39,268	$ 55,682
Money market funds	2,690	1,036
Total	$ 41,958	$ 56,718

NOTE 3 – INVESTMENT SECURITIES

Our investments as of December 31, 2018 and 2017 are classified as held-to-maturity. Held-to-maturity investments are recorded at amortized cost.

The following tables summarize our investment securities at December 31, 2018 and 2017:

(in thousands)	December 31, 2018			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (maturing between January 2019 and November 2019) (held-to-maturity)	$ 26,848	$ 2	$ 10	$ 26,840
Total short-term investment securities	$ 26,848	$ 2	$ 10	$ 26,840

	December 31, 2017			
	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (maturing between January 2018 and November 2018) (held-to-maturity)	$ 27,999	$ --	$ 35	$ 27,964
Total short-term investment securities	$ 27,999	$ --	$ 35	$ 27,964

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.

As of December 31, 2018 and 2017, 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 $18.4 million at December 31, 2018 and $17.5 million at December 31, 2017. No payments have been made on the 5% Notes as of December 31, 2018.

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, 2018 and 2017. 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, 2018 and 2017:

(in thousands)	Financial liabilities at fair value as of December 31, 2018			
	Level 1	Level 2	Level 3	Total
5% Notes	$ --	$ --	$ 67	$ 67
Total	$ --	$ --	$ 67	$ 67

	Financial liabilities at fair value as of December 31, 2017			
	Level 1	Level 2	Level 3	Total
5% Notes	$ --	$ --	$ 128	$ 128
Total	$ --	$ --	$ 128	$ 128

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

The following table summarizes the changes in Level 3 instruments for the years ended December 31, 2017 and 2018:

(in thousands)		
Balance at January 1, 2017	$	69
Interest accrued on face value of 5% Notes		845
Conversion of 5% Notes		--
Change in fair value of Level 3 liabilities		(786)
Balance at December 31, 2017		128
Interest accrued on face value of 5% Notes		878
Conversion of 5% Notes		--
Change in fair value of Level 3 liabilities		(939)
Balance at December 31, 2018	$	67

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.

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 & Co, LLC (“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.

During the year ended December 31, 2018, we sold a total of 9,025,222 shares of common stock under the 2017 ATM for aggregate total gross proceeds of approximately $115.8 million at an average selling price of $12.83 per share, resulting in net proceeds of approximately $113.7 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 $136.5 million of common stock that remains available for sale under the 2017 S-3 at December 31, 2018. 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, 2018 and 2017, 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 2018. Pursuant to this amendment, 6,000,000 shares were added to the 2012 Incentive Plan. As of December 31, 2018 and 2017, 1,916,900 and zero options, respectively, were outstanding and up to an additional 3,216,213 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.

Stock Options

The estimated fair value of the options granted in the year ended December 31, 2018 was determined utilizing the Black-Scholes option-pricing model at the date of grant. The following table summarizes stock option activity for the years ended December 31, 2018 (there were no stock options granted during the years ended December 31, 2017 and 2016):

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2017	--	--	--	$ --
Granted	1,916,900	6.50		
Exercised	--	--		
Forfeited	--	--		
Expired	--	--		
Outstanding at December 31, 2018	1,916,900	6.50	9.75	--
Exercisable at December 31, 2018	--	--	--	$ --

As of December 31, 2018, the stock options outstanding include options granted to both employees and non-employees which are both time-based and milestone-based that vest upon certain corporate milestones. Stock-based compensation will be recorded if and when a milestone occurs. No expense was recognized during the year ended December 31, 2018 for these stock options.

The fair value of the Company's option awards were estimated using the assumptions below:

	Year Ended December 31, 2018
Volatility	192.76-296.71
Expected term (in years)	5.0-6.25
Risk-free rate	2.49-2.56%
Expected dividend yield	--%

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, 2018, 2017 and 2016:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2016	7,359,915	$ 7.83
Granted	1,924,639	4.99
Vested	(595,726)	7.38
Forfeited	(46,773)	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	(53,875)	8.47
Outstanding at December 31, 2017	6,321,643	7.17
Granted	1,562,211	13.07
Vested	(1,596,966)	9.38
Forfeited	(191,196)	8.13
Outstanding at December 31, 2018	6,095,692	$ 8.07

Total compensation expense associated with restricted stock grants was $12.9 million, $15.9 million and $7.5 million during the years ended December 31, 2018, 2017 and 2016, respectively. As of December 31, 2018, there was approximately $7.6 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 year. This amount does not include, as of December 31, 2018, 1,128,011 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,103,750 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, 2018, 2017 and 2016:

	Warrants	Weighted- average exercise price	Aggregate intrinsic value
Outstanding at January 1, 2016	1,186,749	$ 2.37	$ 11,341,452
Issued	--	--	
Exercised	(273,370)	2.26	
Expired	--	2.25	
Outstanding at December 31, 2016	913,379	2.41	1,961,403
Issued	--	--	
Exercised	(887,585)	2.41	
Expired	(25,794)	--	
Outstanding at December 31, 2017	--	$ --	$ --

There was no warrant activity during the year ended December 31, 2018.

NOTE 6 – LONG-TERM LIABILITIES AND NOTES PAYABLE

The following is a summary of notes payable and long term liabilities:

(in thousands)

	December 31, 2018			December 31, 2017		
	Current portion, net	Non-current portion, net	Total	Current portion, net	Non-current portion, net	Total
Convertible 5% Notes Payable	$ 67	$ --	$ 67	$ 128	$ --	$ 128
Long term liabilities	--	18,350	18,350	128	--	128
Totals	$ 67	$ 18,350	$ 18,417	$ 128	$ --	$ 128

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 $18.4 million at December 31, 2018 and $17.5 million at December 31, 2017. No payments have been made on the 5% Notes as of December 31, 2018.

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).

Long-Term Liabilities

In 2018, we entered into an agreement with a contract manufacturer for the clinical and potential commercial supply of one of our product candidates. As part of this agreement, the contract manufacturer has agreed to defer payment of certain costs and expenses under the agreement in exchange for the payment of an administrative fee. As of December 31, 2018, we have incurred costs related to this agreement of approximately $18.4 million, which includes both service fees and raw material costs. All costs incurred in 2018 are to be invoiced in 2019 and are due in 2020. We will incur an administrative fee of six percent (6%) per year starting from the date of invoice issuance. No payments have been made to the contract manufacturer as of December 31, 2018 and accordingly the entire amount has been classified as long-term liabilities included in our consolidated balance sheet.

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 $142,947,000 and $99,713,000 as of December 31, 2018 and 2017, 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 reduced our corporate federal tax rate from 34% to 21% effective January 1, 2018. As a result, we were 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 as of December 31, 2017; however, with full valuation allowance in place, the expense was reversed through a corresponding adjustment to the valuation allowance, resulting in no impact on income tax expense.

As of December 31, 2018, we have U.S. net operating loss carryforwards ("NOLs") of approximately $550,619,000 and research and development credit carryforwards ("R&D credits") of approximately $15,217,000. For income tax purposes, these NOLs and R&D credits will expire in various amounts through 2037. NOLs generated after 2017 do not expire. 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.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2018 and 2017 are presented below.

(in thousands)

	2018	2017
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 122,678	$ 83,656
Research and development credits	15,217	10,491
Noncash compensation	4,394	4,934
Other	658	632
Deferred tax assets, excluding valuation allowance	142,947	99,713
Less valuation allowance	(142,947)	(99,713)
Net deferred tax assets	$ --	$ --

There was no current or deferred income tax expense for the years ended December 31, 2018, 2017 and 2016. Income tax expense differed from amounts computed by applying the US Federal income tax rate of 21% for the year ending December 31, 2018 and 34% for the years ending December 31, 2017 and 2016 to pretax loss as follows:

	For the year ended December 31,		
(in thousands)	2018	2017	2016
Loss before income taxes, as reported in the consolidated statements of operations	$ (173,482)	$ (118,476)	$ (78,253)
Computed "expected" tax benefit	$ (36,431)	$ (40,282)	$ (26,606)
Increase (decrease) in income taxes resulting from:			
Expected benefit from state and local taxes	(2,243)	(1,106)	(835)
Research and development credits	(4,726)	(3,697)	(2,364)
Other	639	1,563	(8)
Stock awards	(473)	8,213	--
Enactment of federal tax reform	--	51,768	--
Change in the balance of the valuation allowance for deferred tax assets	43,234	(16,459)	29,813
	$ --	$ --	$ --

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 2015. 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, related 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 2018. 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.

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.

TGR-1202 (Umbralisib)

On September 22, 2014, we exercised our option to license the global rights to umbralisib, thereby entering into an exclusive licensing agreement (the "TGR-1202 License") with Rhizen Pharmaceuticals, SA ("Rhizen") for the development and commercialization of umbralisib. Prior to this, we had been jointly developing umbralisib 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 umbralisib, 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 umbralisib 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 umbralisib 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 umbralisib, provided that they are price competitive with alternative manufacturers.

TG-1101 (Ublituximab)

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong relating to the development and commercialization of ublituximab 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 ublituximab 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, 2018, 2017 and 2016, and, at December 31, 2018, 2017 and 2016, have deferred revenue of approximately $1.1 million, $1.2 million and $1.4 million, respectively, associated with this $2 million payment (approximately $152,000 of which has been classified in current liabilities at December 31, 2018).

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 ublituximab in the sublicense territory.

TG-1701: BTK

In January 2018, we entered into a global exclusive license agreement with Jiangsu Hengrui Medicine Co. ("Hengrui"), 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 Hengrui's Bruton's Tyrosine Kinase inhibitors containing the compounds of either TG-1701 (SHR1459 or EBI1459) or TG1702 (SHR1266 or EBI1266). Pursuant to the agreement, in April 2018, we paid Jiangsu an upfront fee of $1.0 million in our common stock recorded to non-cash stock expense associated with in-licensing agreements in our consolidated statement of operations. 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.

TG-1801: anti-CD47/anti-CD19

In June 2018, we entered into a Joint Venture and License Option Agreement with Novimmune SA ("Novimmune") to collaborate on the development and commercialization of Novimmune's novel first-in-class anti-CD47/anti-CD19 bispecific antibody known as TG-1801 (previously NI-1701). The companies will jointly develop the product on a worldwide basis, focusing on indications in the area of hematologic B-cell malignancies. We serve as the primary responsible party for the development, manufacturing and commercialization of the product. Pursuant to the agreement, in June 2018 we paid Novimmune an upfront payment of $3.0 million in our common stock recorded to non-cash stock expense associated with in-licensing agreements in our consolidated statement of operations. Further milestone payments will be paid based on early clinical development, and the Company will be responsible for the costs of clinical development of the product through the end of the Phase 2 clinical trials, after which the Company and Novimmune will be jointly responsible for all development and commercialization costs. The Company and Novimmune will each maintain an exclusive option, exercisable at specific times during development, for the Company to license the rights to TG-1801, in which case Novimmune is eligible to receive additional milestone payments totaling approximately $185 million as well as tiered royalties on net sales in the high single to low double digits upon and subject to the achievement of certain milestones.

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, LFB Group maintained the right to nominate a board member until such time as LFB Group owns less than 10% of the outstanding common stock. As of April 2018, LFB no longer has the right to nominate a board member as LFB's ownership had fallen below 10% of the outstanding shares of the Company's Common Stock.

Under the terms of the LFB License Agreement, we utilize LFB Group for certain development and manufacturing services. We incurred approximately $0.2 million, $2.3 million and $8.1 million in expenses for such services during the years ended December 31, 2018, 2017 and 2016, respectively, which have been included in other research and development expenses in the accompanying consolidated statements of operations.

Other Parties

In October 2014, we entered into an agreement (the "Office Agreement") with FBIO to occupy approximately 45% (which shall be adjusted based on utilization as discussed below) 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, 2018 and 2017, we recorded rent expense of approximately $1.3 million and $1.2 million, and at December 31, 2018, have deferred rent of approximately $1.5 million. Mr. Weiss, our Executive Chairman and Chief Executive Officer, is also Executive Vice Chairman of FBIO.

During the year ended December 31, 2018, we paid FBIO $0.1 million for our portion of the build-out costs (as required under the Desk Agreement), which have been allocated to us at the 45% rate mentioned above. The allocated build-out costs have been recorded in Leasehold Interest, net on the Company's consolidated balance sheets 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. Additional collateral of $0.6 million was pledged in April 2018 to increase the letter of credit for the office space.

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 $1.6 million, $1.2 million and $0.8 million for shared services for the years ended December 31, 2018, 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 a sublicense 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 which is recorded in other research and development in the accompanying consolidated statement of operations.

In March 2015, we entered into a Global Collaboration Agreement ("Collaboration Agreement") with Checkpoint for the development and commercialization of anti-PD-L1 and anti-GITR antibody research programs in the field of hematological malignancies. We incurred expenses of approximately $0.6 million for the year ended December 31, 2018 related mainly to manufacturing costs of PD-L1, while no costs were incurred during the years ended December 31, 2017 and 2016. The relevant expenses are recorded in other research and development in the accompanying consolidated statement of operations.

NOTE 10 – COMMITMENTS AND CONTINGENCIES

As of December 31, 2018, we have known contractual obligations; commitments and contingencies of $35.4 million related to our long term liabilities and operating lease obligations.

Payment due by period (in thousands)

ontractual obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating leases	$ 16,996	$ 1,362	$ 2,701	$ 2,742	$ 10,191
Contract manufacturer	18,350	--	18,350	--	--
Total	$ 35,346	$ 1,362	$ 21,051	$ 2,742	$ 10,191

Contract Manufacturer

See Note 6 for a detailed description of our long term liabilities. Future minimum contractual commitments as of December 31, 2018 total approximately $18.4 million and are due in 2020.

Leases

See Note 9 for a detailed description of our lease arrangement in New York. Total rental expense was approximately $1.4 million, $1.4 million and $1.6 million for the years ended December 31, 2018, 2017, and 2016, respectively.

Future minimum lease commitments as of December 31, 2018, in the aggregate total approximately $17.0 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, 2018.

NOTE 12 – QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

(in thousands)	3 Months Ended			
	March 31, 2018	June 30, 2018	September 30, 2018	December 31, 2018
License revenue	$ 38	$ 38	$ 38	$ 38
Total costs and expenses	40,615	44,383	34,366	54,188
Net loss	$ (41,529)	$ (44,142)	$ (33,951)	$ (53,861)
Basic and diluted net loss per common share	$ (0.59)	$ (0.59)	$ (0.43)	$ (0.68)

(in thousands)	3 Months Ended			
	March 31, 2017	June 30, 2017	September 30, 2017	December 31, 2017
License revenue	$ 38	$ 38	$ 38	$ 38
Total costs and expenses	27,704	28,463	31,623	31,073
Net loss	$ (27,727)	$ (28,353)	$ (31,536)	$ (30,860)
Basic and diluted net loss per common share	$ (0.52)	$ (0.45)	$ (0.48)	$ (0.46)

NOTE 13 – LITIGATION

In October 2018, a purported securities class action complaint was filed in the U.S. District Court for the Southern District of New York (the "Southern District") against the Company and one of its officers on behalf of all shareholders who purchased or otherwise acquired TG Therapeutics common stock between June 4, 2018 and September 25, 2018 (the "Class Period"). The case is captioned Randall Reinmann v. TG Therapeutics Inc., and Michael S. Weiss, Case No. 1:18-cv-09104-KPF. The complaint alleges that, throughout the Class Period, the Company made false and/or misleading statements and/or failed to disclose various facts and circumstances regarding its UNITY-CLL study allegedly in violation of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. In December 2018, the Southern District appointed Co-Lead Plaintiffs to represent the putative class, and approved their selection of Lead Counsel. On March 1, 2019, Co-Lead Plaintiffs filed a notice with the Southern District seeking to voluntarily dismiss the action in its entirety without prejudice.

