[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Secur	ities
and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.	

Exhibit 10.11

COLLABORATION AGREEMENT BY AND BETWEEN ASTELLAS PHARMA INC. AND FIBROGEN, INC.

June 1, 2005

TABLE OF CONTENTS

ARTIC	LE 1 DEFINITIONS	1
1.1	"Actions"	1
1.2	"Affiliate"	1
1.3	"Astellas Indemnitees"	1
1.4	"Astellas Territory"	1
1.5	"Authorized Designee"	1
1.6	"Bridging Strategy"	1
1.7	"Bulk Product"	2
1.8	"Commercialize"	2
1.9	"Completion"	2
1.10	"Confidential Information"	2
1.11	"Control" or "Controlled"	2
1.12	"Controlling Party"	2
1.13	"Data"	2
1.14	"Delivery" or "Delivered"	2
1.15	"Development Plan"	2
1.16	"Development Program"	2
1.17	"Enforcement Action"	2
1.18	"Event"	2
1.19	"Expanded Field"	2
1.20	"Expenses"	2
1.21	"FDA"	2
1.22	"FG Acquired Patents"	3
1.23	"FG Development Program"	3
1.24	"FG Indemnitees"	3
1.25	"FG Technology"	3
1.26	"FG Patents"	3
1.27	"FG Technical Information"	3
1.28	"FG Territory"	3
1.29	"Field"	4
1.30	"First Commercial Sale"	4
1.31	"Force Majeure Event"	4
1.32	"Fully Burdened Costs"	4
1.33	"Future Third Party Intellectual Property"	4
1.34	"GMP Guidelines"	4
1.35	"[*]"	4
1.36	"[*] Percentage"	5
1.37	"HIF"	5

1 20	"DID"	Page
1.38	"IND" "Indiamatica"	
1.39	"Indemnitee" "Indemnitor"	
1.40	"Indications"	
1.41 1.42	"Initial Development Plan"	
	"Initiate" or Initiation"	
1.43	"Inspected Party" and "Inspecting Party"	
1.44 1.45	"Joint Development Committee" or "JDC"	-
1.45	"Lead Compound"	-
1.47	"Listed Price"	-
1.48	"Litigation Agreement"	4
1.49	"Major Indication"	
1.50	"Marketing Approval"	6
1.51	"Marketing Approval Application" or "MAA"	ě
1.52	"Net Sales"	$\widetilde{\epsilon}$
1.53	"Phase I"	$\tilde{\epsilon}$
1.54	"Phase II"	ě
1.55	"Phase III"	ė
1.56	"Product Specification"	7
1.57	"Preexisting Third Party Intellectual Property"	7
1.58	"Proof of Concept"	7
1.59	"Prosecution and Interference Activities"	7
1.60	"Protected Field"	7
1.61	"Reference Materials"	7
1.62	"Relevant Standards"	7
1.63	"Sales Price"	7
1.64	"Standard Materials"	7
1.65	"Sublicensee"	8
1.66	"Technical Product Failure"	8
1.67	"Third Party Agreements"	8
1.68	"Third Party Licensor"	8
ARTIO	ICLE 2 JOINT DEVELOPMENT COMMITTEE	8
2.1	Joint Development Committee	8
2.2	Membership	8
2.3	JDC Meetings	8
2.4	Decisions	Ş
ARTIO	ICLE 3 DEVELOPMENT PLANS	Ģ
3.1	General	Ç
3.2	Annual Review	ç
3.3	Periodic Reviews	ç
ARTIC	ICLE 4 DEVELOPMENT PROGRAM	10
4.1	Development Program for the Astellas Territory	10

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

-ii-

4.2 4.3 4.4	Global Harmonization Selection of Lead Compounds Regulatory Matters	Page 10 10 11
ARTI	ICLE 5 RECORDKEEPING; PUBLICATION	13
5.1 5.2	Reports and Records Review of Publications	13 14
ARTI	ICLE 6 DEVELOPMENT PROGRAM FUNDING	15
6.1	Payments for Reimbursement; Net Payments	15
ARTI	ICLE 7 USE OF PRECLINICAL AND CLINICAL DATA	17
7.1 7.2 7.3 7.4	Exchange Disclosure Regulatory Requirements Review of Protocols	17 18 18 18
ARTI	ICLE 8 MARKETING RIGHTS	19
8.1 8.2 8.3	Astellas FibroGen Covenants	19 19 19
ARTI	ICLE 9 TRANSFER PRICING	20
9.1 9.2 9.3 9.4	Transfer for Non-Commercial Purpose Transfer for Commercial Purpose Payment Reference Materials; Standard Materials	20 21 22 22
ARTI	ARTICLE 10 ADDITIONAL PAYMENTS; BOOKS AND RECORDS	
10.1 10.2 10.3 10.4 10.5	Quarterly Reports Payment Method Currency Conversion Taxes Records; Inspections	22 22 23 23 24
ARTI	ICLE 11 DUE DILIGENCE	24
11.1 11.2 11.3	Astellas' Due Diligence FG's Due Diligence Development Diligence	24 24 25
ARTI	ICLE 12 MANUFACTURING RIGHTS	26
12.1 12.2 12.3 12.4 12.5	Procedures FG Right Manufacture and Supply Product Specifications Orders Forecast	26 27 27 27 27 27

-iii-

^{[*] =} Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

12.6	Shipment	Page 28
12.7	Inspection of Shipment/Right to Reject	28
12.8	Inspection of Facilities	28
12.9	Recall	29
12.10	Warranty	29
12.11	Interruption in Supply	29
12.12	Reference and Standard Materials	29
ARTICI	LE 13 LICENSE GRANTS	29
13.1	Grant to Astellas	29
13.2	Sublicenses	29
13.3	No Rights Beyond Lead Compounds	30
13.4	Expanded Field Negotiation	30
ARTICI	LE 14 INTELLECTUAL PROPERTY	30
14.1	Ownership of Inventions	30
14.2	Patent Prosecution	31
14.3	Defense of Third Party Infringement Claims	31
14.4	Enforcement	32
14.5	Third Party Agreements	33
ARTICI	LE 15 REPRESENTATIONS AND WARRANTIES	34
15.1	FG Warranties	34
15.2	Astellas Warranties	34
15.3	Disclaimer of Warranties	34
ARTICI	LE 16 CONFIDENTIALITY	35
16.1	Confidential Information	35
16.2	Permitted Disclosures	35
16.3	Clinical Data	36
16.4	Press Releases	36
ARTICI	LE 17 INSURANCE; INDEMNIFICATION	36
17.1	Insurance	36
17.2	Indemnification of FG	36
17.3	Indemnification of Astellas	37
17.4	Procedure	37
ARTICI	LE 18 TERM AND TERMINATION	37
18.1	Term	37
18.2	Termination for Cause or Technical Product Failure	37
18.3	Termination in case of Generic Competition	38
18.4	Negative Advice from Authorities	39
18.5	Admission of Invalidity or Unenforceability of FG Patent	39
18.6	Termination upon Notice	39

[*] = Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

-iv-

		Page
18.7	Effect of Termination	39
ARTICI	LE 19 DISPUTE RESOLUTION	40
19.1	Disputes	40
19.2	Full Arbitration	40
ARTICI	LE 20 MISCELLANEOUS	41
20.1	Confidential Terms	4
20.2	Governing Law	4.
20.3	Force Majeure	4:
20.4	No Implied Waivers; Rights Cumulative	42
20.5	Independent Contractors	42
20.6	Notices	42
20.7	Assignment	43
20.8	Modification	43
20.9	Severability	43
20.10	Counterparts	43
20.11	Headings	43
20.12	Export Laws	43
20.13	Language	43
20.14	Entire Agreement	43
EXHIB	IT A LIST OF PATENTS	45
EXHIB	I <u>T B</u> INDICATIONS	46
EXHIB	IT C INITIAL DEVELOPMENT PLAN	47

-v-

^{[*] =} Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

COLLABORATION AGREEMENT

This COLLABORATION AGREEMENT ("Agreement"), effective as of June 1, 2005 (the "Effective Date"), is made by and between FibroGen, Inc., a Delaware corporation having offices at 225 Gateway Boulevard, South San Francisco, California 94080 ("FG" or "FibroGen"), and Astellas Pharma Inc., a Japanese corporation having offices at 3-11 Nihonbashi-Honcho, 2-Chome, Chuo-ku, Tokyo, 103-8411 Japan ("Astellas").

BACKGROUND

- A. FG has a research and development program focused on the development of small molecule prolyl hydroxylase inhibitors which stabilize hypoxia inducible factor ("HIF"), for the treatment of anemia.
- B. Astellas desires to collaborate with FG on the development and commercialization of, and license the rights to use as therapeutics, certain small molecule prolyl hydroxylase inhibitors on the terms and conditions set forth below for use in the Astellas Territory (as defined below).

NOW THEREFORE, for and in consideration of the covenants, conditions, and undertakings hereinafter set forth, it is agreed by and between the parties as follows:

ARTICLE 1 DEFINITIONS

- 1.1 "Actions" shall have the meaning as set forth in Section 14.3 below.
- 1.2 "Affiliate" shall mean any entity which controls, is controlled by or is under common control with Astellas or FG. For purposes of this definition only, "control" shall mean beneficial ownership (direct or indirect) of at least fifty percent (50%) of the shares of the subject entity entitled to vote in the election of directors (or, in the case of an entity that is not a corporation, for the election of the corresponding managing authority).
 - 1.3 "Astellas Indemnitees" shall have the meaning as set forth in Section 17.3 below.
 - 1.4 "Astellas Territory" shall mean the country of Japan.
- 1.5 "Authorized Designee" shall mean an officer of FG or Astellas, as the case may be, designated by the Chief Executive Officer of the respective corporation, that has been granted full authority to resolve a dispute arising between FG and Astellas as required under Section 2.4 or Section 19.1 hereof.
- 1.6 "Bridging Strategy" shall mean the decision by Astellas to file an MAA in the Astellas Territory by submitting the data from the Phase III clinical trial of FG or its Affiliate or Sublicensee.

-1-

1.7 "Bulk Product" shall mean a Lead Compound supplied by FG to Astellas as a bulk formulated drug (such as in a form, including, but not limited, to a capsule, tablet or caplet formulation) without packaging.

- 1.8 "Commercialize" shall mean directly or indirectly develop, manufacture, sell, market or distribute.
- 1.9 "Completion" shall be deemed to occur, with respect to a particular clinical trial for a Lead Compound, upon clinical database lock for such trial.
 - 1.10 "Confidential Information" shall have the meaning as set forth in Section 16.1 below.
- 1.11 "Control" or "Controlled" shall mean possession of the ability to grant a license or sublicense as provided for herein without violating the terms of an agreement with a third party.
 - 1.12 "Controlling Party" shall have the meaning as set forth in Section 14.3 below.
 - 1.13 "Data" shall have the meaning as set forth in Section 7.1 below.
 - 1.14 "Delivery" or "Delivered" shall mean when Lead Compound is made available by FG to Astellas at the Ex Works location.
- 1.15 "Development Plan" shall mean the plan for the Development Program in effect from time to time, as established in accordance with Article 3 below.
- 1.16 "Development Program" shall mean all Astellas activities with respect to the development and commercialization of Lead Compounds for applications within the Field in the Astellas Territory, in accordance with the Development Plan in effect at that time.
 - 1.17 "Enforcement Action" shall have the meaning as set forth in Section 14.4 below.
 - 1.18 "Event" shall have the meaning as set forth in Article 6 below.
- 1.19 "Expanded Field" shall mean the treatment of any indications in which therapeutic utility is derived from [*], including, without limitation, [*]. The Expanded Field shall not include the Field.
 - 1.20 "Expenses" shall have the meaning as set forth in Section 14.3 below.
 - 1.21 "FDA" shall mean the U.S. Food and Drug Administration, or any successor agency.

-2-

- 1.22 "FG Acquired Patents" shall mean those FG Patents that are in-licensed or otherwise acquired by FG.
- 1.23 "FG Development Program" shall mean those activities by or on behalf of FG directly related to the development and commercialization of Lead Compounds for applications within the Field in the FG Territory that are directly useful or necessary for Commercialization in the Astellas Territory.
 - 1.24 "FG Indemnitees" shall have the meaning as set forth in Section 17.2 below.
 - 1.25 "FG Technology" shall mean FG Patents and FG Technical Information.
- 1.26 "FG Patents" shall mean all patents including all reissues, renewals, re-examinations and extensions thereof, and any patent applications therefor, including all divisionals or continuations, in whole or in part, thereof, which claim or otherwise cover the composition, manufacture, sale or use of a Lead Compound and that are Controlled by FG or its Affiliates during the term of this Agreement, subject to Section 14.5.1. For purposes of this definition, a patent or patent application shall be deemed to "cover" a Lead Compound if the manufacture, use or sale of such Lead Compound would, but for the license granted herein, infringe, contributorily infringe or constitute inducement to infringement of such patent or patent application, if issued or granted as pending. All patents and patent applications listed on Exhibit A, as revised from time to tremove patents and/or patent applications by mutual agreement or to add patents and/or patent applications by FG, shall be within the scope of definition of the FG Patents, provided, however, that in the event FG designates any additional Lead Compounds, FG shall add to the list on Exhibit A patents and patent applications which claim or otherwise cover the composition, or manufacture, sale or use of the additional Lead Compounds within the Field and the Astellas Territory, and upon the cessation of the designation as any compound as Lead Compound and Astellas' cessation of development of such Lead Compound, FG shall remove at its sole discretion the related patent or patent application from Exhibit A.
- 1.27 "FG Technical Information" shall mean confidential information, tangible and intangible, and materials, including, but not limited to: trade secrets and know how, pharmaceutical, chemical, biological and biochemical compositions; and technical and non-technical data and information, and/or the results of tests, assays, methods and processes; and plans, specifications and/or other documents containing said information and data; in each case that is possessed by FG as of the Effective Date or discovered, developed or Controlled by FG or its Affiliates during the term of this Agreement, to the extent such relates to the development, manufacture, sale or use of a Lead Compound subject to Section 14.5.1, and such information related to a candidate for use as a Lead Compound provided by FG to Astellas in connection with the Lead Compound selection decision consultation process described in Section 4.3.

1.28 "FG Territory" shall mean all areas of the world outside of the Astellas Territory.

-3-

1.29 "Field" shall mean the treatment of anemia solely in the Indications, by means of the stabilization of HIF causing the stimulation of erythropoiesis (including an increase in endogenous erythropoietin production) and/or a subsequent increase in hematocrit through modulation of prolyl hydroxylase and/or asparaginyl hydroxylase. For purposes of clarity, FG and Astellas agree and acknowledge that the Field and the Indications exclude [*].

