

TG THERAPEUTICS, INC.

FORM 10-K/A (Amended Annual Report)

Filed 06/10/13 for the Period Ending 12/31/12

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CIK 0001001316

Symbol TGTX

SIC Code 2834 - Pharmaceutical Preparations

Industry Biotechnology & Drugs

Sector Healthcare

Fiscal Year 12/31



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K/A Amendment No. 1

Amenu	incin 140. 1
☒ 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 1	15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to	
Commission F	ile Number 1-32639
TG THERAI	PEUTICS, INC.
(Exact name of registra	nt 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	er, including area code: (212) 554-4484
Securities registered pursu	nant to Section 12(b) of the Act:
Common Stock, Par Value \$0.001 Per Share (Title of Class)	NASDAQ Capital Market (Name of Each Exchange on Which Registered)
· .	nant to Section 12(g) of the Act: None
Indicate by check mark if the registrant is a well-known seas Yes □ No ⊠	soned issuer, as defined in Rule 405 of the Securities Act.
Indicate by check mark if the registrant is not required to file Yes \square No \boxtimes	e reports pursuant to Section 13 or Section 15(d) of the Act.
	all reports required to be filed by Section 13 or 15(d) of the Securities norter period that the registrant was required to file such reports), and (2 No □
	electronically and posted on its corporate Web site, if any, every Rule 405 of Regulation S-T during the preceding 12 months (or for such files). Yes 🗵 No 🗆
	suant to Item 405 of Regulation S-K is not contained herein, and will not yor information statements incorporated by reference in Part III of this

Indicate by check mark whether the registrant is a large accelerated filed, 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 acceler Non-acceler	erated filer □ ated filer □	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 alculation, without conceding, that all executive officers and directors are "affiliates") was \$69,293,694 as of June 30, 2012, based or losing sale price of such stock as reported on the OTC Bulletin Board.	
calculation, without c		
There were	There were 25,820,738 shares of the registrant's common stock outstanding as of March 1, 2013.	

EXPLANATORY NOTE

TG THERAPEUTICS, INC. (the "Company") is filing this amendment (the "Form 10-K/A") to our Annual Report on Form 10-K for the fiscal year ended December 31, 2012 (the "Form 10-K"), filed with the U.S. Securities and Exchange Commission on March 21, 2013, solely to correct an error in the exhibits. Exhibit 10.37 of the Form 10-K, which is the subject of a confidential treatment request, was not filed in its entirety, and excluded certain exhibits. The license agreement is now being filed in full with this 10-K/A.

This Form 10-K/A should be read in conjunction with the original Form 10-K, which continues to speak as of the date of the Form 10-K. Except as specifically noted above, this Form 10-K/A does not modify or update disclosures in the original Form 10-K. Accordingly, this Form 10-K/A does not reflect events occurring after the filing of the Form 10-K or modify or update any related or other disclosures.

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: June 10, 2013

TG THERAPEUTICS, INC.

By: /s/ Sean A. Power

Sean A. Power Chief Financial Officer

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 June 10, 2013, and in the capacities indicated:

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

EXHIBIT INDEX

Exhibit Number	Exhibit Description		
10.37	Sublicense Agreement between TG Biologics, Inc. and Ildong Pharmaceutical Co. Ltd., dated November 13, 2012.*		
31.1	Certification of Principal Executive Officer .		
31.2	Certification of Principal Financial Officer .		
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.		
* C	onfidential treatment has been requested with respect to omitted portions of this exhibit.		
	Confidential treatment has been requested with respect to offitted portions of this exhibit.		

Exhibit 10.37

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 Schedule 3 Schedule 4 Schedule 5 Schedule 6 Schedule 7	Commercialization Plan Description of LFB-R603 Licensed Patent Rights and Background Patent Rights Description of TG20 Press Release 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, 48 th 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.
 - "Compounds" means ublituximab, collectively, (i) TG20 and/or (b) LFB-R603.
- " Confidential Information" means with respect to each Party, all information, Technology and Proprietary Materials 1.28 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 Authorities 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 <u>Schedule 3</u> 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 full 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 <u>Schedule 5</u> 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.

<u>Additional Definitions</u>. 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. <u>LICENSE GRANTS; EXCLUSIVITY</u>

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
- cr, a minimum of thirty percent (*%) of Sales Target has not been recorded for over a period of more than *(*) years;
- **2.1.3** <u>Disclosure of Technology</u>. 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) <u>Ownership of Trademarks</u>. 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) <u>Grant of License</u>. 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.

- 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) <u>Registration of Licensed Trademark</u>. 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) <u>Use of Licensed Trademark</u>. 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 <u>Sublicense</u>. 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.

