

**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, 2012.

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission File Number 1-32639

TG THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

36-3898269

(I.R.S. Employer
Identification No.)

787 Seventh Avenue

New York, New York

(Address of principal executive offices)

10019

(Zip Code)

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

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

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

OTC Bulletin Board
(Name of Each Exchange on Which Registered)

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

None

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

Yes No

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

Yes No

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

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 \$69,293,694 as of June 30, 2012, based on the closing sale price of such stock as reported on the OTC Bulletin Board.

There were 25,820,738 shares of the registrant's common stock outstanding as of March 1, 2013.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2013 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, 2012

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

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of our pharmaceutical product candidates or any other products we may acquire or in-license;
- use of clinical research centers and other contractors;
- expectations 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;
- acceptance of our products 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;
- expected losses; and
- expectations for future capital requirements.

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

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

PART I

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

ITEM 1. BUSINESS.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently, the company is developing two therapies targeting hematological malignancies. TG-1101 (ublrituximab), is a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202, an orally available PI3K delta inhibitor.

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

CORPORATE INFORMATION

We were incorporated in Delaware in 1993. Our executive offices are located at 787 Seventh Avenue, New York, New York 10019. Our telephone number is 212-554-4484, and our e-mail address is info@tgtxinc.com.

We file reports with the SEC on an annual basis using Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. 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>.

PRODUCTS UNDER DEVELOPMENT

TG-1101 (ublrituximab)

Overview

TG-1101 (formerly referred to as “LFB-R603” or “R603”) is a chimeric monoclonal antibody with the generic name “ublrituximab” that targets a unique epitope on the CD20 antigen found on the surface of B-lymphocytes developed to aid in the depletion of circulating B-cells. We hold exclusive worldwide rights (except France/Belgium) to develop and commercialize ublrituximab for all indications, including the treatment of cancer and autoimmune diseases such as Non-Hodgkin’s Lymphoma (“NHL”) and Chronic Lymphocytic Leukemia (“CLL”).

Multiple preclinical studies both *in vitro* and *in vivo* produced data that support the activity and potency of ublrituximab as an efficient and selective B-cell targeting anti-CD20 antibody with the ability to effectively deplete B lymphocytes in both malignant laboratory cell models as well as NHL and CLL patient donor cell lines.

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”). Ublrituximab has been specifically bio-engineered to enhance ADCC activity, which enhances its ability to deplete B-cells and may improve its anti-cancer effects as compared to Rituxan[®], the leading anti-CD20 monoclonal antibody, which had worldwide sales in 2011 of approximately \$7 billion.

A two part dose escalating Phase I clinical trial was completed in France in which ublrituximab was introduced in relapsed or refractory CLL patients. Though the primary endpoint of this Phase I clinical study was to assess the safety and tolerability of ublrituximab in CLL patients, robust B-cell depletion and an encouraging rate of partial responses may suggest preliminary evidence of efficacy. A portion of the data from Part 2 of this study was presented at the 53rd Annual American Society of Hematology Meeting in December 2011. Currently, the Company has two ongoing clinical studies for ublrituximab: TG-1101-101, a study of single-agent ublrituximab in patients with NHL and CLL, and TG-1101-102 which is a study of ublrituximab in combination with lenalidomide (trade name Revlimid[®]), an immunomodulatory agent, also for patients with NHL and CLL.

Manufacturing of ublituximab is currently performed by our partner, LFB Biotechnologies.

Pre-Clinical Data Overview

The mechanism of action of anti-CD20 antibodies, including rituximab and ublituximab has been elucidated and detailed in numerous academic and clinical studies. Upon conjugation of the antibody to the CD20 surface antigen, rituximab has been found to deplete B-lymphocytes through three primary mechanisms: antibody dependent cell-mediated cytotoxicity (“ADCC”), complement dependent cytotoxicity (“CDC”), and direct cell death (“DCD” or “programmed cell death” or “PCD”),

Antibody dependent cellular cytotoxicity, or ADCC, is a mechanism that is dependent on interactions between the Fc region of the antibody and the FcγR receptors on immune system effector cells, most notably the FcγRIIIA (“CD16”) receptor found on NK cells. These interactions trigger cells to release pre-forming proteins and proteases resulting in B-cell death. Empirically, ADCC has been the most heavily described and studied mechanism of action, and the subsequent focal point in the research and development of improved CD20 targeted antibodies. CDC occurs when binding of the antibody to the CD20 epitope leads to activation of the complement immune system, also known as the “innate” immune system, which can lead to destruction of the target cell. In programmed cell death, or PCD, the binding of the antibody to the CD20 antigen leads to the activation of apoptotic signaling pathways, contributing to cell death.

Ublituximab is a third generation, type I chimeric IgG1 monoclonal antibody with an engineered Fc region designed specifically to induce higher ADCC activity in comparison to rituximab.

In vitro testing has demonstrated superior ADCC induction of ublituximab over rituximab (see Figure 1). Tested on CLL patient B-cell samples at concentrations of 50 ng/mL, ublituximab produces ADCC activity of 35%, while rituximab was found to exhibit ADCC levels of only 5% at the same concentration.

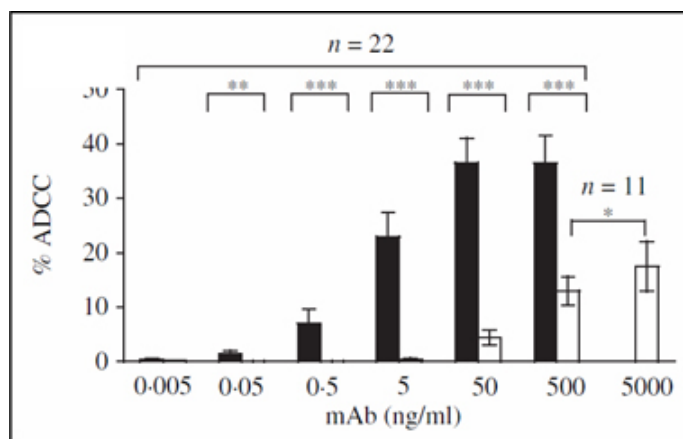


Figure 1: ADCC activity of ublituximab (black) in comparison to rituximab (white) at equivalent concentrations. (de Romeuf et al, 2008)

Additional pre-clinical studies of ublituximab, including *in vivo* assays as a single agent and in combination with chemotherapeutic agents, were presented in abstract and poster form at the 53rd Annual American Society of Hematology Meeting in December 2011 as well as at the 54th Annual American Society of Hematology Meeting in December 2012.

Highlights from the recent American Society of Hematology Meeting in December 2012, included the following:

- *In vitro* / *in vivo* results demonstrated superior efficacy with ublituximab compared to rituximab in primary central nervous system lymphomas, including a significant reduction in tumor burden (p=0.0014) and survival (p=0.016). *CNS Lymphoma Poster Presentation — Poster 2755.*
- Ublituximab induced higher levels of ADCC than rituximab in B-cell NHL cell lines as well as caused a higher degree of CDC lysis in patient-derived tumor cells than rituximab. *Non-Hodgkin Lymphoma Poster Presentation — Poster 2756.*

Ublituximab is more effective than rituximab in inducing ADCC at low doses ($p < 0.01$), and more importantly suggest that ublituximab could be more efficient than rituximab both to induce NK cell activation and ADCC in the presence of peripheral tumor cells from Waldenstrom Macroglobulinemia patients. *Waldenstrom's Macroglobulinemia Poster Presentation — Poster 1654.*

Clinical Data Overview

A multicenter, open-label Phase I/II clinical trial of ublituximab was completed which aimed to assess the safety, tolerability, and efficacy of ublituximab in patients with relapsed or refractory CLL. This two part, first-in-man, dose escalating trial was conducted in 9 centers in France with preliminary results from Parts 1 and 2 presented at the 52nd and 53rd Annual American Society of Hematology (“ASH”) meetings, respectively.

The study regimen in Part 1 involved 21 patients in five dosing cohorts receiving infusions of ublituximab at a dose ranging from 5mg to 450mg once weekly over the course of 4 weeks. Part 2 of this study evaluated the safety and efficacy profile of ublituximab when administered in an 8-dose regimen (150mg initial dose, followed by 7 doses of 450mg). Inclusion criteria were the same in Parts 1 and 2 of the study. In Part 2, 12 patients were enrolled, having a median age of 69.5 years, and a median of 3 prior therapies (58% previously treated with rituximab). Patients were assessed for efficacy every 8 weeks.

Adverse events seen were generally consistent with those exhibited by other anti-CD20 antibodies, consisting mostly of infusion related reactions, infection, headache, neutropenia, thrombocytopenia and transient elevation of AST/ALT levels.

In Part 2 of the study, rapid, near total blood lymphocyte depletion was observed in all patients (see Figure 2). Overall response assessment at month 4 according to NCI-WG guidelines following treatment, ublituximab was found to produce a durable PR in 5/11 (45%) evaluable patients (1 patient not evaluable for efficacy due to early withdrawal as a result of a secondary acute leukemia diagnosis).

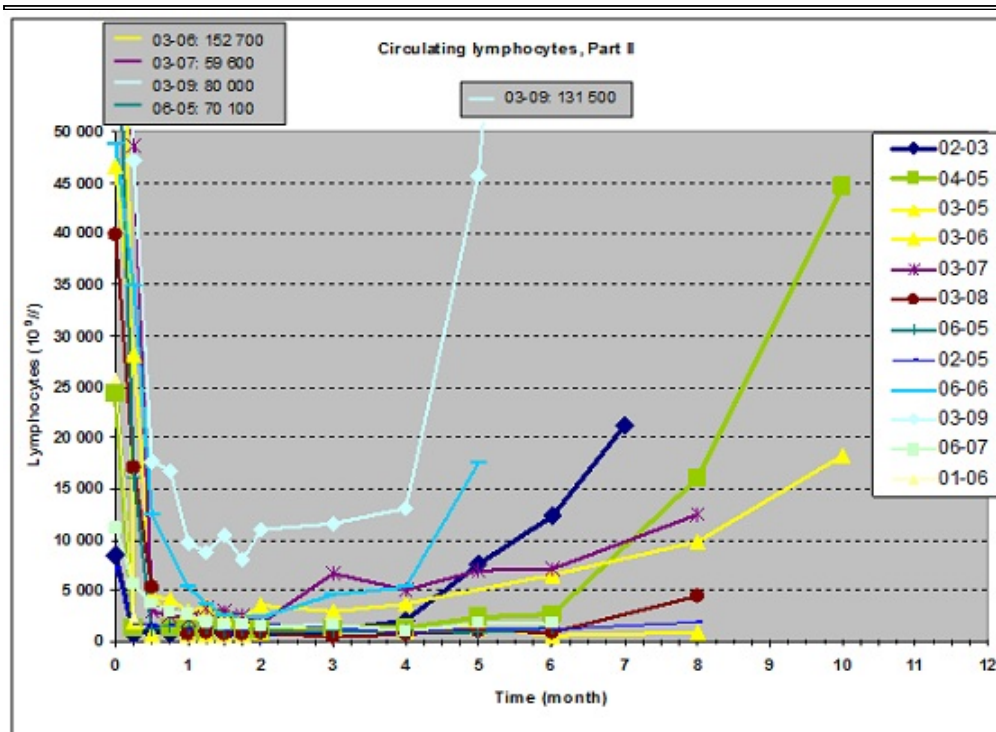


Figure 2: Rapid and profound lymphocyte depletion in study patients from Part 2 of Phase I/II study of ublituximab

Recent Developments

Two Phase I/II trials with ublituximab are currently ongoing, as follows:

TG-1101-101

Our first US based trial was launched in the 3rd quarter of 2012. The trial, entitled "An Open Label Phase I/II Trial of the Efficacy and Safety of Ublituximab in Patients with B-cell Non-Hodgkin Lymphoma who have Relapsed or are Refractory After CD20 Directed Antibody Therapy," is enrolling up to 15 patients total into 4 dose escalation cohorts (450, 600, 900 and 1200 mg). Cohort expansions to confirm safety and efficacy have been included at higher doses prior to entering patients into the Phase 2 portion. Patients will be stratified by subtype of B-cell Lymphoma, including Follicular Lymphoma, Diffuse Large B-cell Lymphoma, Marginal Zone Lymphoma and other NHL subtypes, with a recent amendment to include CLL and CNS lymphoma. All enrolled patients will be relapsed or refractory to Rituxan® or a Rituxan® containing regimen, and in most cases multiple other lines of therapy. Dr. Owen O'Connor, Professor of Medicine and Director, Center for Lymphoid Malignancies at New York Presbyterian Columbia Medical Center is the Principal Investigator for the multi-center study.

We have currently completed enrollment in the first 3 cohorts (450mg, 600mg and 900mg). To date, no dose-limiting-toxicities have been observed. Based on responses seen at all dose levels, we have decided to expand the 900mg cohort to include up to an additional 20 patients. In addition, we have opened an expansion cohort for enrollment of patients with CLL at a dose of 600mg.

In December of 2012, the Company initiated its second US based clinical trial entitled "TG-1101-102: A Phase I/II Study of Ublituximab in Combination with Lenalidomide (Revlimid®) in Patients with B-Cell Lymphoid Malignancies who have Relapsed or are Refractory After CD20 Directed Antibody Therapy". Lenalidomide is an immunomodulatory drug that has displayed activity as a single agent in patients with non-Hodgkin’s lymphoma. In *in vitro* studies, through its activating effects on natural killer cells, lenalidomide has also been shown to enhance the ADCC properties of anti-CD20 antibodies. Ublituximab has demonstrated enhanced ADCC over rituximab, and displayed significant single agent activity in a relapsed CLL setting, providing a strong rationale for the exploration of a combination between lenalidomide and ublituximab in NHL and CLL patients.

The trial is enrolling up to 30 patients in the Phase I dose escalation component/cohort expansion part of the study. Once the optimal dose is determined, the Phase II component may enroll up to an additional 30 patients, with all patients stratified by B-cell malignancy subtype, including CLL and various NHL subtypes. All enrolled patients will be relapsed or refractory to a prior anti-CD20 antibody containing regimen. This multicenter trial is being led by Dr. Marshall Schreeder of the Clearview Cancer Institute in Huntsville, AL.

Currently we are dosing patients at 600mg of TG-1101 in combination with Revlimid® starting at 10mg. If tolerated, patients may have their Revlimid® dose increased in 5mg increments per cycle to a maximum dose of 20mg for patients with NHL and 15mg for patients with CLL. If the combination is well-tolerated, we may increase the dose of TG-1101 to 900mg or higher, with similar dose titration for Revlimid®.

TGR-1202

Overview

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

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

TGR-1202 is being developed jointly with Rhizen Pharmaceuticals, S A, a Switzerland based drug discovery and biotechnology company. The Company and Rhizen will jointly develop the product on a worldwide basis, excluding India, initially focusing on indications in the area of hematologic malignancies and autoimmune disease. Rhizen shall maintain rights to manufacture and supply the product, while we will be responsible for all clinical and regulatory development for TGR-1202 globally.

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

Pre-Clinical Data Overview

In an enzyme based assay, TGR-1202 demonstrated potency and specificity towards PI3Kδ with >1000, 50 and 48-fold selectivity over the α, β, and γ PI3K isoforms.

	IC ₅₀ /EC ₅₀ (nM)	Fold-Selectivity		
		PI3Kδ	PI3Kα	PI3Kβ
Enzyme	22.23	>10000	>50	>48
Cell-based	24.27	>10000	>34	>17

Figure 3: Potency and Specificity of TGR-1202 towards PI3K Delta

Pre-clinical studies of TGR-1202 were presented in abstract and poster form at the 54th Annual American Society of Hematology Meeting in Atlanta, GA in December 2012. Highlights from the meeting included the following:

- In a blinded comparison study of TGR-1202 and GS-1101 completed at Duke University Medical Center, TGR-1202 demonstrated equal efficacy to GS-1101 in regards to in vitro induction of apoptosis and toxicity as well as in suppressing Akt phosphorylation (pAkt) in CLL patient cells. *Chronic Lymphocytic Leukemia (CLL) Poster Presentation — Poster 3914.*
- TGR-1202 is a potent and selective inhibitor of PI3K δ demonstrating significant inhibition in Akt phosphorylation (pAKT) in AML and ALL cell lines and patient cells as well as marked anti-tumor activity in a MOLT-4 (AML) subcutaneous xenograft mouse model. *Acute Leukemia (AML/ALL) Poster Presentation — Poster 2610.*

Recent Developments

In January 2013, the Company initiated a Phase I, open label, multi-center, first-in-human clinical trial of TGR-1202 in patients with hematologic malignancies. The study entitled TGR-1202-101, "A Phase I Dose Escalation Study Evaluating the Safety and Efficacy of TGR-1202 in Patients with Relapsed or Refractory Hematologic Malignancies," is being run in collaboration with the Sarah Cannon Research Institute in Nashville, TN, and will enroll approximately 30 patients during the initial dose escalation phase, followed by up to an additional 30 patients in an expansion phase once the optimal dose has been determined. Enrollment is open to patients with relapsed or refractory NHL, CLL, and Peripheral T-Cell Lymphoma ("PTCL"). Michael R. Savona, MD, the Director of Leukemic Research, Sarah Cannon Research Institute, is acting as Study Chair for the Phase I study. As of February 2013, TGR-1202-101 is ongoing and enrolling patients in the dose escalation component of the Phase I study.

We have completed enrollment of the first dose cohort (50mg, one time per day). Provided no patients experience dose limiting toxicities, additional cohorts evaluating sequentially higher doses of TGR-1202 are planned. We anticipate following completion of the initial cohorts, we will be able to analyze the preliminary pharmacokinetic data ("PK data") to determine whether the dosing regimen of TGR-1202 requires modification in further dose escalation cohorts, if any. We also believe the PK data may provide us preliminary information about the drug properties of TGR-1202 and whether further human study of TGR-1202 is warranted. There can be no assurances given that TGR-1202 will exhibit sufficient pharmaceutical properties following review of the preliminary PK data to support further development of TGR-1202 or that such PK data will be conclusive in any manner to provide assurances that the pharmaceutical properties are adequate. While we do have potential back-up compounds, if we decide to terminate the development of TGR-1202 following review of the PK data, then our PI3K Delta program would be significantly delayed or terminated.

Market Opportunity for TG-1101 & TGR-1202

Our lead development programs, TG-1101 and TGR-1202 are for the treatment of B-cell hematologic malignancies. Hematologic malignancies include cancers derived from the bone marrow and lymph tissue. The non-Hodgkin lymphomas (NHL) represent a heterogeneous subset of these malignancies. Underneath the single rubric of lymphoma exist some of the most aggressive growing cancers (Burkitt's lymphoma, lymphoblastic lymphoma, diffuse large-B-cell lymphoma), as well as some of the most indolent (small lymphocytic lymphoma, follicular lymphoma, and marginal zone lymphoma). In the United States, NHL represents 4-5% of all new cancer cases, and is the fifth leading cause of cancer death. According to the National Cancer Institute, it is estimated in 2012 that there will be 70,130 cases in the United States, and 18,940 deaths from NHL, despite improvements in treatment. Chronic lymphocytic leukemia (CLL) affects mainly older adults and accounts for one third of all diagnosed cases of leukemia. In the US, an estimated 16,060 new cases of CLL will be reported in 2012 with deaths totaling 4,580 due to the disease according to National Cancer Institute (NCI) estimates. Despite improvements in therapy, up to one third of patients with aggressive NHL continue to die from their disease, and indolent lymphomas remain incurable in the absence of allogeneic stem cell transplant. The treatment paradigm for hematologic malignancies is well standardized in front line settings, with the anti-CD20 monoclonal antibody, rituximab, administered generally in combination with chemotherapeutic agents. While front line therapies are generally efficacious, there are numerous downsides, including a high rate of toxicity associated with exposure to chemotherapeutic agents. While initially responsive, most patients with hematologic malignancies will relapse and require second, third, and sometimes more lines of therapy. As a result, there is a pressing need for new, innovative, targeted therapies for the treatment of this heterogeneous group of diseases.

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

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

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

Additionally, advanced novel agents are being developed which target specific signaling pathways and enzymes known to exhibit aberrant activity and overexpression in B-cell malignancies such as Bruton's Tyrosine Kinase (BTK), and Phosphoinositide-3-Kinase delta (PI3K delta). The PI3K/AKT/mTOR pathway has been the target of numerous pharmaceutical agents, both approved and in development, however only recently has the delta isoform of PI3k been identified as a potential target for the treatment of hematologic malignancies and other B-cell lymphoproliferative disorders. GS-1101 (formerly CAL-101) is a PI3K delta specific inhibitor that is under development by Gilead Pharmaceuticals, and has shown promising responses in patients with advanced hematologic malignancies. IPI-145, a PI3K delta and gamma specific inhibitor under development by Infinity Pharmaceuticals has also shown preliminary activity in hematologic malignancies of both B- and T-cell origin. Other agents in development targeting kinases downstream of the B-cell receptor, such as the BTK inhibitor, ibrutinib, have displayed high rates of response in patients with relapsed and refractory B-cell malignancies. While these agents have demonstrated high levels of single agent activity in B-cell disorders, their clinical activity has been shown to be greatly enhanced when utilized in combination with anti-CD20 agents.

The current market for front-line therapy for hematologic malignancies is estimated to be over \$7 billion annually, while subsequent lines of therapy currently consist of generically available chemotherapies which do not contribute significantly to the size of the overall hematologic malignancies market. As novel targeted agents gain FDA approval for the treatment of relapsed and refractory disease, it is anticipated that the size of this market will expand greatly as branded drugs enter use in multiple lines of therapy. Given the nature of the disease state for patients with hematologic malignancies, characterized by indolent disease progression and chronic relapses, the Company anticipates a great and growing need for novel agents that can be used alone or in combination with approved agents, and those currently under development to enhance the quality of life and extend the length of survival for patients suffering from hematologic malignancies.

AST-726

AST-726 is a nasally delivered form of hydroxocobalamin for the treatment of Vitamin B12 deficiency. The Company acquired global rights to AST-726 as part of the Ariston acquisition. AST-726 has demonstrated pharmacokinetic equivalence to a marketed intramuscular injection product for Vitamin B12 remediation.

The Company is currently reviewing its development plans for AST-726, which may include: (1) ceasing further development and attempting to sell or license AST-726, (2) continuing development as originally contemplated under the SPA or (3) evaluating and implementing alternative development plans. No decision has been made as to which approach to execute. A final decision is expected to take 6-12 months, but may occur earlier or later.

AST-915

The Company has a sponsored research arrangement for AST-915, an orally delivered treatment for essential tremor. Patient enrollment, treatment, and follow-up concluded for a Phase 1 dose escalation trial of AST-915 in early June 2012. Upon analysis of the data from this study, it was determined that the Phase 1 dose escalation trial of AST-915 did not meet its primary efficacy endpoint of reduction in dominant hand tremor at a timepoint of 80 minutes following administration. Given the results from this Phase 1 study, the Company has discontinued future development activities for AST-915.

COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

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

Product candidate	Target indication	Development status	Completion of phase	Estimated cost to complete phase
TG-1101 (ublituximab)	Multiple forms of cancer and various autoimmune diseases	Phase I	Mid-2013	Less than \$1 million
TG-1101	Multiple forms of cancer	Phase Ib/II	Mid-2014	Approximately \$3 million
TGR-1202	Multiple forms of cancer	Phase I	Late-2013	Approximately \$2 million

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

INTELLECTUAL PROPERTY AND PATENTS

General

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

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

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

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

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

TG-1101

Pursuant to our license for TG-1101 (ublituximab) with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, we have the exclusive commercial rights to a series of patents and patent applications in the U.S., and in multiple countries around the world. These patents and patent applications 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.

In the United States, we have 5 issued patents for TG-1101 which expire between 2021 and 2024, excluding any patent term extensions, as well as granted and pending foreign counterpart patent filings related to these issued patents. These patents include claims related to the manufacture and use of TG-1101. Additionally, we have over 10 issued patents outside the US, and over 45 patent applications pending worldwide including claims directed to the composition of matter and methods of treatment with TG-1101 in various settings.

TGR-1202

Pursuant to our Collaboration Agreement with Rhizen Pharmaceuticals for TGR-1202, we have the exclusive commercial rights to a series of patents and patent applications in the U.S. and abroad. These patents and patent applications include composition of matter patents relating to the structure and mechanism of action for TGR-1202 as well as method of use patents which cover use of TGR-1202 in combination with various agents and for various therapeutic indications. All patent applications currently filed for TG-1202 are currently pending.

AST-726

The Company has certain patent rights and other intellectual property relating to AST-726 in the U.S. and multiple countries around the world, which expire at various times from 2014 to 2015.

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 section “**Risks Related to the Company’s Intellectual Property.**”

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

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

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

Other Intellectual Property Rights

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

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

Pursuant to these regulations, TG-1101 (ublrituximab) has received Orphan-Drug designation from the FDA for the treatment of CLL in August of 2010, and Orphan-Drug designation by the EMA for the treatment of CLL in November of 2009. We believe that TG-1101 may be eligible for additional orphan drug designations; however, we cannot assure you that TG-1101, or any other drug candidates we may acquire or in-license, will obtain such orphan drug designations. Additionally, upon FDA approval, we believe that ublrituximab would qualify as a New Chemical Entity, or NCE, which provides for five years of exclusivity following approval.

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

LICENSING AGREEMENTS AND COLLABORATIONS

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

TG-1101

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

In January 2012, we entered into an exclusive license agreement with LFB Biotechnologies, GTC Biotherapeutics, and LFB/GTC LLC, all wholly-owned subsidiaries of LFB Group, relating to the development of ublrituximab. Under the license agreement, we have acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of TG-1101 (ublrituximab). To date, we have made no payments to LFB Group and LFB Group is eligible to receive payments of up to an aggregate of approximately \$31.0 million upon our successful achievement of certain clinical development, regulatory and sales milestones, in addition to royalty payments on net sales of ublrituximab. 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.

Ildong Pharmaceutical Co. Ltd.

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong Pharmaceutical Co. Ltd, (“Ildong”) relating to the development and commercialization of ublrituximab 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 ublrituximab 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 and royalty payments on net sales of ublrituximab 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.

TGR-1202

On August 15, 2012, the Company and Rhizen Pharmaceuticals S A (“Rhizen”) entered into an exclusive global agreement to collaborate on the development and commercialization of Rhizen’s lead product candidate (the “Collaboration Agreement”), a novel P13K delta inhibitor, (“TGR-1202”) (previously referred to as RP5264). The companies will jointly develop the product on a worldwide basis, excluding India, initially focusing on indications in the area of hematologic malignancies and autoimmune disease. Beyond TGR-1202, Rhizen would contribute backup molecules providing multiple opportunities for TG to develop differentiated therapies against hematologic cancers and autoimmune diseases.

The Company will make up-front licensing payments and milestones based on early clinical development, and will be responsible for the costs of clinical development of the product through Phase II, after which the Company and Rhizen will be jointly responsible for all development costs of the product. The Company and Rhizen will each maintain an exclusive option, exercisable at specific times during development, for the Company to license the rights to TGR-1202, in which case Rhizen would be eligible to receive upfront, development, and commercialization milestone payments in addition to milestone payments and royalties tied to net sales of the product, the aggregate of which could exceed \$250 million. Rhizen shall maintain rights to manufacture and supply the product to the Company, and the Company will be responsible for all clinical and regulatory development for TGR-1202 globally.

In connection with the Collaboration Agreement, to date we have paid an aggregate of \$1,000,000 to Rhizen, and Rhizen is eligible to receive additional payments of up to \$2,000,000 upon the successful achievement of certain clinical development milestones prior to entering profit and loss sharing for the TGR-1202 development program. Pursuant to the terms of the Collaboration Agreement, should either of the exclusive license options be exercised, Rhizen would be eligible to receive up to an aggregate of \$182.5 million upon the successful achievement of certain clinical development, regulatory, and sales based milestones in addition to royalties on net sales of TGR-1202.

COMPETITION

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

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

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan[®] (Rituximab), Spectrum Pharmaceutical's Zevalin[®] (Y90-Ibritumomab Tiuxetan), GlaxoSmithKline's Bexxar[®] (I¹³¹-Tositumomab), Dr. Reddy's Laboratories' Reditux[®], and Genmab and GlaxoSmithKline's Arzerra[®] (Ofatumomab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing anti-CD20 antibodies which, if approved, would potentially compete with TG-1101, including, but not limited to, GA-101 (obinutuzumab), under clinical development by the Roche Group. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

With respect to TGR-1202, although no PI3K delta inhibitors have been approved by the FDA, there are several PI3K delta targeted compounds in development, including, but not limited to, Gilead's GS-1101 (formerly known as CAL-101), Infinity Pharmaceuticals IPI-145 and Amgen's AMG-319, which if approved we would expect to compete directly with TGR-1202. In addition, there are numerous other novel therapies targeting similar pathways to TGR-1202 in development, which if approved would also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (under clinical development by Pharmacyclics), or the bcr-2 inhibitor ABT-199 (under clinical development by Abbott Laboratories).

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

SUPPLY AND MANUFACTURING

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

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

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

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

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

GOVERNMENT AND INDUSTRY REGULATION

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

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

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

- that the drug is intended to treat a serious or life-threatening condition;

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

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

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

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

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

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

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

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

- insufficient supply of the drug candidates;
- adverse medical events or side effects in treated patients; and
- ineffectiveness of the drug candidates.

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

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

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

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

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

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

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

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

EMPLOYEES

As of March 1, 2013, we had 6 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 the Company's Business and Industry

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

Our product candidates have been in-licensed from third parties. Under the terms of our license agreements, the licensors generally will have the right to terminate such agreement in the event of a material breach by us. The licensors will also have the right to terminate the agreement in the event we fail to use diligent and reasonable efforts to develop and commercialize the product candidate worldwide.

If there is any conflict, dispute, disagreement or issue of non-performance between us and our licensing partners regarding our rights or obligations under the license agreements, including any such conflict, dispute or disagreement arising from our failure to satisfy payment obligations under such agreement, our ability to develop and commercialize the affected product candidate and our ability to enter into collaboration or marketing agreements for the affected product candidate may be adversely affected. Any loss of our rights under these license agreements would delay or completely terminate its product development efforts for the affected product candidate.

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

In order to submit an Investigational New Drug application ("IND"), Biologics License Application ("BLA"), or New Drug Application ("NDA") to the FDA, it is necessary to submit all information on the clinical, non-clinical, chemistry, manufacturing, controls and quality aspects of the product candidate. We rely on our third party contractors and our licensing partners to provide a significant portion of this data. If we are unable to obtain this data, or the data is not sufficient to meet the regulatory requirements, we may experience significant delays in our development programs. Additionally, an IND must be active in each division in which we intend to conduct clinical trials. While we maintain an active IND for ublituximab and TGR-1202 enabling the conduct of studies in the FDA's Division of Hematology and Oncology; there can be no assurance given that we will be successful in obtaining an active IND for ublituximab or TGR-1202 in any other division under whose supervision we may seek to develop our product candidates, or that the FDA will allow us to continue the development of our product candidates in those divisions where we maintain an active IND.

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

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

If we are unable to develop, or receive regulatory approval for or successfully commercialize any of our product candidates, we will not be able to generate product revenues.

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

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

We plan on conducting additional Phase I, II and III clinical trials for ublituximab. Early clinical results seen with ublituximab in a small number of patients may not be reproduced in larger clinical trials. Additionally, individually reported outcomes of patients treated in clinical trials may not be representative of the entire population of treated patients in such studies. If the results from later trials are different from those found in the earlier studies of ublituximab, 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.

TGR-1202 has only recently entered into a first-in-human Phase I clinical trial. At this time it is difficult to predict TGR-1202's pharmacologic properties in humans and whether it will be able to inhibit PI3k delta in humans. We will assess such pharmacologic properties in our first in human phase 1 study. There can be no assurances given that TGR-1202 will exhibit sufficient pharmacologic properties following review of the initial data from this first Phase 1 study to support further development of TGR-1202. Furthermore, such pharmacologic data arising from this first Phase 1 study may be inconclusive or not reproducible in later clinical trials. In such situation, we may conduct additional clinical trials only to learn later that TGR-1202 lacks adequate pharmacologic properties. Additionally, even if we believed that TGR-1202 possessed adequate pharmacologic properties, that still does not ensure that TGR-1202 will be a safe, active, or effective pharmaceutical agent. If TGR-1202 were ultimately determined to lack adequate pharmacologic properties or fail to be a safe, active, or effective pharmaceutical agent, we would have to cease development, which could have a material adverse effect on our business. In such event, despite the rights we retain to back-up compounds, our PI3k Delta program would be significantly delayed or terminated.

Any product candidates we may advance into 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 to commercialize our product candidates.