- 1.30 "First Commercial Sale" shall mean, with respect to each Lead Compound, the first bona fide commercial sale of such Lead Compound to a non-Affiliate third party by or under authority of Astellas or FG, or their Affiliates or Sublicensees, as the case may be, in the FG Territory or the Astellas Territory, respectively.
- 1.31 "Force Majeure Event" shall mean the occurrence of any event causing a failure to perform where failure to perform is beyond the reasonable control of the non-performing party, as described in Section 20.3.
- 1.32 "Fully Burdened Costs" with respect to a Lead Compound shall mean all costs to produce, package and distribute the product to Astellas or its carrier at the Ex Works location (in compliance with Section 12.6) and any royalties or other consideration (not reimbursed by Astellas) paid to third parties related to the acquisition or sale of product, with costs to produce and package the product to include the direct material, labor and indirect costs that are incurred by FG or its Affiliate(s) associated with the manufacture, filling, packaging, labeling, preparation of product for shipment and/or other preparation of such Lead Compound, as applicable, including, but not limited to taxes, fees, and customs incurred, as applicable. Costs will be determined in accordance with U.S. Generally Accepted Accounting Principles (U.S. GAAP) and will include but not be limited to the costs of facilities, labor, purchasing, depreciation of equipment, materials, payments to third parties for any necessary contract work related to the manufacture or testing of the product, the validation studies, quality assurance, quality control and other testing, storage, shipping (if requested by Astellas), costs related to distribution and a reasonable allocation of general and administrative overhead. Costs related to distribution include the labor, materials and overhead necessary to prepare and package the final product for shipment to the Ex Works location.
- 1.33 "Future Third Party Intellectual Property" shall mean any intellectual property rights, including without limitation all patents, trademarks, or copyrights, and any applications therefor, including any applications for registration, issuance, or grant thereof, owned or Controlled by a third party that are necessary for the practice of the license granted hereunder that were not owned or Controlled by FG as of the Effective Date and that do not qualify as Pre-existing Third Party Intellectual Property under Section 1.56.
 - 1.34 "GMP Guidelines" shall mean then-current applicable Good Manufacturing Practices guidelines and regulations of the FDA.
 - 1.35 "[*]" shall have the meaning as set forth in Section 1.36 below.

-4-

1.36 "[*] Percentage" shall be determined, for any Lead Compound, (i) by dividing (a) the [*], which shall be defined as the difference between (x) the [*], and (y) the [*], by (b) the [*]; and (ii) multiplying the result of (i) above by 100.

- 1.37 "HIF" shall mean hypoxia inducible factor.
- 1.38 "IND" shall mean an Investigational New Drug application, as defined in the U.S. Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, or comparable filing in a foreign jurisdiction, in each case with respect to a Lead Compound for use within the Field
 - 1.39 "Indemnitee" shall have the meaning as set forth in Section 17.4 below.
 - 1.40 "Indemnitor" shall have the meaning as set forth in Section 17.4 below.
- 1.41 "Indications" shall mean those indications listed on Exhibit B and any other indications to be agreed upon hereafter between FG and Astellas, each of which shall be referred to as an Indication.
 - 1.42 "Initial Development Plan" shall mean the Initial Development Plan as described in Section 3.2.1 hereof.
- 1.43 "Initiate" or Initiation" shall mean with respect to a particular clinical trial for a Lead Compound, the initial dosing of the first patient in such trial in accordance with the protocol therefor.
 - 1.44 "Inspected Party" and "Inspecting Party" shall have the meanings as set forth in Section 10.5 below.
 - 1.45 "Joint Development Committee" or "JDC" shall have the meaning as set forth in Section 2.1 below.
- 1.46 "Lead Compound" shall mean any compound Controlled by FG that is designated by FG as a lead compound for clinical development in an Indication in accordance with Section 4.3 for the duration of such designation. Any Lead Compound which receives a Marketing Approval in the Astellas Territory shall remain a Lead Compound for the duration of such Marketing Approval. As of the Effective Date, FG-2216 shall be deemed to be a Lead Compound.
 - 1.47 "Listed Price" shall have the meaning as set forth in Section 9.2.
 - 1.48 "Litigation Agreement" shall have the meaning as set forth in Section 14.4 below.

-5-

- 1.49 "Major Indication" shall have the meaning set forth in Section 11.3.1 below.
- 1.50 "Marketing Approval" shall mean, with respect to each Lead Compound, approval in the Astellas Territory by the Japanese Ministry of Health, Labour and Welfare, or in the FG Territory by U.S. or European regulatory authorities, as the case may be, to market such Lead Compound for an indication within the Field. It is understood that pricing or reimbursement approval shall constitute a part of the Marketing Approval. In any event, Marketing Approval shall be deemed to have occurred with respect to a Lead Compound no later than the date of the First Commercial Sale of such Lead Compound in the FG Territory or the Astellas Territory as the case may be, by or under authority of FG or Astellas respectively, or their Affiliate or Sublicensee, as the case may be, whether or not formal approval by the relevant health regulatory authority is required for the First Commercial Sale of such Lead Compound.
- 1.51 "Marketing Approval Application" or "MAA" shall mean, within the FG Territory, a New Drug Application or similar application as required under the U.S. Federal Food, Drug and Cosmetics Act and the regulations promulgated thereunder, or such similar filing in Europe, or a comparable filing for Marketing Approval in the Astellas Territory, in each case with respect to a Lead Compound for use within the Field.
- 1.52 "Net Sales" shall mean the gross amount billed or invoiced by Astellas, its Affiliates and its Sublicensees to unaffiliated third parties for the Lead Compound(s) in bona fide arm's length transaction, less the following deductions:
 - i) credits or allowances, if any, given or made on account of rejection or return of the Lead Compound(s);
 - ii) trade and quantity discounts actually allowed and taken in such amounts as are customary in the trade;
 - iii) duties, sales taxes, excise taxes, insurance and transportation charges actually paid; and
 - iv) charge back payments or rebates actually paid to wholesalers.
- 1.53 "Phase I" shall mean human clinical trials, the principal purpose of which is preliminary determination of safety in healthy individuals or patients as required in 21 C.F.R. §312.21, or similar clinical study in a country other than the United States, and for which there are no primary endpoints relating to efficacy included in the protocol.
- 1.54 "Phase II" shall mean human clinical trials, for which the primary endpoints include a determination of dose ranges and/or a preliminary determination of efficacy in patients with the Indication being studied as required in 21 C.F.R. §312.21, or similar clinical study in a country other than the United States.
- 1.55 "Phase III" shall mean human clinical trials, the principal purpose of which is to establish safety and efficacy of one or more particular doses in patients with the Indication being studied as required in 21 C.F.R. §312.21, or similar clinical study in a country

-6-

other than the United States. For purposes of this Section 1.55, and Sections 1.53 and 1.54 above, a particular trial that (i) is intended to overlap two phases of trials, (ii) combines the elements of two phases of trials, or (iii) is treated by the FDA or comparable foreign agency as two phases of trials, such as a Phase I/II trial or a Phase II/III trial, shall be deemed a trial of the later, as well as the earlier, phase (*i.e.*, a Phase II and a Phase III, respectively).

- 1.56 "Product Specification" shall mean, with respect to a Bulk Product, the written document describing, the testing procedures and results required to determine compliance with release specifications, including, and quality control testing procedures to be determined, and be amended from time to time, by mutual agreement of both parties. The release specifications of such Product Specifications shall be determined taking into account and shall be designed to meet the shelf life requirements of the Japanese Ministry of Health, Labor and Welfare for the Lead Compound, provided, that the Product Specifications shall not require compliance with such shelf life requirements.
- 1.57 "Preexisting Third Party Intellectual Property" shall mean any intellectual property rights, including without limitation all patents, trademarks, copyrights, and any applications therefor, including any applications for registration, issuance, or grant thereof, owned or Controlled by a third party that are necessary for the practice of the license granted hereunder and that the existence of which was discoverable or otherwise could have been known on or prior to the Effective Date and were not owned or Controlled by FG as of the Effective Date.
- 1.58 "Proof of Concept" shall mean for any Indication, a demonstration of correction of anemia in relevant patients in a human clinical study.
- 1.59 "Prosecution and Interference Activities" shall mean the preparation, filing, prosecution and maintenance of patent applications and patents and any continuing applications thereof, and any re-examinations, reissues, renewals and requests for patent term extensions therefor, and any U.S., international or foreign counterparts of any of the foregoing, together with the conduct of any interference, opposition or other similar proceeding pertaining to patent applications or patents.
 - 1.60 "Protected Field" shall have the meaning as set forth in Section 14.1.
 - 1.61 "Reference Materials" shall have the meaning as set forth in Section 12.12 below.
 - 1.62 "Relevant Standards" shall have the meaning as set forth in Section 12.8 below.
- 1.63 "Sales Price" shall mean the price per unit obtained by dividing the Net Sales during the relevant calendar quarter by the number of units sold during the same period.
 - 1.64 "Standard Materials" shall have the meaning as set forth in Section 12.12 below.

-7-

1.65 "Sublicensee" shall mean a third party to whom FG or Astellas has directly or indirectly granted the right in its respective territory to make, use and sell a Lead Compound or a third party to whom FG or Astellas has directly or indirectly granted the right to distribute a Lead Compound supplied by FG or Astellas (respectively). For purposes of this Agreement, FG and Astellas shall not be deemed Sublicensees of the other.

- 1.66 "Technical Product Failure" shall mean as a [*], which is not attributed to Astellas' failure to fulfill its obligations hereunder.
- 1.67 "Third Party Agreements" shall mean collectively those agreements between FG and a third party existing as of the Effective Date, pursuant to which FG obtained rights applicable to the development, manufacture, sale or use of Lead Compounds hereunder (but excluding options or similar agreements to acquire such rights). If, after the Effective Date, FG enters into an agreement to license or acquire rights from a third party with respect to subject matter to be utilized in connection with Lead Compounds in accordance with Section 14.5 below, such agreements shall also be deemed Third Party Agreements for purposes of this Agreement.

1.68 "Third Party Licensor" shall have the meaning as set forth in Section 14.5.1 below.

ARTICLE 2 JOINT DEVELOPMENT COMMITTEE

- 2.1 <u>Joint Development Committee</u>. Astellas and FG shall establish a joint development committee to oversee, review and coordinate the research and development of Lead Compounds for applications within the Field pursuant to the Development Program ("Joint Development Committee" or "JDC"). From time to time, the JDC may establish subcommittees or project teams to oversee particular projects or activities, and such subcommittees or project teams will be constituted as the JDC agrees (*e.g.*, for oversight of the development or other day-to-day matters).
- 2.2 Membership. The JDC shall be comprised of an equal number of representatives from each of Astellas and FG, selected by such party. The exact number of such representatives shall be [*] for each of Astellas and FG, or such other number as the parties may agree. Subject to the foregoing provisions of this Section 2.2, FG and Astellas may replace its respective JDC representatives at any time, upon prior written notice to the other party.
- 2.3 JDC Meetings. The JDC shall meet no fewer than [*] times each calendar year, or as otherwise agreed by the parties, with the understanding that [*] meetings are to be held at mutually agreed locations alternating among Japan, California, Hawaii, or at such other locations as the parties agree, and the other [*] meetings are to be held by means of telecommunication, videoconference or correspondence as deemed appropriate. The parties shall conduct team meetings at the same time and location as the JDC meetings. At its meetings, the JDC will, as applicable, (i) formulate and review the Development Program objectives, including approval of all proposed pre-clinical and clinical studies to be performed, (ii) monitor the progress of the Development Program toward those objectives, (iii) review and approve the

-8-

Development Plan, pursuant to Section 3.3 of this Agreement, including review, approve and monitor the progress of the clinical and regulatory plans, (iv) resolve issues surrounding the marketing of the Lead Compounds, (v) discuss the selection of Lead Compounds, (vi) coordinate manufacturing issues, including the development of standards, scheduling of batch production, and qualification with regulatory requirements for the Astellas Territory, (vii) resolve issues arising out of the Development Program or this Agreement, and (viii) undertake and/or approve such other matters as are specifically provided for the JDC under this Agreement. One meeting each year will be focused specifically on setting Development Program goals and strategy. Other representatives of FG or Astellas may attend JDC or subcommittee meetings as non-voting observers. Astellas' lead representative shall chair the meetings and shall be responsible for preparing the agenda and minutes for such meetings, and shall provide such minutes to FG in English. Such minutes as approved by the JDC shall constitute the official record of the actions of the JDC. The JDC may also convene or be polled or consulted from time to time by means of telecommunications, videoconferences or correspondence, as deemed necessary or appropriate. Each party shall bear its own personnel, travel and lodging expenses relating to JDC meetings.

2.4 <u>Decisions</u>. Decisions of the JDC shall be made by unanimous agreement of the members present in person or by other means (*e.g.*, teleconference) at any meeting; provided that at least two (2) representatives of each party is present at such meeting. In the event that the JDC is unable to reach unanimous agreement on an issue, the issue shall be referred for resolution in accordance with Article 19 hereof.

ARTICLE 3 DEVELOPMENT PLANS

3.1 <u>General</u>. Subject to Section 3.2 below, Astellas shall prepare and propose to the JDC a detailed Development Plan pursuant to which the Development Program will be performed. The Development Plan shall specify the objectives and work plan activities by Astellas with respect to the Development Program.

3.2 Annual Review

- 3.2.1 <u>Initial Development Plan</u>. The initial Development Plan is attached hereto as Exhibit C (the "Initial Development Plan"), and shall be fixed for the period from the Effective Date through March 31, 2006, unless otherwise agreed by the JDC.
- 3.2.2 Other. Beginning upon the date of signing of this Agreement and by December 31 of each year thereafter until expiration or termination of this Agreement, Astellas shall submit to the JDC the proposed plan required under Section 3.1 above for the following fiscal year, including for regulatory activities within the Astellas Territory. The JDC shall review such proposals as soon as possible and shall approve the Development Plan for such following fiscal year, with such changes as the JDC may agree to the plan proposed by Astellas, no later than March 15 of the current fiscal year.
- 3.3 <u>Periodic Reviews</u>. The JDC shall review the Development Plan on an ongoing basis and may make changes thereto including variances to the Development Plan in effect.