In addition, on December 18, 2018, a related shareholder derivative litigation was filed in the Southern District against the Company's directors and one of its officers in litigation captioned Thessalus Capital v. Weiss, et al., 1:18-cv-11918-KPF. The Company is named only as a nominal defendant. The suit alleges that the officer and directors breached their fiduciary duties to the Company, wasted corporate assets, and violated the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with the Company's alleged failure to disclose various facts and circumstances regarding its UNITY-CLL study. The plaintiff asserts that the alleged disclosure violations concerning the Company's UNITY-CLL study have caused the Company to incur losses, including defense costs, and further alleges that the named officer and directors received excessive compensation.

No legal reserve is necessary.

NOTE 14 – SUBSEQUENT EVENTS

On February 28, 2019 (the "Closing Date"), the Company ("Borrower") entered into a term loan facility of up to $60.0 million ("Term Loan") with Hercules Capital, Inc., ("Hercules"), the proceeds of which will be used for its ongoing research and development programs and for general corporate purposes. The Term Loan is governed by a loan and security agreement, dated February 28, 2019 (the "Loan Agreement"), which provides for up to four separate advances. The first advance of $30.0 million was drawn on the Closing Date. Two additional advances of $10.0 million may be drawn at the Borrower's option but subject to the clinical trial milestones, and the fourth advance of $10.0 million, available in minimum increments of $5.0 million, is available through December 15, 2020 subject to the approval of Hercules' investment committee.

The Term Loan will mature on March 1, 2022 (the "Loan Maturity Date"). Each advance accrues interest at a per annum rate of interest equal to the greater of either (i) the "prime rate" as reported in The Wall Street Journal plus 4.75%, and (ii) 10.25%. The Term Loan provides for interest-only payments until October 1, 2020. The interest-only period may be extended to April 1, 2021 if the Borrower, on or before September 30, 2020, achieves either the third milestone or the Company has raised at least an amount equal to $150.0 million in unrestricted net cash proceeds from one or more equity financings, subordinated indebtedness and/or upfront proceeds from business development transactions permitted under theLoan Agreement, in each case after February 7, 2019, and prior to September 30, 2020. Thereafter, amortization payments will be payable monthly in eighteen installments (or, if the period requiring interest-only payments has been extended to April 1, 2021, in twelve installments) of principal and interest (subject to recalculation upon a change in prime rates). At its option upon seven business days' prior written notice to Hercules, the Company may prepay all or any portion greater than or equal to $5.0 million of the outstanding advances by paying the entire principal balance (or portion thereof), all accrued and unpaid interest, subject to a prepayment charge of 3.0%, if such advance is prepaid in any of the first twelve months following the Closing Date, 1.5%, if such advance is prepaid after twelve months following the Closing Date but on or prior to twenty-four months following the Closing Date, and 0% thereafter. In addition, a final payment equal to 3.5% of the aggregate principal amount of the loan extended by Hercules is due on the maturity date. Amounts outstanding during an event of default shall be payable on demand and shall accrue interest at an additional rate of 4.0% per annum of the past due amount outstanding.

The Term Loan is secured by a lien on substantially all of the assets of the Borrower, other than intellectual property and contains customary covenants and representations, including a liquidity covenant, financial reporting covenant and limitations on dividends, indebtedness, collateral, investments, distributions, transfers, mergers or acquisitions, taxes, corporate changes, deposit accounts, and subsidiaries.

The events of default under the Loan Agreement include, without limitation, and subject to customary grace periods, (1) the Borrower's failure to make any payments of principal or interest under the Loan Agreement, promissory notes or other loan documents, (2) the Borrower's breach or default in the performance of any covenant under the Loan Agreement, (3) the occurrence of a material adverse effect, (4) the Borrower making a false or misleading representation or warranty in any material respect, (5) the Borrower's insolvency or bankruptcy, (6) certain attachments or judgments on the Borrower's assets, or (7) the occurrence of any material default under certain agreements or obligations of the Borrower involving indebtedness in excess of $750,000. If an event of default occurs, Hercules is entitled to take enforcement action, including acceleration of amounts due under the Loan Agreement.

The Loan Agreement also contains warrant coverage of 2% of the total amount funded. A warrant (the "Warrant) was issued by Borrower to Hercules to purchase 147,058 shares of common stock with an exercise price of $4.08. The Warrant shall be exercisable for seven years from the date of issuance. Hercules may exercise the Warrant either by (a) cash or check or (b) through a net issuance conversion. The shares will be registered and freely tradeable within six months of issuance.

Additionally, on March 1, 2019, we announced the pricing of a public offering of 4,100,000 shares of our common stock (plus a 30-day underwriter overallotment option to purchase up to an additional 615,000 shares of common stock), with expected gross proceeds to the Company of $25.2 million, less underwriting discounts and commissions. The shares were sold under a shelf registration statement Form S-3 (File No. 333-218293) that was previously filed and declared effective by the SEC in June 2017. The offering is expected to close on March 5, 2019.

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 1, 2019

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 1, 2019, and in the capacities indicated:

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.22	Master Services Agreement, effective February 21, 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

Exhibit 21.1

Subsidiaries of TG Therapeutics, Inc.

Ariston Pharmaceuticals, Inc.

TG Biologics, Inc.

TG Therapeutics AUS Pty Ltd

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in registration statement Nos. 333-181439, 333-210227 and 333-225868 on Form S-8 and registration statement Nos. 333-218293 and 333-226097 on Form S-3 of TG Therapeutics, Inc. of our report dated March 1, 2019 on our audits of the consolidated financial statements of TG Therapeutics, Inc. and Subsidiaries as of December 31, 2018 and 2017, and for each of the three years in the period ended December 31, 2018, and our report on our audit of internal control over financial reporting of TG Therapeutics, Inc. and Subsidiaries as of December 31, 2018, dated March 1, 2019, included in this Annual Report on Form 10-K of TG Therapeutics, Inc. and Subsidiaries for the year ended December 31, 2018.

/s/ CohnReznick LLP

New York, New York
March 1, 2019

Exhibit 31.1

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 1, 2019

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

Exhibit 31.2

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 1, 2019

/s/ Sean A. Power
Sean A. Power
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 32.1

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, 2018 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 1, 2019

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

Exhibit 32.2

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, 2018 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 1, 2019

/s/ Sean A. Power
Sean A. Power
Chief Financial Officer
Principal Financial and Accounting Officer

Exhibit 10.22

CONFIDENTIAL TREATMENT REQUESTED. Confidential portions of this document have been redacted and have been separately filed with the Commission.

MASTER SERVICES AGREEMENT

between

*****

and

TG THERAPEUTICS, INC.

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MASTER SERVICES AGREEMENT

THIS MASTER SERVICES AGREEMENT (this "**MSA**") is made and entered into as of the date of last signature below (the "**Effective Date**") by and between TG Therapeutics, Inc., a Delaware corporation having its principal place of business at 2 Gansevoort St., 9th Floor, New York, NY 10014 (**"Client"**), and * Client and * are sometimes referred to herein individually as a **"Party"** and collectively as the **"Parties".**

WHEREAS, Client and * wish to enter into a business relationship whereby * will provide Client with certain biologics manufacturing services;

NOW, THEREFORE, in consideration of the mutual promises, covenants and agreements hereinafter set forth and for other valuable consideration, the Parties agree as follows:

SECTION 1 DEFINITIONS

1.1 "Acceptance Procedure" shall mean the review of the Batch Related Documents and test(s) of the Product, if necessary, to verify that the Product delivered meets the Specifications and complies with Regulatory Authority requirements, conducted by Client after *'s release of the Product, to determine whether to accept the same, in accordance with the applicable QAG as modified from time to time by written agreement between the Parties.

1.2 "Affected Party" is defined in Section 17.3.

1.3 "Affiliate" shall mean any corporation, company, partnership or other entity which directly or indirectly, controls, is controlled by or is under common control with either Party hereto. A corporation or other entity shall be regarded as controlling another corporation or other entity if it owns or directly or indirectly controls more than fifty percent (50 %) of the voting stock or other ownership interest of the corporation or other entity, or if possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the corporation or other entity or the power to elect or appoint more than fifty percent (50 %) of the members of the governing body of the corporation or other entity.

1.4 "Applicable Laws" shall mean any and all applicable laws of any jurisdiction which are applicable to any of the Parties in carrying out activities described in this MSA or any PSAs that may be in effect from time to time, and shall include all statutes, enactments, acts of legislature, laws, ordinances, rules, regulations, notifications, guidelines, directions, directives and orders of any Regulatory Authority, statutory authority, stock exchange, securities regulatory agency, tribunal, board, or court or any central or state government or local authority or other governmental entity in such jurisdictions.

1.5 "Background IP" shall mean Intellectual Property which has been owned and/or controlled by a Party prior to the Effective Date or outside, or not relating to, the performance of the MSA and any pertinent PSA.

* Confidential material redacted and filed separately with the Commission.

1.6 "Batch" shall mean Product Manufactured by * from a single run of the applicable Manufacturing Process.

1.7 "Batch Record" is defined in the applicable QAG.

1.8 "Batch Related Documents" means Manufacturing Documentation in support of the *'s release of a Product.

1.9 "Binding Year" shall be defined in the applicable PSA.

1.10 "Business Day" shall mean a day on which commercial banks are open for business in both the Republic of Korea and New York, New York.

1.11 "Cell Line" shall mean the aliquot of cells supplied to * by Client to perform the Services and their progeny.

1.12 "Certificate of Analysis" is defined in the applicable QAG.

1.13 "Certificate of Compliance" is defined in the applicable QAG.

1.14 "Change" is defined in Section 6.1.

1.15 "Client" is defined in the preamble.

1.16 "Client Materials" shall mean Client reagents and other materials supplied by Client or its third party supplier to be used in the Service hereunder, as each is further defined in the PSA and/or applicable QAG. In the case of a Drug Product PSA, Client Materials shall also include Drug Substance and/or other active pharmaceutical ingredients, which may or may not be Manufactured by *.

1.17 "Client Technology" shall mean know-how, technology, research and other information of Client including and relating to the Manufacturing Process, analytical methods, quality control analysis, specifications, transportation and storage requirements provided by Client to * in connection with this MSA and applicable PSA.

1.18 "Clinical Product" shall mean a Drug Substance or Drug Product which is Manufactured by * pursuant to a PSA and which is to be used by Client in a research study or studies that investigate the safety of human use or prospectively assign human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes.

1.19 "Commercial Product" shall mean a Drug Substance or Drug Product which is Manufactured by * which is intended for commercial sale and use by humans and for importation or exportation into countries or regions designated in each PSA.

* Confidential material redacted and filed separately with the Commission.

1.20 "Commercially Reasonable Efforts" shall mean with respect to an activity to be carried out by a Party, the carrying out of such activity in a diligent manner, which, in the case of *, requires using the efforts of sufficient numbers of personnel appropriately qualified by experience and training, in the application of such resources as would be reasonably applied by a qualified manufacturer of biologics for human use adhering to recognized standards in the manufacture and testing of such products, or, in the case of Client, using such efforts as would be typically be used in the biopharmaceutical industry by companies of comparable resources and expertise. "Commercially Reasonable Efforts" requires prompt assignment of responsibility for such task or activity to specific qualified employee(s) and allocation of resources designed to advance progress with respect to such task or activity but does not require the taking of actions which would require either Party to violate Applicable Laws or break any existing contractual commitments with third parties which were entered into prior to the Effective Date, the performance of which at such time was not reasonably foreseeable to be in conflict, or otherwise inconsistent, with such Party's obligations under the MSA or any PSA.

1.21 "Common Raw Materials" is defined in Section 5.3.1.

1.22 "Confidential Information" is defined in Section 10.1.

1.23 "Control" (including, with correlative meanings, "Controlled") means possession, directly or indirectly, of power to direct or cause the direction of management or policies (whether through ownership of securities or other ownership interest, by contract or otherwise) of that person or entity and/or the ownership of more than 50% of the voting shares of that person or entity.

1.24 "Core Team" is defined in Section 3.3.

1.25 "current Good Manufacturing Practices" or "cGMP" shall mean current good manufacturing practices and regulations applicable to the Manufacture of Product that are promulgated by any Regulatory Authority, including as promulgated under and in accordance with (i) the U.S. Federal Food, Drug and Cosmetic Act, Title 21 of the U.S. Code of Federal Regulations, Parts 210, 211, 600, 601 and 610, (ii) relevant EU legislation, including European Directive 2003/94/EC or national implementations of that Directive, (iii) relevant guidelines, including the EU Guidelines for Good Manufacturing Practices for Medicinal Products (Eudralex Vol. 4 and Annexes thereto), (iv) International Conference on Harmonisation Good Manufacturing Practice Guide for Active Pharmaceuticals Ingredients and (v) and any analogous set of regulations, guidelines or standards as defined, from time to time, by any relevant Regulatory Authority having jurisdiction over the development, manufacture or commercialization of the Product, as applicable, in each case as in effect as of the date such manufacturing for the Product are or were conducted.

1.26 "Damages" means any damages, costs, expenses, fines, penalties (including reasonable attorneys' fees and costs), losses and liabilities.

1.27 "Disclosing Party" is defined in Section 10.1.

* Confidential material redacted and filed separately with the Commission

1.28 "Drug Product" means a finished or intermediate dosage form that contains a Drug Substance, generally, but not necessarily, in association with one or more other ingredients.

1.29 "Drug Substance" means an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates used in the synthesis of such ingredient.

1.30 "Effective Date" is defined in the preamble.

1.31 "EMA" shall mean the European Medicines Agency, or any successor agency.

1.32 "Engineering Batch" shall mean a Batch that is intended to demonstrate the transfer of the Manufacturing Process to the Facility. After Manufacture, Client shall have the right to make whatever further use of non-cGMP Engineering Batches as it shall determine, provided that Client pays for such Batches according to this MSA, such use is not for human use and does not violate any Applicable Laws. * makes no warranty that Engineering Batches will meet cGMP or the Specifications. If * determines that an Engineering Batch does meet cGMP and the Specifications, it will release such Engineering Batch as a cGMP Batch, and thereafter Client shall be entitled to use such Engineering Batch for human use.

1.33 "Facility" shall mean *.

1.34 "FDA" shall mean the United States Food and Drug Administration or any successor agency thereto.

1.35 "Firm Period" shall be defined in the applicable PSA.

1.36 "Force Majeure Event" is defined in Section 17.3.

1.37 "Implementation Plan and Budget" is defined in Section 6.2(b).

1.38 "Indemnified Party" is defined in Section 13.3.

1.39 "Indemnifying Party" is defined in Section 13.3.

1.40 "Intellectual Property" is shall mean (a) patents, patent rights, provisional patent applications, patent applications, designs, registered designs, registered design applications, industrial designs, industrial design applications and industrial design registrations, including any and all divisions, continuations, continuations-in-part, extensions, restorations, substitutions, renewals, registrations, revalidations, reexaminations, reissues or additions, including supplementary certificates of protection, of or to any of the foregoing items; (b) copyrights, copyright registrations, copyright applications, original works of authorship fixed in any tangible medium of expression, including literary works (including all forms and types of computer software, including all source code, object code, firmware, development tools, files, records and data, and all documentation related to any of the foregoing), pictorial and graphic works; (c) trade secrets, technology, developments, discoveries and improvements, know- how, proprietary rights, formulae, confidential and proprietary information, technical information, techniques, inventions, designs, drawings, procedures, processes, models, formulations, manuals and systems, whether or not patentable or copyrightable, including all biological, chemical, biochemical, toxicological, pharmacological and metabolic material and information and data relating thereto and formulation, clinical, analytical and stability information and data which have actual or potential commercial value and are not available in the public domain; (d) trademarks, trademark registrations, trademark applications, service marks, service mark registrations, service mark applications, business marks, brand names, trade names, trade dress, names, logos and slogans, Internet domain names, and all goodwill associated therewith; and (e) all other intellectual property or proprietary rights, in each case whether or not subject to statutory registration or protection.