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

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

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

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

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

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

We have not completed testing of any of our product candidates for the treatment of the indications for which we intend to seek product approval in humans, and we currently do not know the extent that adverse events, if any, will be observed in patients who receive any of its product candidates. To date, clinical trials using ublituximab and our other product candidates have demonstrated a toxicity profile that was deemed acceptable by the investigators performing such studies. Such interpretation may not be shared by future investigators or by the FDA and in the case of ublituximab and TGR-1202, even if deemed acceptable for oncology applications, it may not be acceptable for diseases outside the oncology setting, and likewise for any other product candidates we may develop. Additionally, the severity, duration and incidence of adverse events may increase in larger study populations. With respect to ublituximab, the toxicity when manufactured under different conditions is not known, nor is the toxicity of transgenically derived ublituximab, and it is possible that additional and/or different adverse events may appear upon the human use of those formulations and those adverse events may arise with greater frequency, intensity and duration than in the current formulation. With respect to TGR-1202, we are unfamiliar with the adverse event profile as it has only recently been dosed in humans. 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, which could have a material adverse impact on the Company.

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

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

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

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

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

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

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

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

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

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

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;

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

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

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

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

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

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

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

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

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

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

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

Our product candidates are in the initial stages of development and are currently manufactured in small batches for use in pre-clinical and clinical studies. Process improvements implemented to date have, and process improvements in the future may change the activity profile of the product candidates, which may affect the safety and efficacy of the products. No assurance can be given that the material manufactured from any of the optimized processes will perform comparably to the product candidates as manufactured to date and used in currently available pre-clinical data and or in early clinical trials reported in this or any previous filing. Additionally, future clinical trial results will be subject to the same level of uncertainty if, following such trials, additional process improvements are made, including without limitation, the introduction of transgenically derived ublituximab.

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

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

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

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

The cancer indications for which we are developing our products have a number of established therapies with which we will compete. Most major pharmaceutical companies and many biotechnology companies are aggressively pursuing new cancer development programs for the treatment of NHL, CLL, and other B-cell proliferative malignancies, including both therapies with traditional, as well as novel, mechanisms of action.

If approved, we expect TG-1101 to compete directly with Roche Group's Rituxan[®] (Rituximab), Spectrum Pharmaceutical's Zevalin[®] (Y⁹⁰-Ibritumomab Tiuxetan), GlaxoSmithKline's Bexxar[®] (I¹³¹-Tositumomab), Dr. Reddy's Laboratories' Reditux[®], and Genmab and GlaxoSmithKline's Arzerra[®] (Ofatumomab) among others, each of which is currently approved for the treatment of various diseases including NHL and CLL. In addition, a number of pharmaceutical companies are developing anti-CD20 antibodies which, if approved, would potentially compete with TG-1101, including, but not limited to, GA-101 (obinutuzumab), under clinical development by the Roche Group. New developments, including the development of other pharmaceutical technologies and methods of treating disease, occur in the pharmaceutical and life sciences industries at a rapid pace.

With respect to TGR-1202, although no PI3K delta inhibitors have been approved by the FDA, there are several PI3K delta targeted compounds in development, including, but not limited to, Gilead's GS-1101 (formerly known as CAL-101), Infinity Pharmaceuticals IPI-145 and Amgen's AMG-319, which if approved we would expect to compete directly with TGR-1202. In addition, there are numerous other novel therapies targeting similar pathways to TGR-1202 in development, which if approved would also compete with TGR-1202 in similar indications, such as the BTK inhibitor, ibrutinib (under clinical development by Pharmacyclics), or the b1c-2 inhibitor ABT-199 (under clinical development by Abbott Laboratories).

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

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

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

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

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

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted only after we submit a BLA or NDA to the FDA, if at all. We do not control the manufacturing process of our product candidates and are completely dependent on our contract manufacturing partners for compliance with the FDA's requirements for manufacture of finished pharmaceutical products (good manufacturing practices, GMP). If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the FDA's strict regulatory requirements of safety, purity and potency, we will not be able to secure and/or maintain FDA approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If our contract manufacturers cannot meet FDA standards, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. No assurance can be given that a long-term, scalable manufacturer can be identified or that they can make clinical and commercial supplies of our product candidates 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. If that is the case, we may need to rely exclusively on transgenically manufactured material, which may introduce additional risk and uncertainty the extent of which cannot be fully determined today.

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

In most cases, our manufacturing partners are single source suppliers. It is expected that our manufacturing partners will be sole source suppliers from single site locations for the foreseeable future. Given this, any disruption of supply from these partners could have a material, long-term impact on our ability to supply products for clinical trials or commercial sale. If the Company's 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 the Company's current or future supply of any of our product candidates should fail to meet specifications during its stability program there could be a significant interruption of our supply of drug, which would adversely affect the Company's clinical development and commercialization of the product. Regarding ublituximab, the proprietary transgenic technology that supports the manufacture of transgenically derived ublituximab is not easily transferrable, if at all, and it is expected that GTC will be the sole supplier of transgenically derived ublituximab at a single site for the foreseeable future.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time consuming and costly process that could require that we provide supporting scientific, clinical and cost-effectiveness data for the use of our products to the payor. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If reimbursement of our future products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

In both the United States and certain foreign countries, there have been a number of legislative and regulatory changes to the healthcare system that could impact our ability to sell our products profitably. In particular, the Medicare Modernization Act of 2003 revised the payment methodology for many products reimbursed by Medicare, resulting in lower rates of reimbursement for many types of drugs, and added a prescription drug benefit to the Medicare program that involves commercial plans negotiating drug prices for their members. Since 2003, there have been a number of other legislative and regulatory changes to the coverage and reimbursement landscape for pharmaceuticals. Most recently, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, the "Affordable Care Act," was enacted. The Affordable Care Act contains a number of provisions, including those governing enrollment in federal healthcare programs, the increased use of comparative effectiveness research on healthcare products, reimbursement and fraud and abuse changes, and 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. An expansion in the government's role in the U.S. healthcare industry may further lower rates of reimbursement for pharmaceutical and biotechnology products.

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

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

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

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

As of March 1, 2013, the Company has 6 full and part time employees. Over time, we will need to expand our managerial, operational, financial and other resources in order to manage and fund our operations and clinical trials, continue research and development activities, and commercialize our product candidates. Our management and scientific personnel, systems and facilities currently in place may not be adequate to support our future growth. Our need to effectively manage our operations, growth, and various projects requires that we:

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

We may utilize the services of outside vendors or consultants to perform tasks including clinical trial management, statistics and analysis, regulatory affairs, formulation development 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 the Company is not able to effectively expand its organization by hiring new employees and expanding its 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.

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

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

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

If the Company fails to comply with healthcare regulations, it could face substantial penalties and its business, operations and financial condition could be adversely affected.

In addition to FDA restrictions on the marketing of pharmaceutical and biotechnology products, several other types of state and federal laws have been applied to restrict certain marketing practices in the pharmaceutical and medical device industries in recent years, as well as consulting or other service agreements with physicians or other potential referral sources. These laws include anti-kickback statutes and false claims statutes that prohibit, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or, in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally-financed healthcare programs, and knowingly presenting, or causing to be presented, a false claim for payment to the federal government, or knowingly making, or causing to be made, a false statement to get a false claim paid. The majority of states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and any practices we adopt may not, in all cases, meet all of the criteria for safe harbor protection from anti-kickback liability. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment. Any challenge to its business practices under these laws could have a material adverse effect on our business, financial condition, and results of operations.

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

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

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

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

The timelines and projections in this filing 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 the Company does 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.

Risks Relating to Acquisitions

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

We may seek to expand our business through the acquisition of, investments in and strategic alliances with companies, technologies, products, and services, such as the Exchange Transaction between the Company and TG Bio and the Collaboration Agreement between the Company and Rhizen. Acquisitions, investments and strategic alliances involve a number of special problems and risks, including, but not limited to:

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

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

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

Risks Relating to the Company's Intellectual Property

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

Our commercial success depends on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. If any of our licensors or partners fails to appropriately prosecute and maintain patent protection for these product candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

Currently, the composition of matter patent and several method of use patents for ublituximab and TGR-1202 in various indications and settings have been applied for but have not yet been issued. The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our partners will be successful in protecting our product candidates by obtaining and defending patents.

These risks and uncertainties include the following:

- the patent applications that we or our partners file may not result in any patents being issued;
- patents that may be issued or in-licensed may be challenged, invalidated, modified, revoked or circumvented, or otherwise may not provide any competitive advantage;
- as of March 16, 2013, the U.S. will convert from a "first to invent" to a "first to file" system. After this time if we do not win the filing race, we will not be entitled to inventive priority;
- our competitors, many of which have substantially greater resources than we do, and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate its ability to make, use, and sell our potential products either in the United States or in international markets;

- there may be significant pressure on the U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have less restrictive patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products.

If patents are not issued that protect our product candidates, it could have a material adverse effect on our financial condition and results of operations.

In addition to patents, we and our partners also rely on trade secrets and proprietary know-how. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, third parties may still obtain this information or we may be unable to protect its rights. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

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

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

Our commercial success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. For example, Roche has the Cabilly patents in the U.S. that block the commercialization of antibody products derived from a single cell line, like ublituximab. Also, Roche, Biogen Idec, and Genentech hold patents for the use of anti-CD20 antibodies utilized in the treatment of CLL in the U.S. While these patents have been challenged, to the best of our knowledge, those matters were settled in a way that permitted additional anti-CD20 antibodies to be marketed for CLL. If those patents are still enforced at the time we are intending to launch 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 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 the Company.

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.

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

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

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

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

We may 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. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly. The adverse result could also put related patent applications at risk of not issuing.

Interference proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office (“PTO”) may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. 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 its 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. Moreover, as of March 16, 2013, the U.S. will convert from a “first to invent” to a “first to file” system. After that time, should there be any innovations that we invented first, but on which we filed the patent application second, we will have limited options available to reclaim invention priority.

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

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

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

Risks Relating to the Company’s Finances and Capital Requirements

The Company will need to raise additional capital to continue to operate its business.

As of December 31, 2012, we had net cash on hand of approximately \$16,456,000. We believe that our cash on hand will sustain our operations for approximately the next 18 months. As a result, we will need additional capital to continue our operations beyond that time. We will need to seek additional sources of financing in the future, which might not be available on favorable terms, if at all, to continue our operations. If we do not succeed in raising additional funds on acceptable terms, we might be unable to complete planned preclinical and clinical trials or obtain approval of any of our product candidates from the FDA or any foreign regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego sales and marketing efforts and forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of the Company’s equity securities, which would have a dilutive effect on your holdings of our capital stock.

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.

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

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

The Company has never been profitable and, as of December 31, 2012, we had an accumulated deficit of approximately \$18,926,000. We have generated operating losses in all periods since the Company was incorporated. We expect to make substantial expenditures resulting in increasing operating costs in the future and our accumulated deficit may increase significantly as we expand development and clinical trial efforts for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses or when we will become profitable, if ever. Even if we achieve profitability, we may not be able to sustain or increase profitability on an ongoing basis.

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

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

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

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

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

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

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

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

- the progress of our clinical trials, including expenses to support the trials and milestone payments that may become payable under our license agreements;

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

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

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

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

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

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

Our directors, executive officers, their affiliates, and our principal stockholders beneficially own approximately 50% percent of our outstanding voting stock, including shares underlying outstanding options and warrants. Our directors, officers and principal stockholders, taken as a whole, have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

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

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

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

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

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

Our common stock is not listed on a national exchange and there is a limited market for the Common Stock which may make it more difficult for you to sell your stock.

Our common stock, par value \$0.001 per share (the "Common Stock"), is quoted on the OTC Bulletin Board under the symbol "TGTX." There is a limited trading market for our Common Stock which negatively impacts the liquidity of our Common Stock not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. Accordingly, there can be no assurance as to the liquidity of any markets that may develop for the Common Stock, the ability of holders of our Common Stock to sell the Common Stock, or the prices at which holders may be able to sell the Common Stock.

The fact that our Common Stock is not listed on a national exchange may negatively impact our ability to attract investors and to use our Common Stock to raise capital to fund our operations.

In order to maintain liquidity in our Common Stock, we depend upon the continuing availability of a market on which our securities may be traded. We need to raise substantial additional funds in the future to continue our operations and the fact that our Common Stock is not listed on a national exchange may impact our ability to attract investors and to use our Common Stock to raise sufficient capital to continue to fund our operations.

If we fail to file periodic reports with the SEC our common stock may be removed from the OTCBB.

Pursuant to the Over-The-Counter Bulletin Board ("OTCBB") rules relating to the timely filing of periodic reports with the SEC, any OTCBB issuer which fails to file a periodic report (Form 10-Qs or 10-Ks) by the due date of such report (as extended by the filing of a Form 12b-25), three (3) times during any twenty-four (24) month period is automatically de-listed from the OTCBB. In the event an issuer is de-listed, such issuer would not be eligible to be re-listed on the OTCBB for a period of one-year, during which time any subsequent late filing would reset the one-year period of de-listing. If the Company is late in its filings three (3) times in any twenty-four (24) month period and is de-listed from the OTCBB, the Common Stock would likely be listed for trading only on the "Pink Sheets," which generally provide an even less liquid market than the OTCBB. In such event, investors may find it more difficult to trade the Common Stock or to obtain accurate, current information concerning market prices for the Common Stock.

We have identified a material weakness in our internal control over financial reporting.

Management has identified a material weakness in our internal control over financial reporting as defined in the Public Company Accounting Oversight Board's Auditing Standard No. 5. See "Item 9A. Controls and Procedures." The material weakness in our internal control over financial reporting relates to an inadequate segregation of duties, as all financial and accounting duties are performed by our Chief Financial Officer. We intend to address this deficiency by hiring additional accounting personnel in 2013 to remediate the segregation of duties issue. We cannot provide assurances that additional significant deficiencies or material weaknesses in our internal control over financial reporting will not be identified in the future. Any failure to maintain or implement required new or improved controls, or any difficulties we encounter in their implementation, could result in additional significant deficiencies or material weaknesses, cause us to fail to meet our periodic reporting obligations or result in material misstatements in our financial statements. Any such failure could also adversely affect the results of periodic management evaluations and annual auditor attestation reports regarding the effectiveness of our internal control over financial reporting. The existence of a material weakness could result in errors in our financial statements that could result in a restatement of financial statements, cause us to fail to meet our reporting obligations and cause investors to lose confidence in our reported financial information, leading to a decline in our stock price.

There is a risk of market fraud.

OTCBB securities are frequent targets of fraud or market manipulation. Not only because of their generally low price, but also because the OTCBB reporting requirements for these securities are less stringent than for listed or NASDAQ traded securities, and no exchange requirements are imposed. Dealers may dominate the market and set prices that are not based on competitive forces. Individuals or groups may create fraudulent markets and control the sudden, sharp increase of price and trading volume and the equally sudden collapse of market prices.

Penny stock regulations may impose certain restrictions on marketability of our securities.

The Securities and Exchange Commission has adopted Rule 15g-9 which establishes the definition of a “penny stock,” for the purposes relevant to us, as any equity security that has a market price of less than \$5.00 per share or with an exercise price of less than \$5.00 per share, subject to certain exceptions. For any transaction involving a penny stock, unless exempt, the rules require:

- that a broker or dealer approve a person’s account for transactions in penny stocks; and
- the broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

In order to approve a person’s account for transactions in penny stocks, the broker or dealer must:

- obtain financial information and investment experience objectives of the person; and
- make a reasonable determination that the transactions in penny stocks are suitable for that person and the person has sufficient knowledge and experience in financial matters to be capable of evaluating the risks of transactions in penny stocks.

The broker or dealer must also deliver, prior to any transaction in a penny stock, a disclosure schedule prescribed by the Commission relating to the penny stock market, which, in highlight form:

- sets forth the basis on which the broker or dealer made the suitability determination; and
- that the broker or dealer received a signed, written agreement from the investor prior to the transaction.

Generally, brokers may be less willing to execute transactions in securities subject to the “penny stock” rules. This may make it more difficult for investors to dispose of our Common Stock and cause a decline in the market value of our stock.

Disclosure also must be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

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

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

ITEM 2. PROPERTIES.

Our corporate and executive office is located in New York, New York. Our New York facility consists of office space at 787 Seventh Avenue, 48th Floor, New York, New York 10019. We are not currently under a lease agreement at 787 Seventh Avenue. We believe that our existing facilities are adequate to meet our current requirements. We do not own any real property.

ITEM 3. LEGAL PROCEEDINGS.

We, and our subsidiaries, are not a party to, and our property is not the subject of, any material pending legal proceedings.

ITEM 4. MINE SAFETY DISCLOSURES.

This item is not applicable to the Company.

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 Over the Counter Bulletin Board (“OTCBB”) and effective January 12, 2012 traded under the symbol “TGTX.” Prior to January 12, 2012 the Company was trading under the symbol “MHAN.”

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

	<u>High</u>	<u>Low</u>
Fiscal Year Ended December 31, 2012		
Fourth Quarter	\$ 3.64	\$ 1.90
Third Quarter	\$ 6.25	\$ 2.24
Second Quarter	\$ 7.31	\$ 5.63
First Quarter	\$ 33.19	\$ 1.13

	<u>High</u>	<u>Low</u>
Fiscal Year Ended December 31, 2011		
Fourth Quarter	\$ 11.25	\$ 1.01
Third Quarter	\$ 28.69	\$ 5.63
Second Quarter	\$ 48.41	\$ 17.09
First Quarter	\$ 93.97	\$ 37.02

Holdings

The number of record holders of our common stock as of February 28, 2013 was 234.

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, 2012, regarding the securities authorized for issuance under our equity compensation plans, consisting of the 1995 Stock Option Plan, the 2003 Stock Option Plan, and the TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan.

Equity Compensation Plan Information

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options</u>	<u>Weighted-average exercise price of outstanding options</u>	<u>Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))</u>
	(a)	(b)	(c)
Equity compensation plans approved by security holders	46,904	\$ 61.08	2,056,989
Equity compensation plans not approved by security holders	—	—	—
Total	46,904	\$ 61.08	2,056,989

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

Recent Sales of Unregistered Securities

On December 30, 2011, we completed the first closing of the private placement of our securities, issuing 4,929,523 shares of Common Stock at a price per share of \$2.25 for total gross proceeds, before placement commissions and expenses, of \$11,091,425 (the "2011 Equity PIPE"). Investors also received warrants to purchase 1,232,381 shares of Common Stock. The warrants have an exercise price of \$2.25 per share and are exercisable for five years. In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Series A preferred stock (the "Company Preferred Stock") at a price per share of \$20.00 for total gross proceeds, before placement commissions and expenses, of \$13,908,560. Each share of Company Preferred Stock was convertible into 8.89 shares of Common Stock; provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012, all shares of preferred stock issued in the 2011 Equity PIPE were converted to Common Stock. Investors also received warrants to purchase 1,545,396 shares of Common Stock. The warrants have an exercise price of \$2.25 per share and are exercisable for five years. The shares of Common Stock, Company Preferred Stock, and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities issued in the offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the offering for their expenses.

Activities Prior to the Exchange Transaction with TG Therapeutics, Inc.

On February 9, 2011, the Company entered into a waiver and forbearance agreement (the "Extension Agreement") with the requisite holders of the Secured 12% Notes whereby the holders of the notes (the "Noteholders") agreed to forbear the exercise of their rights under the Notes and waive the default thereof until December 31, 2011. As part of the Extension Agreement, the Company agreed to take prompt steps to seek to reduce its outstanding indebtedness by permitting the Noteholders to convert the Secured 12% Notes into shares of the Company's common stock at a conversion price of \$28.13 per share and to amend the terms of the warrants issued with the Secured 12 % Notes to include a full-ratchet anti-dilution feature and an exercise price of \$28.13 per share. The Company obtained stockholder approval to, among other things, increase the number of its authorized common stock. The Secured 12% Notes became convertible into common stock at a conversion price of \$28.13, which triggered the antidilution rights of the warrants issued with Secured 12% Notes, the warrants issued with the Convertible 12% Note and the warrants issued in the 2010 Equity Pipe. The Secured 12% Notes and interest thereon, amounting to \$676,072 at the time of conversion, converted into the right to receive 85,372 shares of the Company's common stock on September 15, 2011 (the "Secured Debt Conversion"). In connection with the Exchange Transaction with TG Therapeutics, Inc., the warrant holders of the 12% Notes agreed to waive their anti-dilution feature, in exchange for the exercise price being lowered to \$2.25.

In March and April 2010, the Company raised aggregate gross proceeds of approximately \$2,607,500 pursuant to a private placement of its securities (the "2010 Equity Financing"). The Company entered into subscription agreements (the "Subscription Agreements") with accredited investors (the "Investors") pursuant to which the Company sold an aggregate of 104.3 Units (as defined herein) for a purchase price of \$25,000 per Unit. Pursuant to the Subscription Agreements, the Company issued to each Investor units (the "Units") consisting of (i) 127 shares of common stock, \$0.001 par value per share (the "Common Stock" or "Shares") of the Company and (ii) 190 warrants (each a "Warrant" and collectively the "Warrants"), each of which will entitle the holder to purchase one additional share of Common Stock for a period of five years (each a "Warrant Share" and collectively the "Warrant Shares") at an exercise price of \$225 per share. In connection with the Exchange Transaction with TG Therapeutics, Inc., the warrant holders exercise price was lowered to \$2.25. All of the Investors represented that they were "accredited investors," as that term is defined in Rule 501(a) of Regulation D under the Securities Act, and the sale of the Units was made in reliance on exemptions provided by Regulation D and Section 4(2) of the Securities Act of 1933, as amended. The Company did not use any form of advertising or general solicitation in connection with the sale of the Units. The Shares, the Warrants and the Warrant Shares are non-transferable in the absence of an effective registration statement under the Act, or an available exemption therefrom, and all certificates are imprinted with a restrictive legend to that effect.

In addition, the Company issued a warrant to purchase 10,596 shares of Common Stock at an exercise price of \$225 per share to the Placement Agent as compensation for its services. In connection with the Exchange Transaction with TG Therapeutics, Inc., the warrant holders exercise price was lowered to \$2.25.

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

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

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

Overview

We were incorporated in Delaware in 1993 under the name "Atlantic Pharmaceuticals, Inc." and, in March 2000, we changed our name to "Atlantic Technology Ventures, Inc." In 2003, we completed a "reverse acquisition" of privately held "Manhattan Research Development, Inc". In connection with this transaction, we also changed our name to "Manhattan Pharmaceuticals, Inc." From an accounting perspective, the accounting acquirer is considered to be Manhattan Research Development, Inc. and accordingly, through December 29, 2011, the historical financial statements were those of Manhattan Research Development, Inc.

On March 8, 2010, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among the Company, Ariston Pharmaceuticals, Inc., a Delaware corporation ("Ariston") and Ariston Merger Corp., a Delaware corporation and wholly-owned subsidiary of the Company (the "Merger Sub"). Pursuant to the terms and conditions set forth in the Merger Agreement, on March 8, 2010, the Merger Sub merged with and into Ariston (the "Merger"), with Ariston being the surviving corporation of the Merger. As a result of the Merger, Ariston became a wholly-owned subsidiary of the Company.

On December 29, 2011, the Company 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"). The stockholders of TG Bio received the majority of the voting shares of the Company; therefore, the merger was accounted for as a reverse acquisition whereby TG Bio was the accounting acquirer (legal acquirer) and the Company was the accounting acquiree (legal acquirer) under the acquisition method of accounting. TG Bio was incorporated in Delaware in November 2010, but did not commence operations until April 2011.

On April 30, 2012, the Company filed a Certificate of Amendment to its Certificate of Incorporation to change its name from Manhattan Pharmaceuticals, Inc. ("Manhattan") to TG Therapeutics, Inc. In conjunction with this change, the subsidiary formerly named TG Therapeutics, Inc. filed a Certificate of Amendment changing its name to TG Biologics, Inc.

We are a biopharmaceutical company focused on the acquisition, development and commercialization of innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently, the company is developing therapies targeting hematological malignancies. TG-1101 (ublituximab), is a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202, an orally available PI3K delta inhibitor.

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 (excluding non-cash compensation expense related to research and development) 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, 2012 and 2011 were \$20,572,182, and \$327,283, respectively, excluding non-cash compensation expenses related to research and development.

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

	<u>2012</u>	<u>2011</u>
TG-1101	\$ 19,140,621	\$325,671
TGR-1202	1,259,289	—
AST-726	72,272	—
Terminated programs	100,000	1,612
Total	<u>\$ 20,572,182</u>	<u>\$327,283</u>

Included in the above research and development expenses related to TG-1101 during the years ended December 31, 2012 and 2011 are noncash expenses of \$16,578,000 and \$297,000, respectively, recorded in conjunction with stock issued to LFB Group for the license to TG-1101.

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

For awards of options and restricted stock to consultants and other third-parties, compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized. The Company did not grant any consultant options during the year ended December 31, 2011.

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. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we may need to establish the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA, which would result in us incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

RESULTS OF OPERATIONS

Years Ended December 31, 2012 and 2011

	Years ended December 31,	
	2012	2011
License revenue	\$ 19,048	\$ —
Costs and expenses:		
Research and development:		
Noncash stock expense associated with in-licensing agreement	16,578,000	297,000
Noncash compensation	455,809	—
Other research and development	3,994,182	30,283
Total research and development	21,027,991	327,283
General and administrative:		
Noncash compensation	2,966,373	86,494
Other general and administrative	1,815,083	468,197
Total general and administrative	4,781,456	554,691
Impairment of in-process research and development	1,104,700	—
Total costs and expenses	26,914,147	881,974
Operating loss	(26,895,099)	(881,974)
Other (income) expense	(1,042,147)	7,097
Loss before income taxes	(25,852,952)	(889,071)
Income taxes	330,000	—
Consolidated net loss	<u>\$ (26,182,952)</u>	<u>\$ (889,071)</u>

License Revenue. License revenue was \$19,048 for the year ended December 31, 2012, as compared to zero revenue for the year ended December 31, 2011. License revenue for the year ended December 31, 2012 was 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. Noncash stock expense associated with an in-licensing agreement was \$16,578,000 for the year ended December 31, 2012, as compared to \$297,000 for the year ended December 31, 2011. The expense during the years ended December 31, 2012 and 2011 related to a noncash stock expense recorded in conjunction with the stock issued to LFB Group for the license to TG-1101.

Noncash Compensation Expense (Research and Development). Noncash compensation expense (research and development) related to equity incentive grants equaled \$455,809 for the year ended December 31, 2012. The noncash compensation expense was related to the period's expense for restricted stock grants to research and development personnel. We expect noncash compensation expense (research and development) to increase in 2013.

Other Research and Development Expenses. Other research and development expenses increased by \$3,963,899 to \$3,994,182 for the year ended December 31, 2012, as compared to \$30,283 for the year ended December 31, 2011. The increase in research and development expenses is primarily due to increased research and development expenses related to TG-1101 related to the Company's preparations for and initiation of U.S. based clinical trials, and a \$1,000,000 upfront milestone payment paid to Rhizen in connection with the Collaboration Agreement for TGR-1202. We expect our other research and development costs to increase in 2013 as we continue to recruit patients to our TG-1101 clinical trials and due to the commencement of our clinical development program for TGR-1202.

Noncash Compensation Expense (General and Administrative). Noncash compensation expense (general and administrative) related to equity incentive grants equaled \$2,966,373 for the year ended December 31, 2012. The noncash compensation expense was related to the period's expense for restricted stock grants to general and administrative personnel. We expect noncash compensation expense (general and administrative) to increase modestly during 2013.

Other General and Administrative Expenses. Other general and administrative expenses increased by \$1,346,886 to \$1,815,083 for the year ended December 31, 2012, as compared to \$468,197 for the year ended December 31, 2011. This expense was primarily related to a full year of legal and personnel costs. We expect our other general and administrative expenses to remain at a comparable level during 2013.

Impairment of in-process research and development. During the year ended December 31, 2012, we recorded an impairment charge of \$1,104,700 related to the in-process research and development intangible asset recorded in connection with the Exchange Transaction. Impairment testing of our indefinite lived intangible assets is performed annually or when a triggering event occurs that could indicate a potential impairment. As a result of market changes affecting the commercial potential for the Ariston in-process research and development assets (AST-726 and AST-915), the Company determined that the asset's carrying value was no longer fully recoverable. Also contributing to the impairment charge was the Company's decision during the year ended December 31, 2012 to discontinue future development activities for AST-915, following the analysis from a Phase I dose escalation trial, in which AST-915 failed to meet its primary efficacy endpoint.

Other (Income) Expense. Other income totaled \$1,042,147 for the year ended December 31, 2012 as compared to other expense of \$7,097 for the year ended December 31, 2011. The increase in other income is primarily due to a decrease in the fair value of our non-current notes payable of approximately \$1,660,000, partially off-set by the interest expense recorded on our notes payable of \$905,744.

Income Taxes. During the year ended December 31, 2012 we recorded income tax expense of approximately \$330,000 related to a foreign tax withholding on the \$2,000,000 upfront payment received from Ildong in connection with our sublicensing agreement.

LIQUIDITY AND CAPITAL RESOURCES

Our primary source of cash has been proceeds from the private placement of equity securities and from the upfront payment from our Sublicense Agreement with Ildong. 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, 2012, we had \$16,456,000 in cash and cash equivalents. We currently anticipate that our cash and cash equivalents as of December 31, 2012 are sufficient to fund our anticipated operating cash requirements for approximately 18 months from December 31, 2012. 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, 2012 was \$5,187,964 as compared to \$86,577 for the year ended December 31, 2011. The increase in cash used in operating activities was due primarily to a full year of activity in 2012, and increased expenditures related to our clinical development plan for TG-1101 and the upfront payment associated with TGR-1202.

For the year ended December 31, 2012, net cash used in investing activities was \$1,399, which consisted of purchases of equipment. For the year ended December 31, 2011, net cash provided by investing activities was \$10,386, which consisted of cash that was acquired in the Exchange Transaction between TG Therapeutics and the Company.

Cash provided by financing activities for the year ended December 31, 2012 was \$11,896,867 as compared to \$9,824,682 for the year ended December 31, 2011. The cash provided by financing activities in 2011 and 2012 was primarily related to the 2011 Equity PIPE, as discussed below.

2011 Equity PIPE

On December 30, 2011, we completed the first closing of the private placement of our securities, issuing 4,929,523 shares of Common Stock at a price per share of \$2.25 for total gross proceeds, before placement commissions and expenses, of \$11,091,425 (the "2011 Equity PIPE"). Investors also received warrants to purchase 1,232,381 shares of Common Stock. The warrants have an exercise price of \$2.25 per share and are exercisable for five years. In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Company Preferred Stock at a price per share of \$20.00 for total gross proceeds, before placement commissions and expenses, of \$13,908,560. Each share of Company Preferred Stock was convertible into 8.89 shares of Common Stock; provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012, all shares of preferred stock issued in the 2011 Equity PIPE were converted to Common Stock. Investors also received warrants to purchase 1,545,396 shares of Common Stock. The warrants have an exercise price of \$2.25 per share and are exercisable for five years. The shares of Common Stock, Company Preferred Stock, and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities issued in the offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the offering for their expenses.

Joint Venture Agreement

On April 19, 2011, H Pharmaceuticals K/S (the "Hedrin JV"), of which the Company was a 15% limited partner at the time, filed a demand for arbitration against Thornton & Ross, LTD. ("T&R") with respect to alleged breaches by T&R of an Exclusive License Agreement (the "Hedrin License") dated June 28, 2007, which was originally entered into between the Company and T&R, and which the Company assigned in 2008 to the Hedrin JV, with T&R's consent. The Hedrin JV is seeking damages from T&R in the amount of approximately \$7,000,000. The Company was not a party to the initial arbitration demand.

On May 20, 2011, T&R filed an answer to the arbitration demand in which T&R asserted counterclaims against the Hedrin JV for alleged breaches by the Hedrin JV of the Hedrin License and for declaratory relief that the Hedrin License was properly terminated by T&R. In addition, T&R impleaded an individual (who is not associated with the Company), Nordic Biotech Venture Fund II K/S (an investment fund) and the Company, demanding arbitration against them based on alleged breaches of the Hedrin License and other related claims. The Company has recently been removed by the arbitrator as a party to the arbitration. T&R is seeking damages of approximately \$20,000,000.

The Hedrin JV and T&R held a mediation session in order to avoid the arbitration process. The mediation process did not produce a result. In 2011 Nordic made an additional capital contribution to the Hedrin JV in order to fund the arbitration. As a result of that capital contribution, as of December 31, 2011, the Company owned a 13% interest in the Hedrin JV, and no further information has been available since that date. The arbitration process is ongoing.

SwissPharma Contract LLC Settlement

In October 2009, the Company entered into a Settlement Agreement and Mutual Release with Swiss Pharma Contract LTD ("Swiss Pharma") pursuant to which the Company agreed to pay Swiss Pharma \$200,000 and issue to Swiss Pharma an interest free promissory note due on October 27, 2011 in the principal amount of \$250,000 in full satisfaction of a September 5, 2008 arbitration award. In November 2011, the Company renegotiated the \$250,000 promissory note due October 27, 2011 in which the amount of the promissory note was reduced to \$200,000 and the maturity date was extended to February 15, 2012. This amount was paid on February 14, 2012 in full settlement of this note.

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.