-9-

ARTICLE 4 DEVELOPMENT PROGRAM

4.1 <u>Development Program for the Astellas Territory</u>. Astellas shall follow FG's development activities for the Lead Compounds, (i.e., Astellas shall develop, and shall have the right and obligation to develop, only those compounds that FG has designated as Lead Compounds, for the duration of such designation and for which FG or its Sublicensee is pursuing clinical development in the FG Territory), for those Indications being developed by FG or its sublicensee, and such Astellas development shall comply with, without limitation the procedures set forth in Section 11.3.1. In fulfillment thereof, Astellas shall conduct, directly or through third parties, the Development Program for the Astellas Territory, all in accordance with the Development Plan then in effect, and shall be responsible for all costs related to the Astellas Territory. Astellas agrees to keep the JDC informed as to the progress of its activities under the Development Program for Lead Compounds hereunder. FG shall, subject to Section 4.2.2, provide reasonable assistance to Astellas regarding Astellas' performance of its development activities within the scope of the Development Program hereunder and provide updates to Astellas as to the FG Development Program. It is understood and agreed that the Development Program for the Astellas Territory shall include all clinical trials and other development activities necessary to obtain Marketing Approvals for Lead Compounds for the Astellas Territory.

4.2 Global Harmonization

- 4.2.1 Reporting; Redundant Activities. FG shall provide to Astellas regular reports with respect to the FG Development Program with respect to the Lead Compounds. Such reports may be provided at the JDC meetings provided for in Section 2.3. Recognizing that the Lead Compounds may be developed on a global basis and that regulatory and budget efficiencies can be achieved through the worldwide use of appropriate data and files, the parties will seek to design pre-clinical and clinical development activities included in the Development Plan in a manner to maximize global clinical and regulatory harmonization.
- 4.2.2 <u>Additional Activities</u>. Without limiting the obligations set forth in 4.2.1, the costs of any non-clinical or clinical developmental work, whether performed by Astellas or FG, to support needs specific to the Astellas Territory and not required to be performed for the FG Territory, or at the request of Astellas, shall be borne by Astellas.
- 4.3 Selection of Lead Compounds. FG shall consult with Astellas with respect to Lead Compound selection, and shall provide to Astellas information as reasonably necessary to evaluate Lead Compound candidates in connection with the Lead Compound selection process, including without limitation the information relating to patent situations in the Astellas Territory. For the avoidance of doubt, such Lead Compound candidates shall potentially include any and all compounds Controlled by FG during the term hereof for use in the Field. Notwithstanding anything contained in this Agreement, FG shall designate, at its sole discretion but in line with the basic policy that the same Lead Compound shall be Commercialized both in Astellas Territory and FG Territory for the same Indication(s), Lead Compound(s) in accordance with the terms of this Section 4.3, and shall notify the JDC of such designations. At any one time, FG may designate up to two (2) Lead Compounds for Commercialization in any Indication; provided, that in the event that FG designates two (2) Lead

-10-

Compounds for Commercialization in an Indication, it shall designate one (1) as the primary Lead Compound and one (1) as the secondary Lead Compound. In the event FG determines to cease development of a primary Lead Compound in an Indication, FG may designate the secondary Lead Compound as the primary Lead Compound for such Indication. In the event, prior to Marketing Approval in the Astellas Territory, FG determines to stop development of a Lead Compound, FG shall notify the JDC, and upon such notification, such compound shall no longer be considered a Lead Compound; provided, however, that Astellas may complete those development activities on-going at the time of such notification for such Lead Compound for a reasonable period of time, unless such notification is based on safety concerns. In the event FG determines to [*], FG shall [*] within [*] days of such [*]. In the event that FG [*], Astellas may, subject to the [*], [*], provided, however, that the [*] shall apply upon the [*] set forth in such Sections, rather than the [*].

4.4 Regulatory Matters

4.4.1 Regulatory Filing. FG shall be responsible, directly or through third parties, for the preparation, filing and maintenance of all regulatory documents in the FG Territory with respect to the Lead Compound(s), which shall be filed in the name of FG or its designee. Astellas shall be responsible for all preparation, filing and maintenance of all regulatory documents in the Astellas Territory with respect to the Lead Compound(s), which shall be filed in the name of Astellas. Astellas shall select and own the trademark(s) to be used to identify any Lead Compound in the Astellas Territory.

4.4.2 Reporting Adverse Experiences

(a) With respect to adverse drug experiences relating to any Lead Compound, the parties shall promptly report such experiences to the appropriate regulatory authorities in the countries in which such Lead Compound is being developed or commercialized, in accordance with the appropriate laws and regulations of the relevant countries and authorities, and each party shall ensure that its Affiliates and Sublicensees comply with such reporting obligations. In addition, in order that each party may be fully informed of these experiences, each party shall report to the other party all "adverse events" involving such Lead Compound. "Serious adverse events" for all fatal and life-threatening adverse events shall be reported to the designated safety contact person of the other party by e-mail within five (5) calendar days of a party's and/or its agent's becoming aware of such an event (a "reporting party"), and all other serious adverse events shall be forwarded to the other party within seven (7) calendar days of the reporting party's and/or its agent's becoming aware of such an event. To the extent legally possible, FG and Astellas shall report to the other all serious adverse events with respect to a Lead Compound in the Field at least twenty-four (24) hours prior to reporting the same to a regulatory authority, and shall report adverse events which may constitute a dose limiting toxicity in a reasonably prompt time after the occurrence of such event. The reporting party shall report all non-serious adverse events on a monthly basis; provided that, non-serious adverse event data arising from a clinical trial will be included in the clinical trial report which

-11-

shall be prepared and sent to the other party as soon as practicable following completion of the final clinical report.

- (b) An "adverse event" is any negative symptom experienced at the time of or after the taking of a medicinal (investigational) product, whether or not considered a medicinal (investigational) product related, including any side effects, injury, toxicity or sensitivity reaction, or significant failure of expected pharmacological action. Also included are instances of symptomatic overdose, abuse or withdrawal reactions.
- (c) A "serious adverse event" includes any of the following outcomes: death, a life-threatening event; that is, an adverse event that puts the patient at risk of dying, requires hospitalization, prolongs existing hospitalization or results in persistent or significant incapacity or disability, congenital anomaly/birth defect. Other important medical events that may otherwise jeopardize a patient or may require intervention to prevent one of the statuses of patients listed in the preceding sentence shall also be considered serious.
- (d) The parties also agree to develop and implement such other procedures as may be necessary or appropriate to ensure that each party remains in compliance with all reporting requirements imposed by any regulatory authority in the Astellas Territory, and in the FG Territory. Upon the Initiation of Phase III, FG shall implement and be responsible for the maintenance of a complete global safety database. FG will be responsible for preparing, with Astellas' cooperation set forth below in this Section 4.4.2(d), Periodic Safety Reports for clinical studies requested by European and U.S. authorities, and Periodic Safety Update Reports (PSURs). FG shall send a draft PSUR for review to Astellas in the beginning of week 5 after database lock point. Astellas has one week for review. FG shall provide copies of the final PSURs to Astellas in the same timing as they are submitted to the authorities. Astellas will provide FG with the data needed for making the PSURs. Maintenance of Company Core Safety Information (CCSI) is under the responsibility of FG who will communicate all revisions to Astellas. FG shall prepare the periodic safety reports for clinical studies requested by European and U.S. authorities and provide Astellas with the copy of such reports at the time of submission to the regulatory authorities in the FG Territory. Astellas will provide FG with the data needed for making such periodic safety reports.
- (e) Each party shall immediately inform the other party of measures taken in order not to jeopardize public health or hygiene including but not limited to, discontinuation of manufacture, import and marketing, clinical trial suspension, recall and disposal of the Lead Compound or the product or the prescription product, irrespective of whether it is due to regulatory actions or voluntary actions.

-12-

(f) Both parties hereby nominate the safety contact persons as follows:

Medical Affairs Department

FibroGen, Inc.

225 Gateway Boulevard

San Francisco, California 94080

Attn: Vice President, Medical Affairs

Tel: 1-650-866-7875 Fax: 1-650-866-7360

E-mail:dyeowell@fibrogen.com

With a copy to:

Chief Executive Officer

FibroGen, Inc.

225 Gateway Boulevard

San Francisco, California 94080

Tel: 1-650-866-7200

Fax: 1-650-866-7201

E-mail:tneff@fibrogen.com

Pharmacovigilance Department, QA, RA, and

Pharmacovigilance Division

Astellas Pharma Inc.

[*]

The safety contact persons for each party hereto may be updated from time to time as necessary upon notice to the other party.

ARTICLE 5 RECORDKEEPING; PUBLICATION

5.1 Reports and Records. Each of Astellas and FG shall use best efforts to maintain (or cause such records to be maintained) records of the Development Program and FG Development Program, respectively, in sufficient detail and in good scientific manner as will properly reflect all work done and results achieved in the performance of the Development Program or FG Development Program, as the case may be. Upon [*] days advance notice or such shorter time period as may be required in order to meet any regulatory requirements, each party shall allow the other party to have access to all records, materials and data generated by or on behalf of such party with respect to each Lead Compound for applications within the Field at reasonable times, in a reasonable manner and, upon request, to the extent required under Article 7 hereof.

13

5.1.1 <u>Retention</u>. Each of Astellas and FG shall retain its records for the minimum period of time required by applicable law in all cases, and for not less than [*] following the expiration or termination of this Agreement.

- 5.1.2 Reports. Not less than [*] prior to each JDC meeting under Section 2.3 above, each of Astellas and FG shall provide the JDC with a written report in English; Astellas' report summarizing the progress of the Development Program, including the developmental, clinical and other activities performed by Astellas, its Affiliates and/or Sublicensees with respect to each Lead Compound during the preceding period; and FG's report summarizing the progress of the FG Development Program.
- 5.1.3 Activities Outside the Field. The parties understand and acknowledge that FG is engaged in other research and development activities directed to prolyl hydroxylase inhibition and/or the stabilization of HIF, and that the focus of this collaboration and the Development Program is directed to the Field. Accordingly, it is understood that, notwithstanding any other provision of this Agreement, the obligations of FG specified herein to make available and disclose to Astellas data, technical information, scientific results and findings and other subject matter is limited in each case to subject matter directed to Lead Compounds within the Field.
- 5.2 Review of Publications. As soon as is practicable prior to the oral public disclosure, and prior to the submission to any outside person for publication of scientific data resulting from the Development Program, in each case to the extent the contents of the oral disclosure or publication have not been previously disclosed pursuant to this Section 5.2 before such proposed disclosure, FG or Astellas, as the case may be, shall provide to the other party a copy of the publication, or a written summary of any oral disclosure, to be made or submitted, and shall allow the other party at least [*], to determine whether such disclosure or publication contains subject matter for which patent protection should be sought prior to publication or which either party believes should be modified to avoid disclosure of Confidential Information or regulatory or other issues. With respect to publications by investigators or other third parties of scientific data resulting from the Development Program, such disclosures and publications shall also be subject to review by the reviewing party under this Section 5.2.
- 5.2.1 <u>Publication Rights</u>. Subject to the provisions of Articles 7 and 16, after the expiration of [*] from the date of receipt of such disclosure or publication, unless the authoring party has received the written notice specified below, the authoring party shall be free to submit such publication or to orally disclose or publish the disclosed research results in any manner consistent with academic standards.
- 5.2.2 <u>Disapproval of Publication</u>. Prior to the expiration of the [*] period specified in Section 5.2.1 above, the reviewing party may notify in writing the submitting party of its determination that such oral presentation or publication contains Confidential Information of the reviewing party or objectionable material or material that consists of patentable subject matter of the reviewing party for which patent protection should be sought. In such event, and unless otherwise mutually agreed, the submitting party shall withhold publication of its disclosure.

-14-

ARTICLE 6 DEVELOPMENT PROGRAM FUNDING

6.1 Payments for Reimbursement; Net Payments. FG hereby acknowledges receipt of U.S. \$[*] on February 13, 2004, U.S. \$[*] on January 28, 2005, and U.S. \$[*] on March 22, 2005 as initial payments for reimbursement of historical research and development expenditures for the Lead Compounds. Astellas agrees to pay to FG the amounts set forth in Section 6.1.1 below. The parties hereto acknowledge that the Development Program hereunder involves a high degree of risk and uncertainty; accordingly, both parties hereto expressly disclaim any implied warranty as to the results of the Development Program.

6.1.1 Reimbursement Payments. As reimbursement and payment for FG's historical research and development expenditures with respect to pre-clinical and clinical development of Lead Compounds, Astellas agrees to make the following non-refundable, non-creditable (except as set forth in Section 14.3 below) reimbursement payments to FG upon the first occurrence of each event specified below (each, an "Event"):

1.	EVENT Upon [*], provided, that U.S. \$[*] million of such amount shall be paid no later than [*] irrespective of whether the [*] has occurred.	AMOUNT U.S. \$[*]
2.	Upon each of [*], for a total of U.S. \$[*]	U.S. \$[*]
3.	Upon [*] or in the event that Astellas chooses to utilize the Bridging Strategy, the payment shall be made concurrent with the payment required in paragraph 4 of this Section 6.1.1 below.	U.S. \$[*]
4.	Upon the first [*].	U.S. \$[*]

6.1.2 <u>Product Approval Payments</u>. As reimbursement and payment for FG's historical and ongoing research and development expenditures with respect to pre-clinical and clinical development of Lead Compounds and as payment for the successful marketing and sales of Lead Compound(s), Astellas agrees to make the following non-refundable, non-creditable (except as set forth in Section 14.3 below) reimbursement payments to FG upon the first occurrence of each Event (other than paragraph 5 of this Section 6.1.2 below) specified below. Notwithstanding the foregoing, in the event that Astellas decides not to pursue Commercialization in [*] set forth in paragraph 3 or 4 of this Section 6.1.2, the milestone payment associated with the [*] set forth in paragraph 3

-15-

shall be due and payable upon the first [*] of either [*], and the milestone payment associated with the [*] set forth in paragraph 4 shall be due and payable upon the second [*] for a [*]; and in the event Astellas decides to pursue only [*] set forth in paragraph 3 or 4 of this Section 6.1.2, and pursues Commercialization of either of the [*], the milestone payment for associated with the [*] for the [*] shall be due and payable upon the first [*] for a [*]; and in the event that Astellas decides to pursue [*] set forth in paragraphs 3 and 4 of this Section 6.1.2 and also does not pursue [*], the parties shall a [*] for which the milestone payments associated with the [*] set forth in paragraph(s) 3 and/or 4 of this Section 6.1.2, as the case may be, shall be due, as negotiated in good faith by the parties hereto.

1.	EVENT Upon the first [*] for the [*]; provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. \$[*] for a total of U.S. \$[*]	AMOUNT U.S. \$[*]
2.	Upon the first [*] in the Astellas Territory for the [*]; provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. \$[*] for a total of U.S. \$[*].	U.S. \$[*]
3.	Upon the first [*] in the Astellas Territory for the [*]; provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. \$[*] for a total of U.S. \$[*].	U.S. \$[*]
4.	Upon the first [*] in the Astellas Territory for the first indication within [*] (see Exhibit B); provided, that in the event Astellas chooses the Bridging Strategy, such payment shall be increased by an additional U.S. $[*]$ for a total of U.S. $[*]$.	U.S. \$[*]

-16-

^{[*] =} Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

5. Upon [*] in the Astellas Territory for each of up to [*] indications listed on Exhibit B, including separate indications within [*] up to a total of U.S. \$[*].