* Confidential material redacted and filed separately with the Commission.

1.41 "Joint Steering Committee" or "JSC" is defined in Section 3.2.1.

1.42 "Manufacturing" or to "Manufacture" shall mean the manufacturing of the Product, and any services relating to such manufacturing, including, but not limited to, testing, quality control, documentations, archiving, handling, storage and packaging, release and delivery of the Product, to be performed by * at the Facility under the MSA and any applicable PSA.

1.43 "Manufacturing Documentation" shall mean data acquired and generated, documents and records describing or otherwise related to the Manufacturing Process including, without limitation: documents and records consisting of or containing process descriptions, requirements and specifications; Client Materials and Specifications; analytical methods, process trend and variability data; validations protocols and reports; process development reports; Batch Records; Batch Related Documents, and SOPs, including, without limitation, SOP's for the Raw Materials handling, the Manufacturing operations, equipment operation, in-process, final Product and stability quality control testing, quality assurance, validation, storage and shipping.

1.44 "Manufacturing Process" shall mean the mutually agreed production process and analytical methods for the Manufacturing of the Product pursuant to the applicable PSA, as summarily described in the applicable QAG and as described in the Manufacturing Documentation, as such process may be changed from time to time in accordance with the MSA.

1.45 "Manufacturing Process Transfer" means the Commercially Reasonable Efforts of the parties undertaken pursuant to the Manufacturing Process Transfer Plan to transfer the Manufacturing Process (together with copies of relevant books and records) in *'s possession or under its control, to Client as set forth in greater detail in the Manufacturing Process Transfer Plan. * shall only be obligated to use its Commercially Reasonable Efforts in the implementation of the Manufacturing Transfer Plan, and in no case shall * personnel be required to visit the site of Client or any third party manufacturer. For the avoidance of doubt, the foregoing prohibition shall not be construed as a basis for * refusing to assist in the transfer of analytical methods to an independent laboratory, including a visit by * personnel to such site to assist in method transfer, if, and only as, reasonably necessary, and at Client's cost and expense. For the avoidance of doubt, Manufacturing Process Transfer shall include, without limitation, the transfer of data, information, or samples of validated or * manufactured or partially manufactured Products or other indicia measured at various points during Manufacture, to the extent * possesses such data, information, or samples. * shall not be obligated to deliver the proprietary process information contained in any drug master file with respect to which * has granted Client a right of reference. * shall provide Manufacturing Process Transfer services with a capacity of one (1) full time employee equivalent ("FTE") month for each of upstream, downstream and analytics, for a total maximum of three (3) FTE months. * will have no obligation to provide Manufacturing Process Transfer services more than twelve (12) months after termination of the MSA or applicable PSA. For clarity, *'s assistance shall be time- based, and * shall in no way guarantee or ensure that after Manufacturing Process Transfer services is complete, Client or its third-party manufacturer will be able to manufacture the Product.

* Confidential material redacted and filed separately with the Commission.

1.46 "Manufacturing Process Transfer Plan" means that plan addressing orderly Manufacturing Process Transfer, to be prepared in writing and reasonably agreed to by the parties within the forty (40) Business Day period following notice from Client to * of its intention to commence Manufacturing Process Transfer.

1.47 "Non-Affected Party" is defined in Section 17.3.

1.48 "Non-Conforming Product" shall mean an entire Batch of Product, any portion of which fails to conform to the Specifications, cGMP (if applicable), and any other mutually agreed upon written express requirements for * to follow under the applicable PSA and the applicable QAG.

1.49 "Party" and "Parties" is defined in the preamble.

1.50 "Pilot Batch" means a Batch of Product designated as a pilot Batch which shall not comply with cGMP and is not required to meet the Specifications.

1.51 "Pre-Approval Inspection" means an on-site inspection of the Facility by the Regulatory Authority prior to granting the Regulatory Approval for a Commercial Product as required by various Regulatory Authorities to ensure that the Manufacturing Process and the Facility meet the appropriate requirements and comply with cGMP.

1.52 "Process Validation Batch" shall mean a Batch of Commercial Product produced from a process validation run conducted by * hereunder to (i) demonstrate and document the consistency and reproducibility of the Manufacturing Process at the Facility, and (ii) support the Regulatory Approval of both the Product Manufactured and the Manufacturing Process at the Facility each as defined in the Project Plan.

1.53 "Product" shall mean Clinical Product or Commercial Product to be Manufactured by * pursuant to this MSA and any applicable PSA.

1.54 "Product Purchase Commitment" is defined in Section 5.7.

1.55 "Product specific agreement" or "PSA" is defined in Section 2.1.

1.56 "Project Management Team Leader" is defined in Section 3.3.2.

* Confidential material redacted and filed separately with the Commission.

1.57 "Project Plan" shall mean a formal, approved document used to guide both project execution and project control. The primary uses of the Project Plan are to document planning assumptions and decisions, facilitate communication among project stakeholders, and document approved scope, cost, and schedule baselines. The Project Plan will contain the description and overall objectives of the Services for Manufacturing a Product and shall include, among other things: (a) JSC and Core Team membership rosters, (b) change request procedures, (c) details, intentions, and deliverables for Technology Transfer, (d) project schedule, (e) detailed procurement plan, as needed, and (f) project budgets and invoicing plans.

1.58 "PSA Effective Date" shall mean the effective date of any PSA governed by this MSA.

1.59 "Purchase Order" is defined in Section 5.6.

1.60 "Quality Agreement" or "QAG" shall mean that certain quality agreement between the Parties that governs their respective responsibilities related to quality systems and quality requirements for the Product(s) Manufactured hereunder, including quality control, testing and release of such Product(s) at the Facility. Clinical Products and Commercial Products shall have separate forms of QAGs.

1.61 "Quarter" means each period of three (3) consecutive calendar months beginning on January 1, April 1, July 1, or October 1.

1.62 "Raw Materials" shall mean those materials that are used in the Manufacturing Process, including, but not limited to, chemicals, reagents, filters, excipients, disposable consumables, and secondary packaging materials. Raw Materials exclude the Client Materials.

1.63 "Receiving Party" is defined in Section 10.1.

1.64 "Reference Standards" shall mean materials for standards prepared by Client and/or * in accordance with the applicable QAG.

1.65 "Regulatory Approval" shall mean all approvals, licenses, registrations or authorizations thereof of any national, regional, state or local regulatory agency, department, bureau or other governmental entity in any jurisdiction where the Product is marketed or intended to be marketed, necessary for the manufacture and sale of the Product, which manufacturing includes the Manufacturing of the Products at the Facility.

1.66 "Regulatory Authority" shall mean any national (e.g., the FDA), supra-national (e.g., the EMA), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, in any jurisdiction responsible for granting the Regulatory Approval.

1.67 "* Assignable Error" means: negligence, fraud, recklessness, willful misconduct, or material breach of cGMP (if applicable) on the part of employees, consultants, contractors, sub-contractors, agents or representatives of *.

1.68 "Service" or "Services" is defined in Section 2.1.

* Confidential material redacted and filed separately with the Commission.

1.69 "Service Fee" is defined in Section 9.1.

1.70 "Specialized Raw Materials" is defined in Section 5.3.1.

1.71 "Specification(s)" shall mean the observable and measurable characteristics of the Products, Client Materials, or Raw Materials, as the case maybe, and the criteria for their storage, handling, packaging and shipping, which details are provided in documentation as reviewed and approved in writing by the Parties.

1.72 "Standard Operating Procedure(s)" or "SOP(s)" shall mean the standard operating procedures established by and mutually agreed upon by both Parties regarding the Manufacturing Process.

1.73 "Technology Transfer" shall mean the activities by the Parties necessary to Manufacture the Product for Client at the Facility or otherwise conduct the Services, as further described in the applicable PSA and/or Project Plan which may include: (i) transfer of the Client Technology and Client Material from Client to *; (ii) implementation of the Manufacturing Process at the Facility, including establishing a small scale Manufacturing Process model at *; (iii) all Manufacturing Process fit activities, including required small- and large-scale process development and validation work as allocated between the Parties to * and process engineering required to modify / equip, qualify and validate the Facility for the Manufacturing of the Commercial Product; (iv) stability testing, if applicable, for the Product required for licensure; (v) comparability testing to the appropriate reference product, and (vi) regulatory support for all Regulatory Approvals, each as further described in the Project Plan.

1.74 "Term" is defined in Section 15.1.

1.75 "Warehouse" shall mean *.

SECTION 2 RELATED AGREEMENTS AND EXHIBITS

2.1 **Product specific agreements.** Pursuant to one or more product specific agreements entered into and mutually agreed from time to time by duly authorized representatives of the Parties (**"Product specific agreements" or "PSAs"**), * will perform manufacturing services for Client as specified in such PSAs and applicable Project Plan and in accordance with the terms and conditions of this MSA (**"Services"**). Each PSA shall refer to this MSA and contain as applicable (i) a high level scope of work of the Services to be performed under such PSA which describes key activities, (ii) the Product for which * will perform such Services for Client, (iii) a description of the Cell Line; (iv) fees to be paid to * by Client for the Services with a general timing plan for invoicing and a more detailed plan to be in the Project Plan, (v) if the Services pertain to the manufacture of the Product, the number of batches of Product to be manufactured by * and delivered to Client and the Specifications, (vi) any other deliverables, (vii) the * facility where the Services are to be performed, and (viii) the Regulatory Approvals to be obtained by the Parties. Services shall be governed by the terms and conditions of this MSA, the applicable PSA, and any applicable Quality Agreement. In the event of a conflict between a Quality Agreement and either any provision of this MSA or any PSA, the MSA or PSA shall control except with respect to Product quality terms, in which case, the Quality Agreement will control. In the event of a conflict between any provisio of this MSA and the PSA, this MSA shall control, except as otherwise explicitly specified in the PSA.

* Confidential material redacted and filed separately with the Commission.

2.2 **Project Plan.** Concurrently with the execution of a PSA or within a reasonable time after the PSA effective date, the Parties shall agree upon a Project Plan which will specify in detail scope and schedule of the Services, including Technology Transfer and Manufacture. The Project Plan shall also set forth the JSC members (if applicable), Core Team members, and Project Management Team Leader for the Services as well as the frequency and duration of meetings. The Project Plan may be updated as needed by the mutual agreement of the Client and * and is governed by and incorporated into the applicable PSA by reference. If there is a conflict between the Project Plan and the applicable PSA, the PSA shall control. If any of the assumptions shared in writing by the Parties and on which the Parties have relied in defining the scope of the activities required to effect the Technology Transfer and/or other Services including but not limited to Manufacture, and the associated timeframes, fees, expenditures and costs proves to be invalid, or if for any reason other than a Party's negligence in planning, it becomes apparent that additional activities are required as part of or in connection with the Technology Transfer and/or other Services including but not limited to Manufacture, the Parties shall (acting reasonably and in good faith) discuss and seek to agree appropriate revisions to the Technology Transfer activities, and associated timelines and pricing.

2.3 **Quality Agreement (QAG).** The Parties shall agree upon and finalize a Quality Agreement in good faith within a reasonable period time after each PSA Effective Date which shall cover such PSA. No Manufacturing of Products for human use shall be conducted without an agreed upon, applicable QAG.Clinical Products and Commercial Products shall have separate QAGs. The Quality Agreement may be amended from time to time, subject to the JSC's approval followed by the Parties' written agreement pursuant to Section 17.9 (if applicable), which is incorporated herein by reference.

SECTION 3 MANAGEMENT OF SERVICE

3.1 **General.** Each Party will be responsible for its internal decision making process and for reasonably informing the other Party of decisions affecting the Service in a regular and timely manner. Without limiting the foregoing, the Parties shall establish the joint committees or teams set forth herein to advise the Parties on certain matters including, without limitation, Facility modification, Technology Transfer, and optimization of the Manufacturing operation relating to the Product.

3.2 **Joint Steering Committee.**

3.2.1 **Formation and Composition.** The applicable Project Plan will set forth a Joint Steering Committee for that Product (the "**Joint Steering Committee**" or "**JSC**") if the Parties mutually agree that such JSC is necessary. The JSC will be a cross-functional committee composed of an equal number of representatives appointed by each of Client and * with each of Client and * having at least three (3) representatives, and with one (1) representative from each of Client and * having oversight for quality activities, and with one (1) representative from each of Client and * having oversight for manufacturing and supply chain activities, including the transfer and implementation of the Manufacturing Process at the Facility. Either Party may replace any or all of its representitives at any time. Such Party shall notify, in writing, of such replacement to the other Party.

* Confidential material redacted and filed separately with the Commission.

3.2.2 **Responsibilities.** The JSC shall (i) establish and oversee the governance structure for the Service including the formation of any subcommittee hereunder; (ii) monitor any Facility modification and the Technology Transfer and Manufacturing strategy of the Product at the Facility, including strategies for the Regulatory Approval of the Facility to Manufacture the Product; (iii) provide strategic guidance to the Core Team as required by the Project Plan; (iv) conduct high level project stage reviews with the Core Team as required by the Project Plan at appropriate milestones or completion of key deliverables or a sequence of event to review and approve key deliverables, evaluate the Core Team's progress and performance, all in order to ensure that the Manufacturing Process is being implemented appropriately; (v) advise on and/or resolve business, manufacturing, supply chain, quality, regulatory or other issues unresolved at the Core Team level; (vi) review and recommend for approval by the Parties any changes to the MSA or the applicable PSA; (vii) review and approve changes to the Specifications, analytical methods, the Manufacturing Process, the Facility or equipment as escalated to the JSC by the Core Team or by a Party pursuant to Section 3.6 below; (viii) review completion of the Service; (ix) settle disputes or disagreements unresolved by a subcommittee; and (x) perform such other functions as appropriate to further the purposes of the MSA as determined by the Parties. For the avoidance of doubt, the JSC shall be a reviewing and consultative body, without authority to make decisions not otherwise concurred in by the Parties.

3.3 **Core Team.**

3.3.1 **Formation and Composition.** The applicable Project Plan will set forth a Core Team for that Product (the "**Core Team**"). The Core Team shall be composed of an equal number of representatives from each of * and Client, with up to four (4) representatives appointed by each of Client and *. Such representatives will include the Project Management Team Leaders of Client and * as well as such of their representatives from manufacturing, technical operations, supply chain, quality assurance, quality control, regulatory affairs or other individuals with expertise and responsibilities for those functions required from time-to-time to execute the Facility modification, the Technology Transfer and Manufacturing. Either Party may replace any or all of its representatives at any time. Such Party shall notify, in writing, of such replacement to the other Party.

3.3.2 **Appointment of Project Management Team Leader.** Each Party shall appoint a Project Management Team Leader (each, a "**Project Management Team Leader**") to act as the primary contact for such Party in connection with matters related to the Service. Each Project Management Team Leader, unless otherwise mutually agreed, shall serve as the leaders of the Core Team. A Party may replace its Project Management Team Leader at any time and from time to time for any reason. Such Party shall notify, in writing, of such replacement to the other Party.

3.3.3 **Responsibilities.** The Core Team shall (i) develop and maintain the Project Plan and monitor, review and manage the Service according to the MSA and applicable PSA; (ii) conduct project stage reviews with the JSC as required by the Project Plan at appropriate milestones or completion of key deliverables or a sequence of event to review key deliverables, review its progress and performance against plans; (iii) develop a change management process to identify, review and recommend any significant changes in the project scope, time, fee or risk to the JSC; (iv) investigate and resolve business, manufacturing, supply chain, quality, regulatory or other issues arising during the Service;

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(v) review and escalate to the JSC, as needed, changes to the Project Plan or applicable QAG; (vi) review and recommend to the JSC changes to the Specifications, analytical methods, the Manufacturing Process, the Facility or equipment; (vii) coordinate the activities of the Parties relating to the Manufacturing hereunder, including but not limited to: managing the technical operations and quality aspects of routine manufacturing, conducting Product testing technical operations and quality aspects of routine manufacturing, conducting Product testing and release, and managing supply chain activities including shipping and delivery logistics; (viii) report periodically on operation and quality progress and performance; and (ix) perform such other tasks and undertake such other responsibilities as may be specifically delegate to the Core Team by mutual agreement of the Parties. For the avoidance of doubt, the Core Team shall be without authority to make decisions not otherwise concurred in by the Parties.