CRITICAL ACCOUNTING POLICIES

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

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

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

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

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

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

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

Accounting Related to Goodwill. As of December 31, 2012 and 2011, there was approximately \$799,391 of goodwill on our consolidated balance sheets. Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

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

Accounting For Income Taxes. In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statement 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 February 2013, the FASB issued amendments to the accounting guidance for presentation of comprehensive income to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments do not change the current requirements for reporting net income or other comprehensive income, but do require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where the net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under GAAP that provide additional detail about these amounts. These amendments are effective prospectively for reporting periods beginning after December 15, 2012. The Company does not believe the adoption of this guidance will have a material impact on the consolidated financial statements.

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

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 DISCLOSURE.

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2012, we 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")). Based upon that evaluation, our Chief Executive and Chief Financial Officers concluded that our disclosure controls and procedures were not effective as of that date to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and to ensure that information required to be disclosed by us in such reports is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. There were no changes in our internal controls over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended December 31, 2012 that have materially affected, or is reasonably likely to materially affect, our internal controls over financial reporting.

Our disclosure controls or internal controls over financial reporting were designed to provide only reasonable assurance that such disclosure controls or internal control over financial reporting will prevent all errors or all instances of fraud, even as the same are improved to address any deficiencies. The design of any system of controls is based in part upon certain assumptions about the likelihood of future events, and there can be only reasonable, not absolute assurance that any design will succeed in achieving its stated goals under all potential future conditions. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Over time, controls may become inadequate because of changes in conditions or deterioration in the degree of compliance with policies or procedures. 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.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal control over financial reporting. As defined by the SEC, internal control over financial reporting is a process designed by, or under the supervision of our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with U.S. generally accepted accounting principles.

Our 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 our transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of the financial statements in accordance with U.S. generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our 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.

In connection with the preparation of our annual financial statements, management has undertaken an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2012, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO Framework. Management's assessment included an evaluation of the design of our internal control over financial reporting and testing of the operational effectiveness of those controls.

Based on this evaluation, management has concluded that our internal control over financial reporting is not effective as of December 31, 2012. This conclusion was reached because a lack of segregation of duties exists, as all financial and accounting duties are performed by the Chief Financial Officer. The Company intends to address this deficiency by hiring additional accounting personnel in 2013 to alleviate the segregation of duties issue.

This annual report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to rules of the SEC that permit us to provide only management's report on internal control in this report.

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.

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 2013 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 2013 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 2013 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 2013 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2013 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES.

(a) 1. Consolidated Financial Statements

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

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2. Consolidated Financial Statement Schedules

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

3. Exhibits

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation, of TG Therapeutics, Inc. dated April 26, 2012 (incorporated by reference to Exhibit 3.2 to the Registrant's Form 10-Q for the quarter ended June 30, 2012).
3.2	Certificate of Designations of Series A Convertible Preferred Stock, dated October 31, 2003 (incorporated by reference to Exhibit 3.2 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011).
3.3	Certificate of Ownership Merging Tarpan Therapeutics, Inc. into the Registrant, dated December 28, 2006 (incorporated by reference to Exhibit 3.3 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011).
3.6	Certificate of Designations, Preferences and Other Rights of Series A Preferred Stock, dated December 29, 2011 (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K filed on January 5, 2012).
3.7	Restated Bylaws of TG Therapeutics, Inc. dated May 14, 2012 (incorporated by reference to Exhibit 3.2 to the Registrant's Form 10-Q for the quarter ended March 31, 2012)
4.1	Specimen common stock certificate (incorporated by reference to Exhibit 4.1 to the Registrant's Form 10-K for the year ended December 31, 2011).
4.2	Form of Warrant issued to Noteholders on September 11, 2008 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 15, 2008).

- 4.3 Form of Warrant issued to Noteholders on November 19, 2008 (incorporated by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K filed on November 25, 2008).
- 4.4 Form of warrant to purchase common stock of TG Therapeutics, Inc. (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed on November 13, 2012).
- 10.1 1995 Stock Option Plan, as amended (incorporated by reference to Exhibit 10.18 to the Registrant's Form 10-QSB for the quarter ended September 30, 1996).
- 10.2 Form of Notice of Stock Option Grant issued to employees of the Registrant from April 12, 2000 to February 21, 2003 (incorporated by reference to Exhibit 99.2 of the Registrant's Registration Statement on Form S-8 filed March 24, 1998 (File 333-48531)).
- 10.3 Form of Stock Option Agreement issued to employees of the Registrant from April 12, 2000 to February 21, 2003 (incorporated by reference to Exhibit 99.3 to the Registrant's Registration Statement on Form S-8 filed March 24, 1998 (File 333-48531)).
- 10.4 2003 Stock Option Plan (incorporated by reference to Exhibit 4.1 to Registrant's Registration Statement on Form S-8 filed February 17, 2004).
- 10.5 Summary terms of compensation plan for Registrant's non-employee directors (incorporated by reference to Exhibit 10.1 of Registrant's Current Report on Form 8-K filed February 5, 2007). †
- 10.6 Form of Stock Option Agreement issued under the Registrant's 2003 Stock Option Plan (incorporated by reference to Exhibit 10.15 to the Registrant's Form 10-KSB filed April 2, 2007).
- 10.7 Exclusive License Agreement for "Altoderm" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dates April 3, 2007 (incorporated by reference to Exhibit 10.3 of the registrant's form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007).
- 10.8 Exclusive License Agreement for "Altolyn" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated April 3, 2007 (incorporated by reference to Exhibit 10.4 of the registrant's form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007).
- 10.9 Exclusive License Agreement for "Hedrin" between Thornton & Ross Ltd. , Kerris, S.A. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007 (incorporated by reference to Exhibit 10.5 of the registrant's form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007).
- 10.10 Supply Agreement for "Hedrin" between Thornton & Ross Ltd. and Manhattan Pharmaceuticals, Inc. dated June 26, 2007 (incorporated by reference to Exhibit 10.6 of the Registrant's Form 10-Q for the quarter ended June 30, 2007 filed on August 14, 2007).
- 10.11 Joint Venture Agreement between Nordic Biotech Fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize "Hedrin" dated January 31, 2008 (incorporated by reference to Exhibit 10.19 of the Registrant's Form 10-K filed March 31, 2008).
- 10.12 Amendment No. 1, dated February 25, 2008, to the Joint Venture Agreement between Nordic Biotech Fund II K/S and Manhattan Pharmaceuticals, Inc. to develop and commercialize "Hedrin" dated January 31, 2008 (incorporated by reference to Exhibit 10.20 to the Registrant's Form 10-K filed March 31, 2008).
- 10.13 Omnibus Amendment to Joint Venture Agreement and Additional Agreements, dated June 9, 2008, among Manhattan Pharmaceuticals, Inc., Hedrin Pharmaceuticals K/S, Hedrin Pharmaceuticals General Partner ApS and Nordic Biotech Venture Fund II K/S (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed June 13, 2008).
- 10.14 Assignment and Contribution Agreement between Hedrin Pharmaceuticals K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008 (incorporated by reference to Exhibit 10.21 to the Registrant's Form 10-K filed March 31, 2008).

- 10.15 Registration Rights Agreement between Nordic Biotech Venture Fund II K/S and Manhattan Pharmaceuticals, Inc. dated February 25, 2008 (incorporated by reference to Exhibit 10.22 to the Registrant's Form 10-K filed March 31, 2008).
- 10.16 Letter Agreement, dated September 17, 2008, between Nordic Biotech Venture Fund II K/S and Manhattan Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.24 to the Registrant's Amended Registration Statement on Form S-1/A filed on October 3, 2008).
- 10.17 Form of Secured Promissory Note, dated September 11, 2008 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on September 15, 2008).
- 10.18 Form of warrant issued to Note Holders, dated September 11, 2008 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on September 15, 2008).
- 10.19 Form of Placement Agent Warrant (incorporated by reference to Exhibit 10.9 to the Registrant's Current Report on Form 8-K filed on November 25, 2008).
- 10.20 Warrant, dated October 28, 2009 (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K filed on November 3, 2009).
- 10.21 Form of Placement Agent Warrant (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K filed on November 3, 2009).
- 10.22 Settlement and Release Agreement, dated January 4, 2011, by and among the Registrant, Nordic Biotech Venture Fund II K/S and H Pharmaceuticals K/S (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on January 10, 2011).
- 10.23 Waiver and Forbearance Agreement, dated January 10, 2011 (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on February 14, 2011).
- 10.24 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).
- 10.25 Amendment to Settlement Agreement and Promissory Note between the Registrant and Swiss Pharma Contract Ltd., dated December 13, 2011 (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K filed on December 19, 2011).
- 10.26 Exchange Transaction Agreement dated December 29, 2011, by and among the Registrant, Opus Point Partners, LLC and TG Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on January 5, 2012).
- 10.27 Amendment No. 1 to Exchange Transaction Agreement, dated as of December 29, 2011, by and among Opus Point Partners, LLC, TG Biologics, Inc. and TG Therapeutics, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed on August 8, 2012).
- 10.28 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). †
- 10.29 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). †
- 10.30 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). †
- 10.31 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). †

- 10.32 Form of Warrant issued to stockholders on December 29, 2011, January 31, 2012 and February 24, 2012 (incorporated by reference to Exhibit 10.34 to the Registrant's Form 10-K for the fiscal year ended December 31, 2011).
- 10.33 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). *
- 10.34 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).
- 10.35 Securities Exchange Agreement, dated November 9, 2012, by and between the Company and LFB Biotechnologies S.A.S. (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed on November 13, 2012).
- 10.36 Joint Venture Agreement between TG Therapeutics, Inc. and Rhizen Pharmaceuticals SA, dated August 15, 2012 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 10-Q for the quarter ended September 30, 2012). *
- 10.37 Sublicense Agreement between TG Biologics, Inc. and Ildong Pharmaceutical Co. Ltd., dated November 13, 2012. *
- 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 Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

† Indicates management contract or compensatory plan or arrangement.

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

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
TG Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of TG Therapeutics, Inc. and Subsidiaries (a development stage company) (the "Company") as of December 31, 2012 and 2011, and the related consolidated statements of operations, equity and cash flows for the years then ended and cumulative period then ended. TG Therapeutics, Inc.'s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of TG Therapeutics, Inc. and Subsidiaries as of December 31, 2012 and 2011, and their results of operations and cash flows for the years then ended and cumulative period then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ CohnReznick LLP

Roseland, New Jersey
March 21, 2013

TG Therapeutics, Inc.
(a development stage company)
Consolidated Balance Sheets as of December 31,

	2012	2011
Assets		
Current assets:		
Cash and cash equivalents	\$ 16,455,995	\$ 9,748,491
Prepaid research and development	1,990,759	--
Other current assets	29,128	87,176
Total current assets	18,475,882	9,835,667
Equipment, net	1,164	--
In-process research and development	2,797,600	3,902,300
Goodwill	799,391	799,391
Total assets	<u>\$ 22,074,037</u>	<u>\$ 14,537,358</u>
Liabilities and equity		
Current liabilities:		
Notes payable, current portion	\$ 677,778	\$ 877,778
Accounts payable and accrued expenses	1,117,397	666,640
Accrued compensation	145,000	--
Current portion of deferred revenue	152,381	--
Interest payable, current portion	123,511	61,941
Total current liabilities	2,216,067	1,606,359
Deferred revenue, net of current portion	1,828,571	--
Notes payable, less current portion, at fair value	2,479,098	3,294,797
Total liabilities	<u>6,523,736</u>	<u>4,901,156</u>
Commitments and contingencies		
Equity:		
Preferred stock, \$0.001 par value per share (10,000,000 shares authorized, 0 and 413,388 issued and outstanding as of December 31, 2012 and 2011, respectively, aggregate liquidation value of \$0 and \$8,267,760 at December 31, 2012 and 2011, respectively)	--	413
Common stock, \$0.001 par value per share (500,000,000 shares authorized, 25,820,738 and 5,061,399 shares issued and outstanding at December 31, 2012 and 2011, respectively)	25,821	5,061
Contingently issuable shares	6	6
Additional paid-in capital	34,534,805	10,472,115
Treasury stock, at cost, 13,526 and 0 shares at December 31, 2012 and 2011, respectively	(84,538)	--
Deficit accumulated in the development stage	(18,925,793)	(853,074)
Total stockholder's equity	15,550,301	9,624,521
Non-controlling interest in subsidiary	--	11,681
Total equity	<u>15,550,301</u>	<u>9,636,202</u>
Total liabilities and equity	<u>\$ 22,074,037</u>	<u>\$ 14,537,358</u>

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

TG Therapeutics, Inc.
(a development stage company)
**Consolidated Statements of Operations for the Years Ended December 31, 2012 and 2011 and the Cumulative
Period Ended December 31, 2012**

	<u>2012</u>	<u>2011</u>	<u>Amounts accumulated during the development stage</u>
License revenue	\$ 19,048	\$ --	\$ 19,048
Costs and expenses:			
Research and development:			
Noncash stock expense associated with in-licensing agreement	16,578,000	297,000	16,875,000
Noncash compensation	455,809	--	455,809
Other research and development	3,994,182	30,283	4,024,465
Total research and development	<u>21,027,991</u>	<u>327,283</u>	<u>21,355,274</u>
General and administrative:			
Noncash compensation	2,966,373	86,494	3,052,867
Other general and administrative	1,815,083	468,197	2,283,280
Total general and administrative	<u>4,781,456</u>	<u>554,691</u>	<u>5,336,147</u>
Impairment of in-process research and development	<u>1,104,700</u>	<u>--</u>	<u>1,104,700</u>
Total costs and expenses	<u>26,914,147</u>	<u>881,974</u>	<u>27,796,121</u>
Operating loss	<u>(26,895,099)</u>	<u>(881,974)</u>	<u>(27,777,073)</u>
Other (income) expense:			
Interest income	(15,787)	--	(15,787)
Other income	(272,232)	--	(272,232)
Interest expense	905,744	7,097	912,841
Change in fair value of notes payable	(1,659,872)	--	(1,659,872)
Total other (income) expense	<u>(1,042,147)</u>	<u>7,097</u>	<u>(1,035,050)</u>
Loss before income taxes	<u>(25,852,952)</u>	<u>(889,071)</u>	<u>(26,742,023)</u>
Income taxes	330,000	--	330,000
Consolidated net loss	<u>(26,182,952)</u>	<u>(889,071)</u>	<u>(27,072,023)</u>
Net loss attributable to non-controlling interest	(8,110,233)	(35,997)	(8,146,230)
Net loss attributable to TG Therapeutics, Inc. and Subsidiaries	<u>\$ (18,072,719)</u>	<u>\$ (853,074)</u>	<u>\$ (18,925,793)</u>
Basic and diluted net loss per common share	<u>\$ (1.38)</u>	<u>\$ (0.44)</u>	
Weighted average shares used in computing basic and diluted net loss per common share	<u>13,113,758</u>	<u>1,926,198</u>	

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

TG Therapeutics, Inc.

(a development stage company)

Consolidated Statements of Equity for the Years Ended December 31, 2012 and 2011 and the Cumulative period Ended December 31, 2012

	Preferred stock		Common stock		Contingently issuable shares	Additional paid-in capital	Treasury Stock		Deficit accumulated in the development stage	Non- controlling interest in subsidiary	Total
	Shares	Amount	Shares	Amount			Shares	Amount			
Common stock issued to founders in exchange for seed capital in April 2011			2,500,000	\$ 2,500		\$ 104,078					\$ 106,578
Stock issued at \$2.25 per share in exchange for license option			132,000	132		296,868					297,000
Issuance of restricted stock to employees			1,150,000	1,150							1,150
Effect of reverse acquisition	281,250	\$ 281	(2,500,124)	(2,501)	\$ 6	277,500			\$ 47,678		322,964
Conversion of note payable to preferred stock	2,763	3				55,268					55,271
Issuance of replacement restricted preferred stock to employees	129,375	129	(1,150,000)	(1,150)		1,021					--
Common stock issued at \$2.25 per share, net of expenses			4,929,523	4,930		9,650,886					9,655,816
Compensation in respect of restricted stock preferred stock granted to employees						86,494					86,494
Net loss								\$ (853,074)		(35,997)	(889,071)
Balance at December 31, 2011	413,388	413	5,061,399	5,061	6	10,472,115		(853,074)		11,681	9,636,202
Compensation in respect of restricted preferred stock granted to employees						188,509					188,509
Preferred stock issued at \$20.00 per share, net of expenses	695,428	696				12,180,710					12,181,406
Shares issued in subsidiary to non-controlling interest in connection with in-licensing agreement										16,578,000	16,578,000
Conversion of preferred stock to common stock in conjunction with reverse stock split	(1,108,816)	(1,109)	9,857,596	9,858		(8,749)					--
Issuance of restricted stock			5,901,743	5,902		(5,902)					--
Compensation in respect of restricted common stock granted to employees, directors and consultants						3,233,674					3,233,674
Non-controlling interest subsidiary shares exchanged for shares in TG Therapeutics, Inc.			5,000,000	5,000		8,474,448				(8,479,448)	--
Surrender of common stock for tax withholding							13,526	\$ (84,538)			(84,538)
Net loss								(18,072,719)		(8,110,233)	(26,182,952)
Balance at December 31, 2012	--	\$ --	25,820,738	\$ 25,821	\$ 6	\$ 34,534,805	13,526	\$ (84,538)	\$ (18,925,793)	\$ --	\$ 15,550,301

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

TG Therapeutics, Inc.
(a development stage company)
Consolidated Statements of Cash Flows for the Years Ended December 31, 2012 and 2011 and the Cumulative Period Ended December 31, 2012

	2012	2011	Amounts accumulated during the development stage
CASH FLOWS FROM OPERATING ACTIVITIES			
Consolidated net loss	\$ (26,182,952)	\$ (889,071)	\$ (27,072,023)
Adjustments to reconcile consolidated net loss to cash used in operating activities:			
Stock compensation expense	3,422,182	86,494	3,508,676
Noncash stock expense associated with in-licensing agreement	16,578,000	297,000	16,875,000
Impairment of in-process research and development	1,104,700	--	1,104,700
Depreciation	235	--	235
Change in fair value and accrued interest of notes payable	(815,699)	--	(815,699)
Changes in assets and liabilities, net of effects of acquisition:			
(Increase) decrease in other current assets	(1,932,710)	3,593	(1,929,117)
Increase in accounts payable and accrued expenses	595,757	408,310	1,004,067
Increase in interest payable	61,571	7,097	68,668
Increase in deferred revenue	1,980,952	--	1,980,952
Net cash used in operating activities	<u>(5,187,964)</u>	<u>(86,577)</u>	<u>(5,274,541)</u>
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(1,399)	--	(1,399)
Cash acquired in connection with acquisition	--	10,386	10,386
Net cash (used in) provided by investing activities	<u>(1,399)</u>	<u>10,386</u>	<u>8,987</u>
CASH FLOWS FROM FINANCING ACTIVITIES			
Payments of short-term loans	(200,001)	--	(200,001)
Proceeds from sale of common stock, net	--	9,824,682	9,824,682
Proceeds from sale of preferred stock, net	12,257,309	--	12,257,309
Offering costs paid	(75,903)	--	(75,903)
Purchase of treasury stock	(84,538)	--	(84,538)
Net cash provided by financing activities	<u>11,896,867</u>	<u>9,824,682</u>	<u>21,721,549</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	6,707,504	9,748,491	16,455,955
Cash and cash equivalents at beginning of year	<u>9,748,491</u>	<u>--</u>	<u>--</u>
CASH AND CASH EQUIVALENTS AT END OF YEAR	<u>\$ 16,455,995</u>	<u>\$ 9,748,491</u>	<u>\$ 16,455,995</u>
NONCASH TRANSACTIONS			
Conversion of notes payable to preferred stock	\$ --	\$ 55,271	\$ 55,271
Accrued financing costs	\$ --	\$ 61,138	\$ 61,138

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

TG Therapeutics, Inc.
(a development stage company)
Notes to 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 focused on the acquisition, development and commercialization of innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs. We aim to acquire rights to these technologies by licensing or otherwise acquiring an ownership interest, funding their research and development and eventually either out-licensing or bringing the technologies to market. Currently, the Company is developing therapies targeting hematological malignancies. TG-1101 (ublituximab), is a novel, third generation monoclonal antibody that targets a specific and unique epitope on the CD20 antigen found on mature B-lymphocytes. We are also developing TGR-1202, an orally available PI3K delta inhibitor. We also hold the development rights to AST-726, a nasally delivered product for the treatment of Vitamin B₁₂ deficiency.

Exchange Transaction with TG Therapeutics, Inc. and its majority shareholders

On December 29, 2011, the Company entered into and consummated an Exchange Transaction Agreement with Opus Point Partners, LLC (“Opus”) and TG Biologics, Inc. (formerly known as TG Therapeutics, Inc.) (“TG Bio”) (the “Agreement”). Under the Agreement, Opus exchanged (the “Exchange Transaction”) its shares of common stock in TG Bio (“TG Bio Common Stock”) for shares of Series A preferred stock in the Company (“Company Preferred Stock”). In accordance with the terms of the Agreement, 95% of the holders of common stock of TG Bio (one (1) minority shareholder of TG Bio holding in aggregate 132,000 shares of common stock of TG Bio did not participate) surrendered their TG Bio common stock. The Agreement caused the Company to issue to TG Bio’s shareholders 281,250 shares of Company Preferred Stock. Each share of Company Preferred Stock was convertible into 8.89 shares of the Common Stock provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012 (as discussed below), all shares of preferred stock issued in connection with the Agreement were converted to Common Stock. The Company Preferred Stock issued in connection with the Agreement provided the former TG Bio shareholders with direct and/or indirect ownership of approximately 95% of the Company’s outstanding Company Common Stock immediately following the consummation of the transaction.

Since the stockholders of TG Bio received the majority of the voting shares of the Company, the merger was accounted for as a reverse acquisition whereby TG Bio was the accounting acquirer (legal acquiree) and the Company was the accounting acquiree (legal acquirer) under the acquisition method of accounting. TG Bio was incorporated in Delaware in November 2010, but did not commence operations until April 2011.

The filings with the Securities and Exchange Commission (the “SEC”) include the historical financial results of TG Bio and will hereafter collectively be referred to as the Company.

On April 30, 2012, the Company filed a Certificate of Amendment to its Certificate of Incorporation to change its name from Manhattan Pharmaceuticals, Inc. (“Manhattan”) to TG Therapeutics, Inc. In conjunction with this change, the subsidiary formerly named TG Therapeutics, Inc. filed a Certificate of Amendment changing its name to TG Biologics, Inc.

CORRECTION OF AN IMMATERIAL ERROR

The Company has identified certain immaterial errors in its previously issued consolidated financial statements for the year ended December 31, 2011. In connection with the Exchange Transaction (see description above), a valuation using the guidance in the accounting literature for business combinations was performed to determine the fair value of the assets acquired and liabilities assumed. The Company has determined that certain methodologies and assumptions utilized in this valuation were incorrect. As a result of this, the Company has recorded an adjustment to previously reported in-process research and development, goodwill, and notes payable, less current portion, at fair value, at December 31, 2011 as follows:

- In-process research and development decreased from \$5,441,839 to \$3,902,300
- Goodwill increased from \$629,752 to \$799,391
- Notes payable, less current portion, at fair value decreased from \$4,664,697 to \$3,294,797

The net effect of this adjustment is a decrease to total assets and liabilities, as previously reported, of \$1,369,900.

The adjustment was recorded as of December 31, 2011 and has no effect on the statement of operations or statement of equity for any period. The Company assessed the impact of this adjustment under the provisions of SEC Staff Accounting Bulletin Nos. 99 and 108 and determined the impact of the errors to be immaterial to the financial statements. The accompanying consolidated balance sheet as of December 31, 2011 reflects the corrections of the aforementioned immaterial errors.

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, 2012, we have an accumulated deficit of \$18,925,793.

Our primary source of cash has been proceeds from the private placement of equity securities. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on 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, 2012, we had \$16,455,995 in cash and cash equivalents. We currently anticipate that our cash and cash equivalents to be sufficient to fund our anticipated operating cash requirements for approximately 18 months from December 31, 2012. 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 OTC Bulletin Board and trades under the symbol "TGTX."

REVERSE STOCK SPLIT

On April 30, 2012, the Company effected a reverse split of its Common Stock at a ratio of 56.25 for 1, pursuant to a previously obtained stockholder authorization. All share amounts and per share prices in this Annual Report on Form 10-K have been retroactively adjusted to reflect the effect of our reverse stock split, on a fifty-six and one quarter (56.25) for one (1) basis, unless otherwise indicated. The exercise price for all stock options and warrants and the conversion price for convertible securities in the accompanying consolidated financial statements have been adjusted to reflect the reverse stock split by multiplying the original exercise or conversion price by fifty-six and one quarter (56.25).

2011 MANAGEMENT CHANGES

In connection with the Exchange Transaction with TG Therapeutics, Inc., effective December 29, 2011, Douglas Abel, David C. Shimko and Richard Steinhart resigned from their positions on the Board of Directors of the Company. Michael McGuinness resigned both his seat as a director and as an officer of the Company, effective December 29, 2011.

Effective December 29, 2011, Michael S. Weiss was appointed Executive Chairman, Interim Chief Executive Officer and President of the Company. In connection with the appointment, the Company assumed Mr. Weiss' employment agreement with TG, effective November 1, 2011, under which Mr. Weiss is to serve as the Company's Executive Chairman, Interim Chief Executive Officer and President until such employment is terminated pursuant to the terms of the agreement.

In connection with the Exchange Transaction and the appointment of Mr. Weiss to his position, the Company issued replacement awards and granted 112,500 shares of Series A Preferred Stock, to Mr. Weiss on December 29, 2011. Each share of Series A Preferred Stock was convertible into 8.89 shares of the Common Stock provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012 (as discussed above), all shares of preferred stock issued in connection with the Agreement were converted to Common Stock.

Under the terms of his employment agreement, on an annual basis, the Company will also grant Mr. Weiss a number of shares of restricted common stock equal to 1.25% of the shares of Common Stock outstanding on the date of grant on a fully-diluted basis. Each of these annual grants of restricted stock will vest and become non-forfeitable as to 25% of the shares on the first anniversary of the respective date of grant, as to 25% of the shares on the second anniversary of the respective date of grant and as to 50% of the shares on the date that the "market capitalization" (as defined in the employment agreement) is \$100 million greater than the market capitalization on the respective date of grant, provided that Mr. Weiss remains an employee, director and/or consultant of the Company through each vesting date.

Effective December 29, 2011, Sean A. Power was appointed Chief Financial Officer, Treasurer and Secretary of the Company. In connection with the appointment, the Company assumed Mr. Power's employment agreement with TG, effective November 1, 2011, under which Mr. Power is to serve as the Company's Chief Financial Officer, Treasurer and Secretary until such employment is terminated pursuant to the terms of the agreement.

In connection with the Exchange Transaction and the appointment of Mr. Power to his position, the Company issued replacement awards and granted 16,875 shares of Series A Preferred Stock, to Mr. Power on December 29, 2011. Each share of Series A Preferred Stock was convertible into 8.89 shares of the Common Stock provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012 (as discussed above), all shares of preferred stock issued in connection with the Agreement were converted to Common Stock.

The Company will grant Mr. Power a number of shares of restricted common stock of the Company as determined by the CEO and board. Each of these annual grants of restricted stock will be subject to vesting terms, which will be determined at the time of grant by the CEO and Board.

RECENTLY ISSUED ACCOUNTING STANDARDS

In February 2013, the Financial Accounting Standards Board ("FASB") issued amendments to the accounting guidance for presentation of comprehensive income to improve the reporting of reclassifications out of accumulated other comprehensive income. The amendments do not change the current requirements for reporting net income or other comprehensive income, but do require an entity to provide information about the amounts reclassified out of accumulated other comprehensive income by component. In addition, an entity is required to present, either on the face of the statement where the net income is presented or in the notes, significant amounts reclassified out of accumulated other comprehensive income by the respective line items of net income but only if the amount reclassified is required under GAAP to be reclassified to net income in its entirety in the same reporting period. For other amounts that are not required under GAAP to be reclassified in their entirety to net income, an entity is required to cross-reference to other disclosures required under GAAP that provide additional detail about these amounts. These amendments are effective prospectively for reporting periods beginning after December 15, 2012. The Company does not believe the adoption of this guidance will have a material impact on the consolidated financial statements.

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

BASIS OF PRESENTATION

The Company has generated limited revenue from its operations and, accordingly, the financial statements have been prepared in accordance with the provisions of accounting and reporting for Development Stage Enterprises.

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. 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.

REVENUE RECOGNITION

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

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.

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. Impairment is tested on an annual basis, and consists of a comparison of the fair value of the in-process research and development with its carrying amount.

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.

STOCK - BASED COMPENSATION

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

For share-based payments 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.

BASIC AND DILUTED NET (LOSS) INCOME PER COMMON SHARE

Basic net income (loss) per common share is calculated by dividing net income (loss) applicable to common shares by the weighted-average number of common shares outstanding for the period. Diluted net loss per common share is the same as basic net income (loss) per common share, since potentially dilutive securities from stock options, stock warrants and convertible preferred stock would have an antidilutive effect either because the Company incurred a net loss during the period presented or because such potentially dilutive securities were out of the money and the Company realized net income during the period presented. The amounts of potentially dilutive securities excluded from the calculation were 10,746,837 and 5,320,173 at December 31, 2012 and 2011, respectively. During the years ended December 31, 2012 and 2011 the Company incurred a net loss, therefore, all of the dilutive securities are excluded from the computation of diluted earnings per share.

LONG LIVED ASSETS AND GOODWILL

Long lived assets are reviewed for an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management’s policy in determining whether an impairment indicator 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 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.

NOTE 2 – CASH AND CASH EQUIVALENTS

	<u>December 31, 2012</u>	<u>December 31, 2011</u>
Checking and bank deposits	\$ 16,455,995	\$ 9,748,491
Total	<u>\$ 16,455,995</u>	<u>\$ 9,748,491</u>

NOTE 3 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of 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, 2012 and 2011, the fair values of cash and cash equivalents, and notes and interest payable, current portion approximate their carrying value.

Upon the merger between Manhattan and Ariston Pharmaceuticals, Inc. (“Ariston”) in March 2010, Ariston issued \$15,452,793 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. The Company has 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.

In connection with the Exchange Transaction in December 2011, the Company performed a valuation of the assets and liabilities of Manhattan immediately prior to the transaction. The cumulative liability including accrued and unpaid interest of these notes was approximately \$16,876,000 immediately prior to the Exchange Transaction, and \$17,727,000 and \$16,883,000 at December 31, 2012 and 2011, respectively. As these notes payable are tied directly to net product cash flows derived from the preexisting products of the Company, this note and accrued interest was recorded at fair value of \$3,287,700 as of the date of the Exchange Transaction. No payments have been made on these notes as of December 31, 2012.

We elected the fair value option for valuing the 5% Notes upon the completion of the reverse merger with TG Bio, as discussed above. The Company elected the fair value option in order to reflect in our financial statements the assumptions that market participants use in evaluating these financial instruments.

The valuation method used to estimate the 5% Notes' fair value was a discounted cash flow model, where the expected cash flows of AST-726 and AST-915 are discounted to the present using a yield that incorporates compensation for the probability of success in clinical development and marketing, among other factors. The discount rate used in this discounted cash flow model approximated 20% at December 31, 2012 and 2011. The assumptions, assessments and projections of future revenues are subject to uncertainties, are 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 Company's financial liabilities measured at fair value on a recurring basis as of December 31, 2012 and 2011 were as follows:

Financial liabilities at fair value as of December 31, 2012				
	Level 1	Level 2	Level 3	Total
5% Notes	\$ --	\$ --	\$ 2,479,098	\$ 2,479,098
Totals	<u>\$ --</u>	<u>\$ --</u>	<u>\$ 2,479,098</u>	<u>\$ 2,479,098</u>

Financial liabilities at fair value as of December 31, 2011				
	Level 1	Level 2	Level 3	Total
5% Notes	\$ --	\$ --	\$ 3,294,797	\$ 3,294,797
Totals	<u>\$ --</u>	<u>\$ --</u>	<u>\$ 3,294,797</u>	<u>\$ 3,294,797</u>

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, 2011 and 2012:

Balance at January 1, 2011	\$ --
Transfer into Level 3	3,287,700
Interest accrued on face value of 5% Notes	7,097
Change in fair value of Level 3 liabilities	--
Balance at December 31, 2011	<u>3,294,797</u>
Interest accrued on face value of 5% Notes	844,173
Change in fair value of Level 3 liabilities	<u>(1,659,872)</u>
Balance at December 31, 2012	<u>\$ 2,479,098</u>

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

Nonrecurring Fair Value Measurements

The Company's assets measured at fair value on a nonrecurring basis as of December 31, 2012 were as follows:

Fair value measurements as of December 31, 2012				Total impairment charge for the year ended December 31, 2012
	Level 1	Level 2	Level 3	
Assets:				
In-process research and development	\$ --	\$ --	\$ 2,797,600	\$ (1,104,700)
Total	<u>\$ --</u>	<u>\$ --</u>	<u>\$ 2,797,600</u>	<u>\$ (1,104,700)</u>

As a result of market changes affecting the commercial potential for the Ariston in-process research and development assets (AST-726 and AST-915), the Company determined that the asset's carrying value was no longer fully recoverable. Accordingly, during the year ended December 31, 2012, we recorded a non-cash impairment charge of approximately \$1,104,700, which was recorded as impairment of in-process research and development in our consolidated statements of operations. The fair value of this asset was determined using a discounted cash flow model, where the expected cash flows of the Ariston assets are discounted to the present using a yield that incorporates compensation for the probability of success in clinical development and marketing, among other factors. This fair value measurement technique is based on significant inputs not observable in the market and thus represents a Level 3 measurement within the fair value hierarchy. Changes in the market or any of the assumptions used in determining the fair value of this asset may result in a further reduction to its estimated fair value and could result in additional and potentially full future impairment charges. Also contributing to the impairment charge was the Company's decision during the year ended December 31, 2012 to discontinue future development activities for AST-915, following the analysis from a Phase I dose escalation trial, in which AST-915 failed to meet its primary efficacy endpoint.