U.S. \$[*]

6.1.3 <u>Sales Success Payments</u>. As reimbursement and payment for FG's historical and ongoing research and development expenditures with respect to pre-clinical and clinical development of Lead Compounds and as payment for the successful marketing and sales of the Lead Compound(s), Astellas agrees to make the following non-refundable, non-creditable (except as set forth in Section 14.3 below) reimbursement payments to FG upon the first occurrence of the Event specified below.

EVENT AMOUNT

U.S. [*] Lead Compounds by Astellas and its Affiliates and Sublicensees.

If at the occurrence of an Event (except for Event 2) as set forth in Section 6.1.1 above with respect to a particular Lead Compound the payment corresponding to the occurrence of any preceding Event (except for Event 2) (i.e., "previous" as contemplated by the Event number sequence specified above) has not been made, then the corresponding payment(s) for such preceding Event (except for Event 2) shall then be due.

The payments set forth in Sections 6.1.1, 6.1.2 and 6.1.3 hereof shall each be due and payable within [*] after occurrence of the corresponding Event. Astellas agrees to promptly notify FG in writing of its achievement of any Event under Sections 6.1.1, 6.1.2 and 6.1.3.

ARTICLE 7 USE OF PRECLINICAL AND CLINICAL DATA

7.1 Exchange. Subject to the provisions of this Article 7 and Article 16 below, the parties shall have access to the underlying preclinical and clinical data (including raw data thereof), analysis, reports, protocols and correspondence (collectively with such filings, "Data"), at reasonable times, upon fifteen (15) days advance notice or such shorter notice as may be required in order to meet any regulatory requirements and (upon request) in English, (it being understood and agreed that Astellas shall provide in English without cost to FG summaries of all final reports and all documents necessary to comply with regulatory and legal requirements, and

_17.

shall provide all other documents in English with reasonable costs shared equally between the parties) of the other party in accordance with the following:

- (a) FG shall have access to and the right to use for any purpose, any Data developed by or on behalf of Astellas or its Affiliates or Sublicensees in the course of the Development Program with respect to indications within the Field for Lead Compounds. Astellas shall obtain from such Sublicensees access to all Data prepared by or for such Sublicensee with respect to a Lead Compound, with the right to provide such Data and/or access to FG and its Sublicensees, and any sublicense failing to provide such obligation on the part of the Sublicensee shall be voidable at the option of FG.
- (b) Astellas shall have access to and the right to use solely for the purpose of this Agreement, any Data developed by or on behalf of FG or its Affiliates or Sublicensees with respect to Lead Compounds in connection with the Field (i) to the extent necessary to support the application to the regulatory authority in the Astellas Territory or to fulfill other Japanese Ministry of Health, Labor and Welfare regulatory requirements, or (ii) if not necessary to support such application or to fulfill such Japanese Ministry of Health, Labor and Welfare regulatory requirements, to the extent FG is permitted subject to FG's third party obligations; provided that FG shall [*] negotiate the availability of such Data to Astellas from such Sublicensee, and provided, further, that Astellas agrees not to use or disclose to third parties any such data for purposes outside the Field except as authorized under this Agreement.
- 7.2 <u>Disclosure</u>. Subject to the provisions of this Section 7.2, FG and Astellas may each provide copies or summaries of Data to its Affiliates and/or its permitted Sublicensees to the extent reasonably necessary for the development and commercialization of Lead Compounds in accordance with this Agreement, or in the case of FG of products other than Lead Compounds. It is understood that the foregoing shall include the right to disclose Data to third parties with whom Astellas or FG are discussing entering into agreements for such permitted purposes, subject to reasonable conditions of confidentiality, provided, that Astellas may not disclose any Data to any third party competitor of FG within the Field worldwide without the prior written consent of FG.
- 7.3 <u>Regulatory Requirements</u>. Notwithstanding the provisions of Section 7.2, in all agreements with third parties or Affiliates involving the development of Data, FG and Astellas, respectively, shall require that such third parties and Affiliates provide the other party with all such Data, to the extent such Data is required in order for each party to meet its obligations to the other party under Section 4.4.2 above.
- 7.4 Review of Protocols. Astellas agrees that all final protocol summaries for all clinical trials and GLP toxicology studies to be conducted by or under authority of Astellas will be subject to the review and approval of the JDC, in accordance with the following procedures set forth in this Section 7.4. Astellas shall submit to FG and the JDC the original draft protocol summary in English for any clinical trial or GLP toxicology study it proposes to conduct, and such protocol summary shall be reviewed and approved by the JDC. The protocol summary shall contain all information as may be requested by the JDC. Upon Astellas' completion of the final protocol for the proposed clinical trial or GLP toxicology study, in the

-18-

event that such protocol deviates from the original protocol summary, Astellas shall resubmit to FG and the JDC for review and approval a revised, final protocol summary that indicates all changes from the original protocol summary. Notwithstanding the foregoing, FG reserves the right to request and Astellas shall provide any portion of full text of the protocols in English for review by the JDC, which portion is at issue. In the event FG requests such a full text protocol, it shall review and provide comments to the JDC as soon as practicable, and within five (5) business days of receipt.

ARTICLE 8 MARKETING RIGHTS

8.1 <u>Astellas</u>. Astellas shall have the exclusive right to market, sell and distribute the Lead Compounds supplied by FG for use in the Astellas Territory within the Field under the license granted in Article 13. Astellas may exercise its rights under this Section 8.1 through one or more Sublicensees; provided, that any such Sublicensee agrees to terms identical in all material respects to those contained in this Agreement, and, provided, further, that any arrangement between Astellas and an Astellas Sublicensee with respect to a Lead Compound shall be subject to the requirements of Section 13.2.

8.2 <u>FibroGen</u>. FG shall have the exclusive right, including the right to authorize others, to market, sell and distribute the Lead Compounds for any use in the FG Territory. Subject to the restrictions contained in Section 8.3.4 hereof, FG retains the exclusive right, including the right to authorize others, to market, sell and distribute worldwide the Lead Compounds for use outside the Field.

8.3 Covenants

8.3.1 <u>General</u>. It is understood that, with respect to any particular Lead Compound, whether or not the use and sale of such Lead Compound by FG and/or Astellas in any country requires a license under intellectual property rights of the other, neither FG nor Astellas shall market, sell or distribute a Lead Compound anywhere in the world except in accordance with this Agreement, including this Article 8.

8.3.2 Independent Activities by Astellas. During the term of this Agreement, in the event Astellas seeks to Commercialize any molecules for the Field or the Expanded Field, except for actions taken within the Field in the course of the exercise of the license granted under Section 13.1 hereof and expressly authorized under this Agreement, Astellas shall notify FG immediately upon the commencement of any such activities, and provided that [*] such activities are and will be in the future conducted completely independently of any of FG Technology and/or any other FG materials, confidential information, intellectual property or other related information provided by or on behalf of FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, Astellas may proceed with such Commercialization, subject at all times to the obligations contained in this Agreement with respect to any intellectual property in connection with or related to such activities and FG's right to terminate this Agreement pursuant to Section 18.2.1 hereof.

-19-

8.3.3 <u>Use of FG Technology by Astellas</u>. Astellas shall use the FG Technology only to exercise the rights granted under Section 13.1 of this Agreement and as expressly authorized under the Development Program, and shall not under any circumstances use or apply any FG Technology, including without limitation any FG know-how and/or any other FG materials, confidential information, intellectual property or other related information provided by FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, for any use outside the Field at any time or within the Field after the expiration or termination of this Agreement.

8.3.4 Activities Outside Field by Astellas. Without limiting the foregoing, Astellas agrees that during the term of this Agreement it will not (and will not authorize any third party, including, without limitation, any Affiliates or Sublicensees, to) (i) Commercialize any Lead Compound within the Field in the Astellas Territory, except a Lead Compound that has been designated a Lead Compound by the JDC and that has received Marketing Approval in the Astellas Territory for use in the Field, (ii) Commercialize any Lead Compound for use outside the Field or outside the Astellas Territory, (iii) provide any supplies of any Lead Compound to any third party, including, without limitation, any Affiliates or Sublicensees, which Astellas knows or has reason to know is being marketed, sold or distributed for use outside the Field or outside the Astellas Territory, (iv) conduct or sponsor, or provide any supplies of any Lead Compound for use in, any clinical trial designed to demonstrate that a Lead Compound can be used outside the Field, or (v) seek regulatory approval of, or use labeling for a Lead Compound stating that such Lead Compound is for use outside the Field.

8.3.5 Activities in Astellas Territory by FG During the term of this Agreement, FG shall not Commercialize by itself or through its Sublicensee any Lead Compound or other compound, whether or not designated as a Lead Compound, within the Field in the Astellas Territory, or any Lead Compound outside the Field in the Astellas Territory, provided, however, that FG may develop a Lead Compound or other compound in the Astellas Territory in those Indications for which Astellas has determined not to pursue Commercialization or for which Astellas has lost the right to pursue Commercialization due to failure to meet diligence obligations hereunder; and provided, further, that FG may Commercialize compounds other than Lead Compounds outside the Field in the Astellas Territory, irrespective of whether such compound has the effect of stabilizing HIF causing the stimulation of erythropoiesis (including an increase in endogenous erythropoietin production) and/or a subsequent increase in hematocrit through modulation of prolyl hydroxylase and/or asparaginyl hydroxylase.

ARTICLE 9 TRANSFER PRICING

9.1 <u>Transfer for Non-Commercial Purpose</u>. In exchange for the transfer of any Lead Compound to Astellas for a non-commercial purpose, Astellas shall pay FG the total amount of the Fully Burdened Costs for such Lead Compound as reasonably determined by FG. Lead Compound transferred to Astellas for a non-commercial purpose shall not be used for a commercial purpose.

-20

9.2 <u>Transfer for Commercial Purpose</u>. For any Lead Compound transferred to Astellas to be used for any commercial purpose, in exchange for the transfer of such Lead Compound to Astellas, Astellas shall pay FG the amounts set forth in this Section 9.2. All transfers of Lead Compound for use following Marketing Approval shall be deemed transfers for a commercial purpose, except transfers under Section 9.2(c), and transfers for the purpose of conducting clinical trials, which shall be considered transfers for a non-commercial purpose.

- (a) For any quantities of Lead Compound shipped by FG to Astellas prior to the issuance of the national health insurance price as determined by the Japanese Ministry of Health, Labour and Welfare (the "Listed Price"), Astellas shall pay for such quantities at a price equal to [*] of the estimate of the Listed Price as determined in good faith by FG and Astellas, subject to adjustment upon the issuance of the actual Listed Price. Upon the issuance of such Listed Price by the Japanese Ministry of Health, Labour and Welfare, Astellas shall pay to FG, or FG shall reimburse Astellas, as the case may be, the amount of any difference between the payment made for such Lead Compound at the estimated Listed Price and the payment required based upon the actual Listed Price.
- (b) For all other transfers of Lead Compound, except as set forth in subparagraphs (c) or (d) below, Astellas shall pay for such quantities at a price equal to [*] of the Listed Price. In the event that a new Listed Price has been notified to Astellas by the Japanese Ministry of Health, Labour and Welfare before implementation of the new Listed Price, then such new Listed Price shall be used for calculation of the price of Lead Compound to be shipped on and after the later to occur of (i) [*] before implementation of the new Listed Price, and (ii) the date upon which Astellas has amended the price of Lead Compound to wholesalers in response to such notification by the Japanese Ministry of Health, Labour and Welfare, even before implementation of the new Listed Price.
- (c) With respect to Lead Compound to be distributed as samples to medical providers and for which Astellas shall not receive any payment or other consideration, Astellas shall pay to FG the sum of its Fully Burdened Costs for amounts of Lead Compound shipped to Astellas; provided, however, that the parties shall mutually agree upon the amount of such samples for distribution without consideration in the Astellas Territory.
- (d) Upon the later of (i) the initial retail sale of a generic equivalent (as defined by the Japanese Ministry of Health, Labour and Welfare) of such Lead Compound in the Territory, and (ii) and the expiration of the last to expire of the FG Patents with respect to such Lead Compound effectively precluding third parties from selling said generic equivalent, for any quantities shipped by FG to Astellas, Astellas shall pay FG for such quantities [*] of the Sales Price; provided, however, that in the event that the payment of the [*] of the Sales Price would result in FG's [*] Percentage falling below [*], FG shall have the option to initiate a renegotiation of the transfer price upon notice to Astellas, in which case the parties shall use best efforts in good faith to renegotiate reasonable terms for the transfer price; provided, further, that in the event the transfer price is not renegotiated to FG's satisfaction or FG elects not to initiate a renegotiation, FG may elect to terminate its manufacturing obligations by written notice to Astellas, and FG and Astellas shall negotiate reasonable terms for transfer of manufacturing. During such period of renegotiation, FG shall transfer the Lead Compound to Astellas at a price

-21

equal to the greater of [*] of the Sales Price and the price resulting if FG's [*] Percentage for such Lead Compound is equal to [*].

9.3 Payment. Any payments to be made with respect to the transfer of any Lead Compound in accordance with Section 9.1 or 9.2 above shall be immediately due to FG upon shipment, which shall be paid by Astellas to FG no later than [*] of the date of invoice, which invoice FG shall deliver to Astellas upon Delivery of Lead Compound to Astellas pursuant to Section 9.2(a), (b) or (c), and shall be made in U.S. dollars. For transfer of any Lead Compound in accordance with Section 9.1 or 9.2(c) above, FG shall deliver to Astellas, within ten (10) days of receipt of a firm commitment order from Astellas, an invoice for the estimated Fully Burdened Costs of the Lead Compound to be transferred to Astellas. Within [*] after the transfer of the Lead Compound to Astellas, FG shall provide a revised final invoice to Astellas that shall indicate the actual Fully Burdened Costs of the Lead Compound. If the actual Fully Burdened Costs are less than the estimated Fully Burdened Costs, FG shall include a reimbursement payment to Astellas for the difference between the initial estimated Fully Burdened Costs and the actual Fully Burdened Costs. If the actual Fully Burdened Costs are greater than the estimated Fully Burdened Costs, Astellas shall pay such difference within [*] of receipt of an invoice from FG for such amounts. For payments for the transfer of Lead Compound under Section 9.2(d) hereof, FG's invoice to Astellas shall be calculated based on the current Listed Price as set by the Japanese Ministry of Health, Labour and Welfare. Upon calculation of the Sales Price, Astellas shall submit, for any amounts actually sold, the Sales Price to FG, and FG shall credit Astellas for the difference between the invoice cost, cost calculated based on the Listed Price and the cost calculated based on the Sales Price.