3.4 **Meetings.**

3.4.1 **JSC.** The JSC shall meet by audio or video teleconference or in-person as agreed by the JSC or as necessary to make determinations as required of it. Any member of the JSC may designate a substitute to attend and perform the functions of that member at any meeting of the JSC and each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend such meeting with advance notice to the other Party; provided, however, such non-member representatives are subject to enforceable obligations of confidentiality to the inviting Party.

3.4.2 **Core Team.** The Core Team shall meet by audio or video teleconference or in-person as agreed by the Core Team. Any member of the Core Team may designate a substitute to attend and perform the functions of that member at any meeting of the Core Team and each Party may, in its reasonable discretion, invite non-member representatives of such Party to attend such meetings with advance notice to the other Party; provided, however, such non-member representatives are subject to enforceable obligations of confidentiality to the inviting Party.

3.4.3 **Travel Expenses.** Each Party shall be responsible for all of its own expenses of traveling to and participating in any joint committee or team meeting, including the JSC and Core Team.

3.5 **Decisions.** All decisions of JSC, the Core Team and any other joint committee or team formed under the MSA or any applicable PSA, except as expressly set forth herein, shall be made by the unanimous agreement of its members or their designated representatives, with a Party's members of designated representatives having, in the aggregate, one (1) vote (with the casting of fractional votes being impermissible), and shall be reflected in written meeting minutes which summarily address topics discussed, delegation of work, schedules and decision of such committee or team. * shall prepare written minutes of the JSC and Core Team within fifteen (15) Business Days of the meeting to which they relate, which shall be subject to approval by the authorized representatives of the Parties; provided, however, no joint committee or team herein may amend or waive any provision of theMSA or applicable PSA, including without limitation, the financial terms set forth in Section 9. The MSA or any PSA may be amended, and provision of the MSA or any PSA may be waived, pursuant to Section 17.9 only.

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3.6 **Disputes.**

3.6.1 **General.** In the event that the Core Team and any other joint committee or team formed under the MSA or any applicable PSA, is unable, despite the good faith efforts of all members, to resolve a disputed issue that is within the purview of such joint committee or team within ten (10) Business Days of meeting request by either Party, the disputed issue shall be referred immediately by such joint committee or team to the JSC. If the disputes still cannot be resolved within an additional twenty (20) Business Days of meeting request by the JSC, the matter may be handled in accordance with Section 16.

3.6.2 **Project Management Team Leaders.** Subject to Section 3.6.1, the Project Management Team Leaders (or their respective designees) will in good faith attempt to mutually resolve in a timely fashion any disagreement with respect to the Service hereunder, which could reasonably affect the quality of the Manufacturing of the Product, including without limitation, the related management processes and operations, control of production planning and scheduling, prioritization decisions, allocation of resources, timing of in-process and release testing, oversight of auxiliary facilities (e.g., in-process tests that need to be conducted at laboratories other than those at the Facility), Facility modification, the Technology Transfer, registration and troubleshooting decisions, and any other matters relating to implementation of the Manufacturing Process and the Manufacturing of the Product hereunder.

SECTION 4 SERVICES

4.1 **Services.** During the Term, in accordance with and subject to the terms and conditions set forth in this MSA, applicable PSA, and the applicable QAG, * shall provide the Services to Client relating to the Product(s). * shall at all times make Commercially Reasonable Efforts to complete the Services in accordance with the timelines set forth in the applicable PSA. Except as otherwise expressly set forth in the MSA, applicable PSA, or the applicable QAG or as otherwise mutually agreed in writing by the Parties, * shall be responsible at its own cost and discretion for operating and maintaining the Facility.

4.2 **Compliance with Applicable Law.** Subject to the provisions of Section 6 below, * shall maintain the Facility in accordance with cGMP and in such condition as will allow * to Manufacture the Products in accordance with the terms of the MSA and the applicable QAG. * shall perform the Services under the MSA in conformance with cGMP, if applicable, any requirements of the Regulatory Authorities that shall be mutually agreed upon by the Parties, and all Applicable Laws.

4.3 **Project Personnel.** * shall adequately staff the Facility with personnel necessary (including consultants and contractors), who have sufficient technical expertise by virtue of training and experience to perform its obligations under the MSA and any applicable PSA. Notwithstanding anything to the contrary and in addition to the JSC and Core Team meetings described in Section 3 above, Client and * may arrange for core project personnel to have regular meetings, which shall be by audio or video teleconference. The Project Plan shall specify the frequency and duration of such meetings; provided that the associated costs for meetings requested solely by Client in excess of the number set forth in the Project Plan shall be passed through to Client by *, unless such meeting is for the purpose of addressing a deficiency in Manufacturing caused by * Assignable Error or assessing remediation thereof.

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4.4 **Subcontract.** * may subcontract any portion of the Services without approval from Client; provided, however, that * will not subcontract or otherwise engage subcontractors or other third party agents to manufacture, conduct quality control testing, or perform Services directly related to manufacturing or quality control testing without the prior written approval of Client, which shall not be unreasonably withheld, conditioned, or delayed. Notwithstanding any subcontracting, * shall be primarily obligated to Client for any subcontracted services as if it were providing the Services itself, and shall be jointly and severally liable to Client for the performance of any such Service. The preceding sentence is not meant to nor shall it be construed as altering or eliminating any mutually agreed upon limitations of liability contained within this MSA or any applicable PSA. Every subcontractor or other third party agent of * performing pursuant to this Section 4.4 shall be required by * to agree in writing to comply with relevant portions of this MSA, together with pertinent PSAs and QAGs. For the avoidance of doubt, * shall not directly or indirectly use on its own behalf or through any subcontractor, other vendor or any third party in the performance of this MSA or any PSA, any invention, technology, data or information that would require Client to obtain a license from * not otherwise granted pursuant to this MSA or an applicable PSA, or obtain a license from any such subcontractor, vendor or third party a license in order to make, have, made, use, offer for sell, sell, import or otherwise exploit any Product, unless Client has agreed in advance in writing.

4.5 **Development and Manufacturing Site.** Except as is provided in Section 4.4 or otherwise agreed by Client, all Services shall be performed by * at the Facility.

4.6 **Access to the Facility.**

4.6.1 * shall accommodate visits by Client personnel in the Facility during operational hours during the Term, upon Client's request, to coordinate, expedite and guide the Service. Client will provide * with written notice at least one (1) month prior to any visit, and the Parties shall decide on a mutually agreeable date, duration, visitor list, and agenda prior to the visit. Additionally, Client may, at no cost to *, request up to two (2) of its personnel to be on-site at the Facility to observe and consult with * during the performance of Services under this MSA and such additional personnel in such numbers as deemed necessary by Client shall be accommodated upon mutual agreement. * shall make reasonable efforts to provide such Client personnel working space and access to guest wireless connections. All applicable out- of-pocket expenses associated with such on-site Client personnel shall be passed through to Client by *.

4.6.2 While at the Facility, all such Client personnel shall have reasonable access to all areas as are relevant to *'s performance of the Service hereunder, provided that * may reasonably restrict Client personnel's access to those portions of the Facility as it deems reasonably necessary for safety, confidentiality and cGMP, and visitors admitted pursuant to this Section, upon request of *, shall comply with * policies and procedures as they apply to * personnel generally while at the Facility.

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4.7 **Manufacturing Documentation**. * shall maintain in the English language, complete, true and accurate Manufacturing Documentation, and shall keep them in strict confidence and shall not use them for purposes other than providing or performing the Service or other obligations hereunder. * shall maintain all such Manufacturing Documentation for at least that period specified in the applicable QAG or such longer period as may be required by Applicable Law. Upon written request of Client and at mutually agreeable times, Client shall have the right to review Manufacturing Documentation, including the Batch Records, at the Facility as further defined in the applicable QAG; provided, however, * shall not delay any such request of Client for more than fifteen (15) Business Days. Client may also request scanned or printed copies of such Manufacturing Documentation, but shall be responsible for reasonable costs associated therewith. * shall record and maintain such records, data, documentation and other information in the language as so required in the applicable QAG or as so required by a Regulatory Authority and in compliance with Applicable Law, or as otherwise may be set forth in an applicable PSA. The form and style of Batch documents, including, but not limited to, Batch production records, lot packaging records, equipment set up control, operating parameters, and data printouts, raw material data, and laboratory notebooks are the exclusive property of *. Notwithstanding anything to the contrary, * SOPs not specific to the Client's Products may be provided to Client for on-site review if deemed necessary by both * and Client. Such SOPs cannot be removed from the * premises, copied, photographed or otherwise replicated, but to the extent required for filing in connection with any Regulatory Approval related to a Product including, but not limited to, an IND, BLA or MAA, * will file, maintain and update such SOPs with appropriate Regulatory Authorities by means of a Drug Master File, Common Technical Document or other means by which such SOPs may remain confidential, but available by reference to Client to effect Regulatory Approvals, and * shall formally authorize such reference.

SECTION 5 SERVICE DESCRIPTIONS

5.1 **Technology Transfer Requirements.** The Parties shall make their personnel available at the Facility to enable the transfer and implementation in accordance with the Project Plan. Client shall transfer to and grant * the limited license set forth below in Section 11.2 in respect of the Reference Standards, Client Technology, Client Materials, and Cell Line In the event that Client agrees to utilize *, Client agrees that (a) in the event of any relevant change that affects a Client user's authorization to use such portal, Client shall promptly notify * so that * may disable their usernames and remove / change passwords in order to secure the * Portal and (b) Client shall ensure that all of Client's users have up-to-date antivirus software installed on the computer devices used to access such portal.

5.2 **Facility Modification and Equipment.** Except as otherwise specifically provided herein to the contrary, and upon mutual agreement of the Parties, Client and * will agree on what equipment in the Facility is necessary to perform the Services, and if it is necessary or Client deems it necessary to procure additional equipment beyond that which is in the Facility as of the applicable PSA Effective Date, the Core Team shall determine equitable allocation of costs including, as applicable, procurement, validation, installation, maintenance, commissioning, and decommissioning/validation (which determination shall be escalated to the JSC if in dispute). Thereafter, if any additional equipment is necessary at the request of Client, such costs shall be dealt with by the Change provisions of this MSA. * shall modify the Facility and engineer, procure, install, commission, test, qualify, troubleshoot and validate necessary equipment and instruments in order to accommodate Manufacture of the Product at the Facility, as further described in the Project Plan and applicable QAG. Except as provided in this Section 5.2 or any applicable PSA, the Facility, Warehouse and all the equipment shall be maintained, tested, validated, calibrated and qualified for their intended uses by * at *'s expense. For the avoidance of doubt, it shall be the responsibility of * to effect such changes at the Facility including, but not limited to changes in equipment, as are required by changes in laws, rules or regulations related to the manufacture, handling, storage, packaging and disposal of biologics generally, compliance therewith being necessary in order for * to hold itself out as a qualified manufacturer of biologics for human use. It shall be the responsibility of * to obtain, maintain and pay all costs associated with establishment licenses required for the Facility, the Warehouse and any other facilities used by * in the performance of its obligations under this MSA and any applicable PSA.

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5.3 Raw Materials.

5.3.1 **Management**. * shall procure and maintain a reasonable quantity of the Raw Materials, required for the Services in accordance with the MSA and any applicable PSA, as further described in the applicable QAG. On a per-Product basis, the Core Team shall finalize the categorization of the Raw Materials into Raw Materials which shall be used for that specific Product only ("**Specialized Raw Materials**"), Raw Materials which can be used across multiple products and/or customers ("**Common Raw Materials**"), and Raw Materials which will not be charged on a cost-plus basis to the Client, and shall attach such list to the applicable PSA. Such list of Common Raw Materials and Specialized Raw Materials may be amended from time to time, subject to the Parties' approval. Prior to the commencement of Manufacture, the Core Team shall agree on estimates for quantities of Raw Materials anticipated to be consumed in the Manufacture of each Batch. Although * will make Commercially Reasonable Efforts to use no more than those amounts, * will not be responsible for Raw Materials used in excess of the agreed-upon estimate; provided, however, that * shall be responsible for any such excessive use, loss, spoilage, or waste of such Raw Materials caused by an * Assignable Error. In order to become effective, *'s reasonable strategies regarding Raw Material safety stock and sourcing from qualified vendors shall be agreed upon by Client. In the event * is not able to utilize any capacity reserved to Manufacture Product according to an agreed-upon forecast or manufacturing plan due to Client's failure to agree to such reasonable strategies, then Client shall be responsible for the costs of such reserved capacity regardless of whether it is utilized or not.

5.3.2 **Data Transfer**. Client and * shall agree on the Specifications for the Raw Materials, including without limitation analytical methods, supplier information including supplier site information, and other information concerning the stability, storage, and safety thereof that are available and required for the Manufacturing hereunder, as further described in the applicable QAG.

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5.3.3 **Testing and Evaluation**. * or vendors qualified by * shall perform all testing and evaluation of the Raw Materials as required by the Specifications for the Raw Materials and the cGMPs, as further described in the applicable QAG, if applicable. * shall not release any Raw Materials from quarantine that do not meet their Specifications or are not otherwise suitable for cGMP use.

5.3.4 **Storage.** * shall secure sufficient and suitable cGMP storage facilities and/or equipment at the Facility that meet the Specifications for storage of the Raw Materials. * shall preserve and protect the Raw Materials from loss and damage while in *'s possession, consistent with reasonable technical and business judgment, the Specifications and any relevant SOPs or other instructions provided by Client; provided however, * shall be responsible for loss of Raw Materials after receipt by * and prior to Manufacture only in cases of * Assignable Error or breach of this Section 5.3.4. In all other cases, Client shall be responsible for the risk of loss of the Raw Materials. Upon obsolescence, or upon expiration or earlier termination of a PSA, Client shall be responsible for the loss of Raw Material purchased in reliance on a Purchase Order, Firm Period, or Binding Year which Client fails to honor and * cannot reasonably otherwise utilize such Raw Material.

5.3.5 **Service Fee Related to Raw Material.** Common Raw Materials and Specialized Raw Materials will be charged on a cost-plus basis to Client in accordance with Sections 9.1(ii) and 9.2.2, subject to any changes in the scope of work.

5.4 Client Materials.

5.4.1 **Management.** Client shall provide to * free of charge, either by itself or through its third party supplier, Client Materials in amounts reasonably necessary to carry out the Services as agreed by the Parties. The applicable PSA shall set forth the exact timing of such provision of Client Materials to *. * shall make Commercially Reasonable Efforts to import the Client Materials to the Republic of Korea in a timely manner, provided that Client provides reasonable assistance. The title to such Client Materials shall remain at all times with the Client. Prior to the commencement of Manufacture, the Core Team shall agree on estimates of quantities for Client Material anticipated to be consumed in the Manufacture of each Batch. Although * will make Commercially Reasonable Efforts to use no more than those amounts, * will not be responsible for Client Materials used in excess of the agreed-upon estimate; provided, however, that * shall be responsible for any such excessive use, loss, spoilage, or waste of such Client Materials caused by an * Assignable Error, and further provided that * shall not be liable for the monetary value of Cell Line loss if it complied with risk mitigation measures to protect the Cell Line, as reasonably agreed to by the Parties and set forth in the Quality Agreement. In order to become effective, *'s reasonable strategies regarding Client Material safety stock and sourcing from qualified vendors shall be agreed to by Client. In the event * is not able to utilize any capacity reserved to Manufacture Product according to an agreed-upon forecast or manufacturing plan due to Client's failure to agree to such reasonable strategies, then Client shall be responsible for the costs of such reserved capacity regardless of whether it is utilized or not.