NOTE 4 – ACQUISITION

On December 29, 2011, the Company completed a reverse acquisition of privately held TG Bio, a Delaware Corporation. The acquisition was effected pursuant to an Exchange Transaction Agreement (the "Agreement") dated December 29, 2011 by and among the Company, TG Bio and Opus, the largest shareholder of TG Bio. In accordance with the terms of the Agreement, 95% of the holders of common stock of TG Bio (one (1) minority shareholder of TG Bio holding in aggregate 132,000 shares of common stock of TG Bio did not participate) surrendered their TG Bio common stock. The Agreement caused the Company to issue to TG Bio's shareholders 281,250 shares of Company Preferred Stock. Each share of Company Preferred Stock was convertible into 8.89 shares of the Common Stock provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012 (as discussed above), all shares of preferred stock issued in connection with the Agreement were converted to Common Stock. The Company Preferred Stock issued in connection with the Agreement provided the former TG Bio shareholders with direct and/or indirect ownership of approximately 95% of the Company's outstanding Company Common Stock immediately following the consummation of the transaction.

The shares of Common Stock issued upon the conversion of the Company Preferred Stock are not registered for resale and, therefore, shall remain subject to the rights and restrictions of Rule 144 under the Securities Act of 1933, as amended.

Based on fair value of the Company's Common Stock of \$2.25 per share at December 29, 2011, the purchase price was \$295,933, plus the fair value of restricted stock assumed of \$82,305. In connection with the Exchange Transaction, the Company incurred \$231,580 of acquisition related costs.

A summary of the purchase price calculation is as follows:

Number of shares of Manhattan common stock outstanding at the time of the transaction	131,526		
Multiplied by Manhattan's fair value of the Common Stock	\$ 2.25	\$	295,933
Fair value of restricted stock assumed			82,305
Total purchase price		\$	<u>378,238</u>

The purchase price has been allocated as follows based on the fair values of the assets and liabilities acquired:

Cash and cash equivalents	\$ 10,386
Other assets	90,770
In-process research and development acquired	3,902,300
Total identifiable assets	4,003,456
Accounts payable and accrued expenses	197,191
Notes payable (ICON and Swiss Pharma)	939,718
5% notes payable and accrued interest	3,287,700
Total identifiable liabilities	4,424,609
Net identifiable assets (liabilities)	(421,153)
Goodwill	799,391
Total	\$ 378,238

The fair value of certain identifiable intangible assets was determined using the income approach. This method starts with a forecast of the expected future net cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk of achieving the asset's projected cash flows. The present value of the estimated cash flows are then added to the present value equivalent of the residual value of the asset, if any, at the end of the discrete projection period to estimate the fair value.

The valuations are based on information that is available as of the acquisition date and the expectations and assumptions that have been deemed reasonable by our management. No assurance can be given, however, that the underlying assumptions or events associated with such assets will occur as projected. For these reasons, among others, the actual results may vary from the projected results.

The following supplemental pro forma information for the year ended December 31, 2011 presents the financial results as if the transaction had occurred on January 1, 2011. This supplemental pro forma information has been prepared for comparative purposes and does not purport to be indicative of what would have occurred had the acquisition been made on January 1, 2011, nor are they indicative of future results.

	2011
Revenue	\$ --
Net loss	\$ (818,279)
Basic and diluted loss per common share	\$ (0.31)

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.

There were 413,388 shares of preferred stock outstanding as of December 31, 2011. In connection with the Exchange Transaction with TG Therapeutics, Inc., on December 29, 2011, the Company filed a Certificate of Designation with respect to its Series A Preferred Stock with the Secretary of State of the State of Delaware. The Company Preferred Stock ranks senior to the Company Common Stock with regard to dividend rights, and has a liquidation preference of \$20 per share over the Company Common Stock and any other junior securities. The Company Preferred Stock is automatically convertible into 500 shares of Company Common Stock provided that prior to conversion, the Company has sufficient authorized Company Common Stock to effect such conversion. In conjunction with the reverse split effected on April 30, 2012 (as discussed in Note 1), all outstanding Company Preferred Stock automatically converted to 9,857,596 shares of Common Stock as of that date.

Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 500,000,000 shares of \$0.001 par value common stock.

On December 30, 2011, we completed the first closing of the private placement of our securities, issuing 4,929,523 shares of Common Stock at a price per share of \$2.25 for total gross proceeds, before placement commissions and expenses, of \$11,091,425 (the "2011 Equity PIPE"). Investors also received warrants to purchase 1,232,381 shares of Common Stock. The warrants have an exercise price of \$2.25 per share and are exercisable for five years.

In 2012, we completed two additional closings of the 2011 Equity PIPE. These closings were held on January 31, 2012, and February 24, 2012. In these closings, the Company issued 695,428 shares of our Company Preferred Stock at a price per share of \$20.00 for total gross proceeds, before placement commissions and expenses, of \$13,908,560. Each share of Company Preferred Stock was convertible into 8.89 shares of Common Stock; provided that such conversion rights were subject to sufficient available authorized shares of Common Stock. In connection with the reverse stock split effected by the Company on April 30, 2012, all shares of Preferred Stock issued in the 2011 Equity PIPE were converted to Common Stock. Investors also received warrants to purchase 1,545,396 shares of Common Stock. The warrants have an exercise price of \$2.25 per share and are exercisable for five years. The shares of Company Preferred Stock and warrants sold in these closings were offered and sold to accredited investors, including members of management, without registration under the Securities Act, or state securities laws, in reliance on the exemptions provided by Section 4(2) of the Securities Act, and Regulation D promulgated thereunder and in reliance on similar exemptions under applicable state laws. Accordingly, the securities issued in the offering have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The placement agent received cash commissions equal to 10% of the gross proceeds of the offering, five-year warrants to purchase shares of the Company's stock equal to 10% of shares sold in the offering, and a non-accountable expense allowance equal to two percent of the gross proceeds of the offering for their expenses.

Treasury Stock

On May 17, 2012, our Chief Financial Officer surrendered to the Company 13,526 shares of common stock in order to satisfy his tax withholding obligation upon the vesting of 37,500 shares of restricted stock. The 13,526 shares of common stock are being held by the Company in Treasury, at a cost of approximately \$85,000, representing the fair market value on the date the shares were surrendered.

Equity Incentive Plans

We have in effect the following stock option and incentive plans.

a. In July 1995, the Company established the 1995 Stock Option Plan (the "1995 Plan"), which provided for the granting of options to purchase up to 2,600 shares of the Company's common stock to officers, directors, employees and consultants. The 1995 Plan was amended several times to increase the number of shares reserved for stock option grants. In June 2005, the 1995 Plan expired and no further options can be granted. At December 31, 2012, options to purchase 313 shares were outstanding and no shares were reserved for future stock option grants under the 1995 Plan.

b. The Company has shareholder-approved incentive stock option plans for employees under which it has granted non-qualified and incentive stock options. At December 31, 2012, 5,333 shares were authorized for issuance. The options have a maximum term of 10 years and vest over a period determined by the Company's Board of Directors (generally 3 years) and are issued at an exercise price equal to or greater than the fair market value of the shares at the date of grant. At December 31, 2012, options to purchase 591 shares were outstanding, 10 shares of common stock were issued and there were 4,732 shares reserved for future grants under the Plan.

c. In May 2012, the Company established the TG Therapeutics, Inc. Amended and Restated 2012 Incentive Plan (“2012 Incentive Plan”). Under the 2012 Incentive Plan, the compensation committee of the Company’s board of directors is authorized to grant stock-based awards to directors, consultants, employees and officers. The 2012 Incentive Plan authorizes grants to purchase up to 6,000,000 shares of authorized but unissued common stock. As of December 31, 2012, options to purchase 46,000 shares were outstanding and up to an additional 2,052,257 shares may be issued under the 2012 Incentive Plan.

Stock Options

The following table summarizes stock option activity for the years ended December 31, 2012 and 2011:

	Number of shares	Weighted- average exercise price	Weighted- average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at January 1, 2011	--	--		
Assumed in Exchange Transaction	4,143	\$ 1,375.18	5.60	
Granted	--	--		
Exercised	--	--		
Forfeited	(364)	197.34		
Expired	(400)	2,951.12		
Outstanding at December 31, 2011	3,379	1,315.62	6.39	\$ --
Granted	46,000	4.40		
Exercised	--	--		
Forfeited	(2,475)	720.45		
Expired	--	--		
Outstanding at December 31, 2012	46,904	\$ 61.08	9.44	\$ --
Vested and expected to vest at December 31, 2012	904	\$ 2,945.09	1.73	\$ --
Exercisable at December 31, 2012	898	\$ 2,963.46	1.70	\$ --

As of December 31, 2012, the total compensation cost related to unvested time-based option awards not yet recognized is less than \$1,000. The weighted average period over which it is expected to be recognized is approximately 3 months. This amount does not include, as of December 31, 2012, 46,000 non-employee options outstanding which are milestone-based and vest upon certain corporate milestones. Stock-based compensation will be measured and recorded if and when a milestone occurs.

Restricted Stock- Preferred

Certain employees had been awarded restricted preferred stock. The restricted stock vesting consisted of milestone and time-based vesting. The following table summarizes restricted share activity for the years ended December 31, 2012 and 2011:

	Number of Shares Restricted Series A Preferred Stock ⁽¹⁾	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2011	--	\$ --
Granted	129,375	20.00
Vested	--	--
Forfeited	--	--
Outstanding at December 31, 2011	129,375	20.00
Granted	--	--
Vested	--	--
Forfeited	--	--
Conversion to restricted common stock	(129,375)	20.00
Outstanding at December 31, 2012	--	\$ --

(1) The restricted preferred stock listed in the table above was granted in connection with the Exchange Transaction to certain executives as discussed above. Each share of preferred stock was convertible into 8.89 shares of the Company's Common Stock. In conjunction with the reverse split effected on April 30, 2012 (as discussed in Note 1), all outstanding restricted Preferred Stock automatically converted to 1,150,000 shares of restricted Common Stock as of that date.

Restricted Stock- Common

Certain employees, directors and consultants have been awarded restricted Company Common 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, 2012 and 2011:

	Number of Shares	Weighted Average Grant Date Fair Value
Outstanding at January 1, 2011	--	\$ --
Granted	--	--
Vested	--	--
Forfeited	--	--
Outstanding at December 31, 2011	--	--
Converted preferred stock	1,150,000	2.25
Granted	5,901,743	4.77
Vested	(437,500)	2.25
Forfeited	--	--
Outstanding at December 31, 2012	<u>6,614,243</u>	<u>\$ 4.49</u>

Total expense associated with restricted stock grants (both common and preferred) was \$3,422,182 and \$86,494 during the years ended December 31, 2012 and 2011, respectively. As of December 31, 2012, there was approximately \$8,941,000 of total unrecognized compensation cost related to non-vested time based restricted stock, which is expected to be recognized over a weighted-average period of 2.8 years. This amount does not include, as of December 31, 2012, 2,092,500 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones; and 2,580,000 shares of restricted stock outstanding issued to non-employees (see Note 10 – Related Party Transactions for additional information). Milestone based non-cash compensation expense will be measured and recorded if and when a milestone occurs.

Warrants

The following table summarizes warrant activity for the years ended December 31, 2012 and 2011:

	Warrants	Weighted- average exercise price	Aggregate Intrinsic Value
Outstanding at January 1, 2011	--	\$ --	
Assumed in Exchange Transaction	393,437	14.74	
Issued	1,232,474	2.25	
Exercised	--	--	
Expired	--	--	
Outstanding at December 31, 2011	1,625,911	5.27	\$ --
Issued	5,156,599	1.21	
Exercised	--	--	
Expired	(1,503)	2,739.75	
Outstanding at December 31, 2012	<u>6,781,007</u>	<u>\$ 1.58</u>	<u>\$ 14,563,539</u>

As discussed above, as part of the 2011 Equity PIPE, we issued warrants to purchase up to 2,777,962 shares of our common stock, none of which have been exercised as of December 31, 2012. The warrants have an exercise price of \$2.25 per warrant share. In addition, we issued to the placement agent in the transaction warrants to purchase up to 1,111,111 shares of our common stock at an exercise price of \$2.48 per warrant share, none of which have been exercised as of December 31, 2012.

In connection with the Securities Exchange Agreement between the Company and LFB Group as discussed in Note 8 – License Agreements, we issued LFB Group a warrant to purchase an aggregate of 2,500,000 shares of Company Common Stock at a purchase price of \$0.001 per share.

Stock-Based Compensation

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future. The Company did not grant any stock options during the year-ended December 31, 2011.

The following table summarizes stock-based compensation expense information about stock options and restricted stock for the years ended December 31, 2012 and 2011:

	<u>2012</u>	<u>2011</u>
Stock-based compensation expense associated with restricted stock	\$ 3,422,182	\$ 86,494
Stock-based compensation expense associated with option grants	--	--
	<u>\$ 3,422,182</u>	<u>\$ 86,494</u>

Non-controlling Interest

On November 9, 2012, LFB Group exercised their right to exchange their TG Bio common stock for Company Common Stock. The Company and LFB Group entered into a Securities Exchange Agreement pursuant to which, LFB Group agreed to exchange its 7,500,000 shares of the common stock of TG Bio, for 5,000,000 shares of Company Common Stock, and a warrant to purchase an aggregate of 2,500,000 shares of Company Common Stock at a purchase price of \$0.001 per share. Refer to Note 8 – License Agreements for further information.

Accordingly, in connection with the aforementioned Securities Exchange Agreement, TG Bio became a wholly owned subsidiary of the Company. Prior to the execution of the Securities Exchange Agreement LFB Group owned approximately 42.9% of TG Bio. The non-controlling interest in subsidiary balance was approximately \$8,479,000 immediately prior to LFB Group exercising their option, which was transferred to equity in connection with the transaction.

NOTE 6 – NOTES PAYABLE

The following is a summary of notes payable:

	<u>December 31, 2012</u>			<u>December 31, 2011</u>		
	<u>Current portion, net</u>	<u>Non- current portion, net</u>	<u>Total</u>	<u>Current portion, net</u>	<u>Non- current portion, net</u>	<u>Total</u>
Non-interest Bearing Note Payable, Net	\$ --	\$ -	\$ --	\$ 200,000	\$ -	\$ 200,000
Convertible 5% Notes Payable	-	2,479,098	2,479,098	-	3,294,797	3,294,797
ICON Convertible Note	677,778	-	677,778	677,778	-	677,778
Total	<u>\$ 677,778</u>	<u>\$ 2,479,098</u>	<u>\$ 3,156,876</u>	<u>\$ 877,778</u>	<u>\$ 3,294,797</u>	<u>\$ 4,172,575</u>

We assumed the preceding notes payable as the result of the Exchange Transaction between the Company and TG Therapeutics, Inc. Accordingly, a valuation using the guidance in the accounting literature for business combinations (ASC 805) was performed and these notes have been presented at their fair value on the date of the transaction.

Non-interest Bearing Note Payable

In October 2009, Manhattan entered into a Settlement Agreement and Mutual Release with Swiss Pharma Contract LTD (“Swiss Pharma”) pursuant to which Manhattan agreed to pay Swiss Pharma \$200,000 and issue to Swiss Pharma an interest free promissory note due on October 27, 2011 in the principal amount of \$250,000 in full satisfaction of a September 5, 2008 arbitration award. In November 2011, Manhattan renegotiated the \$250,000 promissory note in which the amount of the promissory note was reduced to \$200,000 and the maturity date was extended to February 15, 2012. This amount was paid on February 14, 2012 in full settlement of this note.

Convertible 5% Notes Payable

On March 8, 2010, Manhattan entered into an Agreement and Plan of Merger (the “Merger Agreement”) by and among the Company, Ariston Pharmaceuticals, Inc., a Delaware corporation (“Ariston”) and Ariston Merger Corp., a Delaware corporation and wholly-owned subsidiary of the Company (the “Merger Sub”). Pursuant to the terms and conditions set forth in the Merger Agreement, on March 8, 2010, the Merger Sub merged with and into Ariston (the “Merger”), with Ariston being the surviving corporation of the Merger. As a result of the Merger, Ariston became a wholly-owned subsidiary of Manhattan.

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. The Company has 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. Interest accrues monthly, is added to principal on an annual basis, every March 8, and is payable at maturity, which is March 8, 2015.

In connection with the Exchange Transaction in December 2011, the Company performed a valuation of the assets and liabilities of Manhattan immediately prior to the transaction. The cumulative liability including accrued and unpaid interest of these notes was approximately \$16,876,000 immediately prior to the Exchange Transaction, and \$17,727,000 and \$16,883,000 at December 31, 2012 and 2011, respectively. As these notes payable are tied directly to net product cash flows derived from the preexisting products of the Company, this note and accrued interest was recorded at fair value of \$3,287,700 as of the date of the Exchange Transaction. No payments have been made on these notes as of December 31, 2012. See Note 3 for further details.

ICON Convertible Note Payable

In connection with the merger with Ariston as discussed above, Ariston satisfied an account payable of \$1,275,188 to ICON Clinical Research Limited (“ICON”) through the payment of \$275,188 in cash and the issuance of a three-year 5% note payable (the “ICON Note”). The principal was to be repaid in 36 monthly installments of \$27,778 commencing in April 2010. Interest was payable monthly in arrears. On March 1, 2011 Ariston entered into an amended and restated convertible promissory note (the “Amended ICON Note”) with ICON. The principal terms of the Amended ICON Note are that monthly payments of principal and interest will be waived for the thirteen month period ended December 31, 2011 (the “Waiver Period”) in exchange for a single payment of \$100,000 on March 31, 2011, an increase in the interest on the Amended ICON Note from 5% to 8% per annum during the Waiver Period and a balloon payment on January 31, 2012. The Amended ICON Note is convertible at the option of the holder into the Company’s common stock at the conversion price of \$562.50 per share. During the year ended December 31, 2012, the Company recorded \$61,571 of interest expense on the Amended ICON Note. As of December 31, 2012 and 2011, the principal amount of the Amended ICON Note was \$677,778, of which the entire balance has been classified as current and is reflected as notes payable, current portion, net in the accompanying consolidated balance sheets. Interest payable on the Amended ICON Note was \$123,511 and \$61,941 as of December 31, 2012 and 2011, respectively, and is reflected as interest payable, current portion, net in the accompanying consolidated balance sheets. This note is currently in default as the Company did not make the balloon payment due on January 31, 2012, or any subsequent payments. The Company is currently attempting to negotiate a settlement or alternative arrangement in satisfaction of this note.

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 \$36,271,000 and \$29,408,000 as of December 31, 2012 and 2011, respectively.

As of December 31, 2012, we have U.S. net operating loss carryforwards (“NOLs”) of approximately \$83,637,000. For income tax purposes, these NOLs will expire in various amounts through 2032. The Tax Reform Act of 1986 contains provisions which limit the ability to utilize net operating loss 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. Accordingly, a substantial portion of the Company’s NOLs above may be subject to annual limitations in reducing any future year’s taxable income.

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2012 and 2011 are presented below.

	2012	2011
Deferred tax assets (liabilities):		
Net operating loss carryforwards	\$ 32,190,080	\$ 27,611,000
Research and development credit	1,882,238	1,858,000
Non-cash compensation	3,051,920	1,735,000
Acquired in-process research and development	(1,202,556)	(2,220,000)
Foreign tax credit	330,000	--
Other	19,241	424,000
Deferred tax asset, excluding valuation allowance	36,270,923	29,408,000
Less valuation allowance	(36,270,923)	(29,408,000)
Net deferred tax assets	\$ --	\$ --

The Company recorded \$330,000 in income tax expense for the year ended December 31, 2012, as a result of South Korean taxes withheld associated with the Ildong sublicense agreement (see Note 8). There was no current or deferred income tax expense for the year ended December 31, 2011. Income tax expense differed from amounts computed by applying the US federal income tax rate of 34% to pretax loss as follows:

	For the year ended December 31,	
	2012	2011
Loss before income taxes, as reported in the consolidated statements of operations	\$ (25,852,952)	\$ (889,071)
Computed “expected” tax benefit	\$ (8,790,003)	\$ (302,284)
Increase (decrease) in income taxes resulting from:		
Expected expense (benefit) from state and local taxes	(1,758,001)	(60,457)
Research and development credits	(75,000)	(75,000)
Other	230,643	(277)
Foreign tax withholding	330,000	--
Change in the balance of the valuation allowance for deferred tax assets	10,392,361	438,018
	\$ 330,000	\$ --

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 2009. However, NOLs and tax credits generated from those prior years could still be adjusted upon audit.

The Company recognizes interest and penalties 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 2012. 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

TG-1101

In April 2011, TG Bio acquired from LFB Biotechnologies, a fully owned subsidiary of France based LFB S.A., an option (the “License Option”) for exclusive worldwide rights (except France/Belgium) to develop and market ublituximab (“TG-1101”), a monoclonal antibody that targets a specific epitope on the B-lymphocyte CD20 antigen. In exchange for the License Option, TG Bio issued 132,000 shares of its common stock to LFB.

On January 30, 2012, TG Bio exercised the License Option and 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 “License Agreement”). Under the License Agreement, we acquired the exclusive worldwide rights (exclusive of France/Belgium) for the development and commercialization of TG-1101 (ublituximab). To date, we have made no payments to LFB Group, who 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. 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.

In connection with the License Agreement, our subsidiary TG Bio issued 7,368,000 shares of its common stock to LFB Group, and the Company agreed to contribute \$15 million, less applicable fees and expenses associated with the financing, to TG Bio to fund the development of ublituximab under the License Agreement in exchange for 7,500,000 shares of TG Bio common stock. The Company recognized approximately \$16,578,000 of noncash research and development expense during the year ended December 31, 2012 in connection with the issuance of these shares. In addition, in connection with this share issuance, the Company and TG Bio provided LFB Group the option to, in its sole discretion, elect to convert its shares of TG Bio common stock into 7,500,000 shares of the Company’s Common Stock. Furthermore, should LFB Group choose to exercise the option for Company Common Stock, the Board of Directors of the Company shall appoint an individual designated by LFB Group to serve as a director of the Company until the next annual meeting of the stockholders and until his or her successor has been duly elected. Thereafter the Board of Directors of the Company shall nominate a designee named by LFB Group for election at each annual meeting of the stockholders until such time as LFB Group owns less than 10% of the outstanding Company Common Stock.

On November 9, 2012, LFB Group exercised their right to exchange their TG Bio common stock for Company Common Stock. The Company and LFB Group entered into a Securities Exchange Agreement pursuant to which, LFB Group agreed to exchange its 7,500,000 shares of the common stock of TG Bio, for 5,000,000 shares of Company Common Stock, and a warrant to purchase an aggregate of 2,500,000 shares of Company Common Stock at a purchase price of \$0.001 per share. In addition, upon the occurrence of certain financing conditions, the Securities Exchange Agreement requires LFB Group to purchase at least \$750,000 in additional shares of Company Common Stock at a purchase price per share equal to the then current Market Price (as defined therein). In addition on November 9, 2012, in connection with the Securities Exchange Agreement, the Board of Directors (the “Board”) of the Company appointed Dr. Yann Echelard to the Board as LFB Group’s nominee. Dr. Echelard will serve as a director until his term expires at the 2013 annual meeting of stockholders, at which time he will stand for reelection by the Company’s stockholders. Effective November 9, 2012, in connection with the aforementioned Securities Exchange Agreement, TG Bio became a wholly owned subsidiary of the Company.

TG-1101 – Ildong Sublicense

In November 2012, we entered into an exclusive (within the territory) sublicense agreement with Ildong Pharmaceutical Co. Ltd, (“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 \$2,000,000, which was received in December 2012 net of \$330,000 of income tax withheld, 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 the Company will have certain ongoing responsibilities under the sublicense agreement. The Company recorded license revenue of approximately \$19,000 and \$0 for the years ended December 31, 2012 and 2011, respectively, and, at December 31, 2012 and 2011, has deferred revenue of approximately \$1,981,000 and \$0, respectively, associated with this \$2,000,000 payment (approximately \$152,000 of which has been classified as a current liability at December 31, 2012).

The Company 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 the Company on net sales of TG-1101 in the sublicense territory.

TGR-1202

On August 15, 2012, the Company and Rhizen Pharmaceuticals S A (“Rhizen”) entered into an exclusive global agreement to collaborate on the development and commercialization of Rhizen’s lead product candidate (the “Collaboration Agreement”), a novel P13K delta inhibitor, (“TGR-1202”) (previously referred to as RP5264). The companies will jointly develop the product on a worldwide basis, excluding India, initially focusing on indications in the area of hematologic malignancies and autoimmune disease. Beyond TGR-1202, Rhizen would contribute backup molecules providing multiple opportunities for TG to develop differentiated therapies against hematologic cancers and autoimmune diseases.

The Company will make up-front licensing payments and milestones based on early clinical development, and will be responsible for the costs of clinical development of the product through Phase II, after which the Company and Rhizen will be jointly responsible for all development costs of the product. The Company and Rhizen will each maintain an exclusive option, exercisable at specific times during development, for the Company to license the rights to TGR-1202, in which case Rhizen would be eligible to receive upfront, development, and commercialization milestone payments in addition to milestone payments and royalties tied to net sales of the product, the aggregate of which could exceed \$250 million. Rhizen shall maintain rights to manufacture and supply the product to the Company, and the Company will be responsible for all clinical and regulatory development for TGR-1202 globally.

In connection with the Collaboration Agreement, the Company incurred upfront milestone payments of \$1,000,000 during the year ended December 31, 2012, which has been included in other research and development expenses in the accompanying consolidated financial statements. Rhizen is eligible to receive additional payments of up to \$2,000,000 upon the successful achievement of certain clinical development milestones prior to entering profit and loss sharing for the TGR-1202 development program. Pursuant to the terms of the Collaboration Agreement, should either of the exclusive license options be exercised, Rhizen would be eligible to receive up to an aggregate of \$182.5 million upon the successful achievement of certain clinical development, regulatory, and sales based milestones in addition to royalties on net sales of TGR-1202.

NOTE 9 – JOINT VENTURE

On April 19, 2011, H Pharmaceuticals K/S (the “Hedrin JV”), of which the Company was a 15% limited partner at the time, filed a demand for arbitration against Thornton & Ross, LTD. (“T&R”) with respect to alleged breaches by T&R of an Exclusive License Agreement (the “Hedrin License”) dated June 28, 2007, which was originally entered into between the Company and T&R, and which the Company assigned in 2008 to the Hedrin JV, with T&R’s consent. The Hedrin JV is seeking damages from T&R in the amount of approximately \$7,000,000. The Company was not a party to the initial arbitration demand.

On May 20, 2011, T&R filed an answer to the arbitration demand in which T&R asserted counterclaims against the Hedrin JV for alleged breaches by the Hedrin JV of the Hedrin License and for declaratory relief that the Hedrin License was properly terminated by T&R. In addition, T&R impleaded an individual (who is not associated with the Company), Nordic Biotech Venture Fund II K/S (an investment fund) and the Company, demanding arbitration against them based on alleged breaches of the Hedrin License and other related claims. In December 2011, the Company was removed by the arbitrator as a party to the arbitration. T&R is seeking damages of approximately \$20,000,000.

The Hedrin JV and T&R held a mediation session in order to avoid the arbitration process. The mediation process did not produce a result. During 2011 Nordic made an additional capital contribution to the Hedrin JV in order to fund the arbitration. As a result of that capital contribution, as of December 31, 2011, the Company owned 13% interest in the Hedrin JV, and no further information has been available since that date. The arbitration process is ongoing.

NOTE 10 – RELATED PARTY TRANSACTIONS

On December 30, 2011, OPN Capital Markets (“OPNCM”) and its affiliated broker-dealer, National Securities Corporation (“NSC” and collectively with OPNCM, “National”), both affiliates of National Holdings Corporation (“National Holdings”), entered into a Placement Agency Agreement (the “PAA”) with the Company in connection with the initial closing of the 2011 Equity PIPE. Pursuant to the PAA, National acted as the Company’s placement agent for 2011 Equity PIPE.

Until April 2012, Michael S. Weiss was a director and Non-Executive Chairman of the Board of Directors of National Holdings. He is also a stockholder of National Holdings and, when combined with his ownership indirectly through Opus and its affiliates, beneficially owns approximately 6.7% of National Holdings, the parent company of NSC. Mr. Weiss disclaims such beneficial ownership other than to the extent of his pecuniary interest. In addition, at the time, Opus and NSC were parties to a 50/50 joint venture that shared profits from OPNCM, the investment banking division of NSC that was responsible for managing the Offering. This joint venture was dissolved in April 2012.

As placement agent, National received cash commissions equal to 10% of the gross proceeds of the 2011 Equity PIPE, five-year warrants to purchase shares of Company Preferred Stock equal to 10% of shares sold in the 2011 Equity PIPE, and a non-accountable expense allowance equal to two percent of the gross proceeds of the 2011 Equity PIPE for National’s expenses (not including up to \$80,000 of National’s legal expenses and any blue sky fees, both of which the Company also reimbursed). In connection with the dissolution of the joint venture, in January 2013 National waived all rights to and surrendered to Opus the warrants discussed above. In addition to acting as placement agent, National provided advisory services in connection with the Exchange Transaction and received an advisory fee of \$150,000 for such services.

Under the terms of the Company’s License Agreement with LFB Group, the Company utilizes LFB Group for certain development and manufacturing services. The Company incurred approximately \$1,447,000 and \$0 in such expenses during the years ended December 31, 2012 and 2011, respectively, which have been included in other research and development expenses in the accompanying consolidated statements of operations. As of December 31, 2012, the Company has approximately \$56,000 recorded in accounts payable related to the aforementioned agreements with LFB Group. In conjunction with the development and manufacturing services discussed above, certain agreements between the Company and LFB Group require payments in advance of services performed or goods delivered. Accordingly, as of December 31, 2012, the Company recorded \$1,719,828 in prepaid research and development for such advance payments.

In connection with the Collaboration Agreement with Rhizen in August 2012, the Company issued Opus 2,000,000 shares of Company common stock subject to certain vesting provisions based on the progress of the joint venture and future success of the products governed by the Collaboration Agreement. The issuance of the Company Common Stock was exempt from registration under the Securities Act of 1933 pursuant to Regulation D and Rule 506 promulgated thereunder. Accordingly, the securities have not been registered under the Securities Act, and until so registered, these securities may not be offered or sold in the United States absent registration or availability of an applicable exemption from registration. The Company recognized approximately \$134,000 of noncash compensation (research and development) expense during the year ended December 31, 2012 in connection with the issuance of these shares.

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.

Date: March 21, 2013

TG THERAPEUTICS, INC.

By: /s/ Michael S. Weiss

MICHAEL S. WEISS
EXECUTIVE CHAIRMAN, INTERIM 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 21, 2013, and in the capacities indicated:

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.37	Sublicense Agreement between TG Biologics, Inc. and Ildong Pharmaceutical Co. Ltd., dated November 13, 2012.*
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	Certifications pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

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

SUBLICENSE AGREEMENT

By And Between

TG BIOLOGICS, INC.

And

ILDONG PHARMACEUTICAL CO. LTD.

November 13, 2012

CONFIDENTIAL

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List of Exhibits and Schedules

Exhibit A	Commercial Supply Agreement(s)
Schedule 2	Commercialization Plan
Schedule 3	Description of LFB-R603
Schedule 4	Licensed Patent Rights and Background Patent Rights
Schedule 5	Description of TG20
Schedule 6	Press Release
Schedule 7	Licensed Trademarks

SUBLICENSE AGREEMENT

This SUBLICENSE AGREEMENT (this “**Agreement**”) is entered into as of November 13, 2012 (the “**Effective Date**”) by and between TG Biologics, Inc., a Delaware corporation with a principal place of business at 787 Seventh Avenue, 48th Floor, New York, New York 10019 (“**TG**” or “**SUBLICENSOR**”) and Ildong Pharmaceutical Co. Ltd., a Korean limited company with a principal place of business at 60 Yangjae-dong, Seocho-ku, Seoul 137-733 KOREA (“**ILDONG**”). Each of ILDONG and SUBLICENSOR is sometimes referred to individually herein as a “**Party**” and collectively as the “**Parties.**”

RECITALS

WHEREAS, SUBLICENSOR is clinical-stage biopharmaceutical company focused on the acquisition, development and commercialization of innovative and medically important pharmaceutical products for the treatment of cancer and other underserved therapeutic needs;

WHEREAS, ILDONG is a pharmaceutical company engaged in producing pharmaceutical specialties, pharmaceutical raw materials and environmental products;

WHEREAS, prior to the signature of the present Agreement, SUBLICENSOR has entered into an exclusive license agreement (the “**LFB/GTC License**”) with LFB Biotechnologies SAS, LFB/GTC LLC, and GTC Biotherapeutics Inc dated on 30th of January, 2012. (collectively the “**Senior Licensors**”) related to the Compounds (as such term is defined below);

WHEREAS, pursuant to the terms of the LFB/GTC License, SUBLICENSOR has acquired rights to certain license agreements related to the Compounds, including:

- A license agreement with Dr. Hadam on an anti CD 20 monoclonal antibody, CAT 13.6.E12 and the hybridoma cell-line producing such murine antibody
- A license agreement with Pharming on the casein promoter
- A license agreement with Start/Viagen on the cloning and nuclear transfer technology;

WHEREAS, pursuant to Article 2.2 of the LFB/GTC License, SUBLICENSOR retains full rights to grant sublicense to certain patents, technology and material related to the Compounds;

WHEREAS, pursuant to that executed term sheet between SUBLICENSOR and ILDONG, dated June 13, 2012, the Parties have agreed to enter into a license on the terms and subject to the conditions set forth in this Agreement; and

WHEREAS, in furtherance of such transaction, SUBLICENSOR and ILDONG have also agreed to enter into a Commercial Supply Agreement on the terms described herein;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. DEFINITIONS

Whenever used in this Agreement with an initial capital letter, the terms defined in this Article 1 shall have the meanings specified.

1.1 “**Acceptance**” means, with respect to a Drug Approval Application filed for a Product, the acceptance of such filing by the applicable Regulatory Authority in any country within the Territory.

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

1.3 “**Affiliate**” means, with respect to any Person, any other Person that, directly or indirectly, controls, or is controlled by, or is under common control with, such Person. For purposes of this definition, “control” means (a) ownership of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors in the case of a corporation, or more than fifty percent (50%) of the equity interests in the case of any other type of legal entity, (or such lesser maximum percentage permitted in those jurisdictions where majority ownership by foreign entities is prohibited); (b) status as a general partner in any partnership; or (c) any other arrangement whereby a Person controls or has the right to control the board of directors of a corporation or equivalent governing body of an entity other than a corporation.

1.4 “**Agreement**” means this sublicense agreement and its Exhibits and Schedules listed in the table of contents.

1.5 “**Annual Net Sales**” means, with respect to any Calendar Year, the aggregate amount of Net Sales for such Calendar Year.

1.6 “**Anticipated Date of Receipt of Marketing Authorization**” means, the date of receipt of Marketing Authorization from the applicable regulatory agency set forth in the Development Plan (Schedule 1)

1.7 “**API**” means the active pharmaceutical ingredient that is intended to be used in the Manufacture of any Product.

1.8 “**Applicable Laws**” means any national, international, federal, state or local laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance or guidelines of Regulatory Authorities having the binding effect of law, or of any national securities exchanges or securities listing organizations or other government authorities other than Regulatory Authorities, that are in effect from time to time during the Term and applicable to a particular activity hereunder.

1.9 “**Background Patent Rights**” means any Patent Rights that are Controlled by SUBLICENSOR, other than Licensed Patent Rights, containing one or more claims that could Cover any Compound or Product (including its Manufacture or its formulation or a method of its delivery or of its use). For the sake of clarity, the Background Patent Rights existing as of the Effective Date are listed on Schedule 4.

1.10 “**BLA**” means (a) any Biologic License Application, as defined in the FDCA and regulations promulgated thereunder, or any successor application or procedure required to market and sell a Product in the Territory; and (b) all supplements and amendments to the foregoing.

1.11 “**Branding**” means all matters relating to the branding of any Product, including any matters related to the selection of any trademarks, brand names, product logos, branding colors, trade dress, positioning and key messages to be incorporated into Promotional Materials used for any Product in the Territory.

1.12 “**Business Day**” means any day other than a Saturday or Sunday on which banking institutions in New York, New York, USA or Seoul, Korea are open for business.

1.13 “**Calendar Quarter**” means the period beginning on the Effective Date and ending on the last day of the calendar quarter in which the Effective Date falls, and thereafter each successive period of three (3) consecutive calendar months ending on March 31, June 30, September 30 or December 31; provided, that, the final Calendar Quarter shall end on the last day of the Term.

1.14 “**Calendar Year**” means the period beginning on the Effective Date and ending on December 31 of the calendar year in which the Effective Date falls, and thereafter each successive period of twelve (12) months commencing on January 1 and ending on December 31; provided, that, the final Calendar Year shall end on the last day of the Term.

1.15 “**Challenge**” means any challenge to the validity or enforceability of any of the Licensed Patent Rights before any administrative, judicial or other governmental authority, court, tribunal or arbitration panel, including by (a) filing a declaratory judgment action in which any of the Licensed Patent Rights is alleged to be invalid or unenforceable; (b) citing prior art pursuant to 35 U.S.C. §301, filing a request for re-examination of any of the Licensed Patent Rights pursuant to 35 U.S.C. §302 and/or §311, or provoking or becoming a party to an interference with an application for any of the Licensed Patent Rights pursuant to 35 U.S.C. §135; or (c) filing or commencing any re-examination, opposition, cancellation, nullity or similar proceedings against any of the Licensed Patent Rights in any country.

1.16 **“Change of Control”** means, with respect to ILDONG, a transaction or series of related transactions (including any merger, consolidation, share exchange, reorganization or combination) involving ILDONG and any Third Party that results in (a) the holders of outstanding voting securities of ILDONG immediately prior to such transaction ceasing to represent at least fifty percent (50%) of the combined outstanding voting power of ILDONG or of the surviving or continuing entity immediately after such transaction or series of transactions; (b) any Third Party (other than a trustee or other fiduciary holding securities under an employee benefit plan) becoming the beneficial owner of fifty percent (50%) or more of the combined voting power of the outstanding securities of ILDONG (including as a single Third Party all persons who in concert or act together as a “group” for purposes of acquiring shares of ILDONG, in accordance with Section 13(d) of the Securities Act of 1934) (other than an investment transaction by an entity not engaged in the pharmaceutical or biotechnology business, the purpose of which is to raise capital for ILDONG); or (c) the sale or other disposition to a Third Party of all or substantially all of ILDONG’s assets or business to which this Agreement relates.

1.17 **“Clinical Data”** means any and all data (together with all Clinical Trial reports and the results of analyses thereof) derived or generated from any Clinical Trial of a Compound or Product or from testing of subjects or the analysis of samples used in any such Clinical Trial.

1.18 **“Clinical Trial”** means, collectively, any Phase 1 Clinical Trial, Phase 2 Clinical Trial, Phase 3 Clinical Trial, as applicable.

1.19 **“Combination Product”** means a single product that includes, in combination with a Product, one or more therapeutically-active ingredients other than a Product that are sold in a single package or as a unit at a single price either as a fixed dosage form or as separate dosage forms.

1.20 **“Commercialization”** or **“Commercialize”** means any and all activities directed to the offering for sale and sale of a Product after Marketing Authorization has been obtained with respect to such Product, including, (a) activities directed to marketing, promoting, detailing, distributing, Manufacturing, importing, selling and offering to sell such Product; (b) interacting with Regulatory Authorities regarding any of the foregoing; and (c) seeking Pricing Approvals and Reimbursement Approvals for such Product (d) Post Approval Clinical Trials. When used as a verb, **“to Commercialize”** and **“Commercializing”** means to engage in Commercialization and **“Commercialized”** has a corresponding meaning.

1.21 **“Commercialization Plan”** means, with respect to any Product, the written report prepared by ILDONG pursuant to Section 5.1 and submitted to SUBLICENSOR for its review that (a) describes the Commercialization activities that ILDONG reasonably expects to conduct with respect to such Product in the Territory, and (b) sets forth (i) a non-binding estimate of projected sales of such Product in the Territory, and (ii) a summary of all actual sales of such Product in the Territory, as such report may be amended or updated by ILDONG from time to time. Without limiting the foregoing, each Commercialization Plan shall include, without limitation, (a) demographics and market dynamics, market strategies, a marketing plan (including advertising, detailing forecasts, Pricing strategies pertaining to discounts and sales forecasts) for the Territory; (b) specific Commercialization and marketing objectives, projected milestones, resource allocation requirements and activities to be performed over such period (including all anticipated Clinical Trials) (collectively, the **“Commercialization Targets”**); (c) a timeline for such activities, including the estimated launch date(s) in the Territory; (d) a sales and expense forecast (including at least five (5) years of estimated sales and expenses in terms of both volume and value) for the Territory; (e) Manufacturing plans and the expected product profile; and (f) the expected Regulatory Filings to be required and prepared, and the expected timetable for making such Regulatory Filings.

1.22 **“Commercially Reasonable Efforts”** means, with respect to the activities of ILDONG, and/or its Affiliates, Sublicensees, Distributors, in the Development or Commercialization, as the case may be, of a particular Compound and/or Product, the level of efforts and resources typically used and expected from a pharmaceutical company of similar size for the development or commercialization of products of comparable market potential, taking into account all relevant factors including, as applicable, the stage of development, observed efficacy and safety of the Product and relative to Competitive Products in the marketplace, actual or anticipated Regulatory Authority approved labeling, the nature and extent of market exclusivity (including patent coverage, regulatory exclusivity and competitiveness of alternative products), the cost and likelihood of obtaining Marketing Authorization, the actual or projected profitability, and the reasonably expected and actual pricing, reimbursement and formulary status. For purposes of clarity, Commercially Reasonable Efforts shall be determined on a market-by-market and Indication-by-Indication basis for a particular Compound and/or Product, and it is anticipated that the level of effort may be different for different markets and may change over time, reflecting changes in the status of the Compound or Product and the market(s) involved.

1.23 **“Competitive Entity”** means any Third Party that (a) together with its Affiliates and subsidiaries, collectively had worldwide sales of ethical pharmaceutical products, in the Calendar Year that preceded the Change of Control, of at least One Billion Dollars (USD \$1,000,000,000), and (b) on the date of such Change of Control is actively working on any research program involving the expenditure of funds or the application of full time equivalents in the aggregate amount of at least \$500,000 per Calendar Year involving a Competitive Program.

1.24 **“Competitive Products”** means any anti CD 20 monoclonal antibody for use in the Field

1.25 **“Competitive Program”** means any program that involves the research, development or commercialization of any (a) transgenically-derived chimeric monoclonal antibody or (b) cell-product anti CD 20 monoclonal antibody for use in the Field.

1.26 **“Completion”** means, with respect to any Clinical Trial, the date on which all material data reasonably expected to be derived therefrom has been generated and the final study report with respect thereto has been finalized.

1.27 **“Compounds”** means ublituximab, collectively, (i) TG20 and/or (b) LFB-R603.

1.28 **“Confidential Information”** means with respect to each Party, all information, Technology and Proprietary Materials that is (i) ILDONG Background Technology, in the case of ILDONG and (ii) Licensed Technology, in the case of SUBLICENSOR, and, that, in any case, is disclosed or provided by or on behalf of such Party (the **“Disclosing Party”**) to the other Party (the **“Receiving Party”**) or to any of the Receiving Party’s employees, consultants, Affiliates or sublicensees; provided, that, none of the foregoing shall be Confidential Information if: (A) as of the date of disclosure, it is known to the Receiving Party or its Affiliates as demonstrated by contemporaneous written documentation maintained in the ordinary course of business, other than by virtue of a prior confidential disclosure to such Receiving Party; (B) as of the date of disclosure it is in the public domain, or it subsequently enters the public domain through no fault of the Receiving Party; (C) it is obtained by the Receiving Party from a Third Party having a lawful right to make such disclosure free from any obligation of confidentiality to the Disclosing Party; or (D) it is independently developed by or for the Receiving Party without reference to or use of any Confidential Information of the Disclosing Party as demonstrated by contemporaneous written documentation maintained in the ordinary course of business. For purposes of clarity, (a) unless excluded from Confidential Information pursuant to the preceding sentence, any scientific, technical, manufacturing or financial information of a Party that is disclosed through any report (including any audit report) shall constitute Confidential Information of the Disclosing Party; (b) all Clinical Data produced by ILDONG in connection with the Development of a Compound or Product and/or in the conduct of Clinical Trials shall be Confidential Information of ILDONG; and (c) any combination of Confidential Information shall not be considered in the public domain or in the possession of the Receiving Party merely because individual elements of such Confidential Information are in the public domain or in the possession of the Receiving Party unless the combination and its principles are in the public domain or in the possession of the Receiving Party.

1.29 **“Control”** or **“Controlled”** means (a) with respect to Technology (other than Proprietary Materials) or Patent Rights, the possession by a Party (or an Affiliate of such Party, as applicable) of the right to grant a license or sublicense to such Technology or Patent Rights as provided herein without violating the terms of any agreement or arrangement with, infringing the Patent Rights of, or misappropriating the proprietary or trade secret information of, any Third Party and without violating any Applicable Laws and (b) with respect to Proprietary Materials, the possession by a Party of the right to supply such Proprietary Materials to the other Party as provided herein without violating the terms of any agreement or arrangement with any Third Party and without violating any Applicable Laws. Notwithstanding the foregoing, no Party (or Affiliate of a Party, as applicable) shall be deemed to Control any Technology, Proprietary Materials or Patent Rights solely by virtue of the license grants set forth in this Agreement.

1.30 **“Cover”** or **“Covered”** means, with respect to a Product, that the manufacture, use or sale of such Product in a particular country by an unlicensed Third Party would infringe a Valid Claim.

1.31 **“Development”** or **“Develop”** means, with respect to a Product, (a) all non-clinical and clinical drug development activities that are undertaken after the Effective Date up to and including the date of obtaining of Marketing Authorization of such Product to obtain including (i) the conduct of Clinical Trials, toxicology and pharmacology testing, test method development and stability testing, process development (including the Manufacture of validation and engineering batches), formulation development, delivery system development, quality assurance and quality control development, analytical method development, human clinical studies and regulatory affairs activities and statistical analysis and report writing; (ii) the preparation of Clinical Trial design and operations; (iii) preparing and filing Drug Approval Applications, and (b) all activities related to Manufacturing Development and (c) any and all other activities that may be necessary or useful to obtain Regulatory Approval, Pricing Approval, or Reimbursement Approval. When used as a verb, **“Developing”** means to engage in Development and **“Developed”** has a corresponding meaning.

1.32 **“Development Plan”** means, with respect to the Compound and/or any Product, the non-binding written plan for, and estimated budget applicable to, the Development activities anticipated to be conducted by ILDONG for the Compound and/or Product, as such written plan may be amended, modified or updated in accordance with Section 3.1.3. Topics that may be covered in the plan, (a) the Clinical Trials (including investigator-initiated clinical trials) that are expected to be conducted and the expected timeline for conducting such Clinical Trials; (b) the expected Drug Approval Applications to be required and prepared, and the expected timetable for making such Drug Approval Applications;

1.33 **“Development Program”** means (a) the Development activities to be conducted by ILDONG during the Term with respect to the Compounds and (b) the Development activities to be conducted by SUBLICENSOR during the Term under the Development Services and Manufacturing Agreement as set forth in the Development Plan and defined in 3.1.2.

1.34 **“Distributor”** means any Person that purchases Product from ILDONG or any of ILDONG’s Affiliates or Sublicensees for purposes of resale of Product to end users in the Territory (including any wholesalers, pharmacists or hospitals).

1.35 **“Divest”** means, with respect to a Competitive Program, a divestiture of such Competitive Program to a Third Party by sale, license or otherwise; provided, that, if such divestiture is made by ILDONG by way of one or more licenses or sublicenses, (a) ILDONG and its Affiliates shall not hold or retain any rights with respect to such Competitive Program other than (i) the right to receive license fees, milestone payments and royalties on sales of products (or other sources of revenue, including with respect to Manufacturing) with respect to such Competitive Program, (ii) the right to defend claims of infringement, (iii) the right to assert claims of infringement against Persons who may infringe its intellectual property rights with respect to products with respect to such Competitive Program and (iv) the right to otherwise control filings and patent term extensions connected with any licensed or sublicensed Patent Rights, and (b) ILDONG and its Affiliates are not consulted with respect to, and do not otherwise participate in, any decisions (other than those described in clauses (ii), (iii) and (iv) above), or otherwise collaborate with any Third Party, with respect to (x) the commercialization of products with respect to such Competitive Program or (y) the commercial strategy with respect to products with respect to such Competitive Program.

1.36 **“Drug Approval Application”** means, with respect to a Product in the Territory, an application for Marketing Authorization for such Product in the Territory. For purposes of clarity, Drug Approval Application shall include, without limitation (a) a counterpart of an NDA or BLA (as in the US), sNDA or sBLA (as in the US), or MAA (as in Europe) in any country or region in the Territory; and (b) and all supplements and amendments to the foregoing.

1.37 **“Excluded Application”** means (a) any application involving the determination or monitoring of (i) the presence or absence of a disease; (ii) the stage, progression or severity of a disease or (iii) the effect on a disease of a particular treatment; (b) any application involving the selection of patients for a particular treatment; and (c) any *in vitro* applications or uses.

1.38 **“Executive Officer”** means the Chief Executive Officer of SUBLICENSOR and the Chief Executive Officer of ILDONG.

1.39 **“FDA”** means the United States Food and Drug Administration or any successor agency or authority thereto.

1.40 **“FDCA”** means the United States Federal Food, Drug, and Cosmetic Act, as amended.

1.41 **“Field”** means the treatment, control, mitigation, prevention and/or cure of all human therapeutic Indications. For purpose of clarity, the definition of **“Field”** shall not include any Excluded Application.

1.42 **“First Commercial Sale”** means, with respect to a Product in the Territory, the first sale, transfer or disposition for value to an end user of such Product in the Territory after Marketing Authorization for such Product has been received in the Territory; provided, that, a First Commercial Sale shall not include: (a) any sale to an Affiliate, Sublicensee or Distributor (unless the Affiliate, Sublicensee or Distributor is the last entity in the distribution chain of the Product), (b) any use of a Product in Clinical Trials, pre-clinical studies or other research or development activities, or (c) the disposal or transfer of Products for a bona fide charitable purpose, including compassionate use or named patient use.

1.43 **“Force Majeure”** means any occurrence beyond the reasonable control of a Party that (a) prevents or substantially interferes with the performance by such Party of any of its obligations hereunder and (b) occurs by reason of any act of God, flood, fire, explosion, earthquake, strike, lockout, labor dispute, casualty or accident, or war, revolution, civil commotion, act of terrorism, blockage or embargo, or any injunction, law, order, proclamation, regulation, ordinance, demand or requirement of any government or of any subdivision, authority or representative of any such government.

1.44 **“GLP”** means the then-current Good Laboratory Practice Standards promulgated or endorsed by the FDA or, in the case of foreign jurisdictions, comparable regulatory standards promulgated or endorsed by the applicable Regulatory Authority.

1.45 **“GMP”** means current Good Manufacturing Practices that apply to the Manufacture of API and/or the clinical or commercial supply of Products, including, without limitation, the United States regulations set forth under Title 21 of the United States Code of Federal Regulations, parts 210 and 211, as amended from time-to-time, as well as all applicable guidance published from time-to-time by the FDA or, in the case of foreign jurisdictions, comparable regulatory standards promoted or endorsed by the applicable Regulatory Authority and the International Conference on Harmonization Guidelines ICHQ7A Good Manufacturing Practice Guidance for API or the principles and guidelines of Good Manufacturing Practices for Medicinal Products as defined with EC Directive 2003/94/EC and associated EC Guide to Good Manufacturing Practice.

1.46 **“Good Clinical Practice”** or **“GCP”** means the applicable regulations or guidance relating to the design, conduct, recording, and reporting of Clinical Trials that involve the participation of human subjects, when generating Clinical Trial data intended to be submitted to Regulatory Authorities, as set forth in the FDCA and any regulations or guidance documents promulgated thereunder, including but not limited to the ICH E6 consolidated guidance on Good Clinical Practice.

1.47 **“Hadam License Agreement”** means that certain License Agreement, dated August 15, 2006, by and between LFB Biotechnologies (“LFB”) and Dr. Martin Hadam and licensed to SUBLICENSOR pursuant to the LFB/GTC License.

1.48 **“Hatch-Waxman Act”** means the Drug Price Competition and Patent Term Restoration Act of 1984, as amended.

1.49 **“IND”** means: (a) an Investigational New Drug Application, as defined in the FDCA and regulations promulgated thereunder, or any counterpart, successor application, or procedure required to initiate clinical testing of a Product in humans in the Territory; and (b) all supplements and amendments to the foregoing.

1.50 **“Indication”** means each separate and distinct disease, illness and/or condition in humans including without limitation Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Lupus, and Rheumatoid Arthritis, for which Regulatory Approval is being sought.

1.51 **“Investigator’s Brochure”** means a compilation of preclinical and clinical data with respect to a new investigational drug that is proposed for filing with a Regulatory Authority and used to provide information to clinical investigators and Regulatory Authorities.

1.52 **“Joint Improvement”** means any Program Technology that is (a) jointly conceived, developed or reduced to practice by one or more employees of, or consultants to, ILDONG and/or its Affiliates, Sublicensees, Distributors and one or more employees of, or consultants to, SUBLICENSOR or (b) conceived, developed, or reduced to practice solely by one or more employees of, or consultants to ILDONG resulting from the use by ILDONG in any material respect of the Licensed Technology, Licensed Patent Rights, Background Patent Right or SUBLICENSOR Materials.

1.53 **“Joint Patent rights”** means any Patent Rights related to Joint Improvements.

1.54 **“Knowledge” or “Known”** means, with respect to a Party, the actual knowledge of the Executive Officer or of any executive officer (as defined for purposes of Section 14 of the Securities Exchange Act of 1934, as amended) of such Party.

1.55 **“LFB-R603”** means the cell-culture produced chimeric monoclonal antibody described on Schedule 3 attached hereto and incorporated herein by reference.

1.56 **“Licensed Patent Rights”** means any Patent Rights that are Controlled by SUBLICENSOR during the Term and that (a) contain one or more claims that Cover any Compound or Product; and (b) are necessary or useful for ILDONG to Develop and/or Commercialize any Compound or Product in the Field and in the Territory. For purposes of clarity, (a) the Licensed Patent Rights existing as of the Effective Date are listed on Schedule 4 attached hereto and (b) Schedule 4 shall be updated by SUBLICENSOR by written notice to ILDONG on an annual basis during the Term to include any additional patents and patent applications not previously listed; provided, that, the exclusion of a patent or patent application from Schedule 4 shall not be deemed to be a conclusive indication of whether that patent or application is or should be considered a “Licensed Patent Right” for purposes of this Agreement.

1.57 **“Licensed Technology”** means any Technology that is Controlled by SUBLICENSOR during the Term and that (a) relates to any Compound or Product and (b) is necessary or useful for ILDONG to Develop, and/or Commercialize any Compound or Product in the Field and in the Territory.

1.58 **“Licensed Trademark”** shall mean the registered trademarks listed in Schedule 7 hereto which are owned or controlled by SUBLICENSOR and which may be used by ILDONG in connection with the sale and marketing of the product in the Territory.

1.59 **“SUBLICENSOR Materials”** means any Proprietary Materials that are Controlled by SUBLICENSOR and used by SUBLICENSOR, or provided by SUBLICENSOR for use, in the Development Program.

1.60 **“SUBLICENSOR Improvement”** means any Program Technology that is conceived or first reduced to practice by employees of, or consultants to, SUBLICENSOR alone or jointly with any Third Party, without the use, in any material respect, of any ILDONG Materials or Joint Improvement.

1.61 **“Manufacture”** or **“Manufacturing”** or **“Manufactured”** means all activities related to the production of any API or Product, including the manufacture, receipt, inspection, storage and handling of materials, and the manufacture, processing, purification, packaging, labeling, warehousing, quality control testing (including in-process release and stability testing), shipping and release of API or Product.

1.62 **“Manufacturing Development”** means, with respect to any API or Product, all activities related to the optimization of a commercial-grade Manufacturing process for the Manufacture of such API or Product including, test method development and stability testing, formulation, validation, productivity, trouble shooting and next generation formulation, process development, Manufacturing scale-up, strain improvements, development-stage Manufacturing, and quality assurance/quality control development.

1.63 **“Marketing Authorization”** means, with respect to any Product, the Regulatory Approval required by Applicable Laws to market and sell such Product for use for any Indication including without limitation Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Lupus, and Rheumatoid Arthritis for humans in the Territory.

1.64 **“NADA”** means a New Animal Drug Application required by the US Food and Drug Administration for the use of any genetically engineered animal in which the gene coding for the API is stably integrated in the genome of the animal.

1.65 **“NDA”** means (a) any New Drug Application, as defined in the FDCA and regulations promulgated thereunder, or any counterpart, successor application, or procedure required to market and sell a Product in the Territory; and (b) all supplements and amendments to the foregoing.

1.66 **“Net Sales”** means the gross amount billed or invoiced by ILDONG or any of its Affiliates, Sublicensees or Distributors (each, a **“Seller”**) to Third Parties in the Territory for sales or other dispositions or transfers for value of Products less (a) allowances for trade, quantity and cash discounts actually allowed and taken; (b) freight, transportation, insurance, postage charges and customs duties included on a Seller's bill or invoice or as a separate item; (c) credits, rebates, allowances, and amounts repaid due to returns, recalls or government regulations, including allowances for uncollectible amounts and/or bad debts on previously sold Products; (d) retroactive price reductions that are actually allowed or granted; (e) sales taxes, excise taxes, value-added taxes and other taxes (other than income taxes) levied on the invoiced amount; and (f) duties, tariffs and other governmental charges. In addition, Net Sales are subject to the following:

(i) Net Sales shall not include sales or transfers between ILDONG and any of its Affiliates, Sublicensees or Distributors unless such Affiliate, Sublicensee or Distributor is the end user of the Product.

(ii) If any Seller effects a sale, disposition or transfer of a Product to a Third Party in a particular country other than on customary commercial terms or for non-monetary consideration, the Net Sales of such Product to such Third Party shall be deemed to be “the fair market value” of such Product. For purposes of this subsection (ii), “fair market value” means the value that would have been derived had such Product been sold as a separate product to another customer in the country concerned on customary commercial terms.

(iii) For purposes of this Agreement, “sale” shall mean any transfer or other distribution or disposition, but shall not include transfers or other distributions or dispositions of Product at no charge for academic research, preclinical, clinical, or regulatory purposes (including the use of a Product in Clinical Trials) or in connection with patient assistance programs or other charitable purposes or to physicians or hospitals for promotional purposes (including free samples to a level and in an amount which is customary in the industry and/or which is reasonably proportional to the market for such Product).

(iv) For the purposes of determining royalty rates and the royalties payable on Combination Products, Net Sales of Product shall be calculated by multiplying the Net Sales of the Combination Product by the fraction $A/A+B$, where A is the average selling price, during the royalty paying period in question, of the Product sold separately in the country in which the sale of the Combination Product is made, and B is the average selling price, during the royalty period in question, of the other active ingredients or components sold separately. In the event that such average selling price cannot be determined for both Product and all other active ingredients and components included in the Combination Product, Net Sales for purposes of determining payments under this Agreement shall be calculated by multiplying the Net Sales of the Combination Product by the fraction $C/(C+D)$ where C is the standard fully-absorbed cost of the Product portion of the combination, and D is the standard fully-absorbed cost of the other active ingredient or component included in the Combination Product, as determined by ILDONG using its standard accounting procedures consistently applied. In the event that the standard fully-absorbed cost of the Product and/or the other active ingredients or components included in such Combination Product cannot be determined, for the purposes of determining royalties payable hereunder, the Parties shall negotiate in good faith to determine an appropriate commercial value for all the components in the Combination Product and calculate Net Sales of such Combination Product accordingly.

1.67 “**Patent Rights**” means the rights and interests in and to issued patents and pending patent applications (which, for purposes of this Agreement, include certificates of invention, applications for certificates of invention and priority rights) in any country or region, including all provisional applications, substitutions, continuations, continuations-in-part, divisions, renewals, all letters patent granted thereon, and all reissues, re-examinations and extensions thereof, and all foreign counterparts of any of the foregoing.

1.68 **“Person”** means an individual, sole proprietorship, partnership, limited partnership, limited liability partnership, corporation, limited liability company, business trust, joint stock company, trust, incorporated association, joint venture or similar entity or organization, including a government or political subdivision, department or agency of a government.

1.69 **“Phase 1 Clinical Trial”** means a human clinical trial conducted for a Product in any country that would satisfy the requirements of 21 CFR 312.21(a), as amended (or its foreign equivalent).

1.70 **“Phase 2 Clinical Trial”** means a human clinical trial conducted for a Product for any Indication that would satisfy the requirements of 21 CFR 312.21(b), as amended (or its foreign equivalent) and is intended to explore one or more doses, dose response, and duration of effect, and to generate initial evidence of clinical activity and safety for such Product in the target patient population.

1.71 **“Phase 3 Clinical Trial”** means a pivotal human clinical trial conducted for a Product for any Indication that would satisfy the requirements of 21 CFR 312.21(c), as amended (or its foreign equivalent) and is intended to confirm with statistical significance the efficacy and safety of such Product with respect to a particular Indication, and is performed to obtain Marketing Authorization.

1.72 **“Pivotal Clinical Trial”** means (a) a Phase 3 Clinical Trial or, (b) a Phase 2 Clinical Trial to the extent: (i) in the United States, the protocol for that Phase 2 Clinical Trial shall have been reviewed by the FDA under its current Special Protocol Assessment Guidelines (or equivalent guidelines issued in the future), and any comments from the FDA on that protocol are incorporated in the final protocol for that Phase 2 Clinical Trial or are resolved to the FDA’s satisfaction as evidenced by further written communications from the FDA; or (ii) a process with a comparable result – acceptance of a Phase 2 Clinical Trial protocol as “potentially pivotal” – has occurred with the EMA/CHMP in the European Union; or (iii) based on the results of that Phase 2 Clinical Trial, either the FDA, EMA, or corresponding Regulatory Authority in the Territory has determined that the Phase 2 Clinical Trial can be considered as a pivotal clinical trial for purposes of obtaining Marketing Authorization.

1.73 **“Post Approval Clinical Trials”** means any Phase 4 clinical trial and/or any clinical trial undertaken after any Marketing Approval is granted such as Investigator sponsored study.

1.74 **“Pricing”** means the determination of Product pricing at all levels, including the Product list price (also referred to as Wholesale Acquisition Cost) and the net price in which the Product is offered to purchasers and payers (including both private sector and government entities).

1.75 **“Pricing Approval”** means, with respect to a Product in the Territory, any pricing and reimbursement approvals, guidance or recommendations reasonably necessary to market such Product in the Territory.

1.76 **“Product”** shall mean any pharmaceutical or medicinal item, substance, formulation or dosage that is comprised of, or contains, a Compound (whether or not such Compound is the sole active ingredient).

1.77 **“Product Improvement”** means any Program Technology related to or concerning the Product and/or Licensed Technology, whether or not patentable, copyrightable or otherwise protectable under any intellectual property rights.

1.78 **“Program Technology”** means any Technology or Proprietary Material that is conceived and first reduced to practice (actually or constructively), by ILDONG and/or its Affiliates or jointly by the Parties, or by any Sublicensee or by any Distributors, whether or not patentable, in the conduct of the Development Program and/or in connection with the Commercialization of Products.

1.79 **“Proprietary Materials”** means any tangible chemical, biological or physical materials that (a) are furnished by or on behalf of one Party to the other Party in connection with this Agreement, whether or not specifically designated as proprietary by such Transferring Party, or (b) that are otherwise conceived or reduced to practice by ILDONG in the conduct of the Development Program and/or in connection with the Commercialization of Products.

1.80 **“Regulatory Approval”** means, with respect to the Territory, any approval, product and establishment license, registration or authorization of any Regulatory Authority required for the Manufacture, use, storage, importation, exportation, transport or distribution of a Product in the Territory, including any Marketing Authorization.

1.81 **“Regulatory Authority”** means any national, international, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity with authority over the distribution, importation, exportation, Manufacture, production, use, storage, transport, clinical testing, marketing, Pricing or sale of a Product in the Territory.

1.82 **“Regulatory Filings”** means, collectively: (a) all INDs, NDAs, BLAs, NADAs, MAAs establishment license applications, Drug Master Files, and all other similar filings (including, without limitation, counterparts of any of the foregoing in the Territory); (b) all supplements and amendments to any of the foregoing; (c) all data and other information contained in, and correspondence relating to, any of the foregoing; and (d) any and all orphan drug applications.

1.83 **“Reimbursement Approval”** means, with respect to a Product in the Territory, any pricing reimbursement registration or listing on formularies and all approval necessary to an optimal introduction of the Product on the market.

1.84 **“Royalty Term”** means with respect to each Product in each country in the Territory, the period beginning on the date of First Commercial Sale of such Product in such country and ending on the later of (a) the expiration of the last to expire Valid Claim of the Licensed Patent Rights or ILDONG Program Patent Rights in such country that Covers the composition of matter, Manufacture, use or sale of such Product, and (b) fifteen (15) years from the date of the First Commercial Sale of such Product in such country.

1.85 **“Sales Target”** means that proportion of the total patient market for the Product provided to Sublicensor by ILDONG and expressed as either a percentage or calculated number of vials of the Product as set forth in Schedule 3.

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

1.87 **“Significant Development Event”** means any of the following material Development events, a summary of which shall be included in any Development Report: (a) any material interaction and/or written correspondence between ILDONG and any Regulatory Authority with respect to the Compound or a Product; (b) any material event with respect to any Clinical Trial involving the Compound and/or a Product, including any such event that is ongoing as of the date of the applicable Development Report, or is reasonably expected to occur or be initiated within twelve (12) months of the date of the applicable Development Report; and (c) any material result obtained in the conduct of any Clinical Trial involving the Compound and/or a Product during the period covered by the Development Report. For purposes of clarity, all information provided to SUBLICENSOR with respect to Significant Development Events, shall be deemed to be Confidential Information of ILDONG. For purposes of this definition, “material” shall be defined as any event and/or result which have had or may have a significant impact on the activities and timelines defined in the Development plan of each Product.

1.88 **“sBLA”** means a Supplemental Biologic License Application, as defined in the FDCA and applicable regulations promulgated thereunder.

1.89 **“sNDA”** means a Supplemental New Drug Application, as defined in the FDCA and applicable regulations promulgated thereunder.

1.90 **“Sublicensee”** means any Third Party to which ILDONG grants a sublicense in accordance with Section 2.2.

1.91 **“Sublicense Agreement”** means any agreement by and between a Party and a Sublicensee which is entered into in accordance with Section 2.2.

1.92 **“Technology”** means, collectively, all inventions, discoveries, improvements, trade secrets and proprietary information and methods, whether or not patentable or patented, including without limitation: (a) methods of Manufacture or use of, and structural and functional information pertaining to, chemical compounds; (b) compositions of matter, data, formulations, processes, techniques, know-how and results (including any negative results) and (c) results of clinical trials, pre-clinical trials and other Development activities.

1.93 “**Territory**” means South Korea, Taiwan, Singapore, Indonesia, Malaysia, Thailand, Philippines, Vietnam, and Myanmar.

1.94 “**TG20**” means the transgenic-derived chimeric monoclonal antibody described more fully on Schedule 5 attached hereto and incorporated herein by reference.

1.95 “**ILDONG Materials**” means any Proprietary Materials that are Controlled by ILDONG and used by ILDONG, or provided by ILDONG for use, in the Development Program.

1.96 “**Third Party**” means (a) with respect to ILDONG, any Person other than ILDONG and its respective Affiliates, Sublicensees and Distributors and (b) with respect to SUBLICENSOR, any Person other than its Affiliates.

1.97 “**Valid Claim**” means any claim of (a) an issued unexpired patent that (i) has not been finally cancelled, withdrawn, abandoned or rejected by any administrative agency or other body of competent jurisdiction, (ii) has not been permanently revoked, held invalid, or declared unpatentable or unenforceable in a decision of a court or other body of competent jurisdiction that is unappealable or unappealed within the time allowed for appeal, (iii) has not been rendered unenforceable through terminal disclaimer or otherwise, and (iv) is not lost through an interference proceeding that is unappealable or unappealed within the time allowed for appeal; or (b) a claim of a pending Patent application, which claim has not been abandoned or finally disallowed without the possibility of appeal.

Additional Definitions. In addition, each of the following definitions shall have the respective meanings set forth in the section of this Agreement indicated below:

Definition	Section
Action	10.2.1(a)(ii)
Anticipated Approval Notice	5.11.1(a)
Claims	13.1
Commercialization Report	5.8
Competitive Program Transaction	2.4.2(a)
Competitive Program Transaction Notice	2.4.2(a)
Development Report	3.4.1
Diligence Failure Notice	5.4
Disclosing Party	1.28
Dispute	14.1
Effective Date	Preamble
Filing Party	10.1.4

Definition	Section
LFB	Preamble
LFB/GTC	Preamble
SUBLICENSOR	Preamble
SUBLICENSOR Indemnities	13.1
ICH	3.4
Indemnified Party	13.3
Indemnifying Party	13.3
Infringement	10.2.1(a)(i)
Infringement Notice	10.2.1(a)(i)
Losses	13.1
Option	Recitals
Option Agreement	Recitals
Party/Parties	Preamble
Patent Coordinator	9.4
Recall	5.10
Receiving Party	1.28
Recipient Party	3.6
ILDONG	Preamble
ILDONG Diligence Failure Notice	5.4
ILDONG Indemnities	13.2
Term	11.1
Transferring Party	3.6

2. LICENSE GRANTS; EXCLUSIVITY

2.1 Sublicense.

2.1.1 Grant of Sublicense to ILDONG. Subject to the terms and conditions of this Agreement, SUBLICENSOR hereby grants to ILDONG, a royalty-bearing, exclusive within the Territory, license or sublicense (with respect to Licensed Technology and/or Licensed Patent Rights licensed by Third Parties to SUBLICENSOR), including the right to grant sublicenses as provided in Section 2.2, under the Licensed Technology and Licensed Patent Rights to Develop the Compounds or Products as part of the Development Program and to Commercialize, use, have used, supply, sell, offer to sell, import, have imported, market, and otherwise Commercialize Products in the Field in the Territory.

In addition, SUBLICENSOR hereby grants to ILDONG a non-exclusive, fully paid up license or sublicense, including the right to grant sublicenses as provided in Section 2.2, under the Background Patent Rights to Develop the Compounds or Products as part of the Development Program and to Commercialize, use, have used, and supply, sell, offer to sell, import, have imported, market, and otherwise Commercialize Products in the Field in the Territory.

2.1.2 Reversion. Should ILDONG or its Sublicensee(s) stop the Commercialization of any Product, any and all license granted to ILDONG by SUBLICENSOR in respect of such Product shall automatically revert back to SUBLICENSOR (including licenses granted according to Sections 2.1.1 and 2.1.4). In such case, ILDONG commits to grant to SUBLICENSOR an exclusive, royalty free license or sublicense (with respect to Rights licensed by Third Parties to ILDONG), including the right to grant sublicenses, under all Patent Rights Controlled by ILDONG, Joint Improvement and Joint Patent Right necessary or useful for SUBLICENSOR to Develop such Compounds or Product and/or use, have used, supply, sell, offer to sell, import, have imported, market, and otherwise Commercialize such Products in the Field and in the Territory.

For the avoidance of doubt, the Commercialization of a Product shall be considered as stopped if, after all Regulatory Approvals and Reimbursement Approvals have been granted in South Korea when:

- the aggregate amount spent by ILDONG or its Sublicensee(s) on the Commercialization activities is less than \$* per year for such Product; and
- or, a minimum of thirty percent (*%) of Sales Target has not been recorded for over a period of more than * (*) years;

2.1.3 Disclosure of Technology. SUBLICENSOR shall provide prompt written notice to ILDONG of all Licensed Patent Rights or Licensed Technology Controlled by SUBLICENSOR and their respective Affiliates that come under the Control of SUBLICENSOR or their respective Affiliates after the Effective Date during the Term.

2.1.4 Grant of License to Licensed Trademark.

(a) **Ownership of Trademarks.** ILDONG hereby acknowledges that SUBLICENSOR has already performed a Trademarks research and has registered the Licensed Trademarks. However, ILDONG is entitled to use and register any other trademarks, on SUBLICENSOR behalf, and at ILDONG'S own cost, for Development and Commercialization purposes ILDONG agrees that it will not apply for the registration of the Licensed Trademark (or any mark confusingly similar thereto) anywhere in the world.

(b) **Grant of License.** Subject to the terms and conditions of this Agreement, SUBLICENSOR hereby grants to ILDONG a royalty bearing, sublicense to use the Licensed Trademark solely for the purpose of registering, using, Commercializing, importing, exporting, selling, offering for sale, and having sold the Product in the Field in the Territory on the terms and subject to the conditions set forth in this Agreement.

* Confidential material redacted and filed separately with the Commission.

(c) **Covenants of ILDONG.** ILDONG hereby agrees that all use of the Licensed Trademark by ILDONG, and any goodwill associated with the use of the Licensed Trademark by ILDONG, shall inure to the benefit of SUBLICENSOR. ILDONG hereby agrees that nothing in this Agreement shall give ILDONG any right, title or interest in the Licensed Trademark other than the right to use the Licensed Trademark in accordance with this Agreement. ILDONG further agrees that it will not: (i) oppose or assist any Third Party in opposing any application for registration, re-registration or renewal of the Licensed Trademark; ii) apply for or otherwise seek (or assist any Third Party in applying for or otherwise seeking) complete or partial revocation, cancellation, invalidation or removal of the Licensed Trademark from any register or (iii) challenge or bring (or assist any Third Party in challenging or bringing) any proceeding or action in relation to the use or ownership of the Licensed Trademark.

(d) **Registration of Licensed Trademark.** SUBLICENSOR shall have the sole right to apply for registration of the Licensed Trademark in the Territory to the extent such registration has not already been obtained by SUBLICENSOR at the Effective Date and for paying all applicable fees, including all registration and application fees and renewal fees. SUBLICENSOR shall update attached the Schedule 7 for ILDONG's use of the Licensed trademarks in the Territory prior to the NDA in each country..

(e) **Use of Licensed Trademark.** ILDONG shall use the Licensed Trademark solely (i) in the manner specified in this Agreement and (ii) in connection with the Product and not for any other goods or services. ILDONG agrees not to use any other trademark or service mark in combination with the Licensed Trademark without the prior written consent of SUBLICENSOR. ILDONG, at its sole cost and expense, will provide to SUBLICENSOR representative samples of all products, product packaging, literature, brochures, signs, and advertising materials prepared by ILDONG which bear, display, or include any reference to the Licensed Trademark, and ILDONG shall obtain the written approval of SUBLICENSOR with respect to all such materials prior to the use thereof. ILDONG will not distribute or otherwise use any samples or materials or other media bearing or displaying the Licensed Trademark unless and until SUBLICENSOR has notified ILDONG in writing of SUBLICENSOR's approval, which approval shall not be reasonably withheld.

(f) **Notice.** ILDONG shall promptly notify SUBLICENSOR (i) of any claim, threat, lawsuit, filing, or other notice or allegation of infringement of which it is aware regarding ILDONG's use of the Licensed Trademark and/or (ii) if it becomes aware of the existence of any Third Party applications to register anywhere in the world any mark or name which consists of or incorporates the Licensed Trademark. SUBLICENSOR shall have the sole right, but not the obligation, to bring infringement, unfair competition, or other claims or proceedings involving the Licensed Trademark and ILDONG hereby acknowledges and agrees that it shall have no such right. If requested by SUBLICENSOR, ILDONG shall cooperate with SUBLICENSOR in connection with any such action.

2.2 **Right to Sublicense.**

2.2.1 Sublicense. ILDONG shall have the right to grant sublicenses under the licenses granted to it under Section 2.1.1 to any Sublicensee; with SUBLICENSOR prior written notification provided, that, (a) the terms of each such sublicense shall be consistent with the rights and obligations of ILDONG under the Agreement; (b) it shall be a condition of any such sublicense that such Sublicensee agrees to be bound by the terms of this Agreement applicable to the Development and Commercialization of Products in the Field in the Territory; (c) ILDONG shall provide SUBLICENSOR with a copy of any such Sublicense Agreement within ten (10) days of the execution of each such Sublicense Agreement; and (d) ILDONG shall not be relieved of its obligations pursuant to this Agreement as a result of such sublicense, except to the extent such obligations are satisfactorily performed by any such sublicense.

2.2.2 Grant of Rights to Distributors. ILDONG or any of its Affiliates and Sublicensees shall have the right, with SUBLICENSOR prior written notification, to appoint one or more Distributors for Products in the Territory. ILDONG shall provide SUBLICENSOR with a copy of each such agreement with any Distributor within ten (10) days of execution of such agreement.

2.3 **No Other Rights.**

2.3.1 ILDONG shall have no rights to use or otherwise exploit Licensed Technology, Licensed Patent Rights, or SUBLICENSOR Proprietary Materials, and SUBLICENSOR shall have no rights to use or otherwise exploit ILDONG Technology, ILDONG Patent Rights or ILDONG Proprietary Materials, in each case, except as expressly set forth in this Agreement.

2.4 **Exclusivity.**

2.4.1 Exclusivity Obligation. During the Term of this Agreement, ILDONG shall not, and shall cause each of its Affiliates to not, conduct any activity, either on its own, or with, for the benefit of, or sponsored by, any Third Party, that, in any case, involves the research, development or commercialization of any other anti CD 20 monoclonal antibody, or any compound that embodies or is derived from any anti CD 20 monoclonal antibody, for use in the Field that is competitive with or adversely affects the Development or Commercialization of any of the Compounds or Products, except hereunder in connection with the research, Development and/or the Commercialization of the Compounds and Products. Notwithstanding the foregoing, at ILDONG's request, SUBLICENSOR may allow ILDONG to Develop and Commercialize all combinations with the Compounds and Products which would be benefit in improving the Development and/or the Commercialization of the Compounds and Products, such consent to not be unreasonably withheld.

2.4.2 Competitive Program Transaction.

(a) Notice. If at any time during the Term, ILDONG grants a sublicense or other rights to any Third Party to utilize any Technology or Patent Rights Controlled by ILDONG or any of its Affiliates for the Development or Commercialization of any of the Compounds or Products, or ILDONG undergoes a Change of Control, or if ILDONG or any of its Affiliates acquires all or substantially all of the assets or common stock of a Third Party (whether by asset or stock purchase, merger, consolidation, share exchange or other similar transaction) and, in any such case, such Third Party or any of such Third Party's Affiliates (in the case of a Third Party Sublicensee or a Third Party acquirer of ILDONG), has a Competitive Program (a "**Competitive Program Transaction**"), ILDONG shall provide SUBLICENSOR with prompt written notice describing such Competitive Program Transaction in reasonable detail which shall include a description of the nature of such Competitive Program (the "**Competitive Program Transaction Notice**"). Such Competitive Program Transaction Notice shall be provided by ILDONG prior to execution of such agreement, if permitted under Applicable Laws and not prohibited by the terms of any agreement between ILDONG or any of its Affiliates and any Third Party, and otherwise as soon as practicable thereafter and, in any event, not later than promptly following the consummation of the transaction contemplated by such agreement.

(b) Meeting of the Parties. As soon as practicable following SUBLICENSOR'S receipt of any Competitive Program Transaction Notice, the Parties shall meet to discuss whether, notwithstanding any provision hereof, such Competitive Program would continue following such Competitive Program Transaction. In any such meeting the Parties will review any restrictions applicable to such Competitive Program that may prevent its combination with this Agreement, and other issues that may impact the potential combination of such Competitive Program with this Agreement.

(c) Integration of Competitive Program. If ILDONG and SUBLICENSOR mutually agree that such Competitive Program may be integrated into this Agreement, then within * (*) days after such determination the Parties shall agree upon an amendment to this Agreement that will provide either (X) (i) that each compound or product that is part of the Competitive Program would be deemed to be a Compound, whether or not such compound or product meets the standards or criteria hereunder for a Compound and (ii) the Parties' rights and obligations under this Agreement will apply in all relevant respects to any such deemed Compounds (including the payment of the milestones, and royalties set forth in this Agreement) or (Y) that the Development and Commercialization diligence standards of this Agreement shall be revised to ensure that the effort and resources that the Third Party applies (or ILDONG, if ILDONG is the surviving entity) applied to the Competitive Program shall be equally applied to the Development and Commercialization of the Compounds and Products.

(d) Termination/Divesting of Competitive Program. If the Parties are unable to reach agreement on the terms pursuant to which the integration of any Competitive Program into this Agreement would occur, ILDONG shall have an additional * (*) days during which it shall determine whether to (i) terminate the Competitive Program or (ii) Divest itself of the Competitive Program. If ILDONG notifies SUBLICENSOR in writing that it will terminate such Competitive Program, ILDONG shall promptly terminate such Competitive Program as quickly as possible with due regard for patient safety and the rights of any subjects that are participants in any clinical studies relating to such Competitive Program and Applicable Laws, and in any event within * (*) days after its delivery of such written notice to SUBLICENSOR. If ILDONG notifies SUBLICENSOR in writing that it will Divest itself of the Competitive Program, then it shall do so as promptly as practicable but in any event on or before * (*) months from the date of such notice; provided, that, during the period during which such Divestiture is pending, ILDONG shall maintaining separate teams working on such Competitive Program and this Agreement. If ILDONG does not notify SUBLICENSOR in writing at the conclusion of the * (*) day period provided above that ILDONG will terminate or Divest itself of such Competitive Program, or if ILDONG does so notify SUBLICENSOR but fails to terminate or Divest the Competitive Program within the periods provided above, SUBLICENSOR shall have the right to immediately terminate this Agreement by providing written notice to ILDONG.

* Confidential material redacted and filed separately with the Commission.

3. DEVELOPMENT OF PRODUCTS

For the sake of clarity, in this Section 3, ILDONG means ILDONG, and where applicable, its Affiliates, Sublicensees, and Distributors.

3.1 Development Program.

3.1.1 Objective of Development Program. The objective of the Development Program shall be the Development by ILDONG, in conjunction with the Development activities of the SUBLICENSOR, of the Compounds and Products in the Field in order to obtain Marketing Authorization for such Products in the Field in the Territory as promptly as practicable.

3.1.2 Responsibility for Development. ILDONG shall have the sole right and responsibility for, and shall have full control and authority over, at its sole cost and expense (including without limitation all costs attributable to the supply of Product for the conduct of Clinical Trials), the Development of Products in the Territory, including conducting all Development activities (including bridging study(ies), if such study(ies) are necessary due to regulatory gaps) beyond the Development activities being conducted by the SUBLICENSOR outside of the Territory (which should be supportive of obtaining Marketing Authorization by the FDA and/or EMA, but may or may not be sufficient to support the obtaining of Marketing Authorization in the Territory) and establishing the methods and means by which it performs such activities under this Agreement. Should ILDONG, for any regulatory filing, desire to utilize data from any clinical trials or studies conducted in indications outside *, *, *, and *, which have been fully funded by the SUBLICENSOR, ILDONG shall pay to the SUBLICENSOR *% of the full cost of the trial which produced such data. ILDONG shall have the right to engage Third Party contractors to perform any of its Development activities in the Territory, provided such Third Party contractors are approved by SUBLICENSOR, such approval not to be unreasonably withheld, and subject to the execution by each such Third Party contractor of an agreement containing provisions that are consistent with and comparable in scope to, Articles 7 and 8 of this Agreement.

* Confidential material redacted and filed separately with the Commission.

3.2 Development Diligence.

ILDONG, and/or its Affiliates, Sublicensees, and Distributors shall use Commercially Reasonable Efforts during the Term to commit such resources (including employees, consultants, contractors, facilities, equipment and materials) as may be required to support the obtaining of Market Authorization in the Territory as further described in 3.1.2.

3.3 Preparation of Development Plan.

A Development Plan in the Territory shall be prepared by ILDONG for each Product and discussed with the SUBLICENSOR for its information and clinical development and manufacturing planning purposes no less than annually after the Effective Date. During the period commencing on and after such date and continuing for the remainder of the Term, each party shall prepare and provide to the other party additional Development Plans detailing any amendments, modifications and/or updates to any existing Development Plan, within thirty (30) days of the end of each Calendar Year. ILDONG shall seek health authority scientific advice to determine the pivotal studies deemed necessary for product registration in the Territory at the earliest possible time. The advice received should be reflected in updated Development Plans. In the event of any conflict between the terms of the Development Plan and the terms and conditions of this Agreement, the terms and conditions of this Agreement shall prevail..

3.4 Compliance.

The Parties shall perform their activities under the Development Program in good scientific manner and in compliance in all material respects with all Applicable Laws. For purposes of clarity, with respect to each Development activity performed that will or would reasonably be expected to be submitted to a Regulatory Authority in support of a Regulatory Filing or Drug Approval Application, ILDONG shall not willfully fail to comply in all material respects with GLPs, GMPs or Good Clinical Practices (or, if and as appropriate under the circumstances, International Conference on Harmonization (“ICH”) guidance or other comparable regulation and guidance of any Regulatory Authority in the Territory).

3.4.1 Records; Reports. ILDONG and/or its Affiliates, Sublicensees, and Distributors shall (a) maintain records of its activities under the Development Program in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes, which shall fully and properly reflect all work performed and results achieved in the performance of the Development Program and (b) ILDONG shall keep SUBLICENSOR regularly informed of the progress of its efforts to Develop Products in the Territory. To facilitate such progress updates, each Party shall provide the other Party with an annual development report (each, a “Development Report”) (to be delivered with each annual update to the Development Plan) that summarizes: (a) significant Development activities conducted during the preceding Calendar Year and results obtained with respect to Compounds and Products (including the status of all Clinical Trials), (b) Significant Development Events applicable to the Compounds and/or Products, (c) a summary of all Program Technology conceived or reduced to practice by the Parties over such period, (d) a non-binding estimate of the expected timing of any milestone events with respect to Products and (e) such other information that each Party has in its possession as may be reasonably requested from time to time by the other party. The Development Plan and each Development Report shall be deemed Confidential Information. Following the commencement of Commercialization, Development Reports will no longer be required and will be replaced by the annual Commercialization Report as described in Section 5.8.

3.5 Supply of Compound(s) or Products(s) for Development.

SUBLICENSOR's and ILDONG's rights and responsibilities pertaining to the supply of the Compound or the Product for the Development shall be governed by Section 6 below.

3.6 Use of Proprietary Materials.

From time to time during the Term, either Party (the "**Transferring Party**") may supply the other Party (the "**Recipient Party**") with Proprietary Materials of the Transferring Party for use in the Development Program. In connection therewith, each Recipient Party hereby agrees that (a) it shall not use such Proprietary Materials for any purpose other than exercising its rights or performing its obligations hereunder; (b) it shall use such Proprietary Materials only in compliance with all Applicable Laws; (c) it shall not transfer any such Proprietary Materials to any Third Party without the prior written consent of the Transferring Party, except for the transfer of Products for use in Clinical Trials or as otherwise expressly permitted hereby; (d) the Recipient Party shall not acquire any right, title or interest in or to such Proprietary Materials as a result of such supply by the Transferring Party; and (e) upon the expiration or termination of the Development Program, the Recipient Party shall, if and as instructed by the Transferring Party, either destroy or return any such Proprietary Materials that are not the subject of the grant of a continuing license hereunder.

4. REGULATORY ACTIVITIES

For the sake of clarity, in this Section 4, ILDONG means ILDONG, and where applicable, its Affiliates, Sublicensees and Distributors.

4.1 Responsibility for Regulatory Filings.

Subject to the remainder of this Article 4, (a) ILDONG shall have the sole right and responsibility, at its sole cost and expense, for preparing and filing all Regulatory Filings and Drug Approval Applications, Pricing Approval applications, or Reimbursement Approval applications required to Develop Compounds and Commercialize Products in the Territory in its own name; (b) all Regulatory Approvals for Products shall be solely owned by ILDONG; and (c) ILDONG shall have the sole right and responsibility for (i) maintaining all Regulatory Filings and/or Marketing Authorizations and (ii) reporting to any Regulatory Authority within the Territory all Adverse Events and Serious Adverse Events related to any Product if and to the extent required by Applicable Laws. To maximize market protection of Product, ILDONG may file for any orphan drug designations as appropriate within requisite timeframes prior to the submission of any Marketing Authorization Application. Firstly, within * (*) months following the QA approval of the Study Report of the last Clinical Trial as per the Development Program, ILDONG shall file, or cause to be filed, before the Regulatory Authority (KFDA) in South Korea, all authorization and registration applications required for the promotion, marketing, distribution and sale of Product in South Korea. ILDONG shall exercise Commercially Reasonable Efforts to obtain Marketing Authorizations with respect to the Product. Failure to meet this obligation will be considered a material breach of the Agreement and SUBLICENSOR shall have the right to terminate the Agreement for breach of ILDONG in accordance with Section 11.2.2.

* Confidential material redacted and filed separately with the Commission.

4.2 Disclosure; Right of Access.

Upon request from SUBLICENSOR, ILDONG shall promptly provide SUBLICENSOR with (a) a list of all sites at which Clinical Trials with respect to Products are being conducted by or on behalf of ILDONG; (b) copies of all Clinical Trial protocols and Investigator's Brochures with respect to such Clinical Trials; and (c) access to all data (including non-clinical and Clinical Data), results and information found in ILDONG's regulatory files produced by or on behalf of ILDONG, or any of its Affiliates or Sublicensees, in connection with the conduct by ILDONG of Development activities in its original format, without translation except that translations shall be provided at no charge where such translations are produced in the ordinary course of business. SUBLICENSOR shall maintain the confidentiality of such data, results and information and shall only have the right and license to use such data (including Clinical Data), results and information provided by ILDONG under this Section 4.2 for the performance of its obligations and exercise of its rights under this Agreement,

4.3 Disclosure of Certain Events.

The Parties hereby agree to report to each other all Adverse Events and/or Serious Adverse Events with respect to the Product (whether occurring in any Clinical Trial conducted with regard to the Product or in connection with the commercialization of the Product in any country), within timeframes consistent with its reporting obligations under Applicable Laws and in any event, if either Party is actively conducting a clinical trial under its own IND or commercializing the Product under its own Marketing Authorization, then the other Party shall report such events no later than three (3) business days for Serious Adverse Event, and quarterly for Adverse Events, which report shall, in each case, include the circumstances and nature of such Serious Adverse Event or Adverse Event as required for reporting under Applicable Laws. In addition, to the extent requested by either Party, the other Party shall promptly provide to the requesting Party any other information or materials that the requesting Party may require to provide to any Regulatory Authority with respect to any such Adverse Event or Serious Adverse Event. All disclosures made under this Section 4.3 shall be deemed Confidential Information of the disclosing Party; provided, that, the Party receiving such disclosures may, upon written notice to the disclosing Party, report the occurrence, circumstances and nature of such Adverse Event and/or Serious Adverse Event to any Regulatory Authority solely insofar as such reporting is required to comply with Applicable Laws.

4.4 Communication with Regulatory Authorities in the SUBLICENSOR Commercialization Territory.

4.4.1 Participation in Meetings. ILDONG shall use reasonable efforts to provide SUBLICENSOR with at least thirty (30) days advance notice of any official meeting with a Regulatory Authority regarding any Marketing Authorization for any Product in the SUBLICENSOR Commercialization Territory and SUBLICENSOR may elect to send one (1) person reasonably acceptable to ILDONG to participate as an observer (at SUBLICENSOR'S sole cost and expense) in such meeting.

4.4.2 Access; Notice of Meetings. ILDONG shall use reasonable efforts to provide SUBLICENSOR with at least thirty (30) days' advance notice of any official meeting with Regulatory Authority in the SUBLICENSOR Commercialization Territory regarding any Drug Approval Application for Products and/or any such audit or inspection conducted by any Regulatory Authority at any site at which Clinical Trials with respect to Products are being conducted and SUBLICENSOR may elect to send representatives reasonably acceptable to ILDONG to participate as an observer in such meeting at SUBLICENSOR' sole cost and expense.

5. COMMERCIALIZATION OF PRODUCTS

For the sake of clarity, in this Section 5, ILDONG means ILDONG, and where applicable, its Affiliates, Sublicensees and Distributors.

5.1 Commercialization Plan.

The initial Commercialization Plan in the territory shall be prepared by ILDONG and submitted to SUBLICENSOR for its review as soon as practicable after the submission of the NDA application in South Korea. On and after such date and continuing for the remainder of the Term, additional Commercialization Plans and/or amendments, modifications and/or updates to the Commercialization Plan, shall be prepared by ILDONG and submitted to SUBLICENSOR for its review within thirty (30) days of the end of each Calendar Year.

5.2 Responsibility for Commercialization of Products.

Subject to Section 5.11 below, ILDONG shall have the primary right and responsibility for, and shall have primary control and authority over, at its sole cost and expense, (a) all aspects of the Commercialization of Products in the Field in the Territory including the sole responsibility for booking sales of Product and for all returns, charge-backs and rebates with respect to Products; and (b) the conduct of all pre-marketing, marketing, Branding, promotion, sales, distribution, import and export activities (including securing pricing, reimbursement, sales and marketing and conducting any post-marketing trials or post-marketing safety surveillance and maintaining databases) applicable to the Commercialization of Products in the Field and in the Territory.

5.3 Commercialization Diligence.

ILDONG shall use Commercially Reasonable Efforts during the Term to Commercialize Products for all approved Indications in the Field and in the Territory. Without limiting the foregoing, (a) commencing no later than * (*) days prior to the estimated date of First Commercial Sale of the Product, ILDONG shall conduct pre-marketing activities in the Territory with respect to the Product and (b) following receipt of Marketing Authorization with respect to the Product in the Territory, ILDONG shall initiate and conduct such promotional activities determined by ILDONG as may be required to develop a commercial market for, launch and Commercialize the Product (including through direct conduct with key opinion leaders) in the Territory. In addition, ILDONG, shall establish and maintain a well-trained sales force for the Product, (together with a well-trained support staff) adequate to service all the customers of ILDONG and to keep the sales force knowledgeable and fully informed as to the Product; maintain an effective distribution system for the Product in the Territory; transport and store the Product to preserve its quality in accordance with pre-determined QA requirements; obtain and maintain all licenses, approvals and permits in the Territory necessary for ILDONG to perform its obligations under this Agreement; establish and maintain suitable systems and records to enable a recall of Product in a timely, efficient and accurate manner and otherwise in accordance with applicable laws and regulations in the Territory; abide by all applicable rules and regulations relating to sales, marketing and reimbursement; ensure that no Product shipped by ILDONG is adulterated or misbranded; maintain adequate control over the physical security of the Product; Cause all Affiliates, sublicensees and subcontractors of ILDONG to comply with the above.

5.4 Failure to Satisfy Commercialization Diligence Obligations.

SUBLICENSOR shall have the right, in its sole discretion, to provide ILDONG with written notice if it reasonably believes ILDONG has failed to satisfy its Commercialization diligence obligations under this Agreement (a “**ILDONG Diligence Failure**”). Such written notice (a “**Diligence Failure Notice**”) shall set forth in reasonable detail the nature of the alleged failure and shall request written justification, in the form of detailed reasons that would support the proposition that ILDONG has satisfied such diligence obligations. ILDONG shall provide such written justification to SUBLICENSOR within thirty (30) days after receipt of such Diligence Failure Notice and shall identify any Commercially Reasonable Justifications (as defined below) applicable thereto. If ILDONG fails to provide SUBLICENSOR with a Commercially Reasonable Justification within such thirty (30) day period ILDONG shall have an additional (90) day period to cure such failure. During that period a penalty equal to the * shall accrue on a monthly basis, to the benefit of SUBLICENSOR. Should ILDONG’s failure continue within this additional period, ILDONG shall continue to pay the penalty abovementioned and SUBLICENSOR reserves the right in its discretion to, in addition to all damages caused in relation thereof, convert the licenses and rights granted under any or all of Section 2.1 from exclusive licenses to non-exclusive licenses only as such licenses and rights apply to such Product. Should ILDONG’s failure continue within an additional hundred eighty (180) day period, ILDONG shall continue to pay the penalty abovementioned and SUBLICENSOR reserves the right in its discretion to, in addition to any other remedies it may have as a result of all damages caused in relation thereof, terminate any or all of the licenses and rights granted under Section 2.1 hereof with respect to the Product that is the subject of the Diligence Failure Notice termination or conversion, as the case may be, shall be at the discretion of SUBLICENSOR and be effective immediately upon issuance by SUBLICENSOR of written notice to ILDONG specifying the remedy that SUBLICENSOR is electing to exercise under this Section 5.4.

* Confidential material redacted and filed separately with the Commission.

For purposes of this Section 5.4, “**Commercially Reasonable Justification**” means the existence or occurrence of one or more of the following events or justifications: (i) the occurrence of an event of Force Majeure; (ii) the adoption by a Regulatory Authority of any one or more regulations that become effective after the Effective Date and that materially affect the Development or clinical testing of the Product or the process for obtaining any Regulatory Approval, Pricing Approval, or Reimbursement Approval for the Product; and (iii) the occurrence of any event, condition or circumstance (including an event, condition or circumstance related to the manufacture or supply of the Product (or any material component thereof) for clinical studies or a regulatory action by any Regulatory Authority) with respect to the Product (or any material component thereof) that (A) involves the safety, toxicity, efficacy or pharmacokinetics of the Product or (B) prevents the use of the Product in humans (including, without limitation, as a result of patent or other blocking rights) and, in the case of clauses (A) or (B) above, is not attributable to (1) a breach by ILDONG of any obligation under this Agreement, (2) the failure of ILDONG to comply with any protocol, development plan or Applicable Laws with respect to the development of the Product, or (3) any grossly negligent or willful act or omission of ILDONG; or (C) that the ILDONG Diligence Failure is caused by ILDONG’s failure to take actions that would be in excess of Commercially Reasonable Efforts; provided, that, in any such case, ILDONG shall use Commercially Reasonable Efforts to mitigate the effect and duration of any such acceptable delay with respect to the Product that is the subject of the Diligence Failure Notice.