9.4 <u>Reference Materials</u>; <u>Standard Materials</u>. In exchange for the transfer by FG of any Reference Materials or Standard Materials for the purposes of conducting analytical, release, stability and other studies authorized under the Development Program, Astellas shall pay to FG, FG's Fully Burdened Costs of such materials as reasonably determined by FG.

ARTICLE 10 ADDITIONAL PAYMENTS; BOOKS AND RECORDS

10.1 Quarterly Reports. Astellas shall make quarterly reports to FG within sixty (60) days after the end of each calendar quarter (April 1 though June 30, July 1 through September 30, October 1 though December 31, January 1 through March 31), which reports shall include, (a) the Net Sales, unit shipments and other distributions, including samples, by Astellas, and its Affiliates and Sublicensees, in such calendar quarter and (b) such other information as may be reasonably requested by FG to ensure either proper payment by Astellas of amounts required under this Agreement or to calculate payments with respect to FG's Third Party Agreements. Concurrently with making such report, Astellas shall remit payment to FG for any payments due under this Agreement.

10.2 <u>Payment Method</u>. All payments under this Agreement shall be made by bank wire transfer in immediately available funds to an account designated by the payee. All

-22-

such payments made by or on behalf of Astellas hereunder shall be made by a Japanese entity. All dollar amounts specified in this Agreement, and, except as specifically authorized under Section 10.3 hereof, all payments made hereunder, are and shall be made in U.S. dollars. Any payments due under this Agreement which are not paid by the date such payments are due under this Agreement shall bear interest to the extent permitted by applicable law at the U.S. prime rate per annum quoted in the "Money Rates" column of <u>The Wall Street Journal</u> (U.S., Western Edition) on the first business day after such payment is due, plus an additional [*], calculated on the number of days such payment is delinquent. This Section 10.2 shall in no way limit any other remedies available to either party.

10.3 <u>Currency Conversion</u>. In the event that the amount of an Astellas payment obligation in U.S. dollars must be determined by the calculation of an underlying amount received by Astellas in Japanese Yen utilizing the U.S. dollar-Japanese Yen exchange rate (i.e., a transfer payment under Section 9.2(a), (b) or (d) hereof), currency conversion from Japanese Yen to U.S. dollars shall be made using the closing exchange rate reported in the Wall Street Journal (U.S. Western Edition) for the date on which the Lead Compound is Delivered to Astellas. If any such payment is not made by the due date, the exchange rate utilized for determination of such payment obligation shall be the exchange rate [*] reported in the Wall Street Journal (U.S. Western Edition) during the period from the date of invoice through the due date, not including any additional amounts owed under Section 10.2 hereof.

10.4 <u>Taxes</u>

10.4.1 <u>Generally</u>. Each party shall bear and, except as otherwise expressly provided in this Section 10.4, pay any and all taxes, duties, levies, and other similar charges (and any related interest and penalties), however designated, imposed on that party as a result of the existence or operation of this Agreement. If laws or regulations require that taxes be withheld, the paying party will (i) timely pay the taxes to the proper taxing authority, and (ii) send proof of payment to the other party within [*] following that payment.

10.4.2 <u>Certain Payments</u>. Notwithstanding Section 10.4.1, all payments by Astellas required under this Agreement above, including under Section 6.1.1 are expressed as net amounts and shall be made free and clear of, and without reduction for, any withholding taxes, provided, however, that in the event that any withholding taxes are due on the payments Astellas shall make to FG under Sections 6.1.2 and 6.1.3, Astellas shall make such payments directly to the Japanese Tax Authority and shall be entitled to reduce the amount paid to FG by [*] of the amount of the withholding taxes paid to Japanese Tax Authority in respect of such payment, unless the amount of such withholding taxes is reduced by a decision of the Japanese tax authority, or is subsequently adjusted downward as result of appeal, in which event the next payment due hereunder, including, without limitation, a transfer payment or a payment upon termination, shall be increased by such amount. Any such taxes which are otherwise imposed on payments to FG shall be the sole responsibility of Astellas. Astellas shall provide FG with official receipts issued by the appropriate taxing authority or such other evidence as is reasonably requested by FG to establish that such taxes have been paid. Astellas and FG shall cooperate to minimize the withholding taxes due on the amounts payable by Astellas to FG hereunder to the extent permissible under law, including, but not limited to,

-23-

making appropriate application(s) to the tax authorities within the Astellas Territory. If possible, FG shall use its reasonable efforts to apply for the tax refund from U.S. tax authorities for the withholding taxes paid to the Japanese Tax Authority on the payment U.S. \$[*] payment made by Astellas to FG on January 13, 2004 as set forth in Section 6.1 when such application for the tax refund becomes possible, and if FG has received any such tax refund, FG shall reimburse to Astellas for the amounts corresponding to the withholding taxes paid in Astellas' accounts as set forth above.

10.5 Records; Inspections. Astellas shall keep, and require its Affiliates and Sublicensees to keep, complete, true and accurate books of accounts and records for the purpose of determining payments due pursuant to this Agreement. Such books and records shall be kept for at least [*] following the end of the calendar quarter to which they pertain. FG shall keep, and require its Sublicensee(s) to keep, complete, true and accurate books of accounts and records for the purpose of verifying the accuracy of the [*] Percentage and Fully Burdened Costs. Such records will be open for inspection at the principal place of business of each party (the "Inspected Party") during such [*] period by an independent auditor chosen by the other party (the "Inspecting Party") and reasonably acceptable to the Inspected Party for the purpose of verifying the amounts payable by Astellas to FG hereunder or the accuracy of the [*] Percentage and/or Fully Burdened Costs. Such inspections may be made no more than once each calendar year, at reasonable times and on reasonable notice. Any books of accounts or records shall not be inspected more than once. The independent auditor retained by the Inspecting Party shall be obligated to execute a reasonable confidentiality agreement with the Inspected Party prior to commencing any such inspection, which, among other customary clauses, contains the provisions to the effect that such auditor shall not disclose to the Inspecting Party any information other than as necessary to accomplish the purpose of the inspection. Inspections conducted under this Section 10.5 shall be at the expense of the Inspecting Party. Any underpaid or overcharged amounts that are discovered will be paid by the Inspected Party, and with interest on such underpaid or overcharged amounts at the rate set forth in Section 10.2 above. The parties will endeavor to minimize disruption of the Inspected Party's normal business activities to the extent reasonably practicable.

ARTICLE 11 DUE DILIGENCE

11.1 <u>Astellas' Due Diligence</u>. Astellas shall use its commercially reasonable efforts (i) to conduct any development work undertaken under the Development Program, and any and all clinical trials (including without limitation Phase III) required to obtain, and thereafter to take such other actions as are necessary to obtain, Marketing Approvals for any Lead Compound in the Astellas Territory as soon as practicable, and (ii) to launch each such Lead Compound in the Astellas Territory as soon as practicable after receiving Marketing Approval in the Astellas Territory for such Lead Compound.

11.2 FG's Due Diligence. FG shall use its commercially reasonable efforts to conduct, and to the extent possible taking into account safety and other applicable issues, complete a Phase II clinical trial with FG-2216 or another Lead Compound in the FG Territory.

-24-

11.3 Development Diligence

Commercialization in "Treatment of anemia in patients with chronic kidney disease undergoing dialysis" and "Treatment of anemia in patients with chronic kidney disease undergoing dialysis" and "Treatment of anemia in patients with chronic kidney disease not undergoing dialysis"; (ii) Astellas shall notify FG within six (6) months of the execution of this Agreement whether it shall pursue Commercialization in [*]; (iii) Astellas shall notify FG within six (6) months of the date FG notifies Astellas that it has demonstrated Proof of Concept whether it will pursue Commercialization in [*]; (iv) Astellas shall notify FG within six (6) months of the date FG notifies Astellas that it has demonstrated Proof of Concept whether it will pursue Commercialization in [*]; and (v) Astellas shall notify FG, upon Marketing Approval for any Lead Compound in each of the following Indications, whether it will pursue Commercialization of such Indication: [*], and any other indications to be added hereafter to the definition of the Indication by mutual agreement; and (vi) if FG is pursuing Commercialization of [*], Astellas shall notify FG after Marketing Approval whether it shall pursue Commercialization of such Indication. Should Astellas inform FG that it does not wish to pursue Commercialization of any Indication, or should Astellas fail to meet the due diligence obligations under Section 11.3.2 for any Indication as set forth in Section 11.3.1(iv) or under Section 11.3.3 for any Indication as set forth in Section 11.3.1(v), such Indication shall no longer be considered an Indication for the purposes of this Agreement, and Astellas shall have no right or shall lose any right with respect to such Indication under this Agreement including, without limitation, the licenses granted under Sections 8.1 and 13.1 hereof. Each Indication for which Astellas is obligated to pursue Commercialization under Section 11.3.1(i) or for which it decides to pursue Commercialization under Sections 11.3.1(ii) or (iv) shall be a "Major Indication".

11.3.2 In addition to the obligations set forth in Section 11.1 and 11.3, for each Major Indication, until such time as Astellas obtains Marketing Approval in the Astellas Territory for such Major Indication, with respect to each Lead Compound for each Major Indication, Astellas shall:

(a) If required for development of a Lead Compound in an Indication, Initiate Phase I clinical trials within [*] after the later of (i) the Effective Date, for Indications for which FG has commenced clinical trials prior to the execution of this Agreement, and (ii) FG's or its Sublicensees Initiation of a Phase I clinical trial for other such Indications.

-25-

(b) Initiate Phase II clinical trials within the later of (i) [*] after FG's, or its Sublicensee's, Initiation of Phase II, (ii) [*] after Astellas' Completion of its Phase I clinical trial(s), (iii) if Astellas' obligations under this Subsection 11.3.2(b) are triggered upon FG's notification of demonstration of Proof of Concept in an Indication, [*] after the date Astellas notifies FG that it will pursue Commercialization in such Indication, and (iv) in the event Astellas' obligations under this Section 11.3.2(b) are triggered by the designation of a secondary Lead Compound as a primary Lead Compound, [*] after such designation.

- (c) Either notify FG of its intent to employ the Bridging Strategy, if applicable, or Initiate Phase III clinical trials within [*] of the later of (i) FG's, or its Sublicensee's Initiation of a Phase III clinical trial and (ii) Astellas' Completion of its Phase II clinical trial(s).
- 11.3.3 For each of the Indications set forth in Section 11.3.1(v), Astellas shall Initiate Phase II clinical studies within [*] of its notification to FG that it will pursue Commercialization in such Indication.
- 11.3.4 Astellas' diligence obligations set forth in Section 11.3.2 shall apply to all Lead Compounds designated by FG, provided, that for each Indication for which such diligence obligations apply, the diligence obligations shall only apply to the primary Lead Compound designated by FG, and for the secondary Lead Compound, Astellas' diligence obligations shall be limited to those set forth in Section 11.3.2(a) until the designation of the secondary Lead Compound as the primary Lead Compound, provided, further, upon such designation, that such diligence obligation shall be expanded to include the requirement that Astellas complete the Phase I clinical studies required to Initiate Phase II clinical studies in the Indication with such secondary Lead Compound.

ARTICLE 12 MANUFACTURING RIGHTS

12.1 <u>Procedures.</u> FG shall have the exclusive right to determine the methods and procedures for the manufacture of all Lead Compounds. If FG intends to make any change in the methods or procedures, including, without limitation, manufacturing process, analyzing process and/or site change for manufacture of the Lead Compounds, FG shall notify Astellas in writing of such intended change; provided, that if in Astellas' reasonable opinion, such change may lead to any amendment to the relevant Marketing Approval or Marketing Approval Application, Astellas shall use best efforts to (i) as soon as possible petition the Japanese Ministry of Health, Labor and Welfare to make the change without an amendment to the Marketing Approval or MAA and shall concurrently prepare an application for amendment to the Marketing Approval or MAA, and (ii) if the Japanese Ministry of Health, Labor and Welfare determines such an amendment is required, shall notify FG and submit the application for amendment immediately following notice of such requirement, and FG shall not make the intended change without a prior written consent from Astellas, such consent not to be unreasonably withheld or delayed, provided, further, that consent shall be deemed granted upon notice that an amendment is not required or approval of an amendment from the Japanese

-26-

Ministry of Health, Labor and Welfare. FG shall provide Astellas with all the data and information necessary for Astellas to amend the Marketing Approval or MAA in Astellas Territory and shall continue to supply Astellas with the Lead Compound as manufactured with the manufacturing methods and procedures or at the manufacturing site described in Astellas' (or its Affiliate's or Sublicensee's) then current Marketing Approval or MAA until Astellas will have finished the necessary amendment to the relevant Marketing Approval or MAA or received notice that an amendment is not required.

12.2 FG Right. FG shall have the worldwide exclusive right (itself or through third party vendors) to manufacture (or have manufactured) Lead Compounds. Astellas and its Affiliates and Sublicensees shall not directly or indirectly make, produce or manufacture any Lead Compounds.

12.3 Manufacture and Supply. FG shall have the exclusive right and obligation to supply the Lead Compounds to Astellas and its Affiliates and Sublicensees for all development and commercial purposes, and Astellas and its Affiliates and Sublicensees shall purchase such Lead Compounds exclusively from FG. It is understood that FG may engage subcontractors with respect to the manufacture of such Lead Compounds to fulfill its supply obligations to Astellas hereunder. In all cases, supply by FG of Lead Compounds hereunder shall be Ex Works (Incoterms 2000) the manufacturing facility. Subject to Section 8.3.5 hereof, nothing herein is intended to preclude FG from granting rights to supply or supplying (a) any Lead Compound outside of the Astellas Territory to any third party for use within or outside the Field, or (b) any compound Controlled by FG within the Astellas Territory except for a Lead Compound for the duration of its designation in compliance with the terms and conditions of this Agreement.

12.4 <u>Product Specifications</u>. The Lead Compounds to be supplied by FG hereunder shall meet the Product Specifications. In addition to, but not in limitation of, the foregoing, FG and Astellas agree that upon Marketing Approval for any Lead Compound, FG's obligation to supply Astellas with Lead Compound shall be limited to, and all payment obligations set forth in Section 9.2 shall be based on, the supply of Bulk Product, unless otherwise agreed by the parties. The packaging for the Lead Compound to be distributed commercially by Astellas shall contain a clearly visible acknowledgment that the Lead Compound was manufactured by FG, and shall contain a registered trademark of the FG logo or other trademark approved by FG.

12.5 Orders Forecast

12.5.1 Orders for Non-Commercial Use. In connection with the supply of any Lead Compound for non-commercial use in the Territory, Astellas shall provide FG with a firm purchase order as early as possible prior to its requirements, and in no event less than [*] prior to the shipment or other release date(s) requested by Astellas for such Lead Compound. FG shall provide such Lead Compound to Astellas as soon as practicable within such time period, subject, prior to Marketing Approval, to the reasonable lead time requirements of third party contract manufacturers. All forecasts shall be prepared in good faith in order to facilitate FG's manufacture and shipment of the Lead Compound in compliance with this Agreement.

-27-

12.5.2 <u>Forecast and Order for Commercial Use</u>. In connection with the supply of any Lead Compound for commercial use in the Astellas Territory upon FG's request, Astellas and FG shall negotiate in good faith appropriate forecasting and firm purchase order lead times, taking into consideration the reasonable notice requirements of FG and its third party manufacturers. All forecasts shall be prepared in good faith in order to facilitate FG's manufacture and shipment of the Lead Compound in compliance with this Agreement.

12.6 Shipment. Astellas, or FG at Astellas' request if specified in a purchase order by Astellas, shall arrange for shipment of the Lead Compound as specified in each purchase order by Astellas, Ex Works (Incoterms 2000) the manufacturing facility. For purposes of this Agreement, and notwithstanding anything to the contrary contained within the term "Ex Works", it is hereby acknowledged and agreed that title and risk of loss shall transfer to Astellas from receipt by Astellas at the manufacturing facility. Astellas shall bear the costs of such carrier, including the costs of insurance of the shipment, and all customs, duties, sales taxes and other governmental charges related to the importation and sales of the Lead Compound.

12.7 Inspection of Shipment/Right to Reject. Each shipment of Lead Compound from FG to Astellas shall contain such laboratory and quality control certificate as are necessary to show that the Lead Compound is in conformity with the Product Specifications. Astellas shall promptly inspect each shipment. In the event that any portion of the shipment fails to conform to the Product Specifications, Astellas shall notify FG within [*] of Astellas' receipt of such shipment. Such notice shall specify the manner in which the Lead Compound fails to meet the Product Specifications. In the absence of such notification, Astellas shall be deemed to have accepted the shipment. FG and Astellas agree to consult with each other to resolve any discrepancy between each other's determinations regarding any possible nonconformity of the Lead Compound. If such consultation does not resolve the discrepancy, the parties agree to nominate a reputable independent laboratory or other independent third party, in each case acceptable to both parties, to carry out tests on representative samples taken from such shipment, and the results of such tests shall be binding on both parties. If the results of such tests demonstrate that the Lead Compound does not meet the Product Specifications, then FG shall pay the costs of such tests; otherwise, Astellas shall pay for the costs of such tests. FG shall, at its expense, promptly replace any Lead Compound to the extent that, in accordance with this Section 12.7, it is determined that it does not conform to the Product Specifications. Unless otherwise instructed by FG, all non-conforming Lead Compound shall be returned to FG at the place of manufacture at FG's direction and at FG's expense. If Astellas detects at any time any defect in the Lead Compound which has not been found through Astellas' inspection, it shall notify FG to that effect within [*] of the discovery of such defect, and the procedures set forth above in this Section 12.7 shall be applied to such defective Lead Compound, provided, that FG shall only be responsible to pay for costs of defects that are the result of FG's gross negligence or willful misconduct.

12.8 <u>Inspection of Facilities</u>. Astellas shall have the right, upon reasonable advance notice and during regular business hours, to inspect and audit, either by itself or through its Affiliates or consultants, the facilities (including any facilities of sub-contractors) being used by FG for production of the Lead Compound to assure compliance with applicable laws, rules and regulations, including, without limitation, Japanese regulatory standards and FG quality control procedures ("Relevant Standards"). FG shall also reasonably comply with inspection

-28-

requests of the Japanese Ministry of Health, Labor & Welfare. Such inspection and audit shall be conducted at Astellas' sole cost and expense in a manner so as to minimize disruption of FG's, or its subcontractor's or Sublicensee's, business operations. FG shall, within [*] after FG's receipt of written notice from Astellas detailing any deficiencies which may be noted in any such audit which relate to the Relevant Standards use good faith efforts to remedy such deficiencies, and submit a plan to the Astellas outlining steps proposed to be taken.

- 12.9 Recall. In the event that Astellas deems it necessary to recall any Lead Compound from the market, it may do so in its sole discretion, after notification to the FG. The costs and expenses for such recall shall be borne by Astellas unless caused by a failure for which FG is required to indemnify Astellas pursuant to Section 17.3, or by FG's gross negligence or willful misconduct, in which event it shall be borne by FG.
- 12.10 Warranty. FG represents and warrants that the Lead Compounds to be supplied to Astellas under this Agreement shall conform to the Product Specifications and shall, as appropriate, be manufactured in compliance with GMP Guidelines. Subject to Sections 12.9 and 17.3 hereof, FG's sole obligation and Astellas' sole remedy with respect to Lead Compound which does not meet the warranty contained herein is limited to replacement of such Lead Compound and reimbursement of Astellas' out of pocket expenses for shipping to FG at the address designated by FG.
- 12.11 <u>Interruption in Supply</u>. For any particular Lead Compound, in order to minimize any interruptions in supply hereunder, FG and Astellas agree that within [*], FG shall maintain two separate, validated manufacturing sites (which may either be its own manufacturing facilities or facilities of a contract manufacturer) for such Lead Compound.
- 12.12 <u>Reference and Standard Materials</u>. For any Lead Compound provided to Astellas hereunder, upon Astellas' request and pursuant to Section 9.4 hereof, FG shall provide to Astellas reasonable quantities of reference materials, including analogs, metabolites, impurities, degradates and radio-labeled compounds ("Reference Materials") and standard materials, i.e. defined, highly purified Lead Compound ("Standard Materials") for such Lead Compound for the purposes of conducting analytical, release, stability and other studies as may be authorized by the JDC under the Development Program.

ARTICLE 13 LICENSE GRANTS

- 13.1 <u>Grant to Astellas</u>. Subject to the terms and conditions of this Agreement including Article 12 above, FG hereby grants to Astellas an exclusive license under the FG Technology to: use, package, sell, have sold, import, market and otherwise distribute the Lead Compounds for use solely in the Field in the Astellas Territory
- 13.2 <u>Sublicenses</u>. The licenses granted under Section 13.1 above include the right to grant and authorize sublicenses, subject to the requirements of this Agreement and Section 7.2. Notwithstanding the foregoing, Astellas shall not have the right to authorize a Sublicensee to market, sell or distribute Lead Compounds without FG's prior written consent

-29-

(which consent shall not be unreasonably withheld). For the purposes of the foregoing, and without limitation, it shall be deemed reasonable for FG to withhold consent for competitive concerns.

13.3 No Rights Beyond Lead Compounds. Except as expressly provided herein, nothing in this Agreement shall be deemed to grant to Astellas rights in FG Technology other than the rights granted hereunder to the Lead Compounds, or for applications outside the Field or outside the Astellas Territory, or to manufacture Lead Compounds; nor shall any provision of this Agreement be deemed to restrict FG's right to exploit any FG Technology and/or the Lead Compounds outside the Astellas Territory.

13.4 Expanded Field Negotiation. Following the signing of this Agreement, FG agrees to negotiate in good faith with Astellas for a license to develop compounds for the Expanded Field in the Astellas Territory, exclusively for a period of [*] following such date, and non-exclusively thereafter until the execution of a license agreement with a third party to develop compounds for the Expanded Field. FG and Astellas hereby agree that FG's obligation to negotiate non-exclusively for the Expanded Field shall not constitute a right of first offer, right of first refusal, right of first negotiation or any obligation to enter into any agreement with Astellas at any time, and the failure of such negotiations to result in an agreement between FG and Astellas with respect to the Expanded Field shall not constitute a breach of this Agreement.

ARTICLE 14 INTELLECTUAL PROPERTY

14.1 Ownership of Inventions. Subject to Section 14.1.1, title to all inventions and other intellectual property made related to (i) the Development Program, (ii) the Lead Compounds, (iii) FG Technology or FG Confidential Information, (iv) the Field, or (v) the Expanded Field (subsections 14.1(i)-(v), collectively, the "Protected Field") shall be owned by or is hereby assigned to FG; provided, however that Astellas shall own inventions of general applicability relating solely to drug delivery systems created exclusively by Astellas under subsection 14.1(i), excluding inventions related to or based on subsections 14.1(ii), (iii), (iv), or (v), and provided, further, that Astellas hereby grants to FG a worldwide, fully paid non-exclusive license with the right to sublicense to practice such inventions with respect to the FG Technology. Astellas agrees to execute any and all assignments and other documents necessary to effectuate the foregoing.

14.1.1 Notwithstanding Section 14.1, in the event that Astellas develops, completely independently from any FG Technology and/or any other FG materials, confidential information, intellectual property or other related information provided by or on behalf of FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, any inventions or intellectual property rights related to the Field or the Expanded Field, [*], Astellas shall own such intellectual property and hereby grants to FG and its Sublicensees a non-exclusive, royalty-free, irrevocable license to such intellectual property for the FG Territory. Astellas agrees to execute any and all assignments and other documents necessary to effectuate the foregoing.

-30-

14.2 Patent Prosecution

14.2.1 FG Inventions. FG shall control all Prosecution and Interference Activities pertaining to FG Patents and patent applications and patents related to its, its Affiliate's or its Sublicensee's inventions in the Protected Field worldwide using counsel of its choice and shall bear the costs of such Prosecution and Interference Activities, provided, however, that; and Astellas shall reimburse to FG, within [*] of receipt by Astellas of invoice therefor, any such costs to the extent incurred in connection with or reasonably allocable to the FG Patents registered and/or to be registered in the Astellas Territory and related to the Field and the Lead Compounds, provided, further, that, with respect to patents or patent applications excluding those covering composition of matter claims and all patents listed on Exhibit A hereto as of the Effective Date, Astellas may postpone such reimbursement until the respective FG Patent will have been registered in the Astellas Territory if [*], on condition that once the respective FG Patent has been registered in the Astellas Territory, Astellas shall pay to FG such costs, plus interest to the extent permitted by applicable law at the U.S. prime rate per annum quoted in the "Money Rates" column of The Wall Street Journal (U.S., Western Edition), calculated in each case from the date such costs were incurred, plus an additional [*] thereof.

14.2.2 <u>Astellas Inventions</u>. Astellas shall not file for or otherwise seek to obtain (directly or indirectly) patent or other intellectual property protection for inventions that are related to the Protected Field, without the prior written consent of FG, which may be withheld at FG's sole discretion, subject to Section 14.1.1, and provided also that Astellas may file for or otherwise seek to obtain patent protection for inventions related to drug delivery systems as described in Section 14.1. To the extent that FG consents to the filing of any patent application or other intellectual property protection related to the foregoing, such patent application or other intellectual property protection shall be subject to Section 14.1, unless otherwise agreed in writing.

14.2.3 <u>Cooperation</u>. Astellas shall cooperate with and assist FG in connection with Prosecution and Interference Activities and shall use best efforts to consult with FG regarding the prosecution and maintenance of the FG Patents for the FG Territory and the Astellas Territory for those FG Patents for which Astellas or its Affiliates, Sublicensees or investigators are inventors, except solely for inventions (i) of general applicability relating solely to drug delivery systems created by Astellas under subsection 14.1(i), or (ii) created in compliance with Section 14.1.1 as determined solely by FG in good faith.

14.3 <u>Defense of Third Party Infringement Claims</u>. If the development, manufacture, sale or use of any Lead Compound pursuant to this Agreement results in a claim, suit or proceeding (collectively, "Actions") alleging patent infringement against FG or Astellas (or their respective Affiliates or Sublicensees), such party shall promptly notify the other party hereto in writing. The party subject to such Action (for purposes of this Section 14.3, the "Controlling Party") shall have the exclusive right to defend and control the defense of any such Action using counsel of its own choice; provided, however, that if such Action is directed to the subject matter of a patent of the other party (*i.e.*, for Astellas, a FG Patent), such other party may participate in the defense and/or settlement thereof at its own expense with counsel of its choice.

-31-

Except as agreed in writing by Astellas and FG, Astellas shall not enter into any settlement relating to a Lead Compound, if such settlement admits the invalidity or unenforceability, or limits any claim, of any patent within the FG Technology. The Controlling Party agrees to keep the other party hereto reasonably informed of all material developments in connection with any such Action. Any cost, liability or expense associated with such action (including amounts paid in settlement) (together, "Expenses") shall be borne by the Controlling Party; provided, that if Astellas is the Controlling Party, and the Action is related to Future Third Party Intellectual Property, with respect to Expenses related solely to such Future Third Party Intellectual Property, it shall be entitled to deduct up to [*] of the Expenses incurred on an annual basis from [*] in such year under this Agreement, provided, however, that (i) the total amount deducted shall not exceed [*] thereunder, and (ii) notwithstanding (i) above, Astellas' right to deduct Expenses incurred shall be further limited such that in no event shall the sum of (a) the Expenses deducted by Astellas under this Section 14.3, and (b) the consideration FG contributes for the acquisition of intellectual property from Third Party Licensors for the Astellas Territory as set forth in Section 14.5, exceed [*] hereunder, and, provided further, that if FG is the Controlling Party, it shall be entitled to reimbursement by Astellas of [*] of such Expenses, as incurred. Notwithstanding the foregoing, Astellas shall be solely responsible (without right of deduction) for all Expenses related to any Action relating to Preexisting Third Party Intellectual Property.

14.4 Enforcement. Subject to the provisions of this Section 14.4, in the event that FG or Astellas reasonably believes that any FG Technology necessary for the development, manufacture, use or sale of a Lead Compound is infringed or misappropriated by a third party or is subject to a declaratory judgment action arising from such infringement, in each case with respect to the development, manufacture, sale or use of a product within the Field and within the Astellas Territory, Astellas or FG (respectively) shall promptly notify the other party hereto. Promptly after such notice the parties shall meet to discuss the course of action to be taken with respect to an Enforcement Action (as defined below) with respect to such infringement or misappropriation, including the control thereof and sharing of costs and expenses related thereto, for the purposes of entering into a litigation agreement setting forth the same ("Litigation Agreement"). If the parties do not enter such Litigation Agreement, FG shall have the initial right (but not the obligation) to enforce the intellectual property rights with respect to the FG Technology, or defend any declaratory judgment action with respect thereto (such action, for purposes of this Section 14.4, an "Enforcement Action").

14.4.1 <u>Information</u>. Absent a Litigation Agreement, the party initiating or defending any such Enforcement Action within the Field shall keep the other party hereto reasonably informed of the progress of any such Enforcement Action, and such other party shall have the right to participate with counsel of its own choice at its own expense.

14.4.2 <u>Enforcement Costs; Recoveries</u>. Absent a Litigation Agreement, FG shall have the initial right to initiate such an Enforcement Action, and shall notify Astellas within a reasonable time whether it elects to exercise such right. In the event that FG elects to initiate or defend such Enforcement Action, FG shall be responsible for [*] of the costs and expenses while Astellas shall be responsible for [*] of the costs and expenses, and all amounts recovered shall first be applied to reimbursement of each

-32-

party's costs and expenses with the remainder to be allocated to FG and Astellas at the ratio of [*] and [*]. In the event that FG elects not to initiate or defend such Enforcement Action, Astellas shall have the right to initiate or defend such Enforcement Action in its own name, and to the extent permitted under Third Party Agreements, in the name of FG or in the names of both FG and Astellas, in which case, Astellas shall be responsible for [*] of the costs and expenses while FG shall be responsible for [*] of the costs and expenses, and all amounts recovered shall first be applied to reimbursement of each party's costs and expenses with the remainder to be allocated to Astellas and FG at the ratio of [*] and [*].

14.4.3 <u>Cooperation in Enforcement Action</u>. Absent a Litigation Agreement, at the request of the party which has the right to initiate or defend an Enforcement Action, the other party shall reasonably cooperate in the Enforcement Action, such cooperation to include, without limitation, furnishing records, information and testimony, and attending conferences, discovery proceedings, hearings, trials and appeals; provided, that the requesting party shall reimburse to the cooperating party for the out-of-pocket expenses incurred for such cooperation pursuant to the reimbursement regime set forth in Section 14.4.2.

14.5 Third Party Agreements

14.5.1 Future Agreements. It is understood that FG may find it necessary to utilize in connection with a Lead Compound intellectual property that is controlled by a non-Affiliate third party (such party, a "Third Party Licensor"), in addition to or in lieu of the FG Technology existing as of the Effective Date. FG shall have the right to obtain (by purchase, license, or otherwise) rights to such intellectual property with the right to sublicense to Astellas. In the event that FG determines that it must obtain such rights, it shall provide notice and submit a description of such rights to Astellas, and shall discuss with Astellas the need to obtain such rights. Astellas shall inform FG within [*] of receipt of such notice whether it believes it is necessary to obtain such rights for the Astellas Territory and wishes to obtain such rights. In the event Astellas determines to obtain such rights, FG shall obtain a worldwide license for the rights under such terms and conditions as are [*], and such intellectual property of the Third Party Licensor shall be deemed to be the part of FG Technology, provided, however, that, notwithstanding anything contained in this Agreement (i) for Preexisting Third Party Intellectual Property, [*] shall pay [*] of all consideration due in connection with the acquisition of such rights for the Astellas Territory, and (ii) for Future Third Party Intellectual Property, [*] shall [*] pay [*] of all consideration due in connection with the acquisition of such rights for the Astellas Territory, provided, however, notwithstanding FG's obligation to contribute to the consideration due for Future Third Party Intellectual Property under (ii) above, FG's obligation to contribute shall be limited such that in no event shall the sum of (a) the consideration FG contributes for the acquisition of intellectual property from Third Party Licensors for the Astellas Territory, and (b) the Expenses for which Astellas has the right to deduct under Section 14.3 exceed [*] hereunder, and Astellas shall be responsible for all consideration related to the acquisition of rights from Third Party Licensors in excess of such amount. In the event Astellas determines not to obtain such rights for the Astellas Territory, FG shall obtain a license for the FG Territory but not the Astellas Territory, and Astellas shall be solely responsible for the defense of any infringement

-33-

Action, for all Expenses related to any such Action, and any right of Astellas to deduct Expenses under this Agreement against payments required to be made to FG hereunder shall not apply to any action brought with respect to such rights.

- 14.5.2 <u>Payment; Reports</u>. If FG is obligated to pay amounts to a Third Party Licensor, FG shall notify Astellas [*] in advance of the due date of such payment obligation (or such later date as FG may determine), and Astellas shall reimburse its share of such payments within [*] after receipt of notice therefor.
- 14.5.3 <u>Limitation</u>. To the extent that FG Patents includes any intellectual property licensed under FG's License Agreement with Imigen, Inc. relating to HIF stabilization technology dated as of October 30, 2003, and amended as from time to time of which a redacted copy shall have been provided to Astellas prior to the Effective Date, Astellas shall be considered a sublicensee and be subject to the applicable requirements thereunder.
- 14.5.4 <u>Compliance with Third Party Agreements</u>. Notwithstanding anything to the contrary contained herein, Astellas agrees to comply with the requirements (upon sublicensees or otherwise) of FG's License Agreement with Imigen, Inc. relating to HIF stabilization technology dated as of October 30, 2003. In addition, Astellas agrees to comply with the requirements (upon sublicensees or otherwise) of any future Third Party Agreements for which Astellas obtains rights through an FG license pursuant to Section 14.5.1 hereof.

ARTICLE 15 REPRESENTATIONS AND WARRANTIES

- 15.1 FG Warranties. FG warrants and represents to Astellas, as of the execution of this Agreement, that (i) it is a corporation duly organized, validly existing and in good standing under the laws of the State of Delaware; (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of FG; (iii) there is no pending litigation which alleges or any communication alleging that Commercialization of any Lead Compound or any compound Controlled by FG for use in the Field has infringed or misappropriated the intellectual property rights of any Third Party or has been obtained by misappropriating any Third Party's intellectual property right; and (iv) subject to the terms and conditions of the agreements for the FG Acquired Patents, FG has complete title to and ownership of the FG Patents, free and clear from any mortgages, pledges, liens, security interests, conditional and installment sale agreements, encumbrances, charges or claims of any kind.
- 15.2 <u>Astellas Warranties</u>. Astellas warrants and represents to FG, as of the execution of this Agreement, that (i) it is a corporation duly organized, validly existing and in good standing under the laws of Japan; and (ii) the execution, delivery and performance of this Agreement have been duly authorized by all necessary corporate action on the part of Astellas.
- 15.3 <u>Disclaimer of Warranties</u>. EXCEPT AS OTHERWISE SET FORTH HEREIN, FG AND ASTELLAS EXPRESSLY DISCLAIM ANY WARRANTIES OR CONDITIONS, EXPRESS, IMPLIED, STATUTORY OR OTHERWISE, WITH RESPECT TO

-34-

THE DEVELOPMENT PROGRAM, OR THE FG TECHNOLOGY OR LEAD COMPOUNDS, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE, VALIDITY OF FG TECHNOLOGY, PATENTED OR UNPATENTED, AND NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES.

ARTICLE 16 CONFIDENTIALITY

16.1 <u>Confidential Information</u>. Except as expressly provided herein, the parties agree that the receiving party shall not publish or otherwise disclose and shall not use for any purpose other than this Agreement any information furnished to it by the other party hereto pursuant to this Agreement which if disclosed in tangible form is marked "Confidential" or with other similar designation to indicate its confidential or proprietary nature or if disclosed orally is indicated orally to be confidential or proprietary by the party disclosing such information at the time of such disclosure and is confirmed in writing as confidential or proprietary by the disclosing party within a reasonable time after such disclosure (collectively, "Confidential Information"). Notwithstanding the foregoing, Confidential Information shall not include information that, in each case is demonstrated by written documentation:

- (a) was already known to the receiving party, other than under an obligation of confidentiality directly or indirectly to the disclosing party at the time of disclosure hereunder;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving party hereunder;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving party in breach of this Agreement; or
- (d) was subsequently lawfully disclosed to the receiving party by any third party without any confidentiality obligation directly or indirectly to the disclosing party or developed by the receiving party without reference to any information or materials disclosed by the disclosing party.

It is agreed and understood that all matters discussed and presented at the meetings of the JDC shall be considered Confidential Information hereunder, subject to the terms and conditions of this Agreement.

16.2 <u>Permitted Disclosures</u>. Notwithstanding the provisions of Section 16.1 above, each party hereto may disclose the other party's Confidential Information to the extent such disclosure is reasonably necessary to exercise the rights granted to it, or reserved by it, under this Agreement (including, without limitation, entering into and/or performing business or scientific relationships with respect to products outside the Field as permitted hereunder), in filing or prosecuting patent applications, prosecuting or defending litigation, complying with applicable governmental regulations, submitting information to tax or other governmental

-35-

authorities (including regulatory authorities), or conducting clinical trials hereunder with respect to Lead Compounds, provided that if a party is required by law to make any such disclosure of the other party's Confidential Information, to the extent it may legally do so, it will give reasonable advance notice to the latter party of such disclosure and, save to the extent inappropriate in the case of patent applications or otherwise, will use its reasonable efforts to secure confidential treatment of such Confidential Information prior to its disclosure (whether through protective orders or otherwise).

16.3 <u>Clinical Data</u>. Except as expressly permitted under Sections 7.2 and 16.2, and for publications or disclosures in accordance with Section 5.2, neither party shall disclose to third parties pre-clinical data, clinical data or regulatory filings, comprising Confidential Information of the other party.

16.4 <u>Press Releases</u>. Except as may already be, or is agreed to be, publicly disclosed, in the event that either party proposes to release a press release with respect to this Agreement or the Development Program, such party shall obtain the prior written consent of the other party, which shall not be unreasonably withheld.

ARTICLE 17 INSURANCE: INDEMNIFICATION

17.1 <u>Insurance</u>. Each party shall secure and maintain in effect during the term of this Agreement and for a period of five (5) years thereafter insurance policy(ies) underwritten by a reputable insurance company and in a form and having limits standard and customary for entities in the biopharmaceutical industry for exposures related to the Lead Compounds. Such insurance shall include general liability, clinical trial liability and products liability coverage with respect to such party's performance of the Development Program and commercialization of Lead Compounds hereunder. Upon request by the other party hereto, certificates of insurance evidencing the coverage required above shall be provided to the other party.

17.2 Indemnification of FG. Astellas shall indemnify each of FG and its Affiliates and the directors, officers, and employees of FG and such Affiliates and the successors and assigns of any of the foregoing (the "FG Indemnitees"), and hold each FG Indemnitee harmless from and against any and all liabilities, damages, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) incurred by any FG Indemnitee to the extent not otherwise covered by insurance, arising from or occurring as a result of any claim, action, suit, or other proceeding brought by third parties against a FG Indemnitee arising from or occurring as a result of any development, testing, manufacture, importation, use, offer for sale, sale or other distribution of any Lead Compound by or for the benefit of Astellas or its Affiliates or Sublicensees, distributors or agents (including, without limitation, product liability and infringement claims) except to the extent caused by failure of the Lead Compound supplied by FG to meet the Product Specifications in effect at the time of manufacture, or material deviation by FG or its sub-contractor from GMP Guidelines in manufacturing the Lead Compound, or FG's breach of this Agreement or willful misconduct.

-36-

17.3 <u>Indemnification of Astellas</u>. FG shall indemnify each of Astellas and its Affiliates and the directors, officers, and employees of Astellas and such Affiliates and the successors and assigns of any of the foregoing (the "Astellas Indemnitees"), and hold each Astellas Indemnitee harmless from and against any and all liabilities, damages, settlements, claims, actions, suits, penalties, fines, costs or expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) incurred by any Astellas Indemnitee to the extent not otherwise covered by insurance, arising from or occurring as a result of any claim, action, suit, or other proceeding brought by third parties against an Astellas Indemnitee to the extent caused by failure of the Lead Compound supplied by FG to meet the Product Specifications in effect at the time of manufacture, or material deviation by FG or its sub-contractor from GMP Guidelines in manufacturing the Lead Compound, except in each case in this Section 17.3 to the extent caused by Astellas' breach of this Agreement or willful misconduct.

17.4 <u>Procedure.</u> A party (for purposes of this Section 17.4, the "Indemnitee") that intends to claim indemnification under any provision of this Agreement shall promptly notify the indemnifying party (the "Indemnitor") in writing of any claim, action, suit, or other proceeding brought by third parties in respect of which the Indemnitee or any of its Affiliates, or their directors, officers, employees, successors or assigns intend to claim such indemnification hereunder. As between the parties hereto the Indemnitor shall have the right to control the defense and settlement of such claim, action, suit, or other proceeding; provided, that the Indemnitee shall have the right to participate in such defense or settlement with counsel of its own choosing at its expense. The Indemnitee shall not make any settlement of any loss, claim, damage, liability or action without the consent of the Indemnitor, to the extent such consent is not withheld unreasonably or delayed. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any such action, if prejudicial to its ability to defend such action, shall relieve such Indemnitor of any liability to the Indemnitee under this Article 17 but the omission so to deliver written notice to the Indemnitor shall not relieve the Indemnitor of any liability that it may have to any Indemnitee otherwise than under this Article 17. Without limiting the foregoing, the Indemnitee shall keep the Indemnitor fully informed of the progress of any claim, action, suit, or other proceeding for which it intends to claim indemnification under this Article 17.

ARTICLE 18 TERM AND TERMINATION

18.1 <u>Term</u>. This Agreement shall become effective as of the Effective Date and, shall continue in full force and effect until terminated pursuant to this Article 18.

18.2 Termination for Cause or Technical Product Failure

18.2.1 <u>Material Breaches</u>. FG may forthwith terminate this Agreement in the event Astellas fails to make any payment due under Articles 6, 9 or 14, within [*] following receipt of written notice of such default, or materially breaches its obligations under Articles 8 or 14, and fails to cure such breach within [*] following receipt of written notice of such default. Astellas may forthwith terminate this Agreement in the

-37-

event FG materially breaches its obligations under Article 12, and fails to cure such breach within [*] following receipt of written notice of such default. Any termination shall become effective at the end of such [*] or [*] period unless the defaulting or breaching party (or any other party on its behalf) has cured any such default prior to the expiration of the [*] or [*] period, as the case may be.

18.2.2 <u>Independent Activities</u>. Notwithstanding anything contained in Section 8.3.2 or Section 14.1.1, in the event that Astellas Commercializes any molecules for the Field or the Expanded Field, except for actions taken within the Field in the course of the exercise of the licenses granted under Sections 8.1 and 13.1 hereof and expressly authorized under this Agreement, even if FG determines that Astellas' activities are completely independent of any FG Technology and/or any other FG materials, confidential information, intellectual property or other related information provided by FG to Astellas under this Agreement or any other agreement between FG and Astellas relating to the subject matter hereof, FG shall have the right at its sole discretion to terminate this Agreement upon [*] notice to Astellas.