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 <u>Competitive Program Transaction</u>.

- (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) <u>Meeting of the Parties</u>. 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.

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.

^{*} Confidential material redacted and filed separately with the Commission.

3.3 <u>Preparation of Development Plan</u>.

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. <u>COMMERCIALIZATION OF PRODUCTS</u>

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 premarketing, 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 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 <u>Failure to achieve Sales Targets</u>

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 *.

* Confidential material redacted and filed separately with the Commission.

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 <u>Upfront Payment</u>.

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 <u>Sales Milestones</u>.

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) <u>Notice of Milestone Events</u>. 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) <u>Single Milestone Payments</u>. 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.
- 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.

^{*} Confidential material redacted and filed separately with the Commission.

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 <u>Payments; Withholding Tax; Currency Restrictions</u>.

(a) <u>Payments in United States Dollars</u>. 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).

(b) <u>Tax Withholding</u>. 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.

^{*} Confidential material redacted and filed separately with the Commission.

(c) <u>Currency Restrictions</u>. 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 <u>Confidentiality.</u>

- 8.1.1 <u>Confidentiality Obligations</u>. 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.
- 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, <u>upon</u> 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 <u>Schedule 6</u>, 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 expres s 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 <u>Improvement</u>

- **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 <u>Joint Improvement</u>

- **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 <u>Notice; Inventorship</u>.

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 <u>SUBLICENSOR Prosecution Rights</u>. 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 <u>ILDONG Prosecution Rights</u>. 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 <u>Joint Patent Rights</u>. 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.
- 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) <u>Notice</u>. 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.
- 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 a

10.2 Enforcement and Defense.

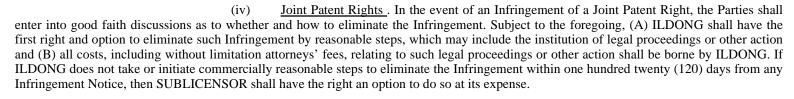
10.2.1 Third Party Infringement.

(a) <u>In General</u>.

(i) <u>Notice</u>. 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) <u>SUBLICENSOR Right to Enforce</u>. 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) <u>ILDONG Right to Enforce</u>. 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.



- (b) <u>Right to Representation</u>. 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) <u>Cooperation</u>. 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 <u>Defense of Claims</u>.

(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.

- 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) <u>Cooperation</u>. 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) <u>SUBLICENSOR Rights to Terminate for Challenge</u>. 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 <u>Termination for Breach</u>. 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 <u>Termination for Insolvency</u>. 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.

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 b	y ILDONG	pursuant to Section	, 11.2.2 or 11.2.3:
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- (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 <u>Surviving Provisions</u>.

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 <u>Organization</u>. 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 <u>No Inconsistent Obligation</u>. 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 <u>No Government Authorization Required</u>. 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 <u>Validity of Patent Rights</u>. All Licensed Patent Rights listed on <u>Schedule 4</u> are existing and, to SUBLICENSOR' Knowledge, no issued patents which are part of the Licensed Patent Rights listed on <u>Schedule 4</u> 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 <u>No Interference</u>. 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 <u>Compliance with Applicable Laws</u>. 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 <u>Electronic Dataroom</u>. 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 <u>Conditions to Indemnification</u>.

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 <u>Warranty Disclaimer</u>.

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. <u>MISCELLANEOUS</u>

14.1 <u>Disputes; Consent to Jurisdiction</u>.

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 <u>Interpretation</u>.

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 <u>Further Assurances</u>.

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

EXHIBIT A

SUPPLY AGREEMENT

COMMERCIALIZATION PLAN

DESCRIPTION OF LFB-R603

Storage conditions: *

Expected * years limitation period

Administration conditions: *

* Confidential material redacted and filed separately with the Commission.

LICENSED PATENT RIGHTS AND BACKGROUND PATENT RIGHTS

1. <u>LICENSED PATENT RIGHTS</u>

- * patent family filed on * Patent applications are pending in * and *
- * patent family filed on *

2. BACKGROUND PATENT RIGHTS

- * patent family filed on *

^{*} Confidential material redacted and filed separately with the Commission.

DESCRIPTION OF TG20

Storage conditions: same as *

 * Confidential material redacted and filed separately with the Commission.

SCHEDULE 6

PRESS RELEASE

TG Therapeutics Announces Exclusive Licensing Agreement with Ildong Pharmaceutical Co., Ltd. for Development and Commercialization of Ublituximab (TGTX-1101) in South Korea and Southeast Asia

New York, NY (November 14, 2012) —TG Therapeutics, Inc. (TG Therapeutics) (Ticker: TGTX) today announced that it has entered into an exclusive licensing agreement with Ildong Pharmaceutical Co. Ltd. (Ildong) for the development and commercialization of the company's novel anti-CD20 antibody, Ublituximab (TGTX-1101) in South Korea and Southeast Asia.