5.5 **Failure to achieve Sales Targets**

5.5.1 Initial Period. For the * following the date of First Commercial Sale (the "Initial Period") ILDONG shall achieve the Sales Target. If ILDONG fails to achieve * percent (*%) of the Sales Target by completion of the Initial Period, ILDONG shall, within * (*)*, pay to SUBLICENSORS a sum equal to the *. For purposes of this Agreement, “Commercial Years” means the period commencing on the date of First Commercial Sale of a Product and ending on the anniversary thereof and thereafter each successive period of twelve (12) months.

5.5.2 Subsequent Periods. For Commercial Years subsequent to the Initial Period ILDONG shall achieve the Sales Target. If ILDONG fails to achieve * percent (*%) of the Sales Target for any Commercial Year subject to the Initial Period, ILDONG shall, within * pay to SUBLICENSOR a sum equal to the *.

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In addition to the above, if ILDONG fails to achieve * percent (*%) of the Sales Target for *, SUBLICENSOR shall have the right to terminate this Agreement with respect to each country within the Territory where * were not achieved. In the case where SUBLICENSOR exercises its rights to terminate this Agreement, SUBLICENSOR shall provide * (*) months prior notice of termination and purchase back any Product stock held by ILDONG valued at the commercial price. If during the above mentioned * month period, ILDONG achieves * for such six-month period, then ILDONG shall be deemed to have cured the breach and the termination shall be null and void.

5.6 Compliance.

ILDONG shall use its Commercially Reasonable Efforts to Commercialize the Products in compliance in all material respects with all Applicable Laws.

5.7 No Unauthorized Sales.

ILDONG shall not, and shall not permit its Affiliates and not permit Sublicensees or Distributors to, distribute, market, promote, offer for sale or sell the Product to any Third Party in any country in the Territory that ILDONG, or its Affiliates, Sublicensees or Distributors, as applicable, reasonably believes is reasonably likely to engage in an unauthorized distribution, marketing, promotion, or sale of the Product outside the country of purchase.

5.8 Records; Reports.

ILDONG shall (a) maintain records of its Commercialization activities under this Article 5 in sufficient detail, which shall fully and properly reflect all work done and results achieved in the Commercialization of Products and (b) following the commencement of Commercialization of the Products provide SUBLICENSOR with annual written reports (each, a “**Commercialization Report**”) which shall (i) summarize ILDONG’s efforts to Commercialize Products, (ii) identify the Regulatory Filings and Drug Approval Applications with respect to such Product that ILDONG or any of its Affiliates or Sublicensees have filed, sought or obtained in the prior twelve (12) month period or reasonably expect to make, seek or attempt to obtain in the following twelve (12) month period and (iii) summarize all Clinical Data generated by ILDONG with respect to Products. Commencing no later than ninety (90) days from the date of receipt by ILDONG of the first Marketing Authorization for each Product and on each anniversary thereof until the expiration of the Royalty Term applicable to such Product, each such Commercialization Report shall also include (i) an outline of the key sales and marketing activities that ILDONG reasonably expects to conduct with respect to Product in the Territory, (ii) a non-binding estimate of projected sales of Product in the Territory for the subsequent three (3) Calendar Year period and (iii) such additional information that it has in its possession as may be reasonably requested by SUBLICENSOR regarding the Commercialization of any Product, which request shall not be made more than once each Calendar Year. The Commercialization Plan and Commercialization Report can be provided as one document.

* Confidential material redacted and filed separately with the Commission.

5.9 Supply of Product for Commercialization.

SUBLICENSOR's and ILDONG's rights and responsibilities pertaining the supply of the Compound for the Commercialization shall be governed by Section 6 below.

5.10 Product Recalls.

In the event that any Regulatory Authority issues or requests a recall or takes similar action in connection with a Product in the Territory, or in the event ILDONG reasonably believes that an event, incident or circumstance has occurred that may result in the need for a recall, market withdrawal or other corrective action regarding a Product in the Territory (each, a "**Recall**"), ILDONG shall promptly advise SUBLICENSOR thereof by e-mail, telephone or facsimile. Following such notification, ILDONG shall have the sole right to decide, and have control of, whether to conduct a recall or market withdrawal (except in the event of a recall or market withdrawal mandated by a Regulatory Authority, in which case it shall be required) or to take other corrective action in the Territory and the manner in which any such recall, market withdrawal or corrective action shall be conducted; provided, that, ILDONG shall keep SUBLICENSOR reasonably informed regarding any such Recall. All expenses incurred by ILDONG in connection with any such Recall (including, without limitation, expenses for notification, destruction and return of the affected Product and any refund to customers of amounts paid for such Product) shall be the sole responsibility of ILDONG.

6. SUPPLY OF THE COMPOUND AND/OR PRODUCT

6.1 Supply of LFB-R603 for Development and Commercialization.

SUBLICENSOR shall use its Commercially Reasonable Effort to provide supply of LFB-R603 as required for the Development and Commercialization of LFB-R603 when and as required by ILDONG for the Development of Products in the Territory. All supplies of Compound and Product for Clinical Trials supplied by SUBLICENSOR shall be billed to ILDONG at a cost equal to *.

For sake of clarity, SUBLICENSOR and its affiliates shall have the exclusive right and responsibility to provide supply of LFB-R603 as required for Development and Commercialization in the Territory.

* Confidential material redacted and filed separately with the Commission.

6.2 Supply of TG20 for Development and Commercialization.

Provided that TG20 has satisfactorily completed non-clinical development, as defined by the acceptance of an IND by the US FDA, SUBLICENSOR shall use its Commercially Reasonable Effort to provide supply of TG20 as required for the Development and Commercialization of TG20 when and as required by ILDONG for the Development and Commercialization of Products in the Territory. All supplies of Compound and Product for Clinical Trials supplied by SUBLICENSOR shall be billed to ILDONG at a cost equal to *.

For sake of clarity, SUBLICENSOR and its affiliates shall have the exclusive right and responsibility to provide supply of TG20 as required for Development and Commercialization in the Territory. Nothing in this section shall be construed as an obligation on the part of SUBLICENSOR to continue the development of TG20.

Upon the approval of the first Drug Approval Application by ILDONG within any country within the Territory and the subsequent determination of the National Health Insurance (“NHI”) price, the parties will enter into a Commercial Supply Agreement which shall be attached in Exhibit B as soon as it is executed by the Parties and which shall include such customary terms of such agreements and shall include the payment by ILDONG to SUBLICENSOR at a transfer price not to exceed *% of the NHI price obtained by the relevant health authority including margin for Cost of Goods manufactured, such that such supply price is not below *. In the event that commercial supply price to ILDONG exceeds *% of the NHI price, the Parties agree to renegotiate the Sales Royalty Rates outlined in Section 7.3 in good faith. For the sake of clarity, in no way shall SUBLICENSOR provide commercial supply to ILDONG at a price that is below *.

7. PAYMENTS

7.1 Upfront Payment.

In consideration for the rights granted to ILDONG hereunder, ILDONG hereby agrees to pay to SUBLICENSOR a non-refundable, non-creditable license fee of two million dollars (USD \$2,000,000) within thirty (30) calendar days after the Effective Date.

7.2 Sales Milestones.

7.2.1 Sales Milestones. ILDONG shall make the following non-refundable, non-creditable milestone payments to SUBLICENSOR upon the occurrence of each of the following milestone events for the first Product that achieves the corresponding Net Sales milestone for the first time in the combined territory of South Korea and Taiwan:

* Confidential material redacted and filed separately with the Commission.

	Milestone Event	Milestone Payment
1.	On achieving annual Net Sales of USD \$*	\$*
2.	On achieving annual Net Sales of USD \$*	\$*
3.	On achieving annual Net Sales of USD \$*	\$*
4.	On achieving annual Net Sales of USD \$*	\$*

7.2.2 Notice and Payment of Milestones.

(a) **Notice of Milestone Events.** ILDONG shall provide SUBLICENSOR with prompt written notice upon the occurrence of each milestone event set forth in Section 7.2.1. In the event that, notwithstanding the fact that ILDONG has not given such a notice, SUBLICENSOR believes any such milestone event has occurred, it shall so notify ILDONG in writing and shall provide to ILDONG data, documentation or other information that supports its belief. Any dispute under this Section 7.2.2(a) that relates to whether or not a milestone event has occurred shall be resolved in accordance with Section 14.1.

(b) **Single Milestone Payments.** ILDONG shall make a milestone payment corresponding to each of the foregoing milestone events only once under Section 7.2.1, regardless of (i) the number of Products that achieve such milestone event and (ii) the number of times such milestone event occurs with respect to a Product. For the sake of clarity, each milestone event shall only trigger one milestone payment.

7.3 Payment of Royalties; Royalty Rates; Accounting and Records.

7.3.1 Payment of Royalties. Subject to the remainder of this Section 7.3, ILDONG shall pay SUBLICENSOR a non-refundable, non-creditable royalty on Annual Net Sales of the Product. The rate of such royalty being determined by the amount of Annual Net Sales as described below:

Annual Net Sales	Royalty Rate
Up to \$* USD	*%
Between \$* and \$* USD	*%
Between \$* and \$* USD	*%
Exceeding \$* USD	*%

* Confidential material redacted and filed separately with the Commission.

The royalty rate shall be applied to Annual Net Sales of each Product in each Calendar Year (or partial Calendar Year) commencing with the First Commercial Sale of such Product in any country in the Territory and ending upon the last day of the last Royalty Term for such Product in such country. For purposes of clarity, Annual Net Sales shall be determined separately for each separate Product that is sold in a given Calendar Year.

7.3.2 Adjustments to Royalties for Generic Products. In the event that a Third Party sells a Generic Product (as defined below) in a country in which a Product is then being sold and such Generic Product is not covered by a Valid Claim under the Licensed Patent Rights or ILDONG Program Patent Rights in such country, then during the period in which sales of the Generic Product by such Third Party are equal to at least * percent (*%) of ILDONG's volume-based market share of the Product in such country (as measured by prescriptions or other similar information available in such country), the royalty rate applicable to Net Sales of the Product in such country shall be reduced to * percent (*%). Notwithstanding the foregoing, ILDONG's right to reduce its royalty obligation under this Section 7.3.3(1) shall expire on the first day of the Calendar Quarter immediately following the Calendar Quarter in which sales of such Generic Product account for less than * percent (*%) of ILDONG's volume-based market share of the Product in such country (as measured by prescriptions or other similar information available in such country). For purposes of this Section 7.3.3), a "**Generic Product**" means a biosimilar product with the same amino acid sequence as the Compound.

7.3.3 Payment Dates and Reports. Royalty Payments. Royalty payments shall be made by ILDONG with respect to each Product within thirty (30) calendar days after the end of each Calendar Quarter in which sales of such Product occur, commencing with the Calendar Quarter in which the First Commercial Sale of such Product occurs. ILDONG shall also provide, at the same time each such payment is made, a report showing: (a) the Net Sales of each Product by type of Product and country in the Territory and, if applicable, by Combination Product; (b) the total amount of deductions from gross sales to determine Net Sales; (c) the applicable royalty rate for Product in each country in the Territory after applying any reductions set forth above; and (d) a calculation of the amount of royalty due to SUBLICENSOR.

* Confidential material redacted and filed separately with the Commission.

7.3.4 Records; Audit Rights. ILDONG and its Affiliates, Sublicensees and Distributors shall keep and maintain for three (3) years from the date of each payment of royalties hereunder complete and accurate records of gross sales and Net Sales by ILDONG and its Affiliates, Sublicensees and Distributors of each Product, in sufficient detail to allow royalties to be accurately determined. SUBLICENSOR shall have the right for a period of three (3) years after receiving any such royalty payment to appoint at its expense an independent certified public accountant reasonably acceptable to ILDONG to audit the relevant records of ILDONG and its Affiliates, Sublicensees and Distributors to verify that the amount of each such payment was correctly determined; provided, that, (a) if requested by ILDONG, SUBLICENSOR shall cause the independent certified public accountant to enter into a confidentiality agreement reasonably acceptable to ILDONG and (b) such independent certified public accountant may only disclose to SUBLICENSOR whether the royalties paid are correct and the details with respect to any discrepancies. ILDONG and its Affiliates, Sublicensees and Distributors shall each make its records available for audit by such independent certified public accountant during regular business hours at such place or places where such records are customarily kept, upon thirty (30) days written notice from SUBLICENSOR. Such audit right shall not be exercised by SUBLICENSOR more than once in any Calendar Year or more than once with respect to sales of a particular Product in a particular period. All records made available for audit shall be deemed to be Confidential Information of ILDONG. The results of each audit, if any, shall be binding on both Parties absent manifest error. In the event there was an underpayment of royalties by ILDONG hereunder, ILDONG shall promptly (but in any event no later than thirty (30) days after ILDONG's receipt of the report so concluding) make payment to SUBLICENSOR of any shortfall. SUBLICENSOR shall bear the full cost of such audit unless such audit discloses an underpayment by ILDONG of * percent (*%) or more of the aggregate amount of royalties payable in any Calendar Year, in which case ILDONG shall reimburse SUBLICENSOR for all costs incurred by SUBLICENSOR in connection with such audit.

7.3.5 Overdue Payments. All royalty payments not made within the time period set forth in Section 7.3.5, and all milestone payments not made within the time period specified in Section 7.2.1, shall bear interest at the rate of * percent (*%) per month until paid in full or, if less, the maximum interest rate permitted by Applicable Laws. Any such overdue royalty or milestone payment shall, when made, be accompanied by, and credited first to, all interest so accrued.

7.3.6 Payments; Withholding Tax; Currency Restrictions.

(a) **Payments in United States Dollars.** Except as set forth in Section 6.3.7(b) below, all payments made by ILDONG under this Article 6 shall be made by wire transfer in United States Dollars in accordance with wire transfer instructions provided to ILDONG in writing from time to time by SUBLICENSOR. If in any Calendar Quarter, Net Sales are made in any currency other than United States Dollars, such Net Sales shall be converted into United States Dollars as follows:

(A/B), where

A = foreign "Net Sales" (as defined above) in such Calendar Quarter expressed in such foreign currency; and

B = foreign exchange conversion rate, expressed in local currency of the foreign country per United States Dollar (using, as the applicable foreign exchange rate, the spot purchase rate published in the *Financial Times* on the last Business Day of each Calendar Quarter in which any payment is due and payable or any other mutually agreed upon source, for such Calendar Quarter).

* Confidential material redacted and filed separately with the Commission.

(b) **Tax Withholding.** If Applicable Laws require withholding of income or other taxes imposed upon any payments made by ILDONG to SUBLICENSOR under this Agreement, ILDONG shall (i) make such withholding payments as may be required, (ii) subtract such withholding payments from such payments to be made to SUBLICENSOR, (iii) submit appropriate proof of payment of the withholding taxes to SUBLICENSOR within a reasonable period of time, and (iv) promptly provide SUBLICENSOR with all official receipts with respect thereto.

(c) **Currency Restrictions.** If any restrictions on the transfer of currency exist in any country in which Products are sold that prevent ILDONG from making royalty payments thereon in United States Dollars, ILDONG shall make royalty payments on the sales in such country in the local currency by deposit in a local bank or other depository designated in writing by SUBLICENSOR (or, in the absence of such designation, at a local bank or other depository selected by ILDONG and identified by ILDONG by written notice to SUBLICENSOR).

8. TREATMENT OF CONFIDENTIAL INFORMATION; PUBLICITY

8.1 Confidentiality.

8.1.1 Confidentiality Obligations. SUBLICENSOR and ILDONG each recognize that the other Party's Confidential Information and Proprietary Materials constitute highly valuable assets of such other Party. SUBLICENSOR and ILDONG each agrees that, (a) subject to Section 8.1.2, during the Term and for an additional ten (10) years after termination or expiration of this Agreement it will not disclose, and will cause its Affiliates, Sublicensees (with respect to ILDONG) and Distributors or Sublicensees (with respect to SUBLICENSOR) not to disclose whether directly or indirectly, in any manner whatsoever, any Confidential Information or Proprietary Materials of the other Party and (b) it will not use, and will cause its Affiliates, Sublicensees (with respect to ILDONG) and Distributors or Sublicensees (with respect to SUBLICENSOR) not to use, any Confidential Information or Proprietary Materials of the other Party, without the prior written consent of the Disclosing Party, except as expressly permitted hereunder.

8.1.2 Limited Disclosure. SUBLICENSOR and ILDONG each agrees that disclosure of its Confidential Information or any transfer of its Proprietary Materials may be made by the other Party on a need-to-know basis to any employee, consultant or Affiliate of such other Party or, to the extent the other Party is ILDONG, to any Third Party subcontractor engaged by ILDONG pursuant to Section 2.2, in each case solely to the extent reasonably necessary to enable such other Party to exercise its rights or to carry out its responsibilities under this Agreement; provided, that, any such disclosure or transfer shall only be made to Persons who are bound by written obligations comparable in scope to the obligations described in Section 8.1.3. SUBLICENSOR and ILDONG each further agrees that the other Party may disclose its Confidential Information (a) on a need-to-know basis to such other Party's legal and financial advisors, (b) as reasonably necessary in connection with an actual or potential (i) permitted sublicense of such Party's rights hereunder, (ii) debt or equity financing of such other Party or (iii) acquisition, consolidation, share exchange or other similar transaction involving such Party and any Third Party, (c) to the extent the other Party is ILDONG, to any Third Party that is or may be engaged by ILDONG to perform services in connection with the Commercialization of Products as necessary to enable such Third Party to perform such services, (d) as reasonably necessary to make Regulatory Filings with respect to Products under this Agreement or to respond to any inquiry made by any Regulatory Authority with respect to Products and to prosecute or maintain Patent Rights, or to file, prosecute or defend litigation related to Patent Rights, in accordance with this Agreement; (e) as required by Applicable Laws (which shall be determined by the Disclosing Party in its reasonable discretion); provided, that, in the case of any disclosure under this clause (e), the Disclosing Party shall (i) if practicable, provide the other Party with reasonable advance notice of and an opportunity to comment on any such required disclosure and (ii) if requested by the other Party, cooperate in all reasonable respects with the other Party's efforts to obtain confidential treatment or a protective order with respect to any such disclosure, at the other Party's expense.

8.1.3 Employees and Consultants. SUBLICENSOR and ILDONG each hereby covenants and agrees that all of its employees and consultants, and all of the employees and consultants of its Affiliates, who have access to Confidential Information or Proprietary Materials of the other Party will, prior to having such access, be bound by written obligations to maintain such Confidential Information or Proprietary Materials in confidence that are no less stringent than those confidentiality and non-use provisions contained in this Agreement. Each Party agrees to use, and to cause its Affiliates to use, reasonable efforts to enforce such obligations and to prohibit its employees and consultants from using such information except as expressly permitted hereunder. Each Party will be liable to the other Party for any disclosure or misuse by its employees of Confidential Information or Proprietary Materials of the other Party.

8.2 Publicity.

Notwithstanding anything to the contrary in Section 8.1, the Parties, upon the execution of this Agreement, shall jointly issue a press release with respect to this Agreement to be reasonably agreed by the Parties in substantially the form attached hereto as Schedule 6, and either Party may make subsequent public disclosure of the contents of such press release without further approval of the other Party. Subject to the foregoing, except as required by Applicable Laws (including those relating to disclosure of material information to investors), neither Party shall issue a press or news release or make any similar public announcement (it being understood that publication in scientific journals, presentation at scientific conferences and meetings and the like are intended to be covered by Section 8.4 and not subject to this Section 8.2) related to the terms or existence of this Agreement or the conduct of the Development Program or the Commercialization of Products without the prior written consent of the other Party; provided, however, that either Party may make such a disclosure (a) to the extent required by Applicable Laws (including the requirements of any nationally recognized securities exchange, quotation system or over-the-counter market on which such Party has its securities listed or traded), or (b) to any investors, prospective investors, lenders and other potential financing sources who are obligated to keep such information confidential. In the event that such disclosure is required as aforesaid, the disclosing Party shall make reasonable efforts to provide the other Party with notice beforehand and to coordinate with the other Party with respect to the wording and timing of any such disclosure. Once any press release or any other written statement is approved for disclosure by both Parties, either Party may make subsequent public disclosure of the contents of such statement without the further approval of the other Party.

8.3 No Use of Name.

Neither Party shall use the name of the other Party in any Promotional Materials or advertising without the prior express written permission of the other Party.

9. INTELLECTUAL PROPERTY RIGHTS

For sake of clarity, in this Section 9, SUBLICENSOR means SUBLICENSOR and, where applicable, Senior Licensors pursuant to the terms of the LFB/GTC License, certain responsibilities of which may be delegated to Senior Licensors, but for the sake of this Agreement will be overseen by SUBLICENSOR.

9.1 SUBLICENSOR Intellectual Property Rights.

SUBLICENSOR shall have ownership of all right, title and interest, or license to, on a worldwide basis in and to any and all Licensed Technology and Licensed Patent Rights.

9.2 Improvement

9.2.1 ILDONG agrees to notify SUBLICENSOR of each Product Improvement ILDONG, its Affiliates, or its Sublicensees has developed, conceived or acquired during the Term of this Agreement. ILDONG shall, upon request of SUBLICENSOR, provide to SUBLICENSOR all data and specifications concerning such Product Improvement. All Product Improvements shall be deemed to be considered as a "Joint Improvement".

9.2.2 All SUBLICENSOR Improvement shall be the exclusive and sole property of SUBLICENSOR and shall become Background Patent Right or Licensed Patent Rights, as the case may be.

9.3 Joint Improvement

9.3.1 Subject to any other provision to the contrary that may be contained in SUBLICENSOR's Licenses as defined in Section 2.1.1, any Joint Improvement shall be jointly owned by ILDONG and SUBLICENSOR.

- 9.3.2 ILDONG shall have the exclusive, fully paid-up, irrevocable, transferable right to Use such Joint Improvements in order to Develop the Compounds or Products as part of the Development Program and to Commercialize, use, have used, Manufacture, have Manufactured, supply, sell, offer to sell, import, have imported, market, and otherwise Commercialize Products in the Field, within the Territory with the right to sublicense.
- 9.3.3 Each Party has the exclusive, fully paid-up, irrevocable, transferable right to Use such Joint Improvements in order to develop and to commercialize have used, Manufacture, have Manufactured, supply, sell, offer to sell, import, have imported, market, any product other than the Product and Compound.
- 9.3.4 Each Party shall reasonably assist the other in preparing, prosecuting and maintaining Patent Rights for Joint Improvements pursuant to section 9.4; 9.5 and 10.

9.4 Patent Coordinators.

Each Party shall, by written notice to the other Party, appoint a patent coordinator reasonably acceptable to the other Party (each, a “Patent Coordinator”) to serve as such Party’s primary liaison with the other Party on matters relating to the filing, prosecution, maintenance and enforcement of Patent Rights. Each Party may replace its Patent Coordinator at any time by notice in writing to the other Party. The initial Patent Coordinators shall be:

For SUBLICENSOR: Hari Miskin

For ILDONG:

9.5 Notice; Inventorship.

The Parties hereby agree to promptly notify to the other Party, through the Patent Coordinators, of the conception or reduction to practice of any Program Technology or Joint-Improvement and to promptly execute any documents that may be necessary to perfect SUBLICENSOR’s rights in and to such Program Technology or Joint-Improvement. The Patent Coordinators shall determine inventorship of Program Technology or Joint-Improvement under U.S. patent law. In case of a dispute between the Patent Coordinators over inventorship and, as a result, whether any particular Technology is SUBLICENSOR Technology or Joint Improvement, such dispute shall be resolved according to U.S. patent law by patent counsel selected by the Patent Coordinators who (and whose firm) is not at the time of the dispute, and was not at any time during the five (5) years prior to such dispute, performing services for either of the Parties. Expenses of such patent counsel shall be shared equally by the Parties.

10. FILING, PROSECUTION AND MAINTENANCE OF PATENT RIGHTS

10.1 Patent Filing, Prosecution and Maintenance.

10.1.1 SUBLICENSOR Prosecution Rights. SUBLICENSOR shall have the sole right and responsibility to prepare and file applications with respect to, and prosecute and maintain, at its sole discretion, and using patent counsel or agents of its choice, all Licensed Patent Rights (including all Joint Patent Rights that are Licensed Patent Rights) throughout the Territory. ILDONG shall cooperate with and assist SUBLICENSOR in all reasonable respects, in connection with SUBLICENSOR's preparation, filing, prosecution and maintenance of Licensed Patent Rights.

10.1.2 ILDONG Prosecution Rights. ILDONG shall have the sole right and responsibility to prepare and file applications with respect to, and prosecute and maintain, at its sole cost, expense and discretion, and using patent counsel or agents of its choice, all ILDONG Program Patent Rights throughout the Territory. SUBLICENSOR shall cooperate with and assist ILDONG in all reasonable respects, in connection with ILDONG's preparation, filing, prosecution and maintenance of ILDONG Program Patent Rights.

10.1.3 Joint Patent Rights. Subject to Section 10.1.1, within ten (10) Business Days after it is determined pursuant to Section 9.5 that any particular Program Technology is Joint Improvement, the Parties will determine which Party will undertake the prosecution of such Joint Patent Rights based on the respective expertise of the Parties and the rights of the Parties under this Agreement. If the Parties fail to agree within such ten (10) Business Day period, then prosecution of such Patent Rights shall be jointly controlled by the Parties, using patent counsel agreed upon by the Patent Coordinators. All patent costs and expenses incurred by a Party or jointly by the Parties in connection with the preparation, filing, prosecution and maintenance of Joint Patent Rights in the Territory that cover any Product for use in the Field shall be shared equally by the Parties. Provided however that, if a Party refuses, declines or fails to assume its obligations under this section 11.1.2, it shall advise the other Party and said other Party shall have the right, at its own expense, to prepare, prosecute and maintain Patent Rights for Joint Improvements. In such a case, upon request of the non-defaulting Party, the Party that refuses, declines or fails to file, prosecute or maintain any such Patent Rights for Joint Improvements shall assign all its co-ownership rights to the other Party.

10.1.4 Information and Cooperation. The Parties hereby agree to cooperate with each other in connection with the filing, prosecution and maintenance of Patent Rights under this Agreement, including through the prompt execution and delivery of documents and instruments as may reasonably be required in connection therewith. Without limiting the foregoing, each Party responsible for the filing, prosecution and/or maintenance of Patent Rights under Sections 10.1.1 and/or 10.1.2 above (a "**Filing Party**") shall (a) promptly provide the other Party with copies of all patent applications filed hereunder and other material submissions and correspondence with applicable patent offices, in sufficient time to allow for review and comment by the other Party; (b) provide the other Party and its patent counsel with an opportunity to consult with the Party and its patent counsel regarding the filing and contents of any such application, amendment, submission or response; and (c) take into consideration in good faith the advice and suggestions of the other Party and its patent counsel in connection with such filing.

10.1.5 Interference, Opposition, Reexamination and Reissue.

(a) Notice. Not more than thirty (30) days following the discovery by either Party of any request for, or the filing or declaration of, any interference, opposition, or reexamination proceeding with respect to any Licensed Patent Rights in the Territory, the discovering or determining Party shall notify the other Party of such event.

(b) Primary Responsibility and Cooperation. SUBLICENSOR shall have primary responsibility, at its own expense, with respect to the course of action taken to defend or prosecute any such interference, opposition, reexamination or reissue, except that the Parties shall share equally the reasonable fees and expenses incurred under this Section 10.1.4(b) with respect to Joint Patent Rights. The Parties shall cooperate fully with each other and each shall provide to the other any information or assistance that the other may reasonably request with respect to any course of action taken under this Section 10.1.4. SUBLICENSOR shall (a) keep ILDONG reasonably informed of all developments in such interference, opposition, reexamination or reissue in the Territory, including to the extent permissible, the status of any settlement negotiations and the terms of any offer related thereto and (b) provide to ILDONG copies of all submissions or agreements arising in connection with such proceeding sufficiently in advance of their filing or due date so as to give ILDONG sufficient time to comment thereon, and SUBLICENSOR shall give good faith consideration to ILDONG's comments, with due regard to the other Party's rights and commercial interests under this Agreement. Neither Party shall enter into any settlement or consent decree regarding Joint Patent Rights, or assent to the grant of any reissued or reexamined patent within the Joint Patent Rights, without the prior written consent of the other Party, which shall not be unreasonably withheld or delayed.

10.1.6 Decision Not to File; Abandonment. SUBLICENSOR shall notify ILDONG in the event SUBLICENSOR decides at any time to abandon or discontinue prosecution of any one or more of the patents or patent applications included in the Licensed Patent Rights and in the Territory. Such notification will be given as early as possible which in no event will be less than fifteen (15) days prior to the date on which said patent(s) or patent application(s) will become abandoned. ILDONG shall have the option, exercisable upon written notification to SUBLICENSOR, to assume full responsibility, at its discretion for the prosecution of the affected patent(s) or patent application(s), which shall be conducted in the name of ILDONG.

10.2 Enforcement and Defense.

10.2.1 Third Party Infringement.

(a) In General.

(i) Notice. In the event either Party becomes aware of (i) any suspected infringement or misappropriation of any Licensed Patent Rights, Joint Patent Rights that covers the development or commercialization of a Compound or Product in the Field in the Territory, or (ii) the submission by any Third Party of an abbreviated NDA under the Hatch-Waxman Act for a product in the Field that comprises the Compound (each, an "**Infringement**"), that Party shall promptly notify the other Party and provide it with all details of such Infringement of which it is aware (each, an "**Infringement Notice**"). The Patent Coordinators shall promptly meet to discuss the Infringement and the strategy for patent enforcement with respect to such Infringement.

(ii) SUBLICENSOR Right to Enforce. SUBLICENSOR shall have the first right, but not the obligation, to address any such Infringement in the Territory by taking reasonable steps, which may include the institution of legal proceedings or other actions (each, an “**Action**”), and to compromise or settle such Action; provided, that, (A) SUBLICENSOR shall keep ILDONG reasonably informed about such Action, (B) ILDONG shall provide reasonable cooperation to SUBLICENSOR in connection with such Action, (C) SUBLICENSOR shall not take any position with respect to, or compromise or settle, such Action in any way that would be reasonably likely to directly and adversely affect the scope, validity or enforceability of the Licensed Patent Rights without the prior consent of ILDONG, which consent shall not be unreasonably withheld, and (D) if SUBLICENSOR does not intend to prosecute or defend an Infringement, or determines to cease to pursue such an Action, it shall promptly inform ILDONG and Section 10.2.1(a)(iii) shall apply. SUBLICENSOR shall incur no liability to ILDONG as a consequence of such Action or any unfavorable decision resulting therefrom, including any decision holding any such claim invalid, not infringed or unenforceable. All costs, including, without limitation, attorneys’ fees, relating to such legal proceedings or other action shall be borne by SUBLICENSOR.

(iii) ILDONG Right to Enforce. If (A) SUBLICENSOR informs ILDONG that SUBLICENSOR does not intend to prosecute an Action in respect of any Licensed Patent Rights or Joint Patent Rights pursuant to Section 10.2.1(a)(ii), (B) within sixty (60) days after the Infringement Notice, SUBLICENSOR has not commenced any Action, or (C) if SUBLICENSOR determine to cease to pursue any such Action with respect to such Infringement, then ILDONG shall have the right, at its own expense, upon notice to SUBLICENSOR to take appropriate action to address such Infringement, including by initiating its own Action or taking over prosecution of any Action initiated by SUBLICENSOR; provided, that, in such event, (1) ILDONG shall keep SUBLICENSOR reasonably informed about such Action and shall consult with SUBLICENSOR before taking any major steps during the conduct of such Action, (2) SUBLICENSOR shall provide reasonable cooperation to ILDONG in connection with such Action, and (3) ILDONG shall not take any position with respect to, or compromise or settle, such Action in any way that is reasonably likely to directly and adversely affect the scope, validity or enforceability of the Licensed Patent Rights without SUBLICENSOR’S prior written consent, which consent shall not be unreasonably withheld. SUBLICENSOR shall incur no liability to ILDONG as a consequence of such Action or any unfavorable decision resulting therefrom, including any decision holding any such claim invalid, not infringed or unenforceable. All costs, including, without limitation, attorneys’ fees, relating to such legal proceedings or other action shall be borne by ILDONG.

(iv) Joint Patent Rights. In the event of an Infringement of a Joint Patent Right, the Parties shall enter into good faith discussions as to whether and how to eliminate the Infringement. Subject to the foregoing, (A) ILDONG shall have the first right and option to eliminate such Infringement by reasonable steps, which may include the institution of legal proceedings or other action and (B) all costs, including without limitation attorneys' fees, relating to such legal proceedings or other action shall be borne by ILDONG. If ILDONG does not take or initiate commercially reasonable steps to eliminate the Infringement within one hundred twenty (120) days from any Infringement Notice, then SUBLICENSOR shall have the right an option to do so at its expense.

(b) Right to Representation. Each Party shall have the right to participate and be represented by counsel that it selects, in any Action instituted under Section 10.2.1(a)(ii), (iii) or (iv) by the other Party. If a Party with the right to initiate an Action under Section 10.2.1(a) to eliminate an Infringement lacks standing to do so and the other Party has standing to initiate such Action, then the Party with the right to initiate an Action under Section 10.2.1(a) may name the other Party as plaintiff in such Action or may require the Party with standing to initiate such Action at the expense of the other Party.

(c) Cooperation. In any Action instituted under this Section 10.2.1, the Parties shall cooperate with and assist each other in all reasonable respects. Upon the reasonable request of the Party instituting such Action, the other Party shall join such Action and shall be represented using counsel of its own choice, at the requesting Party's expense.

(d) Allocation of Proceeds. Any amounts recovered by either Party pursuant to Actions under Sections 10.2.1(a)(ii), (iii) or (iv) with respect to any Infringement, whether by settlement or judgment, shall, after reimbursing ILDONG and SUBLICENSOR for their respective reasonable out-of-pocket expenses incurred in pursuing such Action and obtaining such recovery (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses) be retained by or paid to ILDONG and treated as Net Sales of the Product affected by the Infringement and for purposes of this Agreement, such that ILDONG shall pay to SUBLICENSOR the applicable royalty due on such Net Sales pursuant to Section 7.3.1.

10.2.2 Defense of Claims

(a) Notice. In the event that any action, suit or proceeding is brought against either Party or any Affiliate of either Party or any Sublicensee or Distributor of ILDONG alleging the infringement of the Technology or Patent Rights of a Third Party by reason of or the Development or Commercialization, including the Manufacture, use or sale, of any Compound or Product, by or on behalf of ILDONG, its Affiliates, Sublicensees or Distributors, such Party shall notify the other Party within five (5) days of the earlier of (i) receipt of service of process in such action, suit or proceeding, or (ii) the date such Party becomes aware that such action, suit or proceeding has been instituted and the Patent Coordinators shall meet as soon as possible to discuss the overall strategy for defense of such matter.

(b) **Prosecution of Infringement claims in the Territory.** Except as unanimously agreed by the Patent Coordinators and subject to Article 14, (i) SUBLICENSOR shall have the primary right but not the obligation to institute and control such action, suit or proceeding in its own name and at its sole expense and in such case, SUBLICENSOR and/or any of its Affiliates shall have the right to separate counsel at its own expense in any such action, suit or proceeding and, ILDONG shall cooperate with SUBLICENSOR in all reasonable respects in any such action, suit or proceeding ; (ii) in the event SUBLICENSOR waives its primary right as defined in (i) the Parties may elect, without being obliged, to jointly commence an action, and in this respect shall be represented by a counsel jointly chosen by the Parties, decide on a course of action, and share equally in the costs and expenses, and in the amounts recovered in accordance with, subject to and within the limits set out in SUBLICENSOR's Licenses, or (iii) in the event SUBLICENSOR waives its primary right as defined in (i) ILDONG may defend any action, suit or proceeding in its own name and at its sole expense and in such case ILDONG and/or any of its Affiliates shall have the right to separate counsel at its own expense in any such action, suit or proceeding and SUBLICENSOR shall cooperate with ILDONG in all reasonable respects in any such action, suit or proceeding.

(c) **Cooperation.** Each Party shall promptly furnish the other Party with a copy of each communication relating to the alleged infringement that is received by such Party including all documents filed in any litigation. In no event shall either Party settle or otherwise resolve any such action, suit or proceeding brought against the other Party or any of its Affiliates or sublicensees without the other Party's prior written consent.

10.2.3 Patent Term Restoration. The Parties hereto shall cooperate with each other in obtaining patent term restoration or supplemental protection certificates or their equivalents in any country in the Territory where applicable to Licensed Patent Rights. Such cooperation shall include diligently and timely conferring and coordinating with respect to such matters to ensure compliance with applicable filing deadlines, and agreeing on procedures to be followed by the Parties to ensure such compliance. In the event that elections with respect to obtaining such patent term restoration are to be made, SUBLICENSOR shall have the right to make the election with respect to Licensed Patent Rights.

10.3 Trademark Prosecution and Registration.

SUBLICENSOR shall control the registration of the Licensed Trademark, to be used with Products in the Territory. SUBLICENSOR shall have the primary right but not the obligation to take any actions as are required to continue and maintain in full force and effect and enforce and defend all Licensed Trademarks and registrations thereof, against infringement and misappropriation in the Territory, and shall be solely responsible for all expenses incurred in connection therewith. In the event SUBLICENSOR waives its primary right to take such action, ILDONG may have the right to take any actions as are required to continue and maintain in full force and effect and enforce and defend all Licensed Trademarks and registrations thereof, against infringement and misappropriation in the Territory, and shall be solely responsible for all expenses incurred in connection therewith..

11. TERM AND TERMINATION

11.1 **Term.**

This Agreement shall commence on the Effective Date and shall continue in full force and effect, unless otherwise terminated pursuant to Section 11.2, (a) until such time as ILDONG is no longer Developing at least one (1) Compound and/or at least one (1) Product or (b) if, as of the time ILDONG is no longer Developing at least one (1) Compound and/or at least one (1) Product, ILDONG is Commercializing a Product, until the expiration of all applicable Royalty Terms with respect to Products under this Agreement (the “**Term**”). Upon the expiration of this Agreement as set forth in this Section 11.1, the license rights granted hereunder shall be converted to perpetual and fully paid-up licenses on Licensed Technology and Licensed Patent Rights, with the right to grant unlimited sublicenses. However, ILDONG shall continue to pay to SUBLICENSOR royalties on the use of Licensed Trademarks.

11.2 **Termination.**

This Agreement may be terminated by either Party as follows:

11.2.1 **Unilateral Right to Terminate Agreement.**

(a) **SUBLICENSOR Rights to Terminate for Challenge.** Except to the extent the following is unenforceable under the Applicable Laws of a particular jurisdiction where a patent application within the Licensed Patent Rights is pending or a patent within the Licensed Patent Rights is issued, SUBLICENSOR may terminate this Agreement immediately upon written notice to ILDONG in the event that ILDONG or any of its Affiliates or Sublicenses Challenges any Licensed Patent Rights or assists a Third Party in initiating a Challenge of any Licensed Patent Rights.

11.2.2 **Termination for Breach.** Either Party may terminate this Agreement, effective immediately upon written notice to the other Party, for a material breach (including ILDONG’s failure to meet its diligence requirements and responsibilities as set forth in Section 3; 4 and 5) by the other Party of any term of this Agreement that remains uncured ninety (90) days (sixty (60) days in the event that the breach is a failure of a Party to make any payment required hereunder) after the non-breaching Party first gives written notice to the other Party of such breach and its intent to terminate this Agreement if such breach is not cured. For purposes of clarity, the obligation of the breaching Party to cure any such breach shall be stayed for any time period during which such breach is the subject of a dispute resolution proceeding pursuant to Section 14.1; provided, that, the obligation of the breaching Party to cure such breach shall resume commencing on the date of any final resolution of such proceeding.

11.2.3 Termination for Insolvency. In the event that either Party makes an assignment for the benefit of creditors, appoints or suffers appointment of a receiver or trustee over all or substantially all of its property, files a petition under any bankruptcy or insolvency act or has any such petition filed against it which is not discharged within sixty (60) days of the filing thereof, then the other Party may terminate this Agreement effective immediately upon written notice to such Party.

11.3 Consequences of Termination of Agreement.

In the event of the termination of this Agreement pursuant to Section 11.2, the following provisions shall apply, as applicable.

11.3.1 Termination by SUBLICENSOR. If this Agreement is terminated by SUBLICENSOR pursuant to Section 11.2.1, 11.2.2 or 11.2.3:

(a) All licenses and rights granted by SUBLICENSOR to ILDONG, including all licenses granted to ILDONG pursuant to Section 2.1, shall immediately terminate.

(b) ILDONG shall cease to use all Licensed Trademarks, any Marketing Authorization obtained in accordance with the AGREEMENT and shall further promptly transfer such Marketing Authorizations and/or orphan drug designations to SUBLICENSOR at no cost for SUBLICENSOR..

(c) ILDONG shall cease to conduct any activity related to the Development and Commercialization of the Product.

(d) Upon request of SUBLICENSOR, ILDONG shall promptly, and in any event within sixty (90) days after SUBLICENSOR's request (which request may specify any or all of the actions in clauses (A) through (H)): (A) transfer to SUBLICENSOR all of its right, title and interest in all Drug Approval Applications and then in its name applicable to the Product, if any, and all Confidential Information Controlled by ILDONG as of the date of termination relied on by such Drug Approval Applications; (B) notify the applicable Regulatory Authorities and take any other action reasonably necessary to effect such transfer; (C) provide SUBLICENSOR with copies of all correspondence between ILDONG and such Regulatory Authorities relating to such Drug Approval Applications; (D) unless expressly prohibited by any Regulatory Authority, transfer sponsorship and control to SUBLICENSOR of all Clinical Trials of the Product being conducted as of the effective date of termination and continue to conduct such Clinical Trials after the effective date of termination to enable such transfer to be completed without interruption of any such Clinical Trial for up to twelve (12) months from the effective date of termination, except for termination for breach of ILDONG, the fully burdened cost of such continuation to be paid for by SUBLICENSOR; (E) cooperate with SUBLICENSOR, cause its Affiliates to cooperate with SUBLICENSOR and use commercially reasonable efforts to require any Third Party with which ILDONG has an agreement with respect to the conduct of Clinical Trials for the Product (including agreements with contract research organizations, clinical sites and investigators), to cooperate with SUBLICENSOR in order to accomplish the transfer to SUBLICENSOR of similar rights as held by ILDONG under its agreements with such Third Parties; (F) provide SUBLICENSOR with copies of all reports and Clinical Data generated or obtained by ILDONG or its Affiliates, and all Promotional Materials used by ILDONG, pursuant to this Agreement that relate to the Product that have not previously been provided to SUBLICENSOR and provide SUBLICENSOR with a right of access, a right of reference and a right to use and incorporate all Clinical Data, results and information in all Drug Approval Applications then in its name applicable to the commercialization of Product and all material aspects of Confidential Information Controlled by it as of the date relating to such Drug Approval Applications for SUBLICENSOR to use to seek Regulatory Approvals, Pricing Approvals, or Reimbursement Approvals; (G) provide SUBLICENSOR at cost with all supplies of Compounds and Products in the possession of ILDONG or any Affiliate or contractor of ILDONG; and (H) provide SUBLICENSOR with copies of all reports and data generated or obtained by ILDONG or its Affiliates pursuant to this Agreement that relate to any Product that have not previously been provided to SUBLICENSOR; (I) enter into negotiations with SUBLICENSOR and agree upon and implement a plan for the orderly transition of Development and Commercialization from ILDONG to SUBLICENSOR in a manner consistent with Applicable Laws and standards of ethical conduct of human Clinical Trials and will seek to replace all ILDONG personnel engaged in any Development or Commercialization activities, in each case, as promptly as practicable. In connection therewith, ILDONG shall be deemed to have granted to SUBLICENSOR an exclusive, fully-paid, royalty-free, irrevocable license, with the right to grant sublicenses under ILDONG's interest in Joint Improvements and Joint Patent Rights, for the sole purpose of using, making, having made, offering for sale, selling, having sold, importing and exporting any Products being Developed and/or Commercialized by ILDONG as of the effective date of such termination in the Field and in the Territory.

(e) Each Party shall promptly return all Confidential Information and Proprietary Materials of the other Party that are not subject to a continuing license hereunder; provided, that, each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.

(f) ILDONG shall promptly return to SUBLICENSOR all raw data and results generated in each such Clinical Trial.

SUBLICENSOR agrees that it will not voluntarily terminate the LFB/GTC Agreement (or allow such agreement to be terminated by the Senior Licensors), unless SUBLICENSOR maintains its license for the Territory on terms and conditions no less favorable to ILDONG as in this Agreement or makes arrangements for ILDONG to be granted a direct license from the Senior Licensors with terms and conditions no less favorable to ILDONG as in this Agreement.

(g) Upon any termination of this Agreement by SUBLICENSOR, (excluding termination by SUBLICENSOR pursuant to 11.2.2), or upon termination by ILDONG pursuant to 11.2.2, SUBLICENSOR shall buy back from ILDONG, at the Purchase Price, any unsold, unopened SUBLICENSOR Products in ILDONG's possession that have been purchased from SUBLICENSOR which are in marketable condition (as determined in the sole discretion of SUBLICENSOR) and are of a product designation then included in the products being offered for sales by SUBLICENSOR. The aggregate amount to be paid to ILDONG under this provision may be offset by SUBLICENSOR against claims it has against ILDONG, including payment of goods supplied under this Agreement. In order to ensure the marketable condition of such Products, all documentation must be presented indicating proper storage, handling, and shipment of such Products at all times while in possession by ILDONG. Additionally, and at ILDONG'S sole expense, SUBLICENSOR may request a sample of such Product be analyzed by an independent laboratory (to be agreed upon by both Parties), to assess the Product's marketable condition and adherence to product specifications. In the case that such Product is determined not to be in marketable condition, SUBLICENSOR will not be obligated to purchase back such Product from ILDONG.

11.3.2 Termination by ILDONG. If this Agreement is terminated by ILDONG pursuant to Section, 11.2.2 or 11.2.3:

(a) At ILDONG's election, all licenses granted by SUBLICENSOR to ILDONG pursuant to Section 2.1 shall survive such termination, in each case subject to ILDONG's continued payment of all milestone, royalty and other payments under and in accordance with this Agreement with respect thereto.

(b) Each Party shall promptly return all Confidential Information and Proprietary Materials of the other Party that are not subject to a continuing license hereunder; provided, that, each Party may retain one copy of the Confidential Information of the other Party in its archives solely for the purpose of establishing the contents thereof and ensuring compliance with its obligations hereunder.

(c) ILDONG shall promptly return to SUBLICENSOR all raw data and results generated in each such Clinical Trial.

11.4 Surviving Provisions.

Termination or expiration of this Agreement for any reason shall be without prejudice to:

(a) Survival of rights specifically stated in this Agreement to survive, including without limitation as set forth in Section 11.3;

(b) The rights and obligations of the Parties provided in Sections 8, 9, 10, 12, 13, 14.1 and 14.2 (including all other Sections or Articles referenced in any such Section or Article), all of which shall survive such termination except as provided in this Article 10; and

(c) Any other rights or remedies provided at law or equity which either Party may otherwise have.

12. REPRESENTATIONS AND WARRANTIES

12.1 Mutual Representations and Warranties.

SUBLICENSOR and ILDONG each hereby represent and warrant to the other, as of the Effective Date, as follows:

12.1.1 Organization. It is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement.

12.1.2 Authorization. The execution and delivery of this Agreement and the performance by it of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate (a) such Party's certificate of incorporation or bylaws (or equivalent charter or organizational documents), (b) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (c) any requirement of any Applicable Laws, or (d) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party.

12.1.3 Binding Agreement. This Agreement is a legal, valid and binding obligation of such Party enforceable against it in accordance with its terms and conditions.

12.1.4 No Inconsistent Obligation. It is not under any obligation, contractual or otherwise, to any Person that conflicts with or is inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder.

12.1.5 No Government Authorization Required. No government authorization, consent, approval, license, exemption of or filing or registration with any court or governmental department, commission, board, bureau, agency or instrumentality, domestic or foreign, under any Applicable Laws currently in effect, is or will be necessary for, or in connection with, the transactions contemplated by this Agreement, or for the performance by it of its obligations under this Agreement.

12.1.6 ILDONG represents and warrants that it has all necessary financial and human resources to enter and perform all its commitments and obligations contained in the Agreement.

12.2 Additional Representations of SUBLICENSOR.

SUBLICENSOR further represents and warrants to ILDONG, as of the Effective Date, as follows:

12.2.1 Validity of Patent Rights. All Licensed Patent Rights listed on Schedule 4 are existing and, to SUBLICENSOR' Knowledge, no issued patents which are part of the Licensed Patent Rights listed on Schedule 4 are invalid or unenforceable.

12.2.2 **No Claims.** There are no claims, judgments or settlements against SUBLICENSOR pending, or to SUBLICENSOR' Knowledge, threatened, that invalidate or seek to invalidate the Licensed Patent Rights. There is no litigation pending against SUBLICENSOR or any Affiliate of SUBLICENSOR that alleges that any of SUBLICENSOR' activities relating to the Compound have violated, or by Developing the Compound would violate, any of the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation). To SUBLICENSOR' Knowledge, no litigation has been threatened against SUBLICENSOR or any Affiliate of SUBLICENSOR which alleges that any of its activities relating to the Compound have violated, or by Developing the Compound would violate, any of the intellectual property rights of any Third Party.

12.2.3 **No License.** SUBLICENSOR has not previously entered into any agreement pursuant to which it granted a license with respect to the Compound, or Product or under the Licensed Patent Rights or Licensed Technology to any Affiliate or Third Party, which license grant remains in effect or which agreement has surviving license rights, or other surviving terms, that are inconsistent with the rights and licenses granted to ILDONG under this Agreement.

12.2.4 **Third Party Patents.** Except the patents disclosed during ILDONG'S due diligence and to SUBLICENSOR' Knowledge, no Patent Rights owned or controlled by any Third Party would be infringed by the Development, Manufacture, use of Commercialization by or on behalf of ILDONG of the Compound or any Product pursuant to this Agreement.

12.2.5 **No Interference.** To SUBLICENSOR'S Knowledge, (a) the Licensed Patent Rights are not the subject of any interference proceeding and (b) there is no pending or threatened action, suit, proceeding or claim by any Third Party challenging SUBLICENSOR'S ownership rights in, or the validity or scope of, the Licensed Patent Rights.

12.3 **Additional Representations of ILDONG.**

ILDONG further represents and warrants to SUBLICENSOR, as of the Effective Date, as follows:

12.3.1 **No Claims.** There is no litigation pending against ILDONG or any Affiliate of ILDONG that relates, directly or indirectly, to the subject matter of this Agreement and that alleges that any of ILDONG's activities to be conducted relating to the Development of the Compound would violate any of the intellectual property rights of any Third Party (nor has it received any written communication threatening such litigation).

12.3.2 **Compliance with Applicable Laws.** ILDONG is in compliance with all Applicable Laws, and is not in default under or in violation of any Applicable Laws, that, in any case, would reasonably be expected to adversely affect the ability of ILDONG to comply with and perform its obligations under this Agreement.

12.3.3 Electronic Dataroom. ILDONG represents and warrants that it has been granted access to an electronic dataroom organized by SUBLICENSOR and therefore has a clear and perfect knowledge and a good understanding of all documents, information and data contained in such electronic dataroom, and their consequences on rights granted by LICENCOR under the Agreement. Within thirty (30) days of the date hereof, SUBLICENSOR will use Commercially Reasonable Efforts to transfer a copy of the contents of the electronic dataroom in their original format to ILDONG and will transfer such other manifestations of the Licensed Technology useful or necessary for ILDONG to Develop and Commercialize the Products, including without limitation raw data and results generated in each clinical trial and pre-clinical studies previously conducted and batch reports from manufacturing runs through the date hereof, to the extent not included in the dataroom. On and after the date hereof, SUBLICENSOR will use Commercially Reasonable Efforts to forward such manifestations of the Licensed Technology that it has in its possession to ILDONG on a regular basis or upon request.

13. INDEMNIFICATION; INSURANCE

13.1 Indemnification of SUBLICENSOR by ILDONG.

ILDONG shall indemnify, defend and hold harmless SUBLICENSOR, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the “**SUBLICENSOR Indemnities**”), against all liabilities, damages, losses and expenses (including, without limitation, reasonable attorneys’ fees and expenses of litigation) (collectively, “**Losses**”) incurred by or imposed upon SUBLICENSOR Indemnities, or any of them, as a direct result of claims, suits, actions, demands or judgments of Third Parties, including, without limitation, personal injury and product liability claims (collectively, “**Claims**”), arising out of (a) the Development, testing, sale, offer for sale, or Commercialization by ILDONG or any of its Affiliates, Sublicensees or Distributors of any Product; (b) any breach of this Agreement by ILDONG or any of its Affiliates, Sublicensees, Distributors or agents; and (c) the gross negligence or willful misconduct of any ILDONG Indemnity or Sublicensee of ILDONG; excluding, in each of (a), (b) and (c) above, any Claim or Loss with respect to which SUBLICENSOR has an obligation to indemnify ILDONG Indemnities pursuant to Section 13.2, as to which Claim or Loss each Party will indemnify the other to the extent of their respective liability for such Loss (unless such Claim or Loss is otherwise expressly excluded from a Party’s indemnification obligations under this Agreement).

13.2 Indemnification of ILDONG by SUBLICENSOR.

SUBLICENSOR shall indemnify, defend and hold harmless ILDONG, its Affiliates, their respective directors, officers, employees and agents, and their respective successors, heirs and assigns (collectively, the “**ILDONG Indemnities**”), against all Losses (including, without limitation, reasonable attorneys’ fees and expenses of litigation) incurred by or imposed upon the ILDONG Indemnities, or any of them, as a direct result of Claims arising out of (a) the commercialization by SUBLICENSOR of any SUBLICENSOR Commercialization Product in the SUBLICENSOR Commercialization Territory following exercise of SUBLICENSOR commercialization option (b) any breach of this Agreement by SUBLICENSOR or any of its Affiliates, (sub)licensees, distributors or agents; or (c) the gross negligence or willful misconduct of any SUBLICENSOR Indemnity or (sub)licensee of SUBLICENSOR; excluding, in the case of clauses (a) and (b) above, any Claim or Loss with respect to which ILDONG or any of its Affiliates has an obligation to indemnify SUBLICENSOR pursuant to Section 13.1, as to which Claim or Loss each Party will indemnify the other to the extent of their respective liability for such Loss.

13.3 Conditions to Indemnification.

A Person seeking modification under this Article 13 (the “**Indemnified Party**”) in respect of a Claim shall give prompt notice of such Claim to the Party from which indemnification is sought (the “**Indemnifying Party**”); provided, that, the Indemnifying Party is not contesting its obligation under this Section 13, shall permit the Indemnifying Party to control any litigation relating to such Claim and the disposition of such Claim; provided, that, the Indemnifying Party shall (a) act reasonably and in good faith with respect to all matters relating to the settlement or disposition of such Claim as the settlement or disposition relates to such Indemnified Party and (b) not settle or otherwise resolve such claim without the prior written consent of such Indemnified Party (which consent shall not be unreasonably withheld, conditioned or delayed). Each Indemnified Party shall cooperate with the Indemnifying Party in its defense of any such Claim in all reasonable respects and shall have the right to be present in person or through counsel at all legal proceedings with respect to such Claim.

13.4 Insurance.

Not later than thirty (30) days before the date on which ILDONG or any Affiliate or Sublicensee of ILDONG shall, on a commercial basis, make, use, or sell any Products, and at all times thereafter until the expiration of all applicable statutes of limitation pertaining to any such manufacture, marketing, possession, use, sale of other disposition of any Products, ILDONG will, at its expense, and SUBLICENSOR will, at its expense, with respect to Products, obtain and maintain in full force and effect, comprehensive general liability insurance, including product liability insurance and Clinical Trial insurance in such amounts as each such Party customarily maintains with respect to the development, manufacture and sale of its other products. Notwithstanding the foregoing, either Party may elect to self-insure with respect to any insurance coverage it is required to obtain hereunder as part of a comprehensive self-insurance program adopted by such Party. For the avoidance of doubt, all insurance obligations and associated costs for any sale and development of Product within the Territory and over which SUBLICENSOR has little or no control, shall be borne solely by ILDONG.

13.5 Warranty Disclaimer.

EXCEPT AS OTHERWISE EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO ANY KNOW-HOW, GOODS, SERVICES, RIGHTS OR OTHER SUBJECT MATTER OF THIS AGREEMENT AND EACH PARTY HEREBY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.

13.6 No Warranty of Success.

Nothing contained in this Agreement shall be construed as a warranty, either express or implied, on the part of either Party that (a) the Development Program will yield a Product or otherwise be successful or meet its goals, time lines or budgets, or (b) the outcome of the Development Program will be commercially exploitable in any respect.

13.7 Limited Liability.

EXCEPT AS SET FORTH UNDER SECTIONS 13.1 OR 13.2, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR (I) ANY SPECIAL, PUNITIVE, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING, WITHOUT LIMITATION, LOST PROFITS OR LOST REVENUES, OR (II) COST OF PROCUREMENT OF SUBSTITUTE GOODS, KNOW-HOW OR SERVICES, WHETHER UNDER ANY CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER LEGAL OR EQUITABLE THEORY.

14. MISCELLANEOUS

14.1 Disputes; Consent to Jurisdiction.

The Parties shall use reasonable efforts to settle any Disputed Matter arising from or related to this Agreement or the breach thereof (each, a “**Dispute**”) by promptly referring any such dispute to the Executive Officer of each Party. If the Executive Officers are unable to resolve any Dispute within thirty (30) days of the date on which the Dispute was referred to them for resolution, the Dispute shall be subject to the sole jurisdiction of, and venue in, the U.S. federal courts of competent jurisdiction located within New York, New York, USA (if available), and otherwise the state courts of competent jurisdiction located within New York, New York, USA. ILDONG and SUBLICENSOR each irrevocably consent to the jurisdiction of such courts, irrevocably waive any objection based on inconvenience of forum, and agree that process may be served in the manner provided herein for giving notices or otherwise as allowed by New York or applicable federal law. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party.

14.2 Notices.

All notices and communications shall be in writing and delivered personally or by internationally-recognized overnight express courier providing evidence of delivery or mailed via certified mail, return receipt requested, addressed as follows, or to such other address as may be designated from time to time:

If to SUBLICENSOR:

TG Biologics, Inc.
787 Seventh Ave., 48th Floor
New York, NY 10019
Attention: Hari Miskin
Tel.: 212-554-4492
Fax: 212-554-4531

With a copy to:
Alston & Bird LLP
Attn : Mark McElreath
90 Park Avenue
New York, NY 10016
Tel : 212-210-9595

If to ILDONG:

ILDONG Pharmaceutical Co., Ltd.

Attn: SUNGSANG SEO
Tel: +82-2-526-3357
Fax: +82-2-526-3020

With a copy to:
BD&Licensing Team
ILDONG PHARMACEUTICAL CO., LTD.
Attention: Dong-young Park
Tel: +82-2-526-3383
Fax: +82-2-526-3020

Except as otherwise expressly provided in this Agreement or mutually agreed in writing, any notice, communication or document (excluding payment) required to be given or made shall be deemed given or made and effective upon actual receipt or, if earlier, (a) three (3) Business Days after deposit with an internationally-recognized overnight express courier with charges prepaid, or (b) five (5) Business Days after mailed by certified, registered or regular mail, postage prepaid, in each case addressed to a Parties at its address stated above or to such other address as such Party may designate by written notice given in accordance with this Section 14.2.

14.3 Governing Law.

This Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, without regard to the application of principles of conflicts of law.

14.4 Competition Law.

SUBLICENSOR and ILDONG agree that nothing in this Agreement shall be interpreted in a way that conflicts with EC Block Exemption No: 418/85 on research and development agreements, or EC Block Exemption No: 240/96 on technology transfer agreements, as issued by the European Commission (as these may be amended or replaced from time to time).

14.5 Binding Effect.

This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

14.6 Headings.

Section and subsection headings are inserted for convenience of reference only and do not form a part of this Agreement.

14.7 Counterparts.

This Agreement may be executed simultaneously in two or more counterparts, each of which shall be deemed an original and both of which, together, shall constitute a single agreement.

14.8 Amendment; Waiver.

This Agreement may be amended, modified, superseded or canceled, and any of the terms of this Agreement may be waived, only by a written instrument executed by each Party or, in the case of waiver, by the Party or Parties waiving compliance. The delay or failure of either Party at any time or times to require performance of any provisions shall in no manner affect the rights at a later time to enforce the same. No waiver by either Party of any condition or of the breach of any term contained in this Agreement, whether by conduct, or otherwise, in any one or more instances, shall be deemed to be, or considered as, a further or continuing waiver of any such condition or of the breach of such term or any other term of this Agreement.

14.9 No Third Party Beneficiaries.

Except as set forth in Sections 13.1 and 13.2, no Third Party (including, without limitation, employees of either Party) shall have or acquire any rights by reason of this Agreement.

14.10 Purposes and Scope.

The Parties hereto understand and agree that this relationship is limited to the activities, rights and obligations as set forth in this Agreement. Nothing in this Agreement shall be construed (a) to create or imply a general partnership between the Parties, (b) to make either Party the agent of the other for any purpose, (c) to alter, amend, supersede or vitiate any other arrangements between the Parties with respect to any subject matters not covered hereunder, (d) to give either Party the right to bind the other, (e) to create any duties or obligations between the Parties except as expressly set forth herein, or (f) to grant any direct or implied licenses or any other right other than as expressly set forth herein.

14.11 Assignment and Successors.

Neither this Agreement nor any obligation of a Party hereunder may be assigned by either Party without the consent of the other which shall not be unreasonably withheld, except that each Party may assign this Agreement and the rights, obligations and interests of such Party, (a) in whole or in part, to any of its Affiliates, or (b) in whole, but not in part, to any purchaser of all of its assets or all of its assets to which this Agreement relates or shares representing a majority of its common stock voting rights or to any successor corporation resulting from any merger, consolidation, share exchange or other similar transaction.

14.12 Force Majeure.

Neither ILDONG nor SUBLICENSOR shall be liable for failure of or delay in performing obligations set forth in this Agreement, and neither shall be deemed in breach of its obligations, if such failure or delay is due to a Force Majeure. In event of such Force Majeure, the Party affected shall use reasonable efforts to cure or overcome the same and resume performance of its obligations hereunder.

14.13 Interpretation.

The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to each Party and not in a favor of or against either Party, regardless of which Party was generally responsible for the preparation of this Agreement. In addition, unless a context otherwise requires, wherever used, the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders, the word "or" is used in the inclusive sense (and/or) and the word "including" is used without limitation and means "including without limitation".

14.14 Integration; Severability.

This Agreement, and when executed, the Commercial Supply Agreement(s) set forth the entire agreement with respect to the subject matter hereof and thereof and supersede all other agreements and understandings between the Parties with respect to such subject matter. If any provision of this Agreement is or becomes invalid or is ruled invalid by any court of competent jurisdiction or is deemed unenforceable, it is the intention of the Parties that the remainder of this Agreement shall not be affected.

14.15 Further Assurances.

Each of SUBLICENSOR and ILDONG agrees to duly execute and deliver, or cause to be duly executed and delivered, such further instruments and do and cause to be done such further acts and things, including, without limitation, the filing of such additional assignments, agreements, documents and instruments, as the other Party may at any time and from time to time reasonably request in connection with this Agreement or to carry out more effectively the provisions and purposes of, or to better assure and confirm unto such other Party its rights and remedies under, this Agreement.

[Remainder of page intentionally left blank.]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their duly authorized representatives.

TG BIOLOGICS, INC.

By: /s/ Michael S. Weiss

Name: Michael S. Weiss

Title: Executive Chairman, President, & CEO

ILDONG PHARMACEUTICAL CO., LTD.

By: /s/ Jung-chi Lee

Name: Jung-chi Lee

Title: Chairman & CEO

Consent of Independent Registered Public Accounting Firm

Our report on our audit of the consolidated balance sheets of TG Therapeutics, Inc. and Subsidiaries as of December 31, 2012 and 2011 and the consolidated statements of operations, equity and cash flows for the years then ended and cumulative period ended December 31, 2012, included in this Annual Report on Form 10-K for the year ended December 31, 2012, is dated March 21, 2013. We consent to the incorporation by reference of our report in the following registration statements previously filed by the Company with the Securities and Exchange Commission pursuant to the Securities Act of 1933: the registration statements on Forms S-8 with SEC file Nos. 333-48531, 333-15807, 333-112889 and 333-143838.

/s/ CohnReznick LLP

Roseland, New Jersey
March 21, 2013

**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 consolidated 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 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 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 21, 2013

/s/ Michael S. Weiss

Michael S. Weiss

Executive Chairman, Interim Chief Executive Officer and President

Principal Executive Officer

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

I, Sean A. Power, certify that:

1. I have reviewed this annual report on Form 10-K of TG Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the consolidated 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 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 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 21, 2013

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

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

In connection with the annual report of TG Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2012 as filed with the Securities and Exchange Commission (the "Report"), I, Michael S. Weiss, Executive Chairman, Interim 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 21, 2013

/s/ Michael S. Weiss

Michael S. Weiss

Executive Chairman, Interim Chief Executive Officer and President

Principal Executive Officer

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

In connection with the annual report of TG Therapeutics, Inc. (the "Company") on Form 10-K for the year ended December 31, 2012 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 21, 2013

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