18.2.3 <u>Technical Product Failure</u>. Astellas may terminate this Agreement upon [*] notice to FG upon Technical Product Failure.

18.2.4 <u>Development Diligence Failure</u>. FG may terminate this Agreement upon thirty (30) days notice to Astellas in the event Astellas fails to meet any of its development diligence requirements as set forth in Article 11 hereof, provided, however, that with respect to the development diligence obligations set forth in Section 11.3.2, such termination right on behalf of FG shall be triggered only upon Astellas' failure to meet such development diligence obligations for a Major Indication (except those Major Indications set forth in Section 11.3.1(iv)), and Astellas may terminate this Agreement upon thirty (30) days notice to FG in the event FG fails to meet the development diligence requirement as set forth in Section 11.2 hereof.

18.2.5 Other Material Non-Performance/Misrepresentation. Other than a breach giving rise to a termination right as set forth in Sections 18.2.1 or 18.2.4, or a termination pursuant to a Technical Product Failure as set forth in Section 18.2.3 in the event of (i) a party's breach or default in any other material respect in the performance or observance of any other material term, covenant or provision of this Agreement, or (ii) if any representation by a party contained in this Agreement shall prove to have been incorrect in any material respect when made, resulting in material adverse consequences for the other party, (any such default or material incorrect representation a "Material Non-Performance"), such Material Non-Performance shall be remedied only as provided in Section 18.7.4 below.

18.3 <u>Termination in case of Generic Competition</u>. In the event generic equivalents has captured the [*] of the quantity of Lead Compound sold by Astellas during the [*] preceding such termination calculated on a annual basis; or in the event, after the entry into the market of generic equivalents, that Astellas' annual sales fall below \$[*] for all Lead Compounds, Astellas may terminate this Agreement upon [*] written notice to FG; provided, that Astellas does not Commercialize any Lead Compound after such termination until the expiration of the last to expire FG Patents applicable to such Lead Compound.

-38-

18.4 Negative Advice from Authorities. Astellas may terminate this Agreement upon [*] notice to FG in the event Astellas has commenced Phase III clinical studies in those of the following Indications that FG is developing: "Treatment of anemia in patients with chronic kidney disease undergoing dialysis", "Treatment of anemia in patients with chronic kidney disease not undergoing dialysis" and [*], and the Japanese Ministry of Health, Labor & Welfare has provided written notification that it will not approve the Lead Compounds in such Indications or the JDC determines, after the submission by Astellas of Marketing Approval Applications for such Indications, and the receipt of a response or request of the Japanese Ministry of Health, Labor & Welfare that contains development demands that are so onerous that it is not reasonable to continue with Development of the Lead Compounds in such Indications.

18.5 Admission of Invalidity or Unenforceability of FG Patent. Astellas may terminate this Agreement upon [*] notice to FG in the event that FG enters into a settlement under Section 14.3 that admits the invalidity or unenforceability of all patents within the FG Technology, including patents covering Lead Compounds.

18.6 <u>Termination upon Notice</u>. Subject to Section 18.7.2, Astellas may terminate this Agreement upon six (6) months notice to FG for any reason or no reason.

18.7 Effect of Termination

18.7.1 <u>Accrued Obligations</u>. Termination of this Agreement for any reason shall not release either party hereto from any liability which, at the time of such termination, has already accrued to the other party or which is attributable to a period prior to such termination nor preclude either party from pursuing all rights and remedies it may have hereunder or at law or in equity with respect to any breach of this Agreement.

18.7.2 <u>Termination</u>. In the event of (a) a termination by Astellas under Section 18.6 during the period from the execution of this Agreement until the last to expire of the FG Patents, or (b) by FG under Section 18.2.1, 18.2.2, 18.2.4 or 18.2.5 hereof, Astellas shall, upon the effective date of such termination, pay to FG (i) a termination fee of \$[*] U.S. dollars and (ii) any payments to which FG is otherwise entitled to receive hereunder in the period from the date of such termination notice until the [*].

18.7.3 Survival. Articles 1, 5, 14, 16, 17, 18, 19 and 20, and Sections 8.3.3 and 10.5, shall survive any termination of this Agreement, along with FG's rights and Astellas' obligations (but not Astellas' rights or FG's obligations, except to the extent required by the Japanese Ministry of Health, Labor and Welfare) under Section 5.1.1 and Article 7. In addition, the following provisions shall survive termination of this Agreement for any reason: Astellas shall assign or cause to be assigned to FG (or if not so assignable, Astellas shall take all reasonable actions to make available to FG) all regulatory filings and registrations (including MAAs and Marketing Approvals) with respect to the Lead Compounds that have been filed or made by or under authority of Astellas, and the rights in trademark with respect to each Lead Compound as provided for in Section 4.4.1, in each case such assignment (or availability)

-39-

shall be made within [*] after the notice of termination. From and after the date of a notice of termination, FG shall have no further obligations under this Agreement beyond those obligations that survive termination in such events as specified in this Section 18.7.3.

18.7.4 <u>Material Non-Performance</u>. In the event of any Material Non-Performance by a party, the other party shall, without reasonable delay following discovery of such Material Non-Performance notify the defaulting party in writing, and the parties shall consult with each other in good faith to endeavor to agree upon the most effective means to cure such Material Non-Performance and, if necessary, to effect a remedy in favor of the non-defaulting party for the consequences of such Material Non-Performance by the defaulting party (collectively, the "Resolution"). In the event (i) the parties are unable to agree upon Resolution, or (ii) the defaulting party, in the exercise of reasonable diligence shall have been unable to remedy such Material Non-Performance, then in either such event the remedy of the non-defaulting party with respect to the Material Non-Performance by the defaulting party shall be determined by arbitration pursuant to Section 19.2 hereof, and the arbitrators shall be authorized to fashion such remedy, including equitable relief, which may include termination of this Agreement in whole or in part, as the arbitrators shall determine appropriate, except that termination of this Agreement in whole shall only be the remedy of last resort.

18.7.5 <u>License Upon Termination</u>. In the event of a termination of this Agreement, FG shall have an irrevocable, exclusive, license, with the right to grant and authorize sublicenses, to any trademarks used by Astellas in association with the Lead Compounds hereunder to make, use, sell, import and otherwise exploit products within the Field in the Astellas Territory. Such license shall be royalty-free, provided, however, if such trademark is not a global trademark (i.e. materially different from the trademark used in the FG Territory) and either (i) if Astellas terminates this Agreement under Section 18.2.1 or 18.2.4, or (ii) if this Agreement is terminated in accordance with the procedure as provided for in Section 18.2.5 as a result of FG's Material Non-Performance, in which event FG and Astellas shall negotiate in good faith a reasonable fee for such license.

ARTICLE 19 DISPUTE RESOLUTION

19.1 <u>Disputes</u>. If the parties are unable to resolve any dispute between them regarding the breach, interpretation or enforcement of this Agreement, either party may, by written notice to the other, have such dispute referred to their Authorized Designees, provided that such individuals are not directly involved in the dispute (i.e., the dispute occurs at the JDC, such individuals shall not be members of the JDC), for good faith negotiations. If after [*] such executives are unable to resolve the issue, each of Astellas and FG shall have the right to refer the matter to mediation upon notice to the other party, and the parties shall choose a mediator within [*] of the receipt of such notice, and shall negotiate in good faith to resolve such matter through the mediator within [*] thereafter.

19.2 <u>Full Arbitration</u>. Any dispute, controversy or claim arising out of or relating to the breach, interpretation or enforcement of this Agreement, including disputes relating to termination of this Agreement, shall be settled by binding arbitration in the manner

-40-

described in this Section 19.2. The arbitration shall be conducted pursuant to the rules of Arbitration of the International Chamber of Commerce then in effect. Notwithstanding those rules, the following provisions shall apply to the arbitration hereunder:

- 19.2.1 <u>Arbitrators</u>. The arbitration shall be conducted by a panel of three (3) arbitrators, with one (1) arbitrator chosen by each of FG and Astellas and the third appointed by the other two (2) arbitrators. If the parties are unable to agree upon a single arbitrator, or the third arbitrator in case of a panel of three (3), such third arbitrator (as the case may be) shall be appointed in accordance with the rules of the Arbitration of the International Chamber of Commerce.
- 19.2.2 <u>Proceedings</u>. Except as otherwise provided herein, the parties shall use their best efforts to complete the arbitration within [*] after the appointment of the Panel under Section 19.2.1 above, unless a party can demonstrate to the Panel that the complexity of the issues or other reasons warrant the extension of one or more of the time tables. In such case, the Panel may extend such time table as reasonably required. The Panel shall, in rendering its decision, apply the substantive law of the State of California, without regard to its conflicts of laws provisions, except that the interpretation of and enforcement of this Article 19 shall be governed by the U.S. Federal Arbitration Act. The proceeding shall be conducted in English and shall take place in the city of Vancouver, British Columbia, Canada. The judgment of the Panel shall be binding upon the parties and enforceable in any court of competent jurisdiction.
- 19.2.3 Interim Relief. Notwithstanding anything in this Article 19 to the contrary, FG and Astellas shall each have the right to apply to any court of competent jurisdiction for a temporary restraining order, preliminary injunction, or other similar interim or conservatory relief, as necessary, pending resolution under the above described arbitration procedures. Nothing in the preceding sentence shall be interpreted as limiting the powers of the arbitrators with respect to any dispute subject to arbitration under this Agreement.

ARTICLE 20 MISCELLANEOUS

- 20.1 <u>Confidential Terms</u>. Except as expressly provided herein, each party agrees not to disclose any terms of this Agreement to any third party without the consent of the other party, except (i) as required by securities or other applicable laws or (ii) to prospective and other investors and such party's accountants, attorneys and other professional advisors, or (iii) to others under reasonable conditions of confidentiality.
- 20.2 Governing Law. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed and enforced in accordance with, the laws of the State of California, without reference to conflicts of laws principles.
- 20.3 <u>Force Majeure</u>. Nonperformance of any party (except for payment of amounts due hereunder) shall be excused to the extent that performance is rendered impossible by strike, fire, earthquake, flood, governmental acts or orders or restrictions, failure of suppliers, or any other reason where failure to perform is beyond the reasonable control of the non-

-41-

performing party. In such event FG or Astellas, as the case may be, shall promptly notify the other party of such inability and of the period for which such inability is anticipated to continue. Without limiting the foregoing, the party subject to such inability shall use reasonable efforts to minimize the duration of any force majeure event.

20.4 No Implied Waivers; Rights Cumulative. No failure on the part of FG or Astellas to exercise and no delay in exercising any right under this Agreement, or provided by statute or at law or in equity or otherwise, shall impair, prejudice or constitute a waiver of any such right, nor shall any partial exercise of any such right preclude any other or further exercise thereof or the exercise of any other right.

20.5 <u>Independent Contractors</u>. Nothing contained in this Agreement is intended implicitly, or is to be construed, to constitute FG or Astellas as partners in the legal sense. No party hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of any other party or to bind any other party to any contract, agreement or undertaking with any third party.

20.6 <u>Notices</u>. All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by registered or certified mail, return receipt requested, postage prepaid; facsimile transmission (receipt verified); or express courier service (signature required), in each case to the respective address specified below, or such other address or fax number as may be specified in writing to the other party hereto:

Astellas: Astellas Pharma Inc.

Attn: Director of Legal Department

[*]

with copy to: Astellas Pharma Inc.

Attn: Licensing, Corporate Strategy

[*]

FG: FibroGen, Inc.

Attn: Chief Executive Officer 225 Gateway Boulevard San Francisco, California 94080

Fax: 1-650-866-7202

with a copy

FibroGen, Inc.

to:

Attn: Legal Department 225 Gateway Boulevard San Francisco, California 94080

Fax: 1-650-866-7343

-42-

^{[*] =} Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

20.7 <u>Assignment</u>. This Agreement shall not be assignable by either party to any third party without the written consent of the other party hereto; except that either party may assign this Agreement without the other party's consent to an entity that acquires substantially all of the business or assets of the assigning party within the Field, in each case whether by merger, transfer of assets, or otherwise. Upon a permitted assignment of this Agreement, all references herein to the assigning party shall be deemed references to the party to whom the Agreement is so assigned.

- 20.8 <u>Modification</u>. No amendment or modification of any provision of this Agreement shall be effective unless in writing signed by all parties hereto. No provision of this Agreement shall be varied, contradicted or explained by any oral agreement, course of dealing or performance or any other matter not set forth in an agreement in writing and signed by all parties.
- 20.9 Severability. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, the parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of such provision in any other jurisdiction.
- 20.10 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which together, shall constitute one and the same instrument.
- 20.11 <u>Headings</u>. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement.
- 20.12 Export Laws. Notwithstanding anything to the contrary contained herein, all obligations of FG and Astellas are subject to prior compliance with United States and foreign export regulations and such other United States and foreign laws and regulations as may be applicable, and to obtaining all necessary approvals required by the applicable agencies of the governments of the United States and foreign jurisdictions. FG and Astellas shall cooperate with each other and shall provide assistance to the other as reasonably necessary to obtain any required approvals.
- 20.13 <u>Language</u>. This Agreement is in the English language only, which language shall be controlling in all respects, and all versions hereof in any other language shall not be binding on the parties hereto. All communications and notices to be made or given pursuant to this Agreement shall be in the English language.
- 20.14 Entire Agreement. This Agreement (including the Exhibits hereto) constitutes the entire agreement, both written or oral, with respect to the subject matter hereof, and supersedes all prior or contemporaneous understandings or agreements, including the Binding Term Sheet, dated as of February 9, 2004 by and between FG and Astellas, as amended

-43-

on January 25, 2005, whether written or oral, between FG and Astellas with respect to such subject matter.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed and delivered in duplicate originals as of the date first above written.

ASTELLAS PHARMA INC.		FIBRO	FIBROGEN, INC.	
By:	/s/ Toichi Takenaka	By:	/s/ Thomas B. Neff	
	Toichi Takenaka	•	Thomas Neff	
	President and Chief Executive Officer		President and Chief Executive Officer	
Date:	1.September.05	Date:	23 August 05	

-44-

^{[*] =} Certain confidential information contained in this document, marked by brackets, has been omitted and filed separately with the Securities and Exchange Commission pursuant to Rule 406 of the Securities Act of 1933, as amended.

EXHIBIT A LIST OF PATENTS

[*]

-45-

EXHIBIT B INDICATIONS

Included indications:

- Treatment of anemia in patients with chronic kidney disease undergoing dialysis
- Treatment of anemia in patients with chronic kidney disease not undergoing dialysis
- [*]

-46-

<u>EXHIBIT C</u> INITIAL DEVELOPMENT PLAN

[*]

-47-