Under the terms of the agreement, TG Therapeutics will receive an upfront payment of \$2 Million in addition to sales based milestone and royalty payments in exchange for exclusive rights to develop and commercialize Ublituximab for all therapeutic indications in the territory. TG Therapeutics will retain all rights for the manufacture and supply of Ublituximab within the territory during clinical development and commercialization.

Ublituximab is under development by TG Therapeutics for hematologic malignancies and other B-cell lymphoproliferative disorders, and is currently being evaluated in a North American Phase I/II clinical trial in patients with relapsed or refractory non-Hodgkin's lymphoma.

"Having already demonstrated impressive clinical activity in patients with relapsed and refractory Chronic Lymphocytic Leukemia, Ublituximab has shown itself to be a promising treatment for patients with B-cell related disorders. We are excited to work with the experienced team at Ildong to expand the scope of development for Ublituximab." stated Michael S. Weiss, Chairman and Interim CEO of TG Therapeutics.

"We are delighted to have added Ublituximab to our pipeline in biologics and it is a strategic fit for Ildong," said Jung-Chi Lee, Chairman & CEO of Ildong. "We believe Ublituximab, a next generation anti-CD20 therapy will strengthen our presence in oncology and auto-immune areas and look forward to working with TG Therapeutics in developing Ublituximab in South Korea and Southeast Asia."

MedCI LLC served as licensing advisor and provided assistance to TG Therapeutics with respect to this transaction.

ABOUT UBLITUXIMAB

Ublituximab is a novel, third generation chimeric monoclonal antibody targeting a unique epitope on the CD20 antigen found on B lymphocytes. Ublituximab has been bioengineered for enhanced biological activity with an increased ability to trigger an immune response, delivering superior ADCC effects to aid in B-cell depletion. Ublituximab has displayed high single agent activity in a Phase I/II clinical trial in patients with relapsed Chronic Lymphocytic Leukemia, and is being developed by TG Therapeutics in multiple oncology and autoimmune indications.

Ublituximab has been granted orphan status in Europe and in the USA for B-cell Chronic Lymphocytic Leukemia, and is currently being evaluated in a Phase I/II clinical trial in patients with non-Hodgkin's lymphoma relapsed or refractory to prior anti-CD20 therapy.

ABOUT TG THERAPEUTICS, INC.

TG Therapeutics is an innovative, 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. Currently, the company is developing two advanced therapies targeting hematological malignancies. TGTX-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, currently in clinical development for patients with relapsed and refractory non-Hodgkin's lymphoma. TG Therapeutics is also developing TGR-1202, a highly specific, orally available PI3K delta inhibitor. TG Therapeutics is headquartered in New York City. For more information, visit the TG Therapeutics website at http://www.tgtherapeutics.com .

ABOUT ILDONG PHARMACEUTICAL CO., LTD.

Ildong Pharmaceutical Co., Ltd., (000230 KS) based in Seoul, Korea, is a leading Korean company focused on the development, manufacturing and marketing of pharmaceuticals and OTC products with 340B KRW(or 294MUSD) turnover in 2011. Ildong, founded in 1941, is known to have leading expertise in various therapeutic categories including oncology, neurology, antibiotics, gastrointestinal, and cardiovascular. For more information, visit the Ildong website at http:// www.ildong.com

Cautionary Statement

Some of the statements included in this press release, particularly those anticipating future clinical trials and business prospects for ublituximab may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Among the factors that could cause our actual results to differ materially are the following: our ability to successfully and cost-effectively complete pre-clinical and clinical trials for ublituximab; the risk that the data (both safety and efficacy) from future clinical trials will not coincide with the data analyses from prior pre-clinical and clinical trials; and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at www.tgtherapeutics.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

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Supervisor-BD & Licensing

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SCHEDULE 7

Expiration

LICENSED TRADEMARKS

Registration

Registration

Trademark	Territory	Classes	Filing date	Filing number	date	number	date	Statut
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* Confidential:	material reda	cted and file	ed separately with	the Commission.				
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* Confidential material redacted and filed separately with the Commission.								

Registration

Registration

Expiration

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 amendment on Form 10-K/A to the 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: June 10, 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 amendment on Form 10-K/A to the 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: June 10, 2013 /s/ Sean A. Power

Sean A. Power
Chief Financial Officer
Principal Financial and Acco

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 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: June 10, 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: June 10, 2013 /s/ Sean A. Power

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