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5.4.2 **Data Transfer.** Client shall provide * with the Specifications of the Client Materials, including without limitation analytical methods, supplier information, and other information concerning the stability, storage, and safety thereof that are available and required for the Manufacturing hereunder, as further described in the applicable QAG.

5.4.3 **Testing and Evaluation.** * shall perform testing of the Client Materials in accordance with the applicable QAG and/or Client's instruction prior to the performance of the Manufacturing hereunder, in order to determine whether such Client Materials meet the Specification described in the applicable QAG (if applicable). * shall inform Client of (a) any damage to the Client Materials received that is visually obvious (e.g., damaged or punctured containers and temperature monitoring results outside of predetermined Specifications) within five (5) Business Days after *'s receipt of the Client Materials and (b) any non-conformance of the Client Materials to Specification either: (i) within sixty (60) calendar days after *'s receipt of the Client Materials or (ii) if release testing of Client Materials is not to be performed until it is needed for Manufacture, within sixty (60) calendar days after such release testing is performed; or (iii) as is otherwise agreed between the Parties. If, prior to performing any Service on the Client Materials, * determines that such Client Materials are defective or damaged, * shall not perform the Service on such Client Materials and shall follow Client's written instructions regarding disposal or return of such Client materials to Client, such disposal or return to be at Client's discretion and cost.

5.4.4 **Storage.** * shall secure sufficient and suitable cGMP storage facilities and/or equipment at the Facility that meet the Specifications for storage of reasonable quantities of Client Materials in light of quantities of Product anticipated to be Manufactured. * shall preserve and protect the Client Materials from loss and damage while in *'s possession, consistent with reasonable technical and business judgment, the Specifications and any relevant SOPs or other instructions provided by Client; provided that * shall only be liable for loss and damage after receipt/acceptance by * and prior to Manufacture in cases of * Assignable Error or breach of this Section 5.4.4. In all other cases, Client shall be responsible for the risk of loss of the Client Materials.

5.4.5 **Service Fee Related to Client Material.** Handling fees relating to the Client Material will be charged to Client in accordance with Sections 9.1(iii) and 9.2.3.

5.5 **Forecasts.** For each Commercial Product, the Parties shall determine a mutually agreeable mechanism for forecasting of each Product, which shall be detailed in writing and attached to each relevant PSA. For Clinical Product, the Parties shall agree upon the number and schedule of Batches to be Manufactured by * in the applicable PSA.

5.6 **Purchase Orders.** For each Clinical Product or Commercial Product, Client shall notify * in a binding form and procedure to be agreed upon in the applicable PSA requesting a specific amount of Product to be Manufactured (a "**Purchase Order**").

5.7 **Product Purchase Commitment.** As further set forth in a PSA, during the Term the Parties may agree that Client will purchase a minimum quantity of batches of a certain Product in a given year (a "**Product Purchase Commitment**").

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5.8 **Batch Failure during Manufacture.**

5.8.1 If, during Manufacture of a Batch and prior to *'s Batch release, the Core Team determines that a Batch is Non-Conforming Product (a "**Batch Failure**"), * shall take Commercially Reasonable Efforts to promptly Manufacture (except to the extent prohibited by cGMP or applicable QAG) and deliver to Client a replacement Batch on a date to be mutually agreed by the Parties, which Batch shall be invoiced and paid for as if it were the failed Batch (*i.e.,* Client shall only be invoiced for the Batch conforming to the Specifications and Manufactured in compliance with cGMP, and actually delivered). Client shall be responsible for the costs and fees of the Raw Materials and Client Materials for the replacement Batch as if it were the failed Batch (*i.e.,* Client shall only be invoiced the applicable cost of the Raw Materials and Client Materials actually used to Manufacture the conforming, cGMP compliant replacement Batch). Client shall use Commercially Reasonable Efforts to ensure that * has adequate Client Materials to Manufacture such Batches and Client's failure to provide such Client Materials shall relieve * of its obligations to provide a remedy pursuant to this Section 5.8. The remedies contained in Section 5.8 of this MSA shall be the sole and exclusive remedies of Client regarding a Batch Failure and a Batch Failure shall not constitute a material breach of this MSA or a PSA unless * fails to provide the remedies contained in this Section 5.8.

5.8.2 The Parties shall conduct a root cause analysis (including an analysis of whether the Batch Failure was the fault of *, Client, neither or both) of the Batch Failure, which shall be done through *'s deviation process and which result will be reviewed and confirmed by the JSC. If either the Core Team does not agree on the Batch Failure root cause, and the JSC does not agree on the results of the Core Team's Batch Failure root cause analysis, the Parties shall refer review of such root cause analysis to an independent mutually agreed-on laboratory or firm with international repute, acting as a neutral arbiter, to conduct a root cause analysis of the Batch Failure. The costs of the independent laboratory will be borne by the Party responsible for the Batch Failure, as determined by the independent laboratory, whose written decision shall be binding on the Parties. If the independent laboratory is paid in advance of a final written determination, the Parties shall share equally such expense, and the Party at fault shall reimburse the other Party for its share of any such expenses paid after there has been a final written determination made by the independent laboratory.

5.8.3 The PSA applicable to such Product Batch Failure shall set forth responsibility among the Parties for the following costs in the event of a Batch Failure: (1) the * Service Fee to Manufacture the failed Batch; (2) *'s costs to procure the Raw Materials used in the failed Batch plus applicable * handling fees associated with such Raw Materials; (3) * handling fees associated with the applicable Client Materials used in the failed Batch; and (4) Client's cost to procure the Client Materials (which shall not include Cell Line) used in the failed Batch which amount is to be calculated based on the actual replacement value (as opposed to the market value) of such materials as supported by reasonable documentary evidence by Client.

5.8.4 In the event that any of the foregoing procedures results in a Batch being delivered in a different year than the year in which the original Batch was ordered for delivery by Client, the Service Fee for such re-Manufactured Batch shall be the Service Fee in effect in the Year in

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which such re-Manufactured Batch is actually delivered by * unless the root cause analysis determined the Batch Failure resulted from * Assignable Error, in which case, the Service Fee in effect at the time of the Purchase Order for the failed Batch shall apply.

5.9 **Storage, Packaging and Delivery.**

5.9.1 **Service Deliverables other than Products.** Storage, packaging and delivery of the Service deliverables other than Products Manufactured hereunder shall be made in accordance with the terms of this MSA, applicable PSA, Project Plan, applicable QAG and the Applicable Laws.

5.9.2 **Products.**

(a) Release by * and Acceptance by Client.

(i) * shall perform all testing in accordance with the Specifications of the Product and release the Product in accordance with the terms of the applicable QAG. Upon such release * shall deliver to Client a copy of the Manufacturing Documentation in support of the *'s release of the Product for each Batch ("**Batch Related Documents**"), including a Certificate of Analysis and Certificate of Compliance, in accordance with the applicable QAG;

(ii) **Acceptance of Product.** Client will complete the Acceptance Procedure and determine the acceptability of such Product in accordance with the applicable QAG and notify * of the result within the latter of thirty (30) Business Days of *'s release of Product or Client's receipt of the Batch Related Documents. Upon Client's acceptance, * will have no liability for such Product once entrusted to the carrier (the Parties shall use good-faith efforts to minimize the time-period between Client's acceptance and *'s delivery to the carrier), except as set forth in Section 5.9.2(a)(iv) regarding Latent Defects. If Client does not reject such Product within the thirty (30) Business Day period, the Product will be deemed to have been accepted by Client and * will have no liability for such Product once entrusted to the carrier (the Parties shall use good-faith efforts to minimize the time-period between Client's acceptance and *'s delivery to the carrier), except (A) as set forth in Section 5.9.2(a)(iv) regarding Latent Defects or (B) due to a breach of *'s obligations with regard to (I) handling or storage or (II) the Specifications insofar as they relate to packaging and shipping.

(iii) **Non-Conforming.** If, during the Acceptance Procedure, any Product is determined by Client or * as Non-Conforming Product, at the option of Client, * shall take Commercially Reasonable Efforts to promptly Manufacture replacement Product (except to the extent prohibited by cGMP or applicable QAG) and deliver to Client the quantity of the Product equivalent to the quantity of Non-Conforming Product on a date to be

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mutually agreed by the Parties and such replacement Batch shall be invoiced and paid for as if it were the original Non-Conforming Product. If * does not confirm the non-conformity, the Parties shall refer to an independent and mutually agreed-on laboratory or firm with international repute to test the disputed Product. The costs of the independent laboratory will be borne by the Party responsible for the Batch Failure, as determined by the independent laboratory, whose written decision shall be binding on the Parties. If the independent laboratory is paid in advance of a final written determination, the Parties shall share equally such expense, and the Party at fault shall reimburse the other Party for its share of any such expenses paid after there has been a final written determination made by the independent laboratory. Section 5.9.2(a) (i) and (ii) shall apply to such replaced Product *mutatis mutandis*. Responsibility for the costs of such Non-Conforming Product shall be as if such Non-Conforming Product is a Batch Failure and Section 5.8.2 – 5.8.4 shall apply to such Non-Conforming Product *mutatis mutandis*. The remedies contained in this Section 5.9.2 shall be the sole and exclusive remedy of client for Non-Conforming Product.

(iv) **Latent Defect.** At any time after completion of review of the Batch Related Documents, if Client finds any hidden defects of the Product which could not have been reasonably discovered through the review of the Batch Related Documents (**"Latent Defect"**), Client shall promptly give notice of such claim in writing to *. In such case, if Client proves the Latent Defect is solely due to * Assignable Error, the above Section 5.9.2(a)(iii) and Section 13.1 shall apply. If no written claim for Latent Defect of the Product is received by * within one (1) month from Client's discovery of the Latent Defect, the Product shall be deemed as irrevocably accepted. Notwithstanding anything to the contrary; such claim for Latent Defect must be made within a time period to be set forth in the applicable PSA, but in no event after the expiration date of the Product. For the avoidance of doubt, a Latent Defect is a defect in existence at the time of completion of the Acceptance Procedure.

(b) Delivery. Shipping conditions, title transfer to Client and risk of loss for the Product Manufactured hereunder shall be *. The Parties further agree as follows:

(i) At the time of *'s release of the Product and prior to each pick-up by Client or Client's designated carrier, * shall propose to Client a delivery schedule of the Product, in order for the Parties to agree on it in advance for each pick- up. * shall schedule Delivery with the carrier selected and paid for by Client; Client shall compensate * for storage costs for the Manufactured Product stored with * for more than sixty (60) calendar days following release, as set forth in the applicable PSA;

(ii) * shall not deliver the Product until it has been instructed to by Client in accordance with the applicable QAG. Client shall confirm specific delivery instructions with * prior to * release. Upon *'s release of Product, * shall store the Manufactured Product as described in Section 5.9.2(c) and Client shall compensate * for storage costs for the Manufactured Product stored with * for more than sixty (60) calendar days following release, as set forth in the applicable PSA;

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(iii) * shall provide Client with invoice, packing lists, supporting export documents as specified by Client by separate delivery and shipment documentation instructions, together with each shipment of the Product (or such other deliverables); and

(iv) In cooperation with Client and subject to the delivery schedule agreed by the Parties, * shall adhere to the first-expire-first-out (FEFO) principle in shipping all released Product.

(c) Storage, Packaging and Shipping Container.

(i) Pursuant to the terms of this MSA and any applicable PSA, * shall store the Products Manufactured hereunder.

(ii) * shall store, package, label and prepare shipment according to the Specifications for the Product Manufactured hereunder, the applicable QAG and the SOPs, and using storage and/or shipping containers determined in the applicable PSA.

(iii) If Client does not direct * to prepare Manufactured Product to be picked up by Client or Client's designated carrier with a pick-up date within sixty calendar (60) days of Client's receipt of the Batch Related Documents, * shall store the Product at the Warehouse and Client shall pay storage fees to * as set forth in Section 9.1 for the period of storage at the Warehouse in excess of sixty (60) calendar days from release until the actual delivery date, in accordance with the applicable PSA.

(iv) * shall store and handle all Manufactured Product in accordance with applicable storage and handling Specifications, including all times when * and Client agree that * shall store Manufactured Product per Section 5.9.2(c)(iii), but shall have no obligation regarding risk of loss and damage of Manufactured Product in its possession unless such loss or damage resulted from *'s negligence or willful misconduct.

5.10 **Supply Interruptions**. On a PSA by PSA basis, the Parties will discuss appropriate steps to alleviate any expected or actual shortfall in Manufactured Product. The Parties may agree on a PSA by PSA basis, in what events, if any, such a supply failure could constitute a material breach of this MSA or a PSA.

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SECTION 6 CHANGES TO THE SPECIFICATIONS, ANALYTICAL METHODS, MANUFACTURING PROCESS, FACILITY OR EQUIPMENT

6.1 **Approval for Change.** * shall not make any change to the Manufacturing Process, the Services, or the Specifications (a "**Change**"), without the prior written consent of Client in accordance with the applicable QAG.

6.2 **Changes Required by cGMP, Regulatory Authorities or Requested by Client.** Except as otherwise expressly set forth to the contrary in the applicable QAG, in the event that cGMP, a Regulatory Authority, Applicable Law, or any other regulatory or legal authority requires, or Client requests, a Change, * shall accommodate such requirements or requests, subject to the following:

(a) Client shall promptly notify * in writing of the required and/or requested Change(s), and provide information necessary for * to evaluate the effect of such Change(s); provided, however, in the event * first learns of a required Change it shall notify Client thereof in writing, and * shall promptly advise Client as to any (i) additional equipment required, modifications to the Facility or equipment, and/or additional equipment and the Facility qualification and validation requirements; (ii) Manufacturing Process development, transfer, scale-up, testing, qualification, or validation requirements; (iii) regulatory requirements pursuant to such Changes; (iv) changes to the Manufacturing scheduling and/or Product delivery schedule; and (v) other impacts on the Facility or *'s ability to manufacture products (including the Products) in the Facility, if any, which may result from such Change(s). The notification and formal approval procedure of such Changes shall be in accordance with the applicable QAG (i.e., change control procedures) (if applicable). The Parties shall meet in a timely manner to identify and discuss such Changes as appropriate;

(b) Prior to implementation of any such Change(s), *, subject to Section 5.2, shall provide Client with an estimated plan and budget of the reasonable and necessary costs that would be incurred by * as a result of the implementation of any such Change(s), including, but not limited to for (i) process and analytical development; (ii) equipment and/or the Facility modifications, qualification, validation, maintenance, and decommissioning/disposal; (iii) process and analytical validation; (iv) document revisions or changes, the Facility, equipment, and system modifications or changes; (v) additional stability testing; and (vi) preparing submissions to Regulatory Authorities (collectively, the "**Implementation Plan and Budget**"). Following review and approval by Client of such Implementation Plan and Budget, subject to the Core Team's approval and agreement followed by the Parties' written agreement pursuant to Section 17.9 (if applicable), * shall commence implementation of such Change(s);

(c) During any such implementation, * shall provide Client with regular updates on the progress of implementation. Subject to any timeframe imposed by Applicable Law, * shall exercise Commercially Reasonable Efforts to implement the Change according to the Implementation Plan and Budget's target completion date. * shall provide written notice to Client if * becomes aware of any cause which may create delay with the implementation of Changes. Following any such notice, both Parties shall discuss an amendment of Implementation Plan and Budget; and

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(d) Upon the approval of the Implementation Plan and Budget for Change(s), both Parties shall negotiate in good faith to determine the allocation of the costs incurred by * for the implementation of any such Change(s) between the Parties, in accordance with the following principles:

(i) the costs for the general Facility Changes required by cGMP, any Regulatory Authority, or any Applicable Laws related to the maintaining the Manufacturing Facility by * as set forth in Section 7.2, shall be borne by *, provided that where the Change relates exclusively or partially to the Manufacture of Product in which case the costs shall be borne by Client fully or proportionally, respectively;

(ii) the costs for the Changes other than (i) above, and requested by Client and required uniquely to the Manufacture of the Product and beneficial solely to Client shall be borne by Client; and

(iii) the costs for the Changes other than (i) and (ii) above shall be discussed in good faith by the Parties to achieve equitable allocation of costs.

SECTION 7 REGULATORY APPROVALS AND INSPECTIONS.

7.1 **Regulatory Approvals.** * shall provide reasonable assistance and cooperation in order for Client to obtain and maintain the Regulatory Approvals. The direct costs and fees associated with such assistance and cooperation, to the extent not detailed in the MSA or PSA shall be borne by Client, or as otherwise mutually agreed between the Parties. As specified in the applicable PSA, the Parties shall agree on which Regulatory Approvals are to be obtained.

7.2 **Regulatory Approvals for the Facility.** * shall obtain and continuously maintain all approvals, licenses, registrations or authorizations of any federal, state or local regulatory agency, department, bureau or other governmental entity (other than the Regulatory Approvals, which will be obtained or maintained by Client) that are required to Manufacture and ship the Product at the Facility and perform the Services including, but not limited to, cGMP Manufacture.

7.3 **Regulatory Inspections.** * shall facilitate on-site inspections of the Facility conducted by Regulatory Authorities. * shall notify Client according to the applicable QAG provisions of any contacts or inquiries by the Regulatory Authorities, including inspections, Pre-Approval Inspections, sample requests, and written correspondence and its result, related to the Manufacture of Product by * at the Facility, as further defined in the applicable QAG. Any direct expenses or costs incurred by * for such inspections including Pre-Approval Inspections at the Facility shall be borne by Client. Unless prohibited by the pertinent Regulatory Authority, Client shall be entitled to witness any inspection or audit by a Regulatory Authority of the Facility or Warehouse related to the Manufacture of Product by * at the Facility. Further, Client shall be entitled to attend, as an observer, any wrap-up meeting between * and a Regulatory Authority related to such an inspection related to the Services or the Manufacture of Product by * at the Facility. * shall timely provide Client with a copy of any Form 483, inspection report or regulatory letter issued by a Regulatory Authority, and shall provide Client a meaningful opportunity to review and comment upon any response of * thereto. Client's comments in such regard shall be considered in good faith and be given due regard by * in formulating any proposed response to a Regulatory Authority.

* Confidential material redacted and filed separately with the Commission.

7.4 **Regulatory Support.** During the Term, * will assist Client with all regulatory matters relating to Services and Manufacture and review the Common Technical Document pertaining to the Products, as it relates to Chemistry, Manufacturing and Controls, and make such corrections as are necessary to accurately reflect the Products, in each case at Client's request and reasonable expense; provided, however, * shall review and correct such documents as they relate to * activities at no charge to Client (updates will be made with respect to regulatory filings for which Client has engaged * and paid the associated flat rate fees for support). In addition, * will maintain at *'s expense, the relevant Drug Master File, including any updates thereto, and shall provide a letter authorizing Client to reference *'s Drug Master Files on file with the FDA and other Regulatory Authorities in connection with the pursuit of Regulatory Approval for the Products.

SECTION 8 QUALITY COMPLIANCE

8.1 **Quality Agreement**. Both Parties shall adhere to the provisions of the applicable QAG and the Parties agree that all elements of quality assurance, quality control and the like shall be governed by the terms and conditions of the applicable QAG. In the event of a conflict between the MSA and the applicable QAG, the MSA shall prevail over those of the applicable QAG with the exception of Product quality-related matters, cGMP and related regulatory requirements in which case, the terms of the applicable QAG shall prevail.

8.2 **Responsibility for Recalled Product**. For a Commercial Product, either Party shall notify the other Party as soon as practicably possible if any Commercial Product is the subject of a threatened or actual recall by a Regulatory Authority, (a "**Recall**") which may be attributable to any Service or Manufacture by or on behalf of * hereunder. Client shall be responsible for conducting all Recalls and shall make all decisions regarding, and in all events shall have sole authority for, conducting any recalls, market withdrawals or corrections with respect to the Product and * shall at all times exercise Commercially Reasonable Efforts to provide its assistance and cooperation to Client in conducting such Recalls to the extent the Recall arises out of *'s Manufacture of Product. Details regarding the roles and responsibilities of the Parties in regard to Recalls are set forth in the applicable QAG. If such Recall results solely from * Assignable Error, * shall be responsible for direct and documented out-of-pocket costs associated with such Recall subject to the limitation of liability sections of the PSA applicable to such Recalled Product and, subject to written instructions of Client to the contrary, will use its Commercially Reasonable Efforts to replace the Recalled Products with new Products, contingent upon the receipt from Client free-of-charge of all Client Materials required for the Manufacture of the replacement Product. If * is unable to replace the Recalled or returned Products (except where this inability results from a failure to receive the Client Materials), then * shall credit to Client the price that Client paid to * for Manufacturing and Services for the affected Products. In all other circumstances, Recalls will be made at Client's cost and expense. The provisions of this Section 8.2 shall not apply to any Clinical Product and shall be Client's sole and exclusive remedy with respect to a Recall due to the delivery of Non-Conforming Product.

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For the purpose of this Section, Recall expenses shall not include the value of the Product that is the subject of such Recall or any loss of reputation or good will, or lost profits or any other costs or expenses not associated with the Product that is the subject of the Recall. If * and Client cannot agree which Party is at fault or whether a Recall was reasonably beyond the control of the Parties, then an independent third party technical expert of international repute, acceptable to both Parties, shall be designated to make such determination. The designated technical expert shall not be an employee, consultant, officer, director or shareholder of, or otherwise associated with, or have been retained during the prior five (5) years by, or be retained during the ensuing five (5) years, by *, Client or their respective Affiliates. The technical expert's determination will be, in the absence of fraud or manifest error, binding and conclusive upon the Parties. The cost of designating such technical expert shall be borne by the Party determined at fault, and if neither Party is determined to be at fault, then the cost of such technical expert shall be borne by both Parties in equal proportion.

8.3 Records & Audit.

8.3.1 **Audit by Client.** Upon Client's request, but no more than once per year, * shall accept an audit of the Facility and, if necessary in the judgment of Client, the Warehouse, by Client and allow Client to inspect and audit the Facility and, if necessary in the judgment of Client, the Warehouse, and Manufacture of the Product solely to ascertain compliance by * with the terms of this MSA or any applicable PSA; provided, however that in the event Client uses a designee, * must provide prior written consent, which shall not be unreasonably withheld, conditioned or delayed. * shall be reimbursed for its reasonable costs for audits beyond the audit described in the first sentence of this Section 8.3.1, except for audits conducted to measure corrective action or remediation following a finding of deficiency either by Client in a previous audit or by a Regulatory Authority or as is contemplated by Section 8.3.2(ii). Client shall not be limited in the number of its audits conducted to measure corrective action or remediation, and such audits shall not count against the limit expressed in the first sentence of this Section 8.3.1. * will make Commercially Reasonable Efforts to require vendors or subcontractors to accept an audit or visit to their facilities by Client upon similar notice as described in Section 8.3.2 below.

8.3.2 **Audit Notice.** Client shall provide * with a written notice at least three (3) months prior to the initiation of the audit of the Facility and, if necessary in the judgment of Client, the Warehouse, set forth in Section 8.3.1, which shall be conducted on a mutually agreeable date and time, and with a mutually agreed duration, agenda, and number of attendees, which in the case of Client shall not be limited to less than three (3) without the consent of Client. Notwithstanding the foregoing, if the audit is required for cause (i) due to safety reasons or other reasons that necessitates immediate audit of or visit to the Facility or (ii) due to the * Assignable Error, the foregoing sentence shall not apply and Client may conduct such audit or visit by providing * with a prior notice by email. Access to *'s facilities shall be coordinated with * so as to minimize disruption to *'s ability to perform services for its other clients. Client representatives must comply with all of *'s generally applicable cGMP, confidentiality and security procedures and protocols during such observations, consultations, and inspections. * shall at all times cooperate and provide all the necessary documents reasonably required by Client during such audit; provided that, to the extent necessary, * may redact or withhold documents to protect the confidential information of its other clients. Client shall be solely responsible for any costs and liability caused by Client's or its representatives' failure to comply with *'s security, safety or confidentiality procedures.

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SECTION 9 CONSIDERATION AND PAYMENT TERMS

9.1 **Consideration**. In consideration for *'s performing the Service and other obligations undertaken by * pursuant to a PSA, Client shall pay * amounts as set forth in the applicable PSA (the "**Service Fee**"); (ii) a handling surcharge of a certain percentage or certain amount to be set forth in the applicable PSA of the costs of Raw Materials paid by * (including but not limited to taxes and customs duties/fees); (iii) a handling surcharge of a certain percentage or certain amount to be set forth in the applicable PSA related to the Client Materials (which shall be based on the actual costs of such materials as supported by reasonable documentary evidence as opposed to the market value thereof); and (iv) storage fees as set forth in the relevant PSA.

9.2 **Invoices.**

9.2.1 **Service Fee of the Project Stages and Batches**. According to the invoicing plan set forth in the applicable Project Plan or applicable PSA, or upon *'s release of a Batch of Product, as applicable, * shall invoice Client for the Service Fee set forth in the applicable PSA.

9.2.2 **Raw Materials.** With respect to the Raw Materials, * shall submit invoices to Client for the applicable Raw Materials cost (including any agreed upon safety stock) as set forth according to Section 9.1 as follows. * shall submit an invoice to Client (i) for the cost of Specialized Raw Materials procured upon receipt of the invoice from vendors/suppliers; and

(ii) for the cost of Common Raw Materials used by *'s completion of such project stage or upon *'s release of a Batch of Product as applicable. Notwithstanding the foregoing, the Parties shall collaborate in the selection of the vendors of the Raw Materials. All such vendors shall be approved by Client before supplying * with Raw Materials for Product.

9.2.3 **Client Materials.** With respect to the Client Materials, which shall be supplied by Client to * at no cost during *'s performance the Service, * shall submit an invoice to Client in an amount as set forth in Section 9.1 upon *'s completion of such project stage of the Service *'s release of a Batch of Product, as applicable.

9.3 **Payment**.

9.3.1 **Mode of Payment; Foreign Exchange**. All payments to * due under the MSA or any applicable PSA shall be made within thirty (30) Business Days from the receipt of the *'s invoice in USD $ by means of telegraphic transfer to the account with the bank designated by * in the foregoing invoice. For the purpose of computing payment amounts incurred in a currency other than USD$, such currency shall be converted into USD$ using the basic exchange rate published by Bloomberg (or its successor institution) on its website "http://www.bloomberg.com/markets/currencies" (or any other website that may be used by Bloomberg or its successor institution for publication of currency exchange rates) at the opening of business on such invoice date.

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9.3.2 **Taxes**. All prices and charges are exclusive of any applicable taxes, levies, imposts, duties and fees of whatever nature imposed by any law or regulations in any country in respect of the Services, importation or exportation of Raw Materials, Client Materials, Batches, and Product, which shall be paid by Client. For the avoidance of doubt, the foregoing shall not include any taxes imposed on the income or profit of * and any withholding tax lawfully levied on any payment to be made by Client to *, each of which shall be solely borne by *. Client shall pay or reimburse * for all customs duties and taxes in connection with the purchase, sale, importation or exportation of any Raw Materials, Client Materials, Batches, or Product or the provision of Services, except to the extent such duties and taxes are recoverable by or refundable to *. * agrees to assist Client in claiming exemption under double taxation or similar agreement or treaty from time to time in force to obtain a refund of any customs duties, value added taxes, and other taxes payable by *.

9.3.3 **Price Adjustments**. The Service Fees as set forth in the applicable PSA, shall be adjusted annually, on the last day of January, effective January 1 of each year during the Term, by the percentage change in the consumer price index as published by the Bank of Korea for the immediately preceding twelve (12) months. The relevant date for price adjustment under this Section shall be the issue date of *'s invoice.

9.3.4 **Default Interest.** Any amount that is not paid by a Party to the other when due under the MSA or any PSA shall bear default interest at the rate of ten percent (10%) per annum, or such lesser maximum rate allowed by Applicable Law, from the day following the due date until paid in full. In the event there is an amount which is invoiced by * but not paid by Client for more than six (6) months after the due date, such event shall be considered a material breach of the relevant PSA.

SECTION 10 CONFIDENTIALITY

10.1 **Confidential Information.** "**Confidential Information**" shall mean any data, know-how and other information, whether technical or non-technical disclosed by one Party (hereinafter the "**Disclosing Party**") or otherwise became known to the other Party (hereinafter the "**Receiving Party**") hereunder relating to the subject matter of the MSA, regardless of form or manner of disclosure, i.e., whether disclosed in writing, in electronic file or format or in other tangible manner, or orally, visually or in other intangible manner. If a Party intends to disclose such information in writing, in electronic file or format or in other tangible manner, such Party will make reasonable efforts to indicate it is confidential; and if to disclose orally, visually or in other intangible manner, such Party will make reasonable efforts to reduce it in summary form in writing or in electronic file or format, identified as confidential and delivered to the other Party within thirty (30) days after such oral or visual disclosure; provided, however, in each case, a failure to do so shall not constitute a breach of this term nor shall deny, negate or destroy the confidential nature thereof, and no such failure shall serve as conclusive evidence that the disclosed information shall not be considered Confidential Information by and between the Parties. Furthermore, the existence and terms of the MSA shall be deemed to be the Confidential Information of both Parties and any information, data

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or results disclosed by * to Client relating to the Product, the Services or Manufacture under this MSA or any PSA, as well as the Manufacturing Process, the Project Plan and the Specifications shall be the Confidential Information of Client, unless otherwise specifically identified as * Confidential Information by the terms of this Agreement. The Parties acknowledge and agree that the Manufacturing Process and the Project Plan may contain a mixture of both Party's Background IP, ownership of which shall not be affected by this MSA.

Notwithstanding the foregoing, Confidential Information shall not include the information, which as evidenced by written records:

(a) was at the time of disclosure by the Disclosing Party hereunder publicly known or available;

(b) after disclosure by the Disclosing Party hereunder, became publicly known or available by publication or otherwise, other than by an authorized act or omission by the Receiving Party;

(c) was in the possession of the Receiving Party without confidentiality restriction at the time of the disclosure by the Disclosing Party hereunder;

(d) was lawfully received from any third party having the lawful right to make such disclosure, without obligation of confidentiality; or

(e) was independently developed by the Receiving Party's directors, officers or employees without reference to the Confidential Information, as demonstrated by records created contemporaneously with such development.

10.2 **Confidentiality.** The Receiving Party recognizes the proprietary and confidential nature of the Disclosing Party's Confidential Information and agrees that no right, title, ownership, license, or interest of any character in the Disclosing Party's Confidential Information other than as specifically granted herein, is conveyed or transferred to the Receiving Party. Both Parties further agree to maintain the Disclosing Party's Confidential Information in confidence and not to disclose or divulge the Disclosing Party's Confidential Information, in whole or in part, to any third party, and not use the Disclosing Party's Confidential Information for any purpose other than pursuing the MSA. Each Party shall guard such Confidential Information using the same degree of care as it normally uses to guard its own confidential or proprietary information of like importance, but in any event no less than reasonable care. The Receiving Party shall limit disclosure of the Disclosing Party's Confidential Information to its and those of its Affiliates' directors, officers, employees, consultants and agents ("**Representatives**") who have a need to know the Disclosing Party's Confidential Information for performance of the Service and implementation of the MSA, provided that, the Receiving Party shall undertake procedures to ensure that each of its Representatives to whom the Disclosing Party's Confidential Information is disclosed understands (i) the confidential nature of the Disclosing Party's Confidential Information and (ii) that he or she is under an obligation similar to those contained herein to hold the Disclosing Party's Confidential Information disclosed strictly confidential.

10.3 **Authorized Disclosures.** Disclosure is permitted in the event that (a) the Disclosing Party's Confidential Information is reasonably required to obtain or maintain any Regulatory Approvals for the Products in any or all jurisdictions or (b) the Disclosing Party needs to disclose such Confidential Information to comply with Applicable Law; provided that such Receiving Party shall exercise its Commercially Reasonable Efforts to limit disclosure of the Disclosing Party's Confidential Information to that which is necessary for compliance and to otherwise maintain the confidentiality of the Confidential Information.

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10.4 **Survival of confidential obligations.** The confidential obligations of the Receiving Party shall survive for a period of five (5) years from the expiration or termination of this MSA.

10.5 **Return of the Confidential Information.** All written, printed or other tangible Confidential Information of the Disclosing Party disclosed under the MSA, and all copies thereof shall be returned to the Disclosing Party (or destroyed at the Disclosing Party's request) by the Receiving Party within thirty (30) business days from the written request by the Disclosing Party. All Confidential Information disclosed electronically shall be completely deleted and destroyed by the Receiving Party within thirty (30) business days from the written request by the Disclosing Party. Notwithstanding the foregoing, (i) digital backup files automatically generated by the Receiving Party's customary electronic data processing system may be retained and properly stored as confidential files for the sole purpose of backup and will be deleted in accordance with the Receiving Party's retention policy, and (ii) a single copy of the Confidential Information may be retained in the secured files of the Receiving Party for the sole purpose of determining the scope of obligations incurred by it under the MSA provided that the Receiving Party shall keep such Confidential Information in confidence and will use the Confidential Information solely to comply with the terms of the MSA as well as the applicable law, rule and regulation.

SECTION 11 OWNERSHIP OF MATERIALS AND INTELLECTUAL PROPERTY

11.1 **Reference Standard, Client Technology, Client Materials, Cell Line, and Product.** * hereby understands and agrees that all rights to, titles of and interests in the Reference Standards, Client Technology, Client Materials, Cell Line, Product, the Manufacturing Process and any work in process or semi processed goods thereof belong to Client, unless otherwise provided herein.

11.2 **Background Intellectual Property.** It is acknowledged that each Party possesses Background IP. Any Intellectual Property relating to the Reference Standards, Client Technology, Client Materials and Cell Line owned and/or controlled by Client as of the date of provision of such Reference Standards, Client Technology, Client Materials and Cell Line by Client to * pursuant to Section 5.1, shall be deemed to be included in the Background IP of Client. Client hereby grants * a royalty-free, non-transferable, revocable and non-sublicensable and fully-paid-up right and license to use such Intellectual Property relating to such Reference Standards, Client Technology, Client Materials, Cell Line, during the Term for the sole purposes of Manufacturing of the Product or Services in accordance with the MSA.

11.3 **Inventions.** Any Intellectual Property arising out of or resulting from the Service under the MSA, including but not limited to those contained in the Manufacturing Documentation, shall be hereinafter collectively called an "**Invention**".

11.3.1 **Client Invention.** Any Invention that is conceived and first reduced to practice solely by one or more employees or officers of * (or its third party consultant or subcontractor) and does not constitute an * Invention shall be a "Client Invention". * shall notify Client of such Client Invention(s) to Client immediately after *, the Project Management Team Leader,

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respective project personnel, * employees or officers or other applicable third parties working for * hereunder makes, conceives or reduces to practice such Client Invention, and shall take all necessary measures so that Client would have the sole and exclusive ownership of any and all Client Invention. Client may use any Client Invention for any purpose, including filing patent application and * shall provide reasonable cooperation to Client at the expense of Client (as to all reasonable out-of-pocket expenses incurred by * that are supported by adequate documentation). In the event that * wishes to use the Client Invention for purposes outside the scope of the MSA, Client hereby grants * a worldwide, irrevocable, royalty-free and fully-paid- up license to use such Client Invention. This Section 11.3 shall survive the expiration or earlier termination and continue in effect as long as the intellectual property right to such Client Invention is legally valid.

11.3.2 *** Invention.** Any Invention that is conceived and first reduced to practice solely by one or more employees or officers of * (or its third party consultant or subcontractor) and which is not derived from, or arises out of Client Background IP or Client's Confidential Information or any other proprietary right of Client or its third party vendors, contractors, or other partners or clients under or in connection with the MSA, shall be the property of * ("*** Invention**"), and shall not be deemed to be Client Invention or Joint Invention for the purposes of the MSA. No Background IP of * and the * Invention shall be incorporated into the Product or Manufacturing Process without the joint review and approval of both Parties and the terms of a license to use such Background IP or * Invention shall be agreed upon prior to such incorporation.

11.3.3 **Client-* Joint Invention.** Any Invention that is conceived and first reduced to practice jointly by one or more employees, or officers of * (or its third party consultant or subcontractor) or their respective Affiliates, on the one hand and one or more employees, officers, agents or contractors of Client (or its Affiliates) on the other hand and which is not derived from, or arises out of either Party's Background IP or Confidential Information or any other proprietary right of a Party or its third party vendors, contractors, or other partners or clients under or in connection with the MSA, shall be jointly owned by Client and * (a "**Joint Invention**"), and shall not be a Client Invention or * Invention for the purposes of the MSA. Subject to the terms and conditions of the MSA, any such Joint Invention may be exploited by * or Client without compensation and liability of other obligation (including accounting obligations) to the other Party, and each Party has a non-exclusive, royalty-free, worldwide license, with the right to sublicense, under its interest in such Joint Inventions and any Intellectual Property rights (including patents) covering the same, for any purpose; provided that in the event of sublicense, each Party shall make written notice to the other Party of the fact. This license shall continue for the life of the applicable right.

SECTION 12 WARRANTIES.

12.1 **The Parties General Warranties.** Each Party warrants and represents that: (i) it has the corporate power and authority to enter into this MSA and has taken all necessary action on its part required to authorize the execution, delivery and performance of this Agreement; (ii) it is aware of no legal, contractual or other restriction, limitation or condition that might adversely affect its ability to enter into this MSA and perform its obligations hereunder; (iii) it is duly organized, validly existing

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and in good standing under the laws of the jurisdiction in which it is incorporated; (iv) this MSA (a) has been duly executed and delivered by a duly authorized representative of it, and (b) is the legal, valid and binding obligation of it, enforceable against it in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally; and (v) the execution, delivery and performance of this Agreement by it does not and will not (a) violate any Applicable Laws applicable to it, or (b) violate or conflict with any provision of its Articles of Incorporation or By-laws or other organizational documents.

12.2 **Client's Warranties**. Client represents, warrants and covenants to * that as of the Effective Date of the MSA and during the Term: (a) Client will comply with all Applicable Laws, and that it will keep * informed of any information known to Client which would affect *'s provision of the Service hereunder and (c) to the best of its knowledge, *'s use of the Client Materials, Manufacturing Process, and Client Technology for the purpose of the Service and to the extent as set forth in the MSA will not infringe any third party's Intellectual Property rights.

12.3 ***'s Warranties**. * represents, warrants and covenants that:

12.3.1 As of the Effective Date and during the Term, (i) * is the lawful owner, lessee, operator, or licensee of the Facility, equipment, machinery, as well as permissions required, to enable * to perform its obligations under this MSA, and (ii) to the best of *'s knowledge none of the * Inventions or * Background IP infringes any third party Intellectual Property Right.

12.3.2 All Product Batches, at the time of delivery to Client's designated carrier, shall (a) conform to the Specifications (except for Pilot Batches and Engineering Batches unless otherwise agreed); (b) be Manufactured, packaged, handled and stored in compliance with the requirements of cGMPs (except for Pilot Batches and Engineering Batches unless otherwise agreed) and all Applicable Laws; (c) comply with the Standard Operating Procedures; (d) be Manufactured in compliance with the Quality Agreement; and (e) be transferred free and clear of any liens, claims or encumbrances of any kind.

12.3.3 (i) * is not nor has it ever been, and (ii) * has not used, and will not use, the services of any person excluded, debarred, suspended (or subject to exclusion, debarment or suspension) under 21 U.S.C. §335(a) or (b) or otherwise disqualified by Applicable Law, including, the FDA Debarment List (http://www.fda.gov/ora/compliance_ref/debar/default.htm), as amended or replaced from time to time, in connection with any of the Services or Manufacturing performed under this MSA or any PSA. * agrees to notify Client promptly in the event of any violation of *'s obligations under this Section. This certification applies to * and its respective officers, agents, and employees as well as subcontractors performing on behalf of * under this Agreement.

12.4 **No Other Warranties.** THE REPRESENTATIONS AND WARRANTIES CONTAINED IN THIS SECTION ARE EXPRESSLY IN LIEU OF AND EXCLUDE, AND THE PARTIES HEREBY EXPRESSLY DISCLAIM AND NEGATE, TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAWS, ALL OTHER REPRESENTATIONS AND WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED (ARISING BY OPERATION OF LAW OR OTHERWISE), INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, EVEN IF THAT PURPOSE IS KNOWN.

* Confidential material redacted and filed separately with the Commission.

SECTION 13 INDEMNIFICATION

13.1 **Indemnification by *.** * shall indemnify and hold harmless Client, its Affiliates, and their respective officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude Client Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands, or actions based upon (i) gross negligence or willful misconduct; (ii) breach of the MSA or any PSA; (iii) violation of Applicable Law, in the case of clauses (i) through (iii) of or by * or its officers, directors, employees or agents, including any subcontractor or vendor used in the Manufacture of Product, or (iv) any claim that *'s use of * Background IP infringes any third party's Intellectual Property rights, except to the extent that such Damages are caused by the causes as set forth in Section 13.2 for which Client is obliged to indemnify.

13.2 **Indemnification by Client.** Client shall indemnify and hold harmless *, its Affiliates, and their respective officers, directors, employees or agents from and against any Damages arising or resulting from any third party (which shall exclude * Affiliates) claims to the extent such Damages are relating to, arising out of, in connection with, or resulting from claims, demands or actions based upon (i) gross negligence or willful misconduct, (ii) any claim that *'s use of the Client Materials, Manufacturing Process, and Client Technology for the purpose of the Services and solely to the extent as set forth in the MSA infringes any third party's Intellectual Property rights, (iii) breach of the MSA or any PSA, or (iv) violation of Applicable Law, in each case except to the extent that such Damages are caused by the causes as set forth in Section 13.1 for which * is obliged to indemnify and in the case of clauses (i), (iii), and (iv) of or by Client or its officers, directors, employees, or agents.

13.3 **Indemnification Procedure.** The foregoing indemnification by * or Client shall be conditioned, if and to the extent Damages are based on or related to a third party claim, upon a Party who intends to claim indemnification under Sections 13.1 and 13.2 (the "**Indemnified Party**") (i) providing written notice to the other Party ("**Indemnifying Party**") within twenty (20) calendar days after the Indemnified Party have been given written notice of such third party claim, provided that absence or delay of such prior written notice will not relieve the Indemnifying Party of its obligation to indemnify except to the extent such absence or delay materially prejudices the Indemnifying Party's ability to defend the third party claim; (ii) permitting the Indemnifying Party, upon timely notice by the Indemnified Party, the opportunity to assume full responsibility (at the Indemnifying Party's cost and expense) for the investigation and defense of any such claim with counsel reasonably satisfactory to the Indemnified Party, provided, however, the Indemnifying Party shall keep the Indemnified Party informed as to the progress of the defense of any claim and that the Indemnified Party shall cooperate in such defense and shall make available all records, materials and witness reasonably requested by the Indemnifying Party in connection therewith; and (iii) not settling or compromising any such claim without the Indemnifying Party's prior written consent, with such consent not to be unreasonably denied, withheld or conditioned. Furthermore, the Indemnifying Party shall not settle or compromise any such claim without the Indemnified Party's prior written consent; provided, however, no such consent shall be required if such settlement or compromise involves only the payment of money, does not require a finding or admission of fault or guild on the party of the Indemnified Party, and provides for a general release of the Indemnified Party.

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SECTION 14 DISCLAIMER OF CONSEQUENTIAL DAMAGES: LIMITATION OF LIABILITY

14.1 **Disclaimer of Consequential Damages.** EXCEPT FOR DAMAGES BASED ON OR RELATED TO A THIRD PARTY CLAIM ARISING UNDER SECTIONS 13.1 AND 13.2, OR BASED ON GROSS NEGLIGENCE OR WILLFUL MISCONDUCT, NEITHER PARTY WILL BE LIABLE UNDER THIS AGREEMENT FOR ANY SPECIAL, PUNITIVE, CONSEQUENTIAL, INCIDENTAL OR OTHER INDIRECT DAMAGES OF ANY TYPE OR NATURE, WHETHER BASED IN CONTRACT, TORT, STRICT LIABILITY, NEGLIGENCE OR OTHERWISE, INCLUDING LOSS OF PROFITS OR REVENUES.

14.2 **Limitation of Liability.** Specific caps on Damages shall be set forth in the applicable PSA.

SECTION 15 TERM AND TERMINATION OF AGREEMENT

15.1 **Term.** This MSA will become effective as of the Effective Date and will be in effect for as long as a PSA is in effect (the "**Term**"). Each PSA will have its own initial term as stated therein. Each PSA for clinical supply shall automatically renew for successive terms of one (1) year each or upon execution of a PSA for commercial supply, whichever is earlier, and each PSA for commercial supply, including supply of stocking inventories in advance of Regulatory Approval, shall automatically renew for successive terms of three (3) years each, unless a Party gives written notice to the other Party of its intention to not renew a PSA for clinical supply ninety (90) days prior to the end of the then current PSA term, or a Party gives written notice to the other Party of its intention to not renew a PSA for commercial supply thirty-six (36) months prior to the end of the then current PSA term.

15.2 **Termination**. This MSA or a PSA may be earlier terminated as set forth in this Section 15.2.

15.2.1 **Material Breach**. A Party may terminate any PSA for a material breach by the other Party; provided, however, that the non-breaching Party shall give the breaching Party written notice of such breach and if the breaching Party fails to commence Commercially Reasonable Efforts to cure that breach within twenty (20) Business Days after receipt of such written notice, then the non-breaching Party may terminate this Agreement on twenty (20) Business Days' written notice after expiration of such twenty (20) Business Day period. This MSA shall terminate if all effective PSAs are terminated.

15.2.2 **Insolvency**. This MSA may be terminated by either Party upon written notice at any time during the MSA if the other Party: (a) files in any court pursuant to any statute a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such Party, or of its assets; (b) proposes a written agreement of composition for extension of its debts; (c) is served with an involuntary petition against it, filed in any insolvency proceeding which is admitted in the court; or (d) makes an assignment for the benefit of its creditors. The Party affected shall immediately notify the other Party in writing of the occurrence of any of the foregoing events.

15.2.3 **Force Majeure**. Either Party may terminate a PSA in accordance with Section 17.3 in the event a Party is unable to perform its obligations pursuant to a PSA due to a Force Majeure Event.

15.2.4 **Import Failure**. Client shall be entitled to terminate a PSA upon twenty (20) Business Days' notice to *, if, despite the efforts of * pursuant to Section 5.4.1, Client Material destined for use in connection with the Services have been prohibited from entry into the Republic of South Korea by the Korean Custom Service. Such termination right shall only exist if such Client Materials have been denied entry and shall not be implicated by mere delays in the importation process. If such termination relates to efforts to import into the Republic of Korea Client Materials for the initial Batch of a Product under a PSA, the applicable PSA shall be deemed to be void *ab initio* without further cost or expense to either Party; provided, however, the Party's thereafter shall reasonably cooperate with regard to disposition of such Client Materials at the cost of Client.

15.2.5 **Other Specified Events**. The Parties may additionally terminate a PSA as set forth in the applicable PSA.

15.3 **Effect of Expiration or Termination**.

15.3.1 **Payment of Amounts Due**. Expiration or termination of the MSA or PSA for any reason shall not exempt any Party from paying to any other Party any amounts owing to such Party at the time of such expiration or termination; provided, however, with respect to a termination deemed to be *ab initio*, and up-front fee paid to * shall not be deemed earned and shall be returned to Client.

15.3.2 **Decommissioning**. Upon expiration or termination of a PSA for any reason, * shall cease and refrain from the Services described in any applicable PSA (including the Manufacturing and supplying the Product) for Client unless otherwise provided in the following Sections 15.3.2(a) to 15.3.2(d), and both Parties shall pursue decommissioning activities as set forth hereunder.

(a) Fully Manufactured Product.

(i) If Client terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, 15.2.4 or 15.2.5, upon Client's election, * shall (i) deliver already fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA or (ii) destroy such Product. If Client elected (i) above, Client shall pay the Service Fees and any related costs or fees for the Service relating to such Product in accordance with the terms and conditions of the MSA and applicable PSA, and if Client elected (ii) above, * shall bear the costs and expenses for such destruction, except in the case of Section 15.2.4 or Section 15.2.5 for which destruction Client shall pay the cost.

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(ii) If * terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, or 15.2.5, upon *'s election, * may (i) deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA (including the current Firm Period period or Binding Year in the PSA) or (ii) destroy such Product. If * elected (i) above, Client shall pay the Service Fee and any related costs or fees for the Service relating to such Product in accordance with the terms and conditions of the MSA and applicable PSA, and if * elected (ii) above, Client shall bear the costs and expenses for such destruction and the costs incurred by * for the Service; provided, however, such costs and expenses to be borne by Client shall in no event exceed the Service Fee for the Service relating to such Product.

(iii) If a PSA is naturally expired pursuant to Section 15.1, the provisions of (ii) above shall apply

(b) Client Materials being used for the Service (Product in Process).

(i) If Client terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, 15.2.4, or 15.2.5, upon Client's election, * shall (i) continue to use the Client Materials being used for the Manufacturing hereunder (the Product in process) and deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA, or (ii) deliver to Client or destroy such Product in process. If Client elected (i) above, Client shall pay the Service Fee and any related costs or fees for the Service relating to the fully Manufactured Product in accordance with the terms and conditions of the MSA and applicable PSA, and if Client elected (ii) above, * shall bear the costs and expenses for such activities except in the case of Section 15.2.4 or Section 15.2.5 for which destruction Client shall pay the cost.

(ii) If * terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, or 15.2.5, upon *'s election, * may (i) continue to use the Client Materials being used for the Manufacturing hereunder (the Product in process) and deliver the fully Manufactured Product to Client in accordance with the terms and conditions of the MSA and applicable PSA, or (ii) destroy such Product in process. If * elected (i) above, Client shall pay the Service Fee and any related costs or fees for the Service relating to the fully Manufactured Product in accordance with the terms and conditions of the MSA, and if * elected (ii) above, Client shall bear the costs and expenses for such activities.

(iii) If a PSA is naturally expired pursuant to Section 15.1, the provisions of (ii) above shall apply.

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(c) Client Materials, Cell Line, and Reference Standards. Upon expiration or termination of a PSA, upon Client's election, * shall deliver to Client and/or destroy all remaining Client Materials (subject to Sections 15.3.2(a) and 15.3.2(b)), all remaining Cell Line vials, Reference Standards and other materials required for Manufacturing.

The costs and expenses for such activities shall be borne by the Parties as follows:

(i) If Client terminates the PSA pursuant to Section 15.2.1, 15.2.2 or 15.2.3, * shall deliver or dispose at no additional cost to Client and * shall bear such costs and expenses for such activities;

(ii) If * terminates the PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3, or 15.2.5, or Client terminates the PSA pursuant to Section 15.2.4or 15.2.5, Client shall bear such costsand expenses for such activities;

(iii) If a PSA is naturally expired pursuant to Section 15.1, the provisions of (ii) above shall reply.

(d) Raw Materials.

(i) If Client terminates a PSA pursuant to Section 15.2.1, 15.2.2 or 15.2.3 and if Client so elects, * shall deliver the remaining Raw Materials to Client for Client's payment of *'s cost to procure such Raw Materials, or dispose of them at Client's election. * shall bear the costs and expenses for the delivery of the RawMaterials.

(ii) If * terminates a PSA pursuant to Section 15.2.1, 15.2.2, 15.2.3 or 15.2.5, or Client terminates a PSA pursuant to Section 15.2.4 or 15.4.5, * may deliver the remaining Raw Materials to Client or dispose of them at *'s election. If so delivered, Client shall pay *'s cost to procure such Raw Materials to * and bear the costs and expenses for the deliveryof such Raw Materials by *.

(iii) If a PSA is naturally expired pursuant to Section 15.1, the provisions of (ii) above shall apply.

(e) Outstanding Obligations Regarding Purchase of Product.

(i) If Client terminates a PSA pursuant to Section 15.2.1 or 15.2.2 Client shall be released from any outstanding binding obligations to purchase Product as of the date of notice of termination including but not limited to pursuant to a Firm Period, binding forecast, purchase order, minimum purchase commitment, or otherwise; provided, however, that Client shall purchase Product Manufactured prior to such date of notice, pursuant to the terms of this MSA and PSA.

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(ii) If * terminates a PSA pursuant to Section 15.2.1 or 15.2.2, outstanding binding obligations to purchase Product as of the date of notice of termination shall survive termination of such PSA, including but not limited to pursuant to a Firm Period, binding forecast, purchase order, minimum purchase commitment, or otherwise.

(iii) For all other cases of termination of a PSA, subsection (ii) shall apply.

(f) Survival. Any termination or expiration of this MSA shall not affect any outstanding obligations due hereunder prior to such termination or expiration, nor shall it prejudice any other remedies that the parties may have under this MSA. For greater certainty, except as otherwise expressly provided, termination or expiration of this MSA, irrespective of the cause, shall not affect any rights or obligations which, from the context thereof, are intended to survive termination or expiration of this MSA, including but not limited to Sections 1, 8, 9, 10, 11, 12, 13, 14, 15, 16 and 17.2.

15.3.3 **Outbound Transfer.** Upon any termination of a PSA or in connection with its expiration, Client shall be entitled to give notice to * of a Manufacturing Process Transfer, which shall commence the preparation and effectuation of a Manufacturing Process Transfer Plan for the Product identified therein. In addition, Client shall be entitled to give notice to * of a Manufacturing Process Transfer and commence the preparation and effectuation of a Manufacturing Process Transfer Plan in the absence of a termination or expiration of a PSA in order to establish second source Manufacturing. Client shall pay *'s reasonable costs of assistance related to effectuation of the Manufacturing Process Transfer Plan.

SECTION 16 ARBITRATION

16.1 **Informal Discussions.** Except as otherwise provided herein, in the event of any controversy or claim arising out of or relating to this MSA, or the rights or obligations of the Parties hereunder, the Parties shall first try to settle their differences amicably between themselves through the Core Team and then the JSC. Thereafter, either Party may initiate informal dispute resolution on the executive level by sending written notice of the dispute to the other Party, and within thirty (30) days after such notice appropriate executives of the Parties shall meet for attempted resolution by good faith negotiations. If such representatives are unable to resolve such disputed matter within such thirty (30) day period, either Party may refer the matter by written notice to the Chief Executive Officer of the other Party, or his/her designee, and the Chief Executive Officer of such Party, for discussion and resolution. If such individuals or their designees are unable to resolve such dispute within thirty (30) days of such written notice, and such dispute relates to a claimed breach of this MSA, a PSA or a QAG, either Party may initiate binding arbitration proceedings in accordance with the provisions of this Article 16. For the avoidance of doubt, no claim other than a claim of a breach of this Agreement shall be subject to arbitration.

16.2 **Arbitration.** If the Parties do not fully settle a claimed breach of this MSA, a PSA or a QAG pursuant to Section 16.1, and a Party wishes to pursue the matter, each such claim shall be finally resolved by

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binding arbitration in accordance with the Commercial Arbitration Rules of the International Chamber of Commerce ("ICC"), and judgment on the arbitration award may be entered in any court having jurisdiction thereof to enforce the arbitration award. The arbitration shall be conducted by a panel of three neutral persons experienced in the pharmaceutical business, and within thirty (30) days after initiation of arbitration, each Party shall select one person to act as arbitrator and the two Party-selected arbitrators shall select a third arbitrator within thirty (30) days of their appointment. If the arbitrators selected by the Parties are unable or fail to agree upon the third arbitrator, the third arbitrator shall be appointed by the ICC. The place of arbitration shall be New York, New York, United States and all proceedings and communications shall be in English. Either Party may apply to the arbitrators for interim injunctive relief until the arbitration award is rendered or the controversy is otherwise resolved. Either Party also may, without waiving any remedy under this Agreement, seek from any court having jurisdiction any injunctive or provisional relief necessary to protect the rights or property of that Party pending the arbitration award. The arbitrators shall have no authority to award punitive or any other type of damages not measured by a Party's direct compensatory damages, and in all cases, any decision or determination by the arbitrators shall comply with Article 14, as applicable. The Parties agree that, in the event of a good faith dispute over the nature or quality of performance under this Agreement, neither Party may terminate this Agreement until final resolution of the dispute through arbitration or other judicial determination. The Parties further agree that any payments made pursuant to this Agreement pending resolution of the dispute shall be refunded if an arbitrator or court determines that such payments are not due.

16.3 **Costs and Fees.** Each Party shall bear its own attorneys' fees, costs, and disbursements arising out of the arbitration, and shall pay an equal share of the fees and costs of the arbitrators. Absent the filing of an application to correct or vacate the arbitration award as permitted by Applicable Law, each Party shall fully perform and satisfy the arbitration award within fifteen (15) days after the service of the award on such Party.

SECTION 17 MISCELLANEOUS

17.1 **Notices.** Any notice required or permitted under the MSA shall be in writing with duly authorized signature and made to the following addresses or facsimile numbers:

If to Client:

TG Therapeutics, Inc.2 Gansevoort St., 9th Floor
New York, NY 10014
Attention: Senior Vice President Operations
Facsimile:

If to *:

*

With copy to: * Legal & Compliance Department

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Either Party may change its designated address and facsimile number by notice to the other Party in the manner provided in this Section 17.1.

Any notice shall be deemed to have been delivered on the date of delivery of delivered personally, or on the next day of sending if sent by facsimile, or on the fifth day of posting if sent by registered or certified mail with return receipt requested and postage prepaid.

17.2 **Governing Law.** This MSA shall be construed and interpreted in accordance with the laws of State of New York, United States and all rights and remedies shall be governed by such laws without regard to principles of conflicts of law. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to the transactions contemplated by the MSA.

17.3 **Effect of Force Majeure Event**. Neither Party (the "**Affected Party**") shall be liable to the other Party (the "**Non-Affected Party**") for failure or delay to perform its obligation under the MSA or any applicable PSA when such failure or delay is due to riots, storms, fires, explosions, floods, earthquakes, war, embargoes, blockades, insurrections, terrorism, an act of God or any other cause similar thereto which is beyond the control of the Affected Party including those affected upstream suppliers ("**Force Majeure Event**").

Each Party agrees to give the other Party prompt written notice of the occurrence of any Force Majeure Event, the nature thereof, and the extent to which the affected Party will be unable fully to perform its obligations under the MSA. If a condition constituting Force Majeure Event as defined herein exists for more than one hundred eighty (180) consecutive days, or it is reasonably foreseeable that such Force Majeure Event will persist for more than one hundred eighty (180) days consecutive days, the Parties shall endeavor in good faith to negotiate a mutually satisfactory solution to the problem, if practicable, including use of a third party to fulfill the obligations hereunder of the party invoking Force Majeure Event, at the expense of the party invoking Force Majeure Event. If after good faith efforts to negotiate a mutually satisfactory solution for at least sixty (60) days the Parties have failed to reach agreement, the Non-Affected Party shall have the right to terminate this MSA upon thirty (30) days' written failure.

17.4 **Assignment**. Neither Party shall assign, in whole or in part, the MSA without the prior written consent of the other Party, such approval not to be unreasonably withheld, conditioned or delayed. Notwithstanding the above, Client may, without such consent, assign the MSA to (i) its Affiliate or (ii) any purchaser of Client's rights relating to the Product or all or substantially all of the assets of Client, or of all of its capital stock, or to any successor corporation or entity resulting from any merger or consolidation of such Party with or into such corporation or entity. Notwithstanding the above, * may, without such consent, assign the MSA to (i) its Affiliate or (ii) any purchaser of substantially all of the assets of *, or of all of its capital stock, or to any successor corporation or entity resulting from any merger or consolidation of such Party with or into such corporation or entity.

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17.5 **No Grant of License.** Nothing in the MSA shall affect, or grant any right to, patents, know-how or other intellectual property owned by either Party prior to the commencement of the MSA unless otherwise expressly provided in the MSA.

17.6 **No Right to Use Names.** Except as expressly provided herein, no right, expressed or implied, is granted by the MSA to use in any manner the name of either of the Parties or any other trade name, symbol, logo or trademark of the other Party in connection with the performance of the MSA, without the prior written consent of the other Party.

17.7 **Independent Contractors**. The Parties hereto are independent contractors and nothing contained in the MSA shall be deemed or construed to create a partnership, joint venture, employment, franchise, agency or fiduciary relationship between the Parties.

17.8 **Integration**. This MSA constitutes the entire agreement between the Parties relating to the subject matter of the MSA and supersedes all previous oral and written communications between the Parties with respect to the subject matter of the MSA.

17.9 **Amendment; Waiver**. Except as otherwise expressly provided herein, no alteration of or modification to the MSA shall be effective unless made in writing and executed by an authorized representative of both Parties. No course of dealing or failing of either Party to strictly enforce any term, right or condition of the MSA in any instance shall be construed as a general waiver or relinquishment of such term, right or condition. The observance of any provision of the MSA may be waived (either generally or any given instance and either retroactively or prospectively) only with the written consent of the Party granting such waiver.

17.10 **Severability**. The Parties do not intend to violate any Applicable Law. However, if any sentence, paragraph, clause or combination of the MSA is in violation of any law or is found to be otherwise unenforceable, such sentence, paragraph, clause or combination of the same shall be deleted and the remainder of the MSA shall remain binding, provided that such deletion does not alter the basic purpose and structure of the MSA.

17.11 **Construction**. The Parties mutually acknowledge that they have participated in the negotiation and preparation of the MSA. Ambiguities, if any, in the MSA shall not be construed against any Party, irrespective of which Party may be deemed to have drafted the MSA or authorized the ambiguous provision.

17.12 **Interpretation**. The captions and headings to the MSA are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of the MSA. Unless context otherwise clearly requires, whenever used in the MSA: (a) the words “include” or “including” shall be construed as incorporating, also, “but not limited to” or “without limitation”; (b) the words “hereof,” “herein,” “hereby” and derivative or similar words refer to the MSA; (c) the word “law” or “laws” shall mean any applicable, legally binding statute, ordinance, resolution, regulation, code, guideline, rule, order, decree, judgment, injunction, mandate or other legally binding requirement of a governmental authority (including a court, tribunal, agency, legislative body or other instrumentality of any (i) government or country or territory, (ii) any state, province, county, city or other political subdivision thereof, or (iii) any supranational body); and (d) all references to the word “will” are interchangeable with the word “shall” and shall be understood to be imperative or mandatory in nature. All references to days, months, quarters or years are references to calendar days, calendar months, calendar quarters, or calendar years. Whenever any matter hereunder requires consent or approval, such consent or approval shall not be unreasonably withheld or delayed.

17.13 **Counterparts**. This MSA may be executed in two or more counterparts, each of which will be deemed an original, but all of which together will constitute one and the same instrument.

IN WITNESS WHEREOF, the Parties have executed the MSA as of the date first above written.

TG THERAPEUTICS, INC.

Signature: _____
Name: Michael S. Weiss
Title: Chief Executive Officer

Date:

*

Signature: _____
Name: *
Title: *

Date:

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