**Table of Contents** 

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# FORM 8-K/A

(Amendment No. 1)

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 7, 2005 (December 13, 2004)

# GTx, Inc.

(Exact name of Registrant as specified in its charter)

**Delaware** (State or other jurisdiction of incorporation or organization) **005-79588** (Commission File Number)

3 N. Dunlap Street 3rd Floor, Van Vleet Building

Memphis, Tennessee 38163 (901) 523-9700 zin code, of Begistrant's princi

(Address, including zip code, of Registrant's principal executive offices Registrant's telephone number, including area code,)

(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

**62-1715807** (I.R.S. Employer Identification No.) ITEM 1.01 Entry into a Material Definitive Agreement. ITEM 9.01 Financial Statements and Exhibits. SIGNATURE Ex-10.1 Purchase Agreement with Orion Corporation Ex-10.2 Amended and Restated License Supply Agreement ITEM 1.01 Entry into a Material Definitive Agreement.

Explanatory Note: This Form 8-K/A amends the Current Reports on Form 8-K, filed with the Securities and Exchange Commission on December 14, 2004 and December 30, 2004, in order to include the Purchase Agreement and the Amended and Restated License Supply Agreement with Orion Corporation as exhibits to such current Reports on Form 8-K.

ITEM 9.01 Financial Statements and Exhibits.

(c) Exhibits

Exhibit Number 10.1†	Description Purchase Agreement with Orion Corporation dated December 13, 2004
10.2†	Amended and Restated License Supply Agreement with Orion Corporation dated December 29, 2004.

Portions of the exhibits (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately with the Securities and Exchange Commission.

# SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

GTx, Inc.

Date: March 7, 2005

By: /s/ Henry P. Doggrell

 Name:
 Henry P. Doggrell

 Title:
 Vice President, General Counsel and Secretary

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

\_\_\_\_\_

# EXHIBIT 10.1

### PURCHASE AGREEMENT

# between:

ORION CORPORATION a corporation organized and existing under the laws of Finland;

# and

GTX, INC., a Delaware corporation

-----

Dated as of December 13, 2004

-----

#### PURCHASE AGREEMENT

This Purchase Agreement is entered into as of December 13, 2004 (the "Date of Agreement"), by and between GTx, Inc., a Delaware corporation ("GTx"), and Orion Corporation, a corporation organized and existing under the laws of Finland ("Orion") (GTx and Orion shall hereinafter be referred to individually as a "Party," and collectively as the "Parties").

#### RECITALS

A. GTx and Orion are parties to an Amended and Restated Toremifene License and Supply Agreement effective as of March 30, 2000, as amended, governing the Parties' rights and obligations with respect to the research, development, commercialization and manufacture of certain pharmaceutical products based on the compound known as Toremifene (the "Current Agreement").

B. Orion and Shire US, Inc. ("Shire"), entered into a [ \* ] dated as of September 6, 1999 (the "Shire Agreement"), granting Shire [ \* ] marketed under the brand name Fareston(R) for the treatment of breast cancer in the USA.

C. Orion has negotiated with Shire an agreement whereunder the Shire Agreement will be terminated and Orion will acquire [ \* ] Shire's [ \* ] for the treatment of breast cancer in the USA (the "Fareston Repurchase Agreement"), which rights and interests will be transferred to GTx pursuant to this Agreement and the Amended Agreement (as defined below).

D. Concurrently with the closing of the Fareston Repurchase Agreement, GTx and Orion will, as described below, enter into an agreement that will supercede and replace the Current Agreement, as amended.

 ${\sf E}.$  Orion wishes to sell to GTx, and GTx wishes to acquire from Orion, such assets on the terms set forth in this Agreement.

F. Certain capitalized terms used in this Agreement are defined in Exhibit A.

#### AGREEMENT

GTx and Orion, intending to be legally bound, agree as follows:

1. PURCHASE AND SALE OF ASSETS; RELATED AGREEMENTS

1.1 ASSETS TO BE TRANSFERRED. Upon the terms and subject to the conditions of this Agreement, on the Closing Date (as defined below), Orion shall sell, transfer, convey, assign, grant and deliver to GTx, and GTx shall purchase, acquire and receive, the following properties, rights, claims and assets relating to Products:

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

### (A) PRODUCT FILINGS.

(I) The rights of sponsor in and to NDA [  $^{\ast}$  ] and all related INDs filed with the FDA for Products (but excluding any Drug Master Files filed with the FDA) (such filings and approvals, the "Product Filings").

(B) FARESTON TRADEMARK IN THE USA.

(I) All right, title and interest in the trademark Fareston in the USA (Registration #1460565).

(C) ASSETS FROM SHIRE.

(I) All right, title and interest in and to the Fareston Business Assets.

(II) The Fareston Product inventory [ \* ] (the "Fareston Product Inventory"), consisting of [ \* ]. The Parties will agree on the [ \* ] of the Fareston Product Inventory to be purchased by GTx prior to Closing.

(D) CONTRACTS. All of Seller's rights under the contracts listed in Part 1.1(d) of the Disclosure Schedule (the "Assumed Contracts"), provided that to the extent such contracts prohibit such sale, transfer, conveyance, assignment, grant or delivery ("Restricted Contracts"), then for any such Restricted Contract not transferred or assigned on the Closing Date, the Parties shall [\*] to effect such transfer or assignment to GTx promptly thereafter.

All of the foregoing assets are hereinafter collectively referred to as the "Purchased Assets."

For the avoidance of doubt, all other assets of Orion including, without limitation, other proprietary rights of Orion, equipment and other tangible and intangible personal property, remain the property of Orion and are not subject to this Agreement.

1.2 INTELLECTUAL PROPERTY LICENSE TO PURCHASED ASSETS. Orion hereby grants to GTx a perpetual, irrevocable, royalty-free, nonexclusive license, with the right to grant sublicenses through multiple tiers of sublicensees, to use in or practice under in the USA any and all Intellectual Property Rights of Orion that may be embodied in or cover the Purchased Assets to use, sell, offer for sale and import Fareston Product in accordance with the Amended Agreement, including without limitation the Fareston Business Assets and the Fareston Product Inventory, to the extent not otherwise provided pursuant to the Amended Agreement.

1.3 LIABILITIES TO BE ASSUMED. Upon the terms and subject to the conditions of this Agreement, on the Closing Date, GTx shall assume and agree to perform and discharge Orion's Liability arising on and after January 1, 2005, under and pursuant to the Assumed Contracts; provided, however, that as to any Assumed Contracts that are transferred to GTx after such date, as provided in this Agreement, GTx shall assume, perform and discharge Orion's Liability thereunder only to the extent arising on or after the date upon which such transfer is effected.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.4 LIABILITIES NOT TO BE ASSUMED. Except as specifically set forth in Section 1.3, on the Closing Date, GTx is not assuming any other Liabilities or Contracts of Orion ("Excluded Liabilities and Contracts"), and all such Liabilities and Contracts shall be and remain the responsibility of Orion, including Liabilities that arise under any Assumed Contract prior to January 1, 2005.

1.5 DEPOSIT; PURCHASE PRICE.

(A) On the Date of Agreement, GTx shall pay Orion a deposit of [ \* ] (the "Deposit"). The Deposit will be creditable against the Purchase Price described in Section 1.5(b).

(B) In consideration for the sale and transfer of the Purchased Assets to GTx upon the Closing, the Fareston Product inventory described in Section 1.1(c)(ii), and for other rights granted to GTx pursuant to the Transactional Agreements, including extending GTx's rights in Toremifene under the Amended Agreement, GTx shall pay Orion upon execution of this Agreement an amount equal to (i) [\*], which is the amount paid [\*] under [\*] (such amount, the [\*]), [\*] (ii) [\*], which is [\*]. The payments described in (i) and (ii) together shall be \$5,223,963 (the "Purchase Price"). GTx shall pay to Orion the Purchase Price, less the Deposit, upon the Closing Date.

(C) If Orion fails to execute any of the Transactional Agreements or to otherwise close in accordance with the terms and conditions herein on or before the Scheduled Closing Time (or at any later time as the Parties may mutually agree), then the Deposit shall be immediately returned to GTx and no Party shall have any further rights or obligations hereunder.

(D) Any amounts payable by GTx shall be paid by wire transfer to:

[\*]

1.6 OTHER AGREEMENTS. At the Closing, GTx and Orion shall enter into the Amended Agreement, the Pharmacovigilance Agreement, and the Quality Agreement in substantially the forms attached hereto as Exhibit B, C and D, respectively. The Parties shall also provide to each other any other documents reasonably necessary to evidence or effect the transactions contemplated by this Agreement, including without limitation a bill of sale.

1.7 ALLOCATION OF PURCHASE PRICE. Promptly following the Date of Agreement, GTx and Orion shall in good faith determine the appropriate allocation of the Purchase Price among the Purchased Assets. The Parties shall use commercially reasonable efforts to [\*] arising from the purchase of the Purchased Assets by GTx. The allocation prescribed by such exhibit shall be conclusive and binding upon Orion and GTx for all purposes, and Orion and GTx shall file Tax Returns or other documents with any Governmental Body that are consistent with such allocation; provided, however that if a Governmental Body disagrees with such allocation, then GTx may alter such allocation to conform with such Governmental Body's requirements.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

З.

1.8 FURTHER ACTION. If, at any time after the Closing, any further action shall be necessary on the part of either Party hereto to effect the intentions of the Parties as expressed in this Agreement, as and when requested by a Party and at such Party's expense, each such Party shall take all such further action as may reasonably be necessary to effect such intentions, including without limitation providing to the other Party information relevant to determining the amount of Taxes due with respect to the transactions contemplated in this Agreement.

1.9 CLOSING. The consummation of the transactions contemplated by this Agreement (the "Closing") shall take place at Cooley Godward, 5 Palo Alto Square, Palo Alto, CA 94306 on December 29, 2004 (the "Scheduled Closing Time") (or at such other place as GTx and Orion shall designate), at 9:00 a.m. (Pacific Daylight Time). For purposes of this Agreement, "Closing Date" shall mean the time and date as of which the Closing actually takes place.

2. REPRESENTATIONS AND WARRANTIES OF ORION

Orion hereby represents and warrants as follows:

2.1 DUE ORGANIZATION.

(A) Orion is a corporation duly organized under the laws of Finland, and has all necessary power and authority:

(I) to conduct its business in the manner in which it is currently being conducted; and

 $({\tt II})$  to own and use its assets in the manner in which its assets are currently owned and used.

(B) Orion has never approved, or commenced any proceeding or made any election contemplating, the winding up or cessation of Orion's business or affairs.

2.2 RIGHT TO ASSIGN PURCHASED ASSETS; TITLE TO PURCHASED ASSETS.

(A) The Purchased Assets have been assigned to Orion pursuant to the Fareston Repurchase Agreement and, except for the Assumed Contracts, are owned by Orion free and clear of any Encumbrances, and Orion has good, valid and freely transferable title to all of the Purchased Assets, free and clear of any Encumbrances.

(B) To the Knowledge of Orion, neither the execution, delivery or performance of any of the Transactional Agreements nor the consummation of any of the Transactions will, with or without notice or the lapse of time, result in or give any other Person the right or option to cause or declare: (i) a loss of, or Encumbrance on, any Purchased Asset; (ii) a breach of any Contract; (iii) the release, disclosure or delivery of any Purchased Asset by or to any escrow agent or other Person; or (iv) the grant, assignment or transfer to any other Person of any license or other right or interest under, to or in any of the Purchased Asset.

#### 2.3 CONTRACTS.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(A) Part 1.1(d) of the Disclosure Schedule identifies each Assumed Contract. To Orion's reasonable belief, it has delivered to GTx accurate and complete copies of all Contracts identified in Part 1.1(d) of the Disclosure Schedule, including all amendments thereto. To Orion's Knowledge, each Assumed Contract is valid and in full force and effect.

(B) There is no basis upon which any party to any Assumed Contract may object to (i) the assignment to GTx of any right under such Assumed Contract, or (ii) the delegation to or performance by GTx of any obligation under such Assumed Contract, except for restrictions on assignment or delegation expressly set forth in any such Assumed Contract.

#### 2.4 PROCEEDINGS; ORDERS.

(A) To the Knowledge of Orion, there is no pending Proceeding and no Person has threatened by written notice to commence any Proceeding, that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with, any of the Transactions.

(B) To the Knowledge of Orion, no event has occurred, and no claim, dispute or other condition or circumstance exists, that might give rise to or serve as a basis for the commencement of any Proceeding described in Section 2.4(a).

(C) To the Knowledge of Orion, there is no Order to which any of the Purchased Assets are subject.

2.5 AUTHORITY; BINDING NATURE OF AGREEMENTS.

(A) Orion has the right, power and authority to enter into and to perform its obligations under each of the Transactional Agreements to which it is or becomes a party.

(B) The execution, delivery and performance by Orion of the Transactional Agreements to which it is or may become a party have been duly authorized by all necessary action on the part of Orion.

(C) This Agreement constitutes the legal, valid and binding obligation of Orion, enforceable against Orion in accordance with its terms, subject to (i) laws of general application relating to bankruptcy, insolvency and the relief of debtors and (ii) rules of law governing specific performance, injunctive relief and other equitable remedies.

(D) Upon the execution of each of the other Transactional Agreements at the Closing, each of such other Transactional Agreements to which Orion is a party will constitute the legal, valid and binding obligation of Orion and will be enforceable against Orion in accordance with its terms.

2.6 CONSENTS. Except as set forth in Part 2.6 of the Disclosure Schedule, Orion was not, is not and will not be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with the execution and delivery of any of the Transactional Agreements or the consummation or performance of any of the Transactions.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

2.7 NO DEBARMENT; COMPLIANCE WITH LAWS. Orion hereby certifies that, to the Knowledge of Orion: (i) it has not been debarred or convicted of a crime which could lead to debarment, and (ii) it has not utilized the services of any individual who, or any entity that, in the performance of services in connection with Products has been debarred or has been convicted of a crime which could lead to debarment under the Generic Drug Enforcement Act of 1992, 21 United States Code Section 306(a) and (b), as amended. Orion hereby represents and warrants that, to the Knowledge of Orion and except as set forth in Part 2.7 of the Disclosure Schedule, the marketing, promotion, sale, and/or distribution of the Fareston Products by Shire and the operation of the Purchased Assets have been conducted in material compliance with all applicable laws or regulations.

2.8 FILINGS. All filings, submissions, data and representations made by Shire with regulatory authorities in the USA in connection with Fareston Products, whether in connection with the registration or approval of the Fareston Product, have been true, complete and accurate in all material respects.

3. REPRESENTATIONS AND WARRANTIES OF GTX

GTx represents and warrants as follows:

3.1 DUE ORGANIZATION.

(A) GTx is a corporation duly organized under the laws of the State of Delaware, and has all necessary power and authority:

(I) to conduct its business in the manner in which it is currently being conducted; and

 $({\tt II})$  to own and use its assets in the manner in which its assets are currently owned and used.

(B) GTx has never approved, or commenced any proceeding or made any election contemplating, the winding up or cessation of GTx's business or affairs.

3.2 AUTHORITY; BINDING NATURE OF AGREEMENT.

(A) GTx has the corporate right, power and authority to enter into and perform its obligations under each of the Transactional Agreements to which it is or becomes a party.

(B) The execution, delivery and performance by GTx of the Transactional Agreements shall have been duly authorized by all necessary action on the part of GTx.

(C) This Agreement constitutes the legal, valid and binding obligation of GTx, enforceable against GTx in accordance with its terms, subject to (i) laws of general application relating to bankruptcy, insolvency and the relief of debtors, and (ii) rules of law governing specific performance, injunctive relief and other equitable remedies.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(D) Upon the execution of each of the other Transactional Agreements at the Closing, each of such other Transactional Agreements to which GTx is a party will constitute the legal, valid and binding obligation of GTx and will be enforceable against GTx in accordance with its terms.

3.3 CONSENTS. Except as set forth in Part 3.3 of the Disclosure Schedule, GTx was not, is not and will not be required to make any filing with or give any notice to, or to obtain any Consent from, any Person in connection with the execution and delivery of any of the Transactional Agreements or the consummation or performance of any of the Transactions.

3.4 PROCEEDINGS; ORDERS.

(A) To the Knowledge of GTx, there is no pending Proceeding and no Person has threatened by written notice to commence any Proceeding, that challenges, or that may have the effect of preventing, delaying, making illegal or otherwise interfering with any of the Transactions.

(B) To the Knowledge of GTx, no event has occurred, and no claim, dispute or other condition or circumstance exists, that might directly or indirectly give rise to or serve as a basis for the commencement of any such Proceeding described in Section 3.4(a).

(C) To the Knowledge of GTx, there is no Order to which GTx, or any of the assets owned or used by GTx, is subject.

3.5 NO DEBARMENT. GTx hereby certifies that, to the Knowledge of GTx: (i) it has not been debarred or convicted of a crime which could lead to debarment, and (ii) it has not utilized the services of any individual who, or any entity that, in the performance of services in connection with Products has been debarred or has been convicted of a crime which could lead to debarment under the Generic Drug Enforcement Act of 1992, 21 United States Code Section 306(a) and (b), as amended.

4. PRE-CLOSING COVENANTS OF ORION

4.1 FARESTON REPURCHASE AGREEMENT. On or before the Closing Date, Orion shall have executed the Fareston Repurchase Agreement with Shire.

4.2 OPERATION OF BUSINESS. Orion shall ensure that, prior to the Closing Date:

(A) Shire shall conduct the Fareston Product operations in the ordinary course of business;

(B) Orion does not enter into or permit any of the Purchased Assets or Products to become bound by any Contract that would adversely affect or limit GTx's rights under this Agreement or the Transactional Agreements; and

(C) Shire does not take any action outside the ordinary course of business with respect to the Fareston Product or the Purchased Assets.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

4.3 FILINGS AND CONSENTS. Orion shall ensure that: (a) all filings, notices and Consents required to be made, given and obtained by Orion in order to consummate the Transactions are made, given and obtained on a timely basis; and (b) prior to the Closing Date, Orion cooperates with GTx and prepares and makes available such documents and takes such other actions as GTx may request in good faith, in connection with any filing, notice or Consent that GTx is required or elects to make, give or obtain.

 $4.4\ \text{BEST}$  EFFORTS. During the Pre-Closing Period, Orion shall use its Best Efforts to cause the conditions set forth in Section 6 to be satisfied on a timely basis.

4.5 CONFIDENTIALITY. Orion shall not, during the Pre-Closing Period, without GTx's prior approval, issue or disseminate any press release or other publicity or otherwise make any disclosure of any nature regarding any of the Transactions or the existence or terms of this Agreement, except as permitted in Section 11.4.

# 5. PRE-CLOSING COVENANTS OF GTX

5.1 FILINGS AND CONSENTS. GTx shall ensure that: (a) all filings, notices and Consents required to be made, given and obtained by GTx in order to consummate the Transactions are made, given and obtained on a timely basis; and (b) prior to the Closing Date, GTx cooperates with Orion and prepares and makes available such documents and take such other actions as Orion may request in good faith, in connection with any filing, notice or Consent that Orion is required or elects to make, give or obtain.

 $5.2~{\rm BEST}$  EFFORTS. During the Pre-Closing Period, GTx shall use its Best Efforts to cause the conditions set forth in Section 7 to be satisfied.

5.3 CONFIDENTIALITY. GTx shall not, during the Pre-Closing Period, without Orion's prior approval, issue or disseminate any press release or other publicity or otherwise make any disclosure of any nature regarding any of the Transactions or the existence or terms of this Agreement, except as permitted in Section 11.4.

# 6. CONDITIONS PRECEDENT TO GTX'S OBLIGATION TO CLOSE

GTx's obligation to purchase the Purchased Assets, and enter into the Amended Agreement, the Pharmacovigilance Agreement, and the Quality Agreement in substantially the forms attached hereto as Exhibit B, C and D, respectively, and to take the other actions required to be taken by GTx at the Closing is subject to the satisfaction, at or prior to the Closing, of each of the following conditions (any of which may be waived by GTx, in whole or in part, in writing):

6.1 ACCURACY OF REPRESENTATIONS. All of the representations and warranties made by Orion in this Agreement (considered collectively), and each of said representations and warranties (considered individually), shall have been accurate in all material respects as of the date of this Agreement, and shall be accurate in all material respects as of the Scheduled Closing Time as if made at the Scheduled Closing Time, without giving effect to any update to the Disclosure Schedule.

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

#### 6.2 PERFORMANCE OF OBLIGATIONS.

(A) The Fareston Repurchase Agreement shall have been executed by the parties thereto and a copy shall have been delivered to GTx. Orion shall have executed each of the Amended Agreement, the Pharmacovigilance Agreement and the Quality Agreement as described in Section 1.6.

(B) All of the covenants and obligations that Orion is required to comply with or to perform at or prior to the Closing (considered collectively), and each of said covenants and obligations (considered individually), shall have been duly complied with and performed in all material respects.

6.3 ADDITIONAL DOCUMENTS. GTx shall have received such documents as GTx may request in good faith for the purpose of (i) evidencing the accuracy of any representation or warranty made by Orion, (ii) evidencing the compliance by Orion with, or the performance by Orion of, any covenant or obligation set forth in this Agreement, (iii) evidencing the satisfaction of any condition set forth in this Section 6, or (iv) otherwise facilitating the consummation or performance of any of the Transactions.

6.4 NO PROCEEDINGS. Since the Date of Agreement, there shall not have been commenced or threatened against GTx, or against any Person affiliated with GTx, any Proceeding (a) involving any material challenge to, or seeking material damages or other material relief in connection with, any of the Transactions, or (b) that may have the effect of preventing, delaying, making illegal or otherwise interfering with any of the Transactions.

6.5 NO OTHER CONDITIONS. Subject to the fulfillment (or waiver) of the above conditions, GTx shall at Closing execute the Amended Agreement, the Pharmacovigilance Agreement, and the Quality Agreement in substantially the forms attached hereto as Exhibit B, C and D, respectively.

7. CONDITIONS PRECEDENT TO ORION'S OBLIGATION TO CLOSE

Orion's obligation to sell the Purchased Assets and enter into the Amended Agreement, the Pharmacovigilance Agreement, and the Quality Agreement in substantially the forms attached hereto as Exhibit B, C and D, respectively, and to take the other actions required to be taken by Orion at the Closing is subject to the satisfaction, at or prior to the Closing, of each of the following conditions:

7.1 ACCURACY OF REPRESENTATIONS. All of the representations and warranties made by GTx in this Agreement (considered collectively), and each of said representations and warranties (considered individually), shall have been accurate in all material respects as of the date of this Agreement and shall be accurate in all material respects as of the Scheduled Closing Time as if made at the Scheduled Closing Time.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

### 7.2 GTX'S PERFORMANCE.

(A) GTx shall have made the payments contemplated by Sections 1.5(a) and (b).

(B) All of the other covenants and obligations that GTx is required to comply with or to perform pursuant to this Agreement at or prior to the Closing (considered collectively), and each of said covenants and obligations (considered individually), shall have been complied with and performed in all material respects.

7.3 NO PROCEEDINGS. Since the date of this Agreement, there shall not have been commenced or threatened against Orion or against any Person affiliated with Orion, any Proceeding (i) involving any material challenge to, or seeking material damages or other material relief in connection with, any of the Transactions, or (ii) that may have the effect of preventing, delaying, making illegal or otherwise interfering with any of the Transactions

### 7.4 [\*]

7.5 NO OTHER CONDITIONS. Subject to the fulfillment (or waiver) of the above conditions, Orion shall at Closing execute the Amended Agreement, the Pharmacovigilance Agreement, and the Quality Agreement in substantially the forms attached hereto as Exhibit B, C and D, respectively.

#### 8. INDEMNIFICATION, ETC.

8.1 SURVIVAL OF REPRESENTATIONS.

(A) The representations and warranties made by Orion in this Agreement (including without limitation the representations and warranties set forth in Section 2) shall survive the Closing and shall expire [\*] after the Closing Date (the "Expiration Date" for such representation and warranty) and any Liability of Orion (for indemnification or otherwise) with respect to such representations and warranties shall thereupon cease; provided, however, that if, at any time prior to the Expiration Date, any Indemnitee (acting in good faith) delivers to Orion a written notice alleging the existence of an inaccuracy in or other Breach of any of such representations and warranties and asserting a claim for recovery under Section 8.2 based on such alleged inaccuracy or other Breach, then the claim asserted in such notice shall survive the Expiration Date until such time as such claim is fully and finally resolved.

(B) The representations and warranties made by GTx in this Agreement (including without limitation the representations and warranties set forth in Section 3) shall survive the Closing and shall expire [\*] after the Closing Date, and any Liability of GTx (for indemnification or otherwise) with respect to such representations and warranties shall thereupon cease; provided, however, that if, at any time prior to the Expiration Date, any Orion Indemnitee (acting in good faith) delivers to GTx a written notice alleging the existence of an inaccuracy in or other Breach of any of such representations and warranties and asserting a claim for recovery under Section 8.4 based on such alleged inaccuracy or other Breach, then the claim asserted in

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

such notice shall survive the Expiration Date until such time as such claim is fully and finally resolved.

(C) For purposes of this Agreement, each statement or other item of information set forth in the Disclosure Schedule or in any update to the Disclosure Schedule shall be deemed to be a representation and warranty made by Orion in this Agreement.

8.2 INDEMNIFICATION BY ORION. Subject to Section 8.3 and 8.6, from and after the Closing Date, Orion shall hold harmless and indemnify each of GTx Indemnitees from and against, and shall reimburse each of GTx Indemnitees for, [\*] Damages which are suffered or incurred by any of GTx Indemnitees or to which any of GTx Indemnitees may otherwise become subject at any time [\*] and which arise from or as a result of:

(A) Any Breach of any representation or warranty made by Orion in Section 2 of this Agreement;

(B) Orion's [ \* ] use of the Purchased Assets prior to the Closing Date, including without limitation (i) Orion's [ \* ] sale, distribution, marketing or manufacture of [ \* ], including any rebates, discounts, returns, recalls or allowances attributable to sales [ \* ] prior to the Closing Date, and (ii) any Third Party Claim on account of claims arising prior to the Closing Date, including any regulatory action, proceeding, inquiry or investigation of or pertaining to the Product;

(C) Any Breach of any covenant or obligation of Orion in [  $^{\ast}$  ] or [  $^{\ast}$  ] pursuant to this Agreement;

(D) Any Liabilities not assumed by GTx under Section 1.3.

Orion's obligations to indemnify GTx for claims arising out of the manufacture, use, sale, importation, distribution, and/or marketing of the Product for use in the Breast Cancer Field in all countries or territories worldwide, except the USA, by Orion, its Affiliates, or Unaffiliated Sublicensees are set forth in the Current Agreement and the Amended Agreement.

#### 8.3 LIMITATIONS.

(A) Except with respect to claims based on actual fraud or injunctive or any similar equitable relief that may be available to GTx, the rights of GTx Indemnitees under Section 8.2 shall be the sole and exclusive remedies of GTx Indemnitees with respect to claims resulting from or relating to any misrepresentation, breach of warranty or failure to perform Orion's obligations under this Agreement. Without limiting the generality of the foregoing, in no event shall GTx, its successors or permitted assigns be entitled to claim or seek rescission of the transactions consummated under this Agreement.

(B) Orion shall only be liable under Section 8.2(a) with respect to any claims that are properly asserted in writing pursuant to Section 8.1(a) [\*] of the Closing Date, except for any claim surviving such date pursuant to Section 8.1; provided that any recovery on account

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

of a claim under Section 8.2(a) shall be limited to an amount that does not exceed the total Purchase Price.

(C) In no event shall Orion be responsible or liable for any Damages or other amounts under Section 8.2 that are in the nature of lost profits or lost income, damage to good-will or reputation or the like, or special, indirect, consequential or punitive damages. Each of the GTx Indemnitees shall use commercially reasonable efforts to pursue all legal rights and remedies available in order to minimize the Damages for which indemnification is claimed under Section 8.2.

8.4 INDEMNIFICATION BY GTX. Subject to Sections 8.5 and 8.6, GTx shall hold harmless and indemnify each of Orion Indemnitees from and against, and shall reimburse each of Orion Indemnitees for, [\*] Damages which are suffered or incurred by any of Orion Indemnitees or to which any of Orion Indemnitees may otherwise become subject at any time [\*] and which arise from or as a result of:

(A) Any Breach of any representation or warranty made by GTx in Section 3 of this Agreement;

(B) Any Breach of any covenant or obligation by GTx in [  $^{\ast}$  ] or [  $^{\ast}$  ] pursuant to this Agreement;

(C) Any Liabilities assumed by GTx under Section 1.3.

GTx's obligations to indemnify Orion for claims arising out of the manufacture, use, sale, importation, distribution and/or marketing of Products or the Purchased Assets by GTx, its Affiliates or licensees after the Closing Date are set forth in the Current Agreement and the Amended Agreement.

8.5 LIMITATIONS.

(A) Except with respect to claims based on actual fraud, or injunctive or similar equitable relief that may be available to Orion, the rights of Orion Indemnitees under Section 8.4 shall be the sole and exclusive remedies of Orion Indemnities with respect to claims resulting from any misrepresentation, breach of warranty or failure to perform GTx's obligations under this Agreement. Without limiting the generality of the foregoing, in no event shall Orion, its successors or permitted assigns be entitled claim or seek rescission of the transactions consummated under this Agreement.

(B) GTx shall only be liable under Section 8.4(a) with respect to any claims that are properly asserted in writing pursuant to Section 8.1(a) [\*] of the Closing Date except for any claims that survive such date pursuant to Section 8.1.

(C) In no event shall GTx be responsible and liable for any Damages or other amounts under Section 8.4 that are in the nature of lost profits or lost income, damage to good-will or reputation or the like, or special, indirect, consequential or punitive damages. Each of Orion Indemnitees shall use commercially reasonable efforts to pursue all legal rights and

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

remedies available in order to minimize the Damages for which indemnification is claimed under Section 8.4.

8.6 INDEMNIFICATION PROCEDURES; DEFENSE OF THIRD PARTY CLAIMS. Promptly after receipt by an Indemnitee under Section 8.2 or 8.4 of notice of any Third Party Claim or the commencement of any Proceeding against it, such Indemnitee will, if such claim is to be made against an Indemnitee under such Section, give a Claim Notice to the indemnifying Party of the commencement of such claim, but the failure to notify the indemnifying Party will not relieve the indemnifying Party of any liability that it may have to any Indemnitee (except to the extent that such failure prejudices the defense of such claim or Proceeding). The indemnifying Party shall have the right, at its election and by written notice to the Indemnite within thirty (30) days after it receives a Claim Notice to conduct and control the defense of such claim or Proceeding. If the indemnifying Party makes such election:

(A) Indemnitee shall make available to the indemnifying Party any non-privileged documents and materials in possession of Indemnitee that may be necessary to the defense of such claim or Proceeding;

(B) The indemnifying Party shall keep Indemnitee informed of all material developments and events relating to such claim or Proceeding;

(C) The indemnifying Party shall have the right to participate in the defense of such claim or Proceeding; and

(D) The indemnifying Party shall not settle, adjust or compromise such claim or Proceeding without prior written consent of Indemnitee.

If the indemnifying Party does not so elect, then with respect to any such claim brought against an Indemnitee:

(E) The indemnifying Party shall make available to the Indemnitee any non-privileged documents and materials in its possession that may be necessary or useful to the defense of such claim or Proceeding;

(F) The indemnifying Party shall have the right to participate in the defense of such claim or Proceeding at its own expense;

(G) The Indemnitee shall keep the indemnifying Party informed of all material developments and events relating to such claim or Proceeding and, if requested by the indemnifying Party, shall confer with the indemnifying Party regarding defense strategy; and

(H) The Indemnitee shall not settle, adjust or compromise such claim or Proceeding in a manner that may reasonably give rise to any liability of the indemnifying Party (including by reasons of claims that may be asserted under this Section 8) without the prior written consent of the indemnifying Party.

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

8.7 OTHER CLAIMS. A claim for indemnification for any matter not involving a Third Party Claim may be asserted by Claim Notice to the Party from whom indemnification is sought.

## 9. POST-CLOSING COVENANTS

#### 9.1 TRANSFER OF NDA; ACCEO

(A) Orion shall promptly execute all documents necessary to register GTx as the owner of the Product Filings and the trademark Fareston in the USA (registration number # 1460565). The Parties shall thereafter be responsible for all governmental filings and regulatory actions (including without limitation drug safety database updates and maintenance) after the Closing Date in accordance with the Pharmacovigilance Agreement attached hereto as Exhibit C. Orion may (at its expense) make and retain two (2) electronic copies and photocopies of NDA [ \* ] (one (1) for Orion [ \* ] and one (1) copy of other Product Filings for internal archival purposes and for purposes of defending itself in any litigation (which copies shall not be deemed to confer upon Orion any implied licenses, and shall be GTx's Confidential Information).

(B) Without prejudice to what has been agreed between the Parties in the Amended Agreement, if Orion requires access to certain portions of NDA [ \* ] and the Product Filings for legal or regulatory purposes, or for researching, developing or manufacturing Products for use in the Breast Cancer Field outside the USA or products other than Products (collectively, the "Orion Purposes"); then upon Orion's written request, GTx shall make such portions available to Orion solely for such Orion Purposes on a temporary basis at a reasonable time and at GTx's facilities. Orion may (at its expense) make and retain copies (in electronic and/or paper copy format) of such Orion Purposes. Any such copies of NDA [ \* ] or the Product Filings shall be Confidential Information of GTx.

(C) If (i) the FDA, or equivalent regulatory authority outside the USA (each, a "Regulatory Authority"), requires access to certain portions of NDA [\*] and the Product Filings or their counterparts outside the USA for legal or regulatory purposes of the Party that does not own such items, or (ii) either Party requires access to certain portions of NDA [\*] and the Product Filings or their counterparts outside the USA for legal or regulatory purposes of the Party that does not own such items, or (ii) either Party that does not own such items, including without limitation for making patent-related submissions, then, in either of (i) or (ii), Orion or GTx (as applicable), shall cooperate with such Regulatory Authority or the other Party solely for such purpose on a temporary basis at a reasonable time and at Orion's or GTx's facilities.

(D) The Parties shall cooperate and work together to ensure that the attorney-client privilege is preserved with respect to any documents in NDA [\*] and the Product Filings, in each case that are subject to such privilege (and any other documents, information, or materials that are subject to such privilege and may be transferred from or disclosed by one Party to the other under this Agreement). In addition, the Parties acknowledge and agree that any discovery by or disclosure to GTx of documents, information, or materials that are not related to the Purchased Assets is inadvertent.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

9.2 MARKETING PLAN. After the Closing Date, GTx shall use commercially reasonable efforts to market the Fareston Product in the Breast Cancer Field in the USA in accordance with a Sales and Marketing Plan which shall be attached as Exhibit E within [ \* ] after the Date of Agreement.

9.3 LETTERS REGARDING NDA. Promptly after Closing, Orion shall deliver to GTx an executed letter of "Transfer of Ownership of NDA" substantially in the form set forth in Exhibit G. Promptly after receipt of such executed letter from Orion, GTx shall deliver to Orion an executed "GTx FDA Letter" substantially in the form set forth in Exhibit H.

#### 10. CONFIDENTIALITY

10.1 CONFIDENTIAL INFORMATION. All Confidential Information disclosed pursuant to this Agreement shall be deemed Confidential Information disclosed under the Amended Agreement, and protected pursuant to such Agreement.

#### 11. MISCELLANEOUS PROVISIONS

11.1 FURTHER ASSURANCES. Each Party hereto shall execute and/or cause to be delivered to each other such instruments and other documents, and shall take such other actions, as such other Party may reasonably request (prior to, at or after the Closing) for the purpose of carrying out or evidencing any of the Transactions.

11.2 FEES AND EXPENSES. Each Party to this Agreement shall bear and pay all fees, costs and expenses (including legal fees and accounting fees) that have been incurred or that are incurred in the future by such Party in connection with the transactions contemplated by this Agreement, including all fees, costs and expenses incurred by such Party in connection with or by virtue of:

(A) the negotiation, preparation and review of this Agreement (including the Disclosure Schedule), the other Transactional Agreements and all certificates, opinions and other instruments and documents delivered or to be delivered in connection with the Transactions; and

(B) the consummation and performance of the Transactions.

11.3 NOTICES. Any notice or other communication required or permitted to be delivered to any Party under this Agreement shall be in writing and shall be deemed properly delivered, given and received when delivered (by hand, by registered mail, by courier or express delivery service or by fax) to the address or fax number set forth beneath the name of such Party below (or to such other address or fax number as such Party shall have specified in a written notice given to the other Parties hereto):

if to Orion:

Orion Corporation Orion Pharma Attn: President of Orion Pharma Orionintie 1 (P.O. Box 65)

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

FIN-02200 Espoo Finland Facsimile: 358-9-429-3044 With a copy to: Orion Corporation Orion Pharma Attn: Legal Counsel Orionintie 1 (P.O. Box 65) FIN-02200 Espoo Finland Facsimile: 358-9-429-4088 Notices to GTx shall be sent to: GTx, Inc. Attn: President, with a copy to the General Counsel 3 North Dunlap Avenue Van Vleet Building, Third Floor Memphis, Tennessee 38163 U.S.A. Telephone: 1-901-523-9700 x107 Facsimile: 1-901-523-9772 With a copy to: Cooley Godward LLP Five Palo Alto Square 3000 El Camino Real Palo Alto, CA 94306 Attention: Judith Hasko, Esq. Telephone: (650) 843-5065 Facsimile: (650) 849-7400 11.4 PUBLICITY. With regard to the existence and content of commercial

terms and conditions of this Agreement, unless agreed upon by the Parties, neither Party shall originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, relating to this Agreement, without the approval of the other Party, except as required by law, including, without limitation, provisions regarding the disclosure requirement for publicly quoted companies, and then only to the minimum extent so required, in which event such Party shall give the other Party a reasonable opportunity to review the form and content of the announcement before such legally required announcement is made. Notwithstanding the foregoing, GTx may originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, relating to the use of a Toremifene based Product (except for Toremifene based Products for use in the

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Breast Cancer Field in any country except the USA), provided that GTx forwards to Orion such publicity, news release or other public announcement [ \* ] prior to such publicity, news release or other public announcement, except as otherwise required by law or regulation, including without limitation disclosure requirements promulgated by the Securities and Exchange Commission. It is agreed that such publicity, news release or other public announcement does not require the approval of Orion, unless Orion considers such publicity, news release or other public announcement does not require shall, within [ \* ] after receiving such publicity, news release or other public announcement, so notify GTx and provide written comments specifying changes that Orion reasonably believes will correct such inaccuracy, except as otherwise required by law or regulation. Such publicity, news release or other public announcement shall include wording to the effect that Toremifene is a proprietary compound of Orion, and that Toremifene has been licensed by Orion to GTx for certain uses. [ \* ].

11.5 HEADINGS. The headings contained in this Agreement are for convenience of reference only, shall not be deemed to be a part of this Agreement and shall not be referred to in connection with the construction or interpretation of this Agreement.

11.6 COUNTERPARTS. This Agreement may be executed in several counterparts, each of which shall constitute an original and all of which, when taken together, shall constitute one agreement.

### 11.7 GOVERNING LAW; DISPUTE RESOLUTION.

(A) GOVERNING LAW. This Agreement, including the validity, construction, interpretation and performance thereof, shall be governed entirely by the laws of Sweden. It is the specific intent and agreement of the Parties that the United Nations Convention on the International Sale of Goods shall not apply to this Agreement.

(B) DISPUTE RESOLUTION. All disputes arising out of or in connection with this Agreement (except those involving actions commenced by or involving Third Parties and affecting or involving only one of the Parties) shall be resolved with the following mechanism:

(I) ATTEMPTED AMICABLE RESOLUTION. The Parties shall promptly give each other written notice of any disputes requiring resolution hereunder, which written notice shall specify the Section(s) of this Agreement the other Party is alleged to have breached and shall briefly state the initiating Party's claims, and the Parties shall use reasonable efforts to resolve any such disputes in an amicable manner.

Any disputes arising in connection with this Agreement which cannot be resolved in an amicable manner by representatives of the Parties shall be referred, not later than thirty (30) days after initiation of dispute resolution proceedings under this Section 11.7, to the following corporate officers of the Parties for resolution:

For GTx: President and Chief Executive Officer (or his or her designee)

For Orion: President of Orion-Pharma (or his or her designee)

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Such officers (or their designees) shall attempt to resolve the dispute and shall communicate with each other by facsimile or telephone or in personal meetings in an effort to resolve the dispute.

(II) ARBITRATION. Any disputes (excluding any dispute, controversy or claim arising out of or relating to the validity, enforceability, scope or infringement of patent or trademark rights) arising in connection with this Agreement which cannot be resolved by the Parties within forty-five (45) days after initiation of dispute resolution proceedings under this Section 11.7 shall be finally settled by binding arbitration under the Rules of the Arbitration Institute of the Stockholm Chamber of Commerce, Stockholm, Sweden in accordance with said Rules then in effect with proceedings to be held in Stockholm, Sweden in the English language. Reasonable submission of evidence shall be permitted in any such proceeding to the extent permitted under and consistent with such Rules. Judgment upon any award rendered by the arbitrator(s) in such proceedings may be issued and enforced by any court having competent jurisdiction. Any disputes arising out of or relating to the validity, enforceability, scope or infringement of patent or trademark rights shall be submitted for resolution by a court of competent jurisdiction.

11.8 EFFECT OF COMMENCING DISPUTE RESOLUTION. If either Party in good faith commences dispute resolution proceedings under Section 11.7: (a) any applicable notice periods or cure periods hereunder shall be temporarily suspended pending the outcome of such dispute resolution proceedings, and (b) the non-breaching Party may, at its option, pay any amounts payable to the other Party that are in dispute into an interest-bearing escrow account pending the outcome of such dispute resolution proceedings.

11.9 SUCCESSORS AND ASSIGNS; ASSIGNMENT. Neither Party may assign this Agreement or any of its rights hereunder, nor delegate any of its duties or obligations hereunder, to any Third Party without the prior written consent of the other Party, except (i) to an Affiliate in accordance with the terms of this Agreement, in which case notification thereof shall be provided to the other Party prior to such assignment to an Affiliate, or (ii) in connection with a merger, consolidation or similar reorganization. For clarity, this Agreement shall survive any such merger, consolidation or reorganization of either Party with or into, another party and no consent for such merger, consolidation or reorganization shall be needed. Neither Party shall unreasonably withhold its consent (which shall be provided promptly after a request is made) to any contemplated assignment if such contemplated assignment is in connection with the sale by either Party of all or substantially all of its assets to a Third Party. Any assignment of this Agreement to an Affiliate of the assigning Party shall not relieve the assigning Party of its responsibilities and obligations hereunder. Any purported assignment or transfer in violation of this Section 11.9 shall be void.

11.10 WAIVER. The failure by either Party at any time to enforce any of the terms or provisions or conditions of this Agreement or exercise any right hereunder shall not constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same. No waiver of any of the provisions of this Agreement shall be deemed binding unless executed in writing by the Party to be bound by it.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

11.11 AMENDMENTS. This Agreement may not be amended, modified, altered or supplemented other than by means of a written instrument duly executed and delivered on behalf of GTx and Orion.

11.12 SEVERABILITY. In case one or more of the provisions contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, but this Agreement shall be construed by limiting such invalid, illegal or unenforceable provision, if such is not possible, by deleting such provision from this Agreement.

11.13 PARTIES IN INTEREST. Except for the provisions of Section 8 hereof, none of the provisions of this Agreement is intended to provide any rights or remedies to any Person other than the Parties hereto and their respective successors and assigns (if any).

11.14 INDEPENDENT CONTRACTORS. The Parties hereto are independent contractors and nothing contained in this Agreement shall be construed to place them in the relationship of partners, principal and agent, employer/employee or joint venturer. Both Parties agree that they shall neither have the power or right to bind or obligate the other, nor shall either hold itself out as having such authority.

11.15 ENTIRE AGREEMENT. This Agreement and the Transactional Agreements (including all schedules and exhibits attached thereto) represents the entire Agreement between the Parties relating to the subject matter hereof and supersedes all prior arrangements, understandings, correspondence, notes, minutes and agreements between the Parties (or their predecessors in interest) whether written or oral. No supplement, modification or amendment of this Agreement shall be binding unless executed by the Parties in writing and signed by the duly authorized representatives of both Parties.

11.16 DISCLOSURE SCHEDULE.

(A) The information in the Disclosure Schedule constitutes (i) exceptions to particular representations, warranties, covenants and obligations of Orion as set forth in this Agreement or (ii) descriptions or lists of assets and liabilities and other items referred to in this Agreement. If there is any inconsistency between the statements in this Agreement and those in the Disclosure Schedule (other than an exception expressly set forth as such in the Disclosure Schedule with respect to a specifically identified representation or warranty), the statements in this Agreement will control.

(B) The Disclosure Schedule shall be arranged in sections corresponding to the corresponding provision of this Agreement, and the disclosures in any section of the Disclosure Schedule shall qualify (i) the corresponding subsection of this Agreement and (ii) other subsections of the Agreement to the extent it is clear (notwithstanding the absence of a specific cross reference) from a reading of the disclosure that such disclosure logically relates to such other sections.

REMAINDER OF PAGE INTENTIONALLY LEFT BLANK.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

The Parties hereto have caused this  $\ensuremath{\mathsf{Agreement}}$  to be executed and delivered as of the Date of  $\ensuremath{\mathsf{Agreement}}$  .

ORION CORPORATION		GTX, INC.	
By:	/s/ Pekka Kaivola	By:	/s/ Mitchell Steiner, M.D.
	Pekka Kaivola		Mitchell Steiner, M.D.
Title:	Director Orion Corporation Orion Pharma	Title:	Vice-Chairman and CEO GTx, Inc.
By:	/s/ Timo Lappalainen Timo Lappalainen	By:	/s/ Marc Hanover Marc Hanover
Title:	Senior Vice President Orion Corporation Orion Pharma	Title:	President and COO GTx, Inc.

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# EXHIBITS

Exhibit A:	Certain Definitions
Exhibit B:	Amended and Restated License and Supply Agreement
Exhibit C:	Pharmacovigilance Agreement
Exhibit D:	Quality Agreement
Exhibit E:	Sales and Marketing Plan
Exhibit F:	[ * ] Specifications
Exhibit G:	Letter of Transfer of Ownership of NDA
Exhibit H:	GTx FDA Letter

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# EXHIBIT A

#### CERTAIN DEFINITIONS

#### For purposes of the Agreement (including this Exhibit A):

AFFILIATE. "Affiliate" shall mean and include any officer or director of GTx or Orion or any Person which controls, is controlled by, or is under common control with GTx or Orion.

AGREEMENT. "Agreement" shall mean the Purchase Agreement to which this Exhibit A is attached (including without limitation the Disclosure Schedule and any other exhibits, schedules or attachments thereto), as it may be amended from time to time.

AMENDED AGREEMENT. "Amended Agreement" shall mean the Amended and Restated License and Supply Agreement between the Parties dated as of January 1, 2005.

BEST EFFORTS. "Best Efforts" shall mean efforts that a prudent Person desiring to achieve a particular result would use in order to ensure that such result is achieved as expeditiously as possible and that are commercially reasonable given the nature of the particular result.

BREACH. There shall be deemed to be a "Breach" of a representation, warranty, covenant, obligation or other provision if there is or has been any material inaccuracy in or breach of, or any material failure to comply with or perform, such representation, warranty, covenant, obligation or other provision, and the term "Breach" shall be deemed to refer to any such inaccuracy, breach, failure, claim or circumstance.

BREAST CANCER FIELD. "Breast Cancer Field" shall mean the prevention and treatment of breast cancer.

CLAIM NOTICE. "Claim Notice" shall mean a written notice that contains (i) a description and the amount of any Damages incurred or that may be incurred by GTX Indemnitees or Orion Indemnitees, (ii) a statement that GTX Indemnitees or Orion Indemnitees are entitled to indemnification under Section 8.2 or 8.4 and a reasonable explanation of the basis therefor, and (iii) a demand for payment in the amount of such Damages.

 $\ensuremath{\mathsf{CLOSING}}$  "Closing" shall have the meaning specified in Section 1.9 of the Agreement.

CLOSING DATE. "Closing Date" shall have the meaning specified in Section 1.9 of the Agreement.

CONFIDENTIAL INFORMATION. "Confidential Information" shall mean, with respect to a Party, all information of any kind whatsoever, and all tangible and intangible embodiments thereof of any kind whatsoever, which is disclosed by such Party to the other Party and is marked, identified as or otherwise acknowledged to be confidential at the time of disclosure to the other Party. For purposes of this Agreement, the Purchased Assets shall constitute Confidential Information of GTx.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

CONSENT. "Consent" shall mean any approval, consent, ratification, permission, waiver or authorization (including any Governmental Authorization).

CONTRACT. "Contract" shall mean any written, oral, implied or other agreement, contract, understanding, arrangement, instrument, note, guaranty, indemnity, representation, supply agreement, sourcing agreement, warranty, deed, assignment, power of attorney, certificate, purchase order, sales order, work order, insurance policy, benefit plan, commitment, covenant, assurance or undertaking of any nature.

DAMAGES. "Damages" shall include any loss, damage, injury, Liability, claim, demand, settlement, judgment, award, fine, penalty, Tax, fee (including any reasonable legal fee, expert fee, accounting fee or advisory fee), cost (including any reasonable cost of investigation), or reasonably related Third Party expenses.

DISCLOSURE SCHEDULE. "Disclosure Schedule" shall mean the schedule (dated as of the date of the Agreement) delivered to GTx on behalf of Orion, a copy of which is attached to the Agreement and incorporated in the Agreement by reference.

ENCUMBRANCE. "Encumbrance" shall mean any lien, pledge, hypothecation, mortgage, security interest, encumbrance, equitable interest, preference, right of possession, lease, tenancy, license, proxy, covenant, Order, option, right of first refusal or preemptive right, whether arising out of an obligation to pay any Taxes or otherwise.

ENTITY. "Entity" shall mean any corporation (including any non-profit corporation), general partnership, limited partnership, limited liability partnership, joint venture, estate, trust, company (including any limited liability company or joint stock company), firm or other enterprise, association, organization or entity.

 $\ensuremath{\mathsf{EXPIRATION}}$  DATE. "Expiration Date" shall have the meaning set forth in Section 8.1 of the Agreement.

FARESTON BUSINESS ASSETS. "Fareston Business Assets" shall mean any and all of: (a) [ \* ]; and (b) [ \* ]. For clarity, any information or data described under this paragraph shall include any information or data in written or electronic format.

FARESTON PRODUCT. "Fareston Product" shall mean Orion Product in 60 mg tablet form containing Toremifene that was promoted in the USA under the brand name "Fareston" by Shire prior to the Date of Agreement for use in the Breast Cancer Field.

FDA. "FDA" shall mean the United States Food and Drug Administration and any successor regulatory agency.

FIELD. "Field" shall mean all uses of a Product in humans.

 $\ensuremath{\mathsf{GAAP}}\xspace$  "  $\ensuremath{\mathsf{GAAP}}\xspace$  shall mean generally accepted accounting principles.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# GOVERNMENTAL AUTHORIZATION. "Governmental Authorization" shall mean any:

(A) permit, license, certificate, franchise, concession, approval, consent, ratification, permission, clearance, confirmation, endorsement, waiver, certification, designation, rating, registration, qualification or authorization that is, has been or may in the future be issued, granted, given or otherwise made available by or under the authority of any Governmental Body or pursuant to any Legal Requirement; or

(B) right under any Contract with any Governmental Body.

GOVERNMENTAL BODY. "Governmental Body" shall mean any:

(A) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature;

(B) federal, state, local, municipal, foreign or other government;

(C) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or Entity and any court or other tribunal);

(D) multi-national organization or body; or

(E) individual, Entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.

GTX. "GTx" shall have the meaning set forth in the introductory paragraph to the Agreement.

GTX INDEMNITEES. "GTx Indemnitees" shall mean the following Persons:

(A) GTx;

(B) GTx's current and future Affiliates;

(C) The respective Representatives of the Persons referred to in clauses "(a)" and "(b)" above; and

(D) The respective successors and assigns of the Persons referred to in clauses "(a)", "(b)" and "(c)" above.

IND. "IND" shall mean an Investigational New Drug Application as defined in the United States Food Drug and Cosmetic Act and applicable regulations promulgated thereunder, or any equivalent Application to the equivalent agency in any other country or group of countries, the filing of which is necessary to commence clinical testing of a pharmaceutical product in humans in a particular jurisdiction.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

INDEMNITEE. "Indemnitee" shall mean GTx Indemnitee and/or Orion Indemnitee.

INTELLECTUAL PROPERTY. "Intellectual Property" shall mean rights in database, data collections, diagrams, formulae, inventions (whether or not patentable), know-how, logos, marks (including brand names, product names, logos, and slogans), methods, processes, proprietary information, protocols, schematics, specifications, techniques, URLs, web sites, works of authorship and other forms of technology (whether or not embodied in any tangible form and including all tangible embodiments of the foregoing, such as instruction manuals, laboratory notebooks, prototypes, samples, studies and summaries).

INTELLECTUAL PROPERTY RIGHTS. "Intellectual Property Rights" shall mean all past, present, and future rights of the following types, which may exist or be created under the laws of any jurisdiction in the world: (A) rights associated with works of authorship, including exclusive exploitation rights, copyrights and moral rights; (B) trademark and trade name rights and similar rights; (C) trade secret rights; (D) patent and industrial property rights; (E) other proprietary rights in Intellectual Property; and (F) rights in or relating to registrations, renewals, extensions, combinations, divisions, and reissues of, and applications for, any of the rights referred to in clauses "(A)" through "(E)" above.

KNOWLEDGE. "Knowledge" shall mean, as to Person, that such Person is actually aware of a given factor or matter, or that such Person could be expected to discover or otherwise become aware of such fact or matter in the course of conducting a reasonably diligent and comprehensive investigation concerning the truth or existence of such factor or other matter. An Entity shall be deemed to have Knowledge of a particular fact or matter if any officer or managerial level employee of such Entity has Knowledge of such fact or matter.

LEGAL REQUIREMENT. "Legal Requirement" shall mean any federal, state, local, municipal, foreign or other law, statute, legislation, constitution, principle of common law, resolution, ordinance, code, edict, decree, proclamation, treaty, convention, rule, regulation, ruling, directive, pronouncement, requirement, specification, determination, decision, opinion or interpretation that is or has been issued, enacted, adopted, passed, approved, promulgated, made, implemented or otherwise put into effect by or under the authority of any Governmental Body.

LIABILITY. "Liability" shall mean any debt, obligation, duty or liability of any nature regardless of whether such debt, obligation, duty or liability would be required to be disclosed on a balance sheet prepared in accordance with GAAP and regardless of whether such debt, obligation, duty or liability is immediately due and payable.

[\*].

NDA. "NDA" shall mean a New Drug Application filed pursuant to the requirements of the FDA, as more fully defined in 21 C.F.R. Section 314.5 et seq., a Biologics License Application filed pursuant to the requirements of the FDA, as more fully defined in 21 C.F.R. Section 601, and any equivalent application filed with any equivalent regulatory authority.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

ORDER. "Order" shall mean any:

(A) order, judgment, injunction, edict, decree, ruling, pronouncement, determination, decision, opinion, verdict, sentence, subpoena, writ or award that is, has been or may in the future be issued, made, entered, rendered or otherwise put into effect by or under the authority of any court, administrative agency or other Governmental Body or any arbitrator or arbitration panel; or

(B) Contract with any Governmental Body that is, has been or may in the future be entered into in connection with any Proceeding.

ORION. "Orion" shall have the meaning specified in the introductory paragraph of the Agreement.

ORION INDEMNITEES. "Orion Indemnitees" shall mean the following Persons:

(A) Orion;

(B) Orion's current and future Affiliates;

(C) The respective Representatives of the Persons referred to in clauses "(a)" and "(b)" above; and

(D) The respective successors and assigns of the Persons referred to in clauses "(a), " "(b)" and "(c)" above.

ORION PRODUCT. "Orion Product" shall mean tablets containing [ \* ] of Toremifene respectively, that are manufactured by Orion and are commercially available as of the Date of Agreement, and such other dosage strength or formulation of Toremifene as a therapeutically active ingredient as Orion may manufacture.

PERSON. "Person" shall mean any individual, Entity or Governmental Body.

 $\ensuremath{\mathsf{PRE-CLOSING}}$  <code>PERIOD. "Pre-Closing Period"</code> shall mean the period from the date of the Agreement through the Closing Date.

PROCEEDING. "Proceeding" shall mean any action, suit, litigation, arbitration, proceeding (including any civil, criminal, administrative, investigative or appellate proceeding and any informal proceeding), prosecution, contest, hearing, inquiry, inquest, audit, examination or investigation that is or has been or may be commenced, brought, conducted or heard by or before, or that otherwise has involved or may involve, any Governmental Body or any arbitrator or arbitration panel.

PRODUCT. "Product" shall mean any pharmaceutical product for human use within the Field containing Toremifene as a therapeutically active ingredient.

PURCHASE PRICE. "Purchase Price" shall have the meaning specified in Section 1.5 of the Agreement.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

 $\ensuremath{\mathsf{PURCHASED}}$  ASSETS. "Purchased Assets" shall have the meaning set forth in Section 1.1 to the Agreement.

REGULATORY AUTHORITY. "Regulatory Authority" shall have the meaning specified in Section 9.1.

REPRESENTATIVES. "Representatives" shall mean officers, directors, managerial level employees, agents, attorneys, accountants, advisors and other representatives.

TAX. "Tax" shall mean any tax (including any income tax, franchise tax, capital gains tax, estimated tax, gross receipts tax, value added tax, surtax, excise tax, ad valorem tax, transfer tax, stamp tax, sales tax, use tax, property tax, business tax, occupation tax, inventory tax, occupancy tax, withholding tax or payroll tax), levy, assessment, tariff, impost, imposition, toll, duty (including any customs duty), deficiency or fee, and any related charge or amount (including any fine, penalty or interest), that is, has been, or may in the future be (a) imposed, assessed or collected by or under the authority of any Governmental Body, or (b) payable pursuant to any tax sharing agreement or similar Contract.

TAX RETURN. "Tax Return" shall mean any return (including any information return), report, statement, declaration, estimate, schedule, notice, notification, form, election, certificate or other document or information that is, has been or may in the future be filed with or submitted to, or required to be filed with or submitted to, any Governmental Body in connection with the determination, assessment, collection or payment of any Tax or in connection with any Legal Requirement relating to any Tax.

THIRD PARTY. "Third Party" shall mean any person or entity other than  ${\rm GTx},$  Orion or an Affiliate of either of them.

THIRD PARTY CLAIM. "Third Party Claim" shall mean any claim against any GTx Indemnitee or Orion Indemnitee by a Third Party, whether or not involving a Proceeding.

TOREMIFENE. "Toremifene" shall mean [ \* ].

TRANSACTIONAL AGREEMENTS. "Transactional Agreements" shall mean the Agreement and all other documents or agreements contemplated by Section 1.

TRANSACTIONS. "Transactions" shall mean (a) the execution and delivery of the respective Transactional Agreements, and (b) all of the transactions contemplated by the respective Transactional Agreements, and the exercise by Orion and GTx of their respective rights under the Transactional Agreements.

USA. "USA" shall mean the United States of America including its fifty states, the District of Columbia, Puerto Rico, and all its territories and possessions.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

#### EXHIBIT B

#### AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT

THIS AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT (this "Agreement") is entered into and made effective as of this 1st day of January, 2005 (the "Restatement Date") by and between ORION CORPORATION, a corporation organized and existing under the laws of Finland and having its principal office at Orionintie 1 FIN-02200 Espoo, Finland ("Orion"), and GTX, INC., (fka Genotherapeutics, Inc.) a corporation organized and existing under the laws of the State of Delaware, U.S.A. and having its principal office at 3 North Dunlap Avenue, Van Vleet Building, Third Floor, Memphis, Tennessee 38163, USA ("GTX").

WHEREAS, Orion and GTX entered into a Toremifene License and Supply Agreement effective as of March 30, 2000 (the "Effective Date"), to govern the Parties' rights and obligations with respect to the research, development, commercialization and manufacture of Product (as defined in said agreement) (the "Original Agreement");

WHEREAS, Orion and GTX amended and restated the Original Agreement on October 22, 2001 (the "Amendment Date"), and then amended the Original Agreement on March 5, 2003 (the "First Amendment"), and on December 29, 2003 (the "Second Amendment");

WHEREAS, Shire and Orion have entered into an agreement wherein Orion will acquire all of Shire's rights and interests to Toremifene for the breast cancer indication in the United States;

WHEREAS, GTX desires to expand its license to include all of Orion's other rights and interests in Toremifene for human use, except for the use of Toremifene for the prevention and treatment of breast cancer in countries outside of the United States and use of Toremifene in the animal health field worldwide, and Orion desires to grant to GTX such licenses;

WHEREAS, the Parties desire with this Agreement to supercede and replace the Original Agreement, First Amendment and Second Amendment effective as of the Restatement Date to provide that GTX shall have the sole responsibility for researching, developing, registering and commercializing the Product (as defined below) within the Field (as defined below) worldwide, except for the use of Toremifene either for the prevention and treatment of breast cancer in countries outside of the United States or for animal health; and

WHEREAS, Orion shall have no monetary or other responsibilities for researching, developing, registering or commercializing Product, but shall remain responsible for manufacturing Orion Product (as defined below), as agreed herein;

NOW THEREFORE for and in consideration of the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Orion and GTX (hereinafter individually a "Party"; and collectively the "Parties") hereto agree as follows:

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

B-1

#### 1. DEFINITIONS

For purposes of this Agreement, the following terms shall be defined as set forth below. Additional terms used in specific Sections of this Agreement shall be defined in such Sections.

1.1 "ADDITIONAL PRODUCT" shall have the meaning set forth in Section 2.1.5.

1.2 "AFFILIATE" shall mean any business entity controlled by a Party, or which controls a Party, or which is under common control with a Party. "Control" herein means the direct or indirect ownership of more than fifty percent (50%) of the authorized issued voting shares in such entity, or such other relationship as in fact legally results in effective control over the management, business and affairs of such entity or Party, as the case may be.

1.3 "ANNUAL NET SALES" shall mean Net Sales (as defined below) in any calendar year.

1.4 "BREAST CANCER FIELD" shall mean the prevention and treatment of breast cancer.

1.5 "CALENDAR QUARTER" shall mean each of the three (3) month periods beginning on January 1, April 1, July 1 and October 1 of each year during the Term (as defined below).

1.6 "COMPETING PRODUCT" shall mean any pharmaceutical product containing a SERM as a therapeutically active ingredient as well as any salt thereof, which product is licensed, sold and/or marketed for use in the Field, including, but not limited to, other dosage forms licensed, sold and/or marketed for use in the Field. Competing Product does not include Orion Product, but includes any generic form of the Product.

1.7 "CORRECTION FACTOR" shall have the meaning set forth in Section 3.1.3(b).

1.8 "DMF" shall have the meaning provided in Section 7.5.

1.9 "EUROPEAN UNION" shall include Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, and any such other country or territory that may become part of the European Union after the Restatement Date.

1.10 "FARESTON PRODUCT" shall mean the Orion Product in 60 mg tablet form containing Toremifene that was promoted in the USA under the brand name "Fareston" by Shire prior to the Restatement Date for use in the Breast Cancer Field.

1.11 "FARESTON REPURCHASE AGREEMENT" shall mean the Repurchase Agreement entered by and between Shire and Orion dated \_\_\_\_\_, 2004.

1.12 "FARESTON U.S. WEB PAGES" shall have the meaning set forth in Article 9.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

B-2

1.13 "FIELD" shall mean all uses of a Product in humans. The Parties expressly acknowledge that the use of Product in the field of animal health is excluded from the scope of this Agreement.

1.14 "FIRST COMMERCIAL SALE" means in each country, the date the Product is first sold, marketed, or publicly made available for sale for use in a given portion of the Field by GTX, its Affiliate or a GTX Unaffiliated Sublicensee. Product for use in a given portion of the Field, distributed or used for clinical trial purposes shall not be considered sold, marketed or made publicly available for sale and shall not constitute First Commercial Sale.

1.15 "GENERIC PRODUCT" shall mean a generic pharmaceutical product for human use containing Toremifene as an active ingredient sold by an entity other than GTX, its Affiliate or its Unaffiliated Sublicensee and which can be substituted by the prescriber or dispenser for a Product for use in the Field (excluding Products sold by or on behalf of Orion, in the Orion Territory in the Orion Field or outside the Field).

1.16 "GTX FINAL DEVELOPMENT AND REGISTRATION PLAN" shall mean the final product development and registration plan for each Product in the Prostate Cancer Field prepared by GTX, its Affiliate or a GTX Unaffiliated Sublicensee, as the same may be modified from time to time pursuant to Section 7.4.

1.17 "GTX KNOW-HOW" shall mean such non-patented and unpublished non-clinical, pre-clinical and clinical documentation, information, and data including information and data in U.S. IND [ \* ], U.S. IND [ \* ], and all resulting marketing applications worldwide relating to the use of Toremifene or any SERM in the Field, that is owned or controlled by, and disclosable by and available to, GTX and its Affiliates as of the Effective Date or at any time during the Term, including but not limited to all registration materials for the Product developed, acquired or compiled by GTX and/or its Affiliates as of the Effective Date or at any time during the Term, and all non-patented and unpublished documentation, information and data relating to the formulation, manufacture and/or quality control of the Product that is owned or controlled by GTX and/or its Affiliates as of the Effective Date or at any time during the Term.

1.18 "GTX PATENTS" shall mean the patents issued from GTX Patent Applications as of the Effective Date and other patents owned or controlled by GTX and its Affiliates that are issued at any time during the Term, and that claim technology used for the manufacture, sale or use of any SERM for use in the Prostate Cancer Field (including any divisions, continuations, continuations-in-part, re-examinations, reissues, additions, renewals and extensions thereof). GTX Patents in existence as of the Restatement Date are set forth in Part I of Schedule A. For purposes of this Agreement, the Parties acknowledge that GTX Patents shall include United States Patents as set forth on Schedule A, which claims the use of Product in the Prostate Cancer Field, which patents are in the name of and owned by The University of Tennessee Research Foundation. GTX represents and warrants that it has acquired sufficient rights and licenses from The University of Tennessee Research Foundation to said patents for the purpose of performing its obligations under this Agreement.

1.19 "GTX PATENT APPLICATIONS" shall mean patent applications of the University of Tennessee Research Foundation or GTX, as applicable, and/or Affiliates of GTX pending as of

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

B-3

the Effective Date, and patent applications owned or controlled by the University of Tennessee Research Foundation and/or GTX, as applicable, and/or Affiliates of GTX, that are filed at any time during the Term, in each case that claim technology used for the manufacture, sale or use of any SERM for use in the Prostate Cancer Field (including any divisions, continuations, continuations-in-part, re-examinations, reissues, additions, renewals and extensions thereof). GTX Patent Applications in existence as of the Restatement Date are set forth in Part II of Schedule A.

1.20 "GTX PATENT RIGHTS" shall mean GTX Patents and GTX Patent Applications.

1.21 "GTX PRELIMINARY DEVELOPMENT AND REGISTRATION PLAN" shall mean the preliminary product development plan for the development of the Product in the Prostate Cancer Field prepared by GTX which has been provided to Orion prior to Effective Date, and which was attached to the Original Agreement.

1.22 "GTX TERRITORY" shall mean all countries or territories worldwide.

1.23 "GTX UNAFFILIATED SUBLICENSEE" shall mean any sublicensee of GTX other than a GTX Affiliate. For avoidance of doubt, Orion shall not be a GTX Unaffiliated Sublicensee.

1.24 "MAJOR COUNTRY" shall mean the United States of America including its fifty states, the District of Columbia, Puerto Rico, and all other USA territories and possessions ("USA"), Canada, Japan, Great Britain, France, Germany, Spain and Italy.

1.25 "MANUFACTURING COSTS" shall have the meaning set forth in Section 7.3.

1.26 "MANUFACTURING PATENTS" shall have the meaning provided in Section 7.7.

1.27 "MAT NET SALES OF FARESTON PRODUCT" shall mean the certain moving annual total sales of the Fareston Product as defined in Section 3.1.3(b).

1.28 "NET SALES" shall mean the invoiced gross sales of the Product to a Third Party which is not a GTX Unaffiliated Sublicensee, less: (A) credits and allowances or adjustments (consistent with generally accepted accounting principles), granted to such customers on account of rejections, recalls or returns of the Product previously sold; (B) any customary and reasonable trade and cash discounts, rebates, including government rebates, granted in connection with sale of Product to such customers; (C) sales, tariff duties and/or use taxes directly imposed and with reference to particular sales; and (D) outbound transportation prepaid or allowed, amounts allowed or credited on returns, export licenses, import duties, value added tax, and prepaid freight.

 $1.29\ {\rm "ORION\ FIELD"}$  shall mean the use of Toremifene in the Breast Cancer Field.

1.30 "ORION KNOW-HOW" shall mean such non-patented and unpublished non-clinical, pre-clinical and clinical documentation, information, and data relating to the Orion Product that is owned or controlled by, and disclosable by and available to, Orion and its Affiliates as of the Effective Date or at any time during the Term which is necessary for the development by GTX of Product for use in the Field (including without limitation filing an application for Regulatory

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Approval for the Product for use in the Field), including information and data in the Orion Product NDA relating to Fareston Product, registration materials for the Orion Product, documentation, information and data relating to the formulation and/or quality control of the Orion Product. Except as otherwise provided in Sections 7.7, 14.9, 16.1, 17.3.2, 17.4 and 21.2, Orion Know-How shall exclude information relating to Orion's manufacture of Toremifene (as defined below) and Orion Product (as defined below).

1.31 "ORION PATENTS" shall mean the patents owned or controlled by Orion that are directed to the compound Toremifene per se, and relate to the use or sale of Toremifene and all other patents issued from Orion Patent Applications during the Term (including any divisions, continuations, continuations-in-part, re-examinations, reissues, additions, renewals and extensions thereof). Orion Patents in existence as of the Restatement Date are set forth in Part I of Schedule B. Schedule B shall be amended by Orion from time to time during the Term to include future Orion Patents.

1.32 "ORION PATENT APPLICATIONS" shall mean patent applications owned or controlled by Orion and its Affiliates that are pending as of the Effective Date, and patent applications owned or controlled by Orion and its Affiliates that are filed at any time during the Term, in each case that are directed to the compound Toremifene per se and relate to the use or sale of Toremifene (including any divisions, continuations, continuations-in-part, re-examinations, reissues, additions, renewals and extensions thereof). Orion Patent Applications in existence as of the Restatement Date are set forth in Part II of Schedule B. Schedule B shall be amended by Orion from time to time during the Term to include future Orion Patent Applications.

1.33 "ORION PATENT RIGHTS" shall mean Orion Patents and Orion Patent Applications.

1.34 "ORION PRODUCT" shall mean tablets containing [ \* ] of Toremifene respectively, that are manufactured by Orion and are commercially available as of the Restatement Date, and such other dosage strength or formulation of Toremifene as a therapeutically active ingredient as Orion may agree to manufacture pursuant to Section 17.4.

1.35 "ORION PRODUCT NDA" shall mean U.S. NDA [ \* ].

1.36 "ORION TERRITORY" shall mean all countries and territories worldwide, except for the USA.

1.37 "ORION UNAFFILIATED SUBLICENSEE" shall mean any licensee or sublicensee under the Orion Patent Rights, other than an Orion Affiliate, GTX, a GTX Affiliate or a GTX Unaffiliated Sublicensee.

1.38 "OTHER PRODUCT" shall have the meaning set forth in Section 17.4.

1.39 "PREMIUM" shall mean, with respect to an equity investment by a Third Party in GTX, an amount equal to the difference between the total consideration paid for the purchase of shares of GTX stock and the fair market value of such stock, as defined herein. Such fair market value shall be equal to the trading price of a share of GTX common stock on the date such Third Party investment is made (or, if such date is not a trading day, the price of a share of GTX

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

common stock on the most recent trading day prior to the date of such investment, and if such Third Party investment occurs concurrent with the initial public offering, then the price per share at which stock is offered to the public), multiplied by the number of shares issued to such Third Party investor.

1.40 "PRODUCT" shall mean any pharmaceutical product for human use within the Field containing Toremifene as a therapeutically active ingredient.

1.41 "PRODUCT ROYALTY ADJUSTMENT DATE" shall have the meaning set forth in Section 3.1.3(a).

1.42 "PROSTATE CANCER FIELD" shall mean the prevention and treatment of prostate cancer, which shall mean for the purposes of hereof: preventing prostate carcinogenesis; suppressing or inhibiting prostate cancer; reducing the risk of developing prostate cancer; increasing the survival rate of a subject with prostate cancer; and treating prostate cancer. Furthermore, the Prostate Cancer Field shall include the prevention and/or treatment of osteoporosis, gynecomastia, hot flashes, and other side effects induced by chemical or surgical androgen deprivation therapy in the treatment of prostate cancer.

1.43 "PURCHASE AGREEMENT" shall mean the agreement between Orion and GTX dated December 13, 2004.

1.44 "REGULATORY APPROVAL" shall mean all governmental approvals required to import, market, promote and sell the Product for use in the Field in any given country or territory in the GTX Territory, including but not limited to, product registrations, medical approvals and price and marketing approvals.

1.45 "ROYALTY INCOME" shall have the meaning set forth in Section 3.1.5.

1.46 "SALES OF GENERIC PRODUCT" shall mean the documented sale and use of a Generic Product.

1.47 "[ \* ]" shall have the meaning set forth in Section 3.1.6.

1.48 "SERM" shall mean Toremifene (as described in the Orion Patent Rights), including its isomers, metabolites, derivatives or analogs having either antiestrogenic or estrogenic pharmacological properties.

1.49 "SHIRE" shall mean Shire US, Inc., a corporation duly organized and existing under the laws of New Jersey, USA, and having its principal offices in Wayne, Pennsylvania, which had rights to Product in the USA in the Breast Cancer Field prior to the Restatement Date.

1.50 "SPECIFICATIONS" shall mean the current specifications (as of the Restatement Date) for the Orion Product, as such specifications are, with regard to [ \* ] containing Toremifene, set forth in the Orion Product NDA, and with regard to [ \* ] and [ \* ] tablet of Orion Product set forth in Schedule C (Copies of such current specifications are set forth in Schedule C attached hereto and made a part hereof.) The Specifications shall also include any other modified or additional specifications applicable to Orion Product which may be

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

manufactured by Orion, pursuant to Section 17.3 or 17.4. Schedule C may be amended from time to time as necessary to reflect modifications to the Specifications that may be implemented pursuant to Section 17.3 or to include Specifications for any Other Product that Orion may agree to manufacture pursuant to Section 17.4.

1.51 "TERM" shall mean the period commencing on the effective date of the Original Agreement and continuing, on a country by country basis until the later of (a) the date of expiration or invalidation of the last to expire or be invalidated of the GTX Patent Rights, or (b) the expiration or termination of the last to expire of the marketing or regulatory exclusivity granted by the FDA, the European Medicines Agency or other equivalent regulatory authority for Product, each of (a) and (b) herein as subject to earlier termination under Article 21.

1.52 "THIRD PARTY" or "THIRD PARTIES" shall mean any party or parties other than GTX, Orion, an Affiliate of GTX, or an Affiliate of Orion.

1.53 "TOREMIFENE" shall mean [ \* ].

1.54 "TRADEMARKS" shall mean the trademarks GTX selects and registers for the Product in the GTX Territory in accordance with Article 10 of this Agreement, and the trademark Fareston(R) in the USA used by Shire prior to the Restatement Date for the Fareston Product.

1.55 "USA" shall mean the United States of America including its fifty states, the District of Columbia, Puerto Rico, and all its territories and possessions.

1.56 "U.S. FDA" shall mean the United States Food and Drug Administration and any successor regulatory agency.

1.57  $"\rm U.S.$  IND" shall mean an Investigational New Drug Application filed with the U.S. FDA.

1.58 "U.S. NDA" shall mean a New Drug Application filed with the U.S. FDA.

1.59 "UPFRONT AND MILESTONE INCOME" shall have the meaning provided in Section 3.1.1(c).

1.60 "VALID CLAIM" shall mean a claim of an issued patent which has not expired and which has not been held revoked, invalid or unenforceable by decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed with the time allowed for appeal having expired, and which has not been admitted to be invalid through reissue or disclaimer or otherwise.

2. GRANT AND SCOPE OF RIGHTS GRANTED

2.1 ORION GRANTS TO GTX.

2.1.1 LICENSE GRANTS. Orion hereby grants to GTX for the Term:

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(I) an exclusive right and license, with the right to grant sublicenses as provided in Section 2.1.4, under Orion Patent Rights and Orion Know-How, to develop, use, have used, sell, have sold, import, market and distribute the Product in the Field in the GTX Territory, except in the Orion Field in the Orion Territory; and

(II) a non-exclusive right and license, with the right to grant sublicenses as provided in Section 2.1.4, under the Orion Patents and Orion Know-How, to perform research and preclinical development activities in accordance with Section 2.5 using the Powder (as defined in Section 14.6.2) to be provided to GTX pursuant to Section 14.6.2, except in the Orion Field in the Orion Territory.

For the avoidance of doubt, nothing herein shall limit or restrict or be construed to limit or restrict Orion from using, and GTX acknowledges that Orion may use, Toremifene and Product (i) as a reference compound and reference product in its research and development activities for the Field and for uses outside the Field, and (ii) in conducting business activities in the Orion Field in and for the Orion Territory, as well as in the field of animal health.

Licenses under Section 2.1.1(i) may be expanded to include the right to make and have made Products as provided in Sections 7.7, 14.9, 16.1, 17.3.2, 17.4 and 21.2.2 on such terms as are set forth in such Sections.

2.1.2 MANUFACTURING RIGHTS RESERVED. Except as otherwise provided in Sections 7.7, 14.9, 16.1, 17.3.2, 17.4 and 21.2.2, Orion retains the exclusive right to manufacture or have manufactured Toremifene, Orion Product and Product including, without limitation, any Toremifene and Orion Product to be supplied to GTX under this Agreement and subject to Sections 7.7, 14.9, 16.1, 17.3.2, 17.4 and 21.2.2 herein, during the Term GTX undertakes to purchase all its requirement of Product exclusively from Orion.

2.1.3 USE OF ORION KNOW-HOW. Under the license granted pursuant to Section 2.1.1(i), GTX shall, subject to the terms and conditions of this Agreement, including without limitation Article 8, have the right to use and reference Orion Know-How in support of GTX's clinical trials and applications for Regulatory Approval within the Field for the Product in the GTX Territory. Subject to the license rights granted hereunder, Orion retains full ownership rights to all Orion Know-How.

2.1.4 SUBLICENSING. GTX shall have the right to sublicense its rights received under this Agreement in the GTX Territory to any Third Party, except that GTX shall not have the right to grant sublicenses to any Third Party to market, sell or offer for sale the Fareston Product for use in the Breast Cancer Field in the USA. For any permitted sublicense granted by GTX, GTX shall notify Orion within fifteen (15) days after execution of an agreement between GTX and a GTX Unaffiliated Sublicensee. GTX shall endeavor to include in its agreement with each GTX Unaffiliated Sublicensee a provision stating that, upon termination of this Agreement, such Unaffiliated Sublicensee and Orion shall discuss, and as appropriate, negotiate the terms and conditions under which Orion and such sublicensee would be willing to collaborate with regard to the further development and/or commercialization of the Product for use in the field in which GTX and such sublicensee were previously developing and/or commercialization of the Product by Orion

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

and such sublicensee shall be subject to and conditioned by a definite written agreement, if any, accepted and signed by duly authorized representatives of Orion. GTX shall forward to Orion a complete copy of each sublicense agreement. No sublicense shall relieve GTX of any of its obligations or commitments under this Agreement and GTX shall cause its Affiliates and GTX Unaffiliated Sublicensees to comply with all of GTX obligations and commitments under this Agreement.

GTX shall remain jointly and severally liable to Orion with its Affiliate(s) and GTX Unaffiliated Sublicensee(s) that obtain a sublicense under the licenses granted to GTX pursuant to Section 2.1.1 for performance of GTX's obligations under this Agreement. GTX shall be responsible for complying and ensuring that such of its Affiliates and GTX Unaffiliated Sublicensees, as applicable, comply with all relevant laws, regulations and requirements relating to the importation, packaging, distribution, marketing, promotion, sale and use of Product in the GTX Territory.

Orion shall have the right to propose to GTX one or more potential sub-licensees under GTX's rights to the Product for use in the Field (other than in the Orion Field) in South Korea and China (including, for the purpose of this Agreement, the People's Republic of China and Taiwan). GTX shall consider such proposal(s) in good faith when appointing such a sub-licensee for the Product for use in the Field (other than in the Orion Field) for South Korea and China.

2.1.5 GTX RIGHTS OF FIRST NEGOTIATION. Orion grants GTX, on a country by country basis, the right of first negotiation to negotiate further agreements under commercially reasonable terms and conditions regarding the further development, registration, promotion, marketing, sales and distribution of a pharmaceutical product for human use within the Prostate Cancer Field containing SERMs as the active ingredient (a) which is covered by a Valid Claim within the GTX Patent Rights in such country; and (b) for which Orion has both a license or other right to develop and commercialize such products and has commenced, within five (5) years after the Amendment Date, a Phase I clinical trial for such product anywhere in the world for a primary indication falling within the Prostate Cancer Field (a product fulfilling (a) and (b), hereinafter referred to as "Additional Product"). If Orion decides to offer to any Third Party the opportunity to participate in the development or commercialization of such Additional Product, or if Orion commences Phase I clinical trials for such Additional Product, it shall so notify GTX in writing. [ \* ] after GTX's receipt of such notice from Orion regarding commercially reasonable terms and conditions for obtaining rights in and to such Additional Product, GTX shall notify Orion in writing if it wishes to enter into negotiations with respect to such Additional Product. Should GTX elect to exercise such right, the Parties agree to negotiate in good faith the commercially reasonable terms and conditions for a letter of intent to be completed [ \* ] of receipt by Orion of such notification from GTX. Any deadlines may be extended by mutual written agreement. Should GTX fail to provide written notification to Orion by the end of [ \* ], or GTX notifies Orion that it does not wish to enter into negotiations; or the Parties, despite conducting good faith negotiations, are unable to finalize the commercial terms of the letter of intent [ \* ], GTX shall have no further rights in the SERM, and Orion shall be free to contract with a Third Party concerning same or itself further pursue the development, registration, promotion, marketing, sales and distribution of such Additional Product.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

В-9

2.1.6 GTX RIGHTS TO NEGOTIATE FOR RIGHTS IN THE ORION FIELD IN THE ORION TERRITORY. With respect to the development and commercialization of Products in the Orion Field in the Orion Territory, GTX shall have the following rights:

(A) As of the Restatement Date, Orion has Third Party licensees that have rights to develop and/or commercialize the Product in the Orion Field and in the Orion Territory. If any such sublicense terminates at any time during the Term after the Restatement Date, and if Orion desires to seek another Third Party sublicensee under such rights, then Orion shall so notify GTX and GTX shall have a right to negotiate with Orion the terms under which GTX may obtain such rights to such Product in the Orion Field and in the Orion Territory, on the following basis:

(B) If GTX is interested in negotiating with Orion for such rights to Product in the Orion Field and in the Orion Territory, it shall notify Orion thereof in writing within thirty (30) days of receiving Orion's notice. The Parties shall negotiate in good faith for a period of ninety (90) days after Orion receives GTX's notice of interest on the terms of an agreement governing such rights and during said period Orion shall not grant such rights to any Third Party. If the Parties fail within such ninety (90) day period to execute such an agreement, then Orion shall thereafter be free to contract with any Third Party with respect to the rights in question.

2.2 NO IMPLIED LICENSES. Any rights not expressly granted by either Party to the other Party in this Agreement are expressly reserved by the Party owning or controlling such rights and, accordingly, no licenses other than those specified herein shall be deemed granted by this Agreement by implication, estoppel or otherwise.

2.3 UNITED STATES GOVERNMENT RIGHTS. In the event it is determined that any GTX Patent Rights were developed with the support of the United States Government or any agency thereof (the "Government"), the Government will retain rights in the GTX Patent Rights as set forth in Title 35 U.S.C. Section 200 et seq. All rights herein granted to GTX are subject to any such rights held by the Government and further subject to any restrictions or obligations that may be imposed by the Government pursuant to such rights, at such time that it is determined.

# 2.4 ORION'S RIGHT OF FIRST NEGOTIATION.

2.4.1 Whereas Orion has considerable knowledge and experience in the marketing, sales and distribution of pharmaceutical products in, inter alia, Scandinavia (which term shall for purpose of this Section 2.4 comprise the countries of Denmark, Finland, Norway and Sweden), GTX undertakes to regard Orion as its preferential partner for the marketing, sales and distribution of the Product in Scandinavia for use in the Field (other than in the Orion Field in the Orion Territory), subject to this Section 2.4.1. Consequently, GTX grants, and shall cause its Affiliates and Unaffiliated Sublicensees who receive a sublicense under the license granted to GTX pursuant to Section 2.1.1 in Scandinavia to grant, to Orion a right of first negotiation to negotiate in good faith an agreement(s) under commercially reasonable terms and conditions regarding the marketing, sales and/or distribution by Orion of the Product in Scandinavia for use in the Field (other than in the Orion Field in the Orion Territory), with the express understanding

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

that such commercially reasonable terms and conditions shall not comprise an obligation to develop and register the Product for use in the Field in any country of Scandinavia.

2.4.2 Within thirty (30) days after Orion's receipt of a first written offer from GTX regarding commercially reasonable terms and conditions governing such rights, Orion shall notify GTX in writing if it wishes to negotiate the terms and conditions under which Orion could obtain the rights contemplated in this Section 2.4. Should Orion so exercise such right, the Parties shall negotiate exclusively with each other and in good faith the commercially reasonable terms and conditions for a license and distribution agreement for the marketing, sales and distribution by Orion of the Product in Scandinavia for use in the Field (excluding the Orion Field in the Orion Territory), such negotiations to be completed within one hundred and eighty (180) days from the date of Orion's notification to GTX. Any deadlines may be extended by mutual agreement upon reasonable request. If Orion fails to provide written notification to GTX by the end of the thirty (30) day period; Orion notifies GTX that it does not wish to enter into negotiations; or the Parties, despite conducting good faith negotiations, are unable to finalize the material commercial terms of agreement within such one hundred and eighty (180) day period (any such event, a "Termination of the Orion Right"), Orion shall have no further right under this Agreement to market, sell and distribute the Product in Scandinavia and GTX shall be free to offer to or enter into an agreement with any Third Party or any GTX Affiliate with respect to such activities after the Termination of the Orion Right occurs.

2.4.3 In the event that GTX's Unaffiliated Sublicensee for Product for use in the Field in the USA does not obtain the right and license to sell, have sold, import, market and distribute the Product in the Field in Europe at the time of execution of the sublicense agreement for the Product for use in the Field in the USA, then Orion shall, on the terms and conditions of Sections 2.4.1 and 2.4.2, have a right of first negotiation to negotiate in good faith an agreement(s) under commercially reasonable terms and conditions regarding the marketing, sales, and/or distribution of the Product for use in the Field in Europe.

2.5 USE OF TOREMIFENE BY GTX FOR RESEARCH. Subject to Sections 2.1.1(ii) and 14.6.2, GTX may use the Powder provided to it pursuant to Section 14.6.2 to perform stability studies and other activities with respect to Products for use in the Field that are necessary for supporting Regulatory Approval of Products or expanding the indications for Products within the Field. GTX shall, upon Orion's request therefor, provide Orion with written updates of any and all activities undertaken by or on behalf of it pursuant to this Section 2.5, and with the results thereof in reasonable detail.

2.6 PROHIBITED ACTIONS. During the Term of this Agreement, Orion shall not grant any rights to any Third Party that are inconsistent with the licenses granted to GTX pursuant to Section 2.1.1.

# 3. PAYMENTS

3.1 TYPES OF PAYMENTS. For the rights, privileges and licenses granted hereunder, GTX shall pay Orion in the manner provided as follows:

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

3.1.1 In the event GTX or its Affiliate receives Upfront and Milestone Income (as defined in Section 3.1.1(c)), GTX shall pay Orion as follows:

(A) Any Upfront and Milestone Income for the sublicensing of Product rights in the Prostate Cancer Field shall first be applied to [ \* ] both prior to and after the Effective Date with respect to the [ \* ], and also for the [ \* ].

(B) Upon full reimbursement of such [ \* ] pursuant to Section 3.1.1(a), any remaining Upfront and Milestone Income (the "Net Upfront and Milestone Income") shall then be paid by GTX to Orion as follows:

(I) GTX shall pay Orion [  $^{\ast}$  ] of the portion of Net Upfront and Milestone Income that is [  $^{\ast}$  ]; and

(II) [  $^{\ast}$  ] of the portion of the Net Upfront and Milestone Income that is [  $^{\ast}$  ].

(C) For the purposes of this Agreement, "Upfront and Milestone Income" shall mean any bona fide consideration (either in cash or non-cash form) received by GTX or its Affiliate from a GTX Unaffiliated Sublicensee for sublicensing GTX's rights in and to the Product for use in the Prostate Cancer Field in the GTX Territory excluding: (i) Royalty Income (as defined in Section 3.1.5); (ii) cost of goods payments for supply of Product manufactured by Orion and supplied at the prices set forth in Article 14 herein below, or payments to reimburse GTX's fully burdened costs of manufacturing or having manufactured Product by or on behalf of GTX as permitted under this Agreement; (iii) in the form of a loan; or (iv) for the purchase of an equity interest in GTX (except to the extent such purchase price is a Premium over the fair market value of such stock, in which case the Premium, but not the portion of such price that is at the fair market value of such stock, shall be included in Upfront and Milestone Income). Notwithstanding the foregoing, if GTX receives Upfront and Milestone Income received in the form described in (ii) or (iii) [ \* ]. For example and without limitation, [ \* ].

3.1.2 If GTX is Acquired prior to the first Regulatory Approval of Product for use in the Prostate Cancer Field, then GTX shall pay to Orion an amount equal to the lesser of one million dollars (\$1,000,000) or one percent (1%) of the fair market value of GTX at the time of such acquisition. "Acquired" means that GTX either (i) sells all or substantially all of its assets to a Third Party, or (ii) is merged with or consolidated or reorganized into a Third Party, or becomes a subsidiary of a Third Party, and, as a result of such transaction, the stockholders of GTX immediately prior to such transaction own less than fifty percent (50%) of the surviving parent entity.

3.1.3 ROYALTIES PAYABLE ON COMMERCIAL SALES OF FARESTON PRODUCT UNTIL PRODUCT ROYALTY ADJUSTMENT DATE.

(A) For commercial sales of the Fareston Product by GTX or its Affiliates after the Restatement Date, until the earlier to occur of (y) [ \* ], or (z) the [ \* ] of a Product for use in the Prostate Cancer Field (any such Product in the Prostate Cancer Field,

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

hereinafter referred to as a "New Product", and the date that is the earlier to occur of (y) or (z), hereinafter referred to as the "Product Royalty Adjustment Date"), GTX shall pay to Orion a running royalty on Net Sales of Fareston Product by GTX, its Affiliate or its Unaffiliated Sublicensee, as follows:

(I) Up until the end of the calendar month immediately preceding the month in which the [  $^{\star}$  ] occurs, the royalty due to Orion with respect to Net Sales of the Fareston Product by GTX, its Affiliates and/or Unaffiliated Sublicensees in the USA shall be [  $^{\star}$  ] of Net Sales of Fareston Product.

(II) Commencing upon the first day of the calendar month in which the [\*] occurs, and for the [\*], the royalty due to Orion with respect to Net Sales of the Fareston Product shall be [\*] of Net Sales of Fareston Product by GTX, its Affiliates and/or Unaffiliated Sublicensees during such period of time, or (B) [\*] of the MAT Net Sales of Fareston Product (as calculated and defined in Section 3.1.3(b)).

(III) Upon the first day of the [ \* ] occurs, and for the [ \* ], the royalty due to Orion with respect to Net Sales of Fareston Product by GTX, its Affiliates and Unaffiliated Sublicensees shall be [ \* ] of Net Sales of Fareston Product by GTX, its Affiliates and Unaffiliated Sublicensees during such period of time, or (B) [ \* ] of [ \* ] MAT Net Sales of Fareston Product.

(B) The Parties have agreed to use a moving annual total ("MAT") of sales of Fareston Product in the USA in calculating royalties due on Net Sales of Fareston Product in the USA during [\*] of the first New Product, which MAT takes into account and reflects [\*] during such period of time. Such MAT shall be based upon (i) the [\*] of such New Product and (ii) the actual Net Sales of the Fareston Product in the USA during the [\*], as follows: First, the "Correction Factor" shall be calculated, which shall be equal to the Net Sales of Fareston Product by GTX, its Affiliates and/or Unaffiliated Sublicensees in the USA during the [\*] occurs, divided by the Net Sales of Fareston Product be [\*]. Then, the "MAT Net Sales of Fareston Product" shall be calculated, which shall be equal to the correction Factor be [\*]. Then, the "MAT Net Sales of Fareston Product" shall be calculated, which shall be equal to the Correction Factor be [\*]. Then, the "MAT Net Sales of Fareston Product" shall be calculated, which shall be equal to the Correction Factor be [\*]. Then, the "MAT Net Sales of Fareston Product" shall be calculated, which shall be equal to the Correction Factor be [\*]. Then, the "MAT Net Sales of Fareston Product" shall be calculated, which shall be equal to the Correction Factor be [\*] occurs.

(C) For example and without limitation, if the Net Sales of the Fareston Product have been [ \* ] for [ \* ] prior to the [ \* ] occurs, and [ \* ] for [ \* ] preceding the beginning of the [ \* ] occurs, then the Correction Factor would be [ \* ]. Accordingly, the MAT Net Sales of Fareston Product would be [ \* ] of the actual Net Sales of the Fareston Product during the [ \* ].

(D) Commencing upon the Product Royalty Adjustment Date, the royalty for Fareston Product shall be paid pursuant to Section 3.1.4 and shall no longer be due pursuant to Sections 3.1.3(a) and (b).

(E) For clarity, sales of any New Product shall not be included in the calculation of Net Sales of Fareston Product under this Section 3.1.3, but shall instead be subject to the royalty due pursuant to Section 3.1.4, no matter when such sales occur.

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

3.1.4 ROYALTIES PAYABLE ON OTHER COMMERCIAL SALES OF PRODUCT. Except as provided for the Fareston Product prior to the Product Royalty Adjustment Date in Section 3.1.3, GTX shall pay to Orion a royalty on Net Sales of Product by GTX or its Affiliates, equal to [ \* ] of Net Sales of such Products, on a country by country basis, subject to the provisions of Sections 3.1.8 and 21.2.2.

3.1.5 Subject to the provisions of Sections 3.1.8 and 21.2.2, and except as provided for the Fareston Product prior to the Product Royalty Adjustment Date in Section 3.1.3, in the event GTX receives running royalty income from GTX Unaffiliated Sublicensees for sublicensing GTX's rights in and to any Product and/or based upon sales by GTX Unaffiliated Sublicensees of any Product in the GTX Territory ("Royalty Income"), GTX shall pay Orion the lesser of, on a country by country basis, either (a) [\*] of such Royalty Income; or (b) [\*] of such Product by such GTX Unaffiliated Sublicensees provided, however, that in no event shall the amounts due to Orion pursuant to this Section 3.1.5 be [\*] of Net Sales of such Product by such GTX Unaffiliated Sublicensees

3.1.6 Notwithstanding Sections 3.1.3 through 3.1.5, if GTX enters into an agreement with a Third Party to [ \* ] and GTX is [ \* ] (a [ \* ]), then in lieu of the payments to Orion under Sections 3.1.3 through 3.1.5, GTX shall pay to Orion [ \* ] of [ \* ]. Additionally, GTX shall not be obligated to pay Orion any amounts under Sections 14.4 or 14.6 for Product supplied to GTX for the purpose of [ \* ], as the Parties have agreed that the amounts due to Orion pursuant to this Section 3.1.6 shall be in lieu of any payments that would otherwise be due to Orion for the supply of such Product if this Section 3.1.6 were not applicable.

3.1.7 As of December 31, 2000, an upfront license fee of four hundred thousand dollars (\$400,000) (the "Upfront License Fee"), was paid in full by GTX to Orion. This payment shall be creditable by GTX against fees or payments due to Orion with respect to Upfront and Milestone Income pursuant to Section 3.1.1.

3.1.8 If a Generic Product is sold in any Major Country of the GTX Territory, and, for two (2) succeeding Calendar Quarters the Sales of Generic Product in that country [ \* ] of the sales of Product (calculated on a unit basis) in that country by GTX, its Affiliates and Unaffiliated Sublicensees, then the royalty on Net Sales owed by GTX to Orion under Section 3.1.4 and the payments due to Orion on Royalty Income pursuant to Section 3.1.5, respectively, shall be reduced to [ \* ] of the amount otherwise due to Orion pursuant to either Section 3.1.4 or 3.1.5, as applicable, with regard to such country with such reduction to be applicable to the immediately succeeding Calendar Quarter only.

3.1.9 For clarity, in no event shall a royalty be due with respect to the sale of a given unit of Fareston Product pursuant to more than one of Sections 3.1.3, 3.1.4 or 3.1.5.

3.2 NON-REFUNDABILITY. All milestone payments GTX makes to Orion pursuant to Section 3.1.1 shall be non-refundable once paid. However, if this Agreement is terminated for any reason prior to a given milestone payment becoming due or if the events specified for a given milestone payment do not occur, then GTX shall have no obligation to make such milestone payment.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

3.3 ROYALTY REPORTS AND PAYMENTS. Commencing with the first Calendar Quarter in which GTX, its Affiliates or a GTX Unaffiliated Sublicensees make the First Commercial Sale of a Product, GTX shall provide Orion with a written report of Net Sales and Royalty Income on a country-by-country basis within forty-five (45) days after the last day of March, June, September and December for Royalty Income accruing on Net Sales during the three (3) preceding calendar months. Concurrently with the submission of each such written report, GTX shall pay or cause to be paid to Orion the total amount of royalties shown to be due thereon.

3.4 CURRENCY. GTX shall make all Upfront and Milestone Income and royalty payments to Orion pursuant to Section 3.1 in U.S. Dollars except that GTX shall make all cost of goods payments to Orion pursuant to Article 14 in euros. Where royalty payments are made, payments earned shall be first determined by GTX in the currency of the country where the Net Sales on the sales giving rise to payments were made and then converted directly to its equivalent in U.S. dollars. The rates of exchange for converting the currencies involved to U.S. dollars shall be the Foreign Exchange Rates quoted in the Wall Street Journal rate on the last business day of the quarterly period in which the royalty payments were earned.

3.5 NO ROYALTIES PAYABLE BETWEEN AFFILIATES. No royalties shall be payable to a Party on sales between the other Party, its Affiliates or between the Party's Affiliates.

3.6 NO MULTIPLE ROYALTIES. No multiple royalties shall be payable because the Product, its manufacture, use or sale is or shall be covered by multiple patents.

# 4. LIAISON

Representatives of the Parties shall meet bi-annually or as otherwise agreed to review the development, sales and marketing activities for Product conducted by GTX, its Affiliates or its Unaffiliated Sublicensees for use in the Field in the GTX Territory, with the exact dates and locations of such meetings to be mutually agreed upon. Such meetings shall alternate between GTX's and Orion's offices or be at other mutually agreed upon locations, with each Party to be responsible for the travel and living costs and expenses of its own representatives attending such meetings.

# 5. PAYMENT, RECORD KEEPING AND AUDIT RIGHTS

5.1 METHOD OF PAYMENT. In the event of any required tax withholding, the paying Party will provide the receiving Party with any relevant certificates or documents required for national, state or local tax credit and reporting purposes. Payments hereunder shall not be creditable against any other amounts payable by a Party under this Agreement, except as otherwise expressly stated herein. All payments shall be made by bank wire transfer (e.g., "SWIFT" or other comparable electronic transfer method) to such account(s) as the receiving Party shall be deemed paid once funds are freely available to the receiving Party at such account(s).

 $5.2\ \text{LATE}\ \text{PAYMENTS}.$  The Party entitled to payment hereunder reserves the right to charge the paying Party interest on any amounts owing from the paying Party which are overdue

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

by more than fourteen (14) business days at a rate of [ \* ] per annum, or the maximum rate allowed by law, whichever is lower, calculated from the date any payment was due and payable.

5.3 RECORD KEEPING AND AUDIT RIGHTS. Each Party shall keep or cause to be kept accurate records relating to Net Sales, royalties, development and any other costs and expenses subject to payment, deduction or reimbursement by either Party to the other Party in sufficient detail to enable the amounts payable hereunder to be determined. Upon the written request of either Party (but not more frequently than once in any calendar year), the requesting Party may retain an independent certified public accountant, subject to approval by the other Party (which approval shall not be unreasonably withheld), to review such records to verify the accuracy of the payments made or payable hereunder. Such accountant shall be required to execute a confidentiality agreement in a form reasonably acceptable to the audited Party and shall report to the auditing Party only the amount of any underpayment or overcharge. Within ten (10) business days after completion of such review, the Parties shall reconcile any underpayment or overcharge. The auditing Party shall pay the cost of any review of records conducted at its request under this Section. However, if the review establishes underpayment or overcharge by the audited Party of over three percent (3%) during the period of the review, the audited Party shall promptly reimburse the auditing Party for the fees and expenses of the accountant. Such audit rights may be exercised by the Parties only with respect to records for the current calendar year and the preceding two (2) calendar years.

# 6. GTX PRODUCT MARKETING AND SALES ACTIVITIES

### 6.1 MINIMUM SALES REQUIREMENTS FOR USA.

6.1.1 LEVELS OF MSRS. GTX shall have annual minimum sales requirements for Product for use in the Prostate Cancer Field ("MSRs") in the second year and fourth year after Product Launch in the USA for the Prostate Cancer Field equal to [ ] of GTX's annual Product Sales Projections (as defined below) in the USA for the Prostate Cancer Field. To establish such projections for the purpose of the foregoing sentence, GTX shall provide to Orion quarterly Product Sales Projections in the USA for the Prostate Cancer Field, within ninety (90) days after GTX, its Affiliate or Unaffiliated Sublicensee completes the last pivotal clinical trial as provided in the GTX Final Development and Registration Plan for Product in the Prostate Cancer Field in the USA. The Parties shall set forth in Schedule D GTX's MSR obligations within sixty (60) days after GTX provides such projections, and such MSRs shall be made a part hereof. Beginning with the [\*] year after Product Launch in USA for use in the Prostate Cancer Field until the end of the Term, GTX shall have an annual MSR equal to [ \* ] of the average of GTX's Actual Product Sales (as defined below) in the USA for Product in the Prostate Cancer Field for the [ \* ]. "Product Sales Projections" means GTX's good faith estimates of the target patient population in a given year for Products in the Prostate Cancer Field in the USA for Product Sales Projections." Products in the Prostate Cancer Field in the USA, multiplied by the price per tablet of Product for use in the Prostate Cancer Field in the USA that GTX plans to be able to charge during the [ \* ] after Product Launch. "Actual Product Sales" means GTX's, its Affiliate's or a GTX Unaffiliated Sublicensee's actual Net Sales of Product in the Prostate Cancer Field during a given year in the LISA

For example, in year [ \* ] if the target patient population in the USA is [ \* ] subjects in the Prostate Cancer Field and the Product would be consumed by such patients [ \* ] for the

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Prostate Cancer Field at a hypothetical price of [\*], GTX's Product Sales Projections for the USA would [\*]. The hypothetical price for a tablet set forth above is hypothetical and was only used for the sole purpose of explaining the mechanism for calculating the Product Sales Projections and MSRs. Nothing contained in such example shall be so construed to deny the right of GTX to freely set its resale price of the Product.

6.1.2 PRODUCT LAUNCH DATE. "Product Launch in USA" shall be determined by the date on which the Product has received Regulatory Approval and is commercially available in the USA as follows: (i) if such date occurs during the first six (6) months of any calendar year (i.e., January 1-June 30), Product Launch in USA shall be deemed to have occurred on January 1 of such calendar year, and (ii) if such date occurs during the last six (6) months of any calendar year (i.e., July 1-December 31), Product Launch in USA shall be deemed to have occurred on January 1 of the following calendar year.

6.1.3 ADJUSTMENT. GTX's annual Product Sales Projections for the Prostate Cancer Field in the USA shall be subject to adjustment by written agreement of the Parties, with a corresponding adjustment in the MSRs, in the event of government intervention in given markets (including, but not limited to, government mandated health care reforms, rebates or regulatory changes), failure to obtain (or delay in obtaining) approval for a Product indication in the Prostate Cancer Field, or other events or causes affecting the market for the Product for use in the Prostate Cancer Field beyond the control of GTX, including but not limited to lower than anticipated pricing approvals measured on an aggregate basis throughout USA; GTX Patent Rights and/or Orion Patent Rights invalidation, infringement or expiration; Product safety and/or efficacy issues and/or major therapeutic advances materially affecting the market potential for the Product for use in the Prostate Cancer Field (including but not limited to new surgical procedures or introduction of new competitive products with superior safety and/or efficacy profiles); or a Force Majeure event (as described in Article 27).

6.1.4 FAILURE TO ACHIEVE MSRS. If GTX's annual Product Sales in USA for the Prostate Cancer Field are less than the MSRs in any applicable calendar year, GTX shall, without prejudice to its payment obligations under Section 3.1, pay Orion royalties corresponding to the "shortfall" between the actual royalties paid by GTX for such year and the royalties which would have been payable pursuant to Section 3.1 had GTX achieved the MSRs during such year, subject to Section 6.1.3. GTX's payment of such "shortfall" hereunder shall be Orion's sole and exclusive remedy for GTX's failure to achieve MSRs in USA for such year. However, if GTX fails to pay such "shortfall," then Orion may, without prejudice to its right to such shortfall, also terminate this Agreement pursuant to Section 21.2.2.

6.2 NO MINIMUM SALES REQUIREMENTS OUTSIDE OF USA; NO MINIMUM SALES REQUIREMENTS FOR SALES OF FARESTON PRODUCT. GTX shall not have any minimum sales requirements with respect to sale of Product in any countries in the GTX Territory outside of the USA. GTX shall not have any MSRs with respect to any sales of Fareston Product or for any Product for use outside the Prostate Cancer Field. GTX agrees that it will continue to sell Fareston Product in the Breast Cancer Field in the USA until at least the Royalty Adjustment Date. If GTX desires, after such date, to cease commercialization of the Fareston Product in the Breast Cancer Field in the USA, then it may so notify Orion in writing. In such case, the Parties shall discuss the reasons why GTX desires to cease such commercialization activities. If Orion

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

approves such proposal by GTX to cease commercializing the Fareston Product in the Breast Cancer Field in the USA (such approval not to be unreasonably withheld), then GTX may cease such activities. Without limiting the foregoing, Orion may not withhold its approval of a proposal by GTX under this Section 6.2 if GTX would be incurring, or based on GTX's reasonable projections would be likely to incur, a loss if it continues to commercialize Fareston Product in the Breast Cancer Field in the USA.

6.3 MARKETING AND SALES EFFORTS IN THE MAJOR COUNTRIES.

6.3.1 COMMERCIALLY REASONABLE OBLIGATION. On a country by country basis, subject to Sections 6.3 and 6.4, during the period commencing with Regulatory Approval in a Major Country, and for the remainder of the Term, GTX, its Affiliate and/or a GTX Unaffiliated Sublicensee shall use commercially reasonable efforts to promote, market, distribute and sell the Product for use in the Prostate Cancer Field in such Major Country. For purposes of this Section 6.3, "commercially reasonable" shall mean using, in the relevant Major Countries, an equivalent degree of effort as GTX, its Affiliate or a GTX Unaffiliated Sublicensee would use to promote, market, distribute and sell a product of its own that is of comparable market potential in such Major Country during the same time period (as determined by consideration of, without limitation, potential market, patent protection, and availability of competitive products), including but not limited to, engaging in the following activities (subject to any applicable U.S. FDA restrictions or other applicable legal restrictions):

(A) Using reasonable diligence to establish and maintain good business relationships with hospitals, health systems, doctors and other medical professionals in accordance with standard and customary practices in such Major Country;

(B) Using commercially reasonable efforts to establish and maintain an adequate capacity of sales personnel consisting of reasonably qualified personnel who have been certified, as trained by GTX, its Affiliate or a GTX Unaffiliated Sublicensee, to promote and market the Product for use in the Prostate Cancer Field in such Major Country, and to provide such sales force with adequate sales and promotional materials for the Product;

(C) Promoting and detailing the Product for use in the Prostate Cancer Field throughout such Major Country, provided that GTX, its Affiliate or a GTX Unaffiliated Sublicensee may, in its discretion use relatively greater promotional and detailing efforts (i) in some Major Countries than it uses in other of such countries, and (ii) in some parts of each Major Country than in other parts thereof, consistent with its overall marketing plan; and further provided, however, that the foregoing shall in no event be deemed to limit GTX's its Affiliate or a GTX Unaffiliated Sublicensee overall obligations under the first paragraph of this Section 6.3.1.

(D) Advertising the Product for use in the Prostate Cancer Field in professional journals and publications and sponsoring or attending appropriate symposia, trade exhibitions and medical education programs in a manner equivalent to that used for GTX's, its Affiliate's or a GTX Unaffiliated Sublicensee's, as applicable, own products of comparable market potential in such Major Country; and

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(E) Formulating and using reasonable efforts to implement annual sales and marketing plans for the Product for use in the Prostate Cancer Field in such Major Country and providing copies of such plans to Orion for review and comment, provided that Orion shall not have approval rights with respect to such plans.

6.3.2 SALES OBJECTIVES AND OTHER FACTORS FOR THE USA. GTX and Orion shall agree in writing upon annual target sales objectives for the Product for use in the Prostate Cancer Field in the USA, commencing with the fourth calendar year after First Commercial Sale of the Product for use in the Prostate Cancer Field in the USA, provided that such annual target sales objectives shall not be considered MSRs for any purposes, but instead shall be used by the Parties for informational and planning purposes and shall be one (1) factor, among others, to be considered in assessing whether GTX has complied with its commercially reasonable obligations hereunder. GTX's level of sales and marketing expenses for the Product for use in the Prostate Cancer Field in the USA and events or causes affecting the market for the Product for use in the Prostate Cancer Field beyond the control of GTX shall also be among the factors to be considered in assessing whether GTX has complied with its commercially reasonable obligations hereunder.

# 6.4 PRODUCT LAUNCH.

6.4.1 TIMING OF LAUNCH. GTX shall use commercially reasonable efforts to launch the Product for use in a given indication in the Prostate Cancer Field as soon as practical in every Major Country of the GTX Territory where GTX, its Affiliates and/or GTX Unaffiliated Sublicensees have obtained Regulatory Approval for such indication. Notwithstanding the foregoing, GTX, its Affiliate or a GTX Unaffiliated Sublicensee may, acting in good faith in the exercise of its reasonable business judgment, determine either to delay the launch of the Product for use in a given indication in the Prostate Cancer Field or not to launch the Product for use in a given indication in the Field in any given country in the GTX Territory other than a Major Country, which decision to delay or not to launch shall not be deemed a failure to use commercially reasonable efforts. Further, GTX's, its Affiliates' or a GTX Unaffiliated Sublicensee's decision to delay the launch of the Product for use in the Prostate Cancer Field in any Major Country for up to six (6) months after GTX or its Affiliates have obtained Regulatory Approval in such country, shall not be deemed a failure to use commercially reasonable efforts pursuant to Section 6.3 to the extent that GTX can demonstrate that such delay was attributable to bona fide business reasons affecting the Product.

6.4.2 DECISIONS NOT TO LAUNCH. GTX shall promptly notify Orion in writing if GTX, its Affiliate or a GTX Unaffiliated Sublicensee, as applicable, determines to delay the launch of the Product for use in a given indication in the Prostate Cancer Field in any Major Country after obtaining Regulatory Approval of Product therefor. If such decision is due to any reasons other than the potential for, or the existence of, adverse business effects in such Major Country, then such decision shall be deemed a material breach of this Agreement pursuant to Section 21.2.2 and GTX shall be subject to the provisions of such Section within thirty days (30) after GTX's decision not to launch in such Major Country.

6.5 MARKETING COSTS AND EXPENSES. Except as otherwise provided herein or as otherwise mutually agreed by the Parties, GTX, its Affiliate or a GTX Unaffiliated Sublicensee

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

shall bear all costs and expenses connected with its marketing and sales activities for the Product for use in the Field and its performance under this Agreement.

### 6.6 MARKETING PLANS AND REPORTS.

6.6.1 MARKETING PLANS. GTX shall develop and provide to Orion by October 31 of each year during the Term marketing and sales plans for the Product for each Major Country for the following calendar year, commencing with the calendar year in which Regulatory Approval is obtained in each respective country. Such plans shall include the projected Annual Net Sales and the projected advertising and promotion budgets for such year, and shall not be applicable to the calculation of MSRs in connection with the sale of Products in the Prostate Cancer Field in the USA pursuant to Section 6.1, for which GTX shall separately provide information.

6.6.2 MARKETING AND SALES REPORTS FOR PRODUCT. GTX shall provide to Orion, within forty-five (45) days after the end of each calendar year, a written marketing activities and sales report for each of the Major Countries in which Product is launched. The report shall include at least a description of sales, marketing and promotion activities and a list of scientific conferences or other events involving the particular Product or its therapeutic area, accompanied by a general description of the nature and extent of GTX's participation in such conferences or events.

# 7. GTX PRODUCT DEVELOPMENT AND REGISTRATIONS

7.1 GTX DEVELOPMENT AND REGISTRATION ACTIVITIES.

7.1.1 GTX ACTIVITIES. In accordance with the GTX Preliminary Development and Registration Plan and the GTX Final Development and Registration Plan, GTX shall undertake development and registration activities for the Product for use in the Prostate Cancer Field in the GTX Territory, including but not limited to, conducting or sponsoring, and completing or having completed in accordance with U.S. FDA regulations and Good Clinical Practice regulations under the European Union legislation and directives requirements, all clinical studies and other activities required for Regulatory Approval under the GTX Final Development and Registration Plan. Without limiting the provisions of Section 7.7, GTX shall use its commercially reasonable efforts to pursue such development and registration activities under the GTX Final Development and Registration Plan with the objective of filing applications for Regulatory Approval in all Major Countries throughout the GTX Territory in the Prostate Cancer Field according to the anticipated filing dates set forth in the GTX Final Development and Registration Plan timetable [\*]. GTX's Regulatory Approvals in the GTX Territory shall be owned solely by GTX.

# 7.1.2 ORION ACTIVITIES.

(A) Orion shall use its commercially reasonable efforts to assist GTX in obtaining and maintaining the U.S. FDA Regulatory Approval of Products in the Prostate Cancer Field and of the Fareston Product in the Breast Cancer Field in the USA (including obtaining and/or maintaining the Orion Product NDA and all related U.S. INDs filed with the

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

U.S. FDA for such Products, and any other required Regulatory Approvals in the Major Countries of the GTX Territory relating to the manufacture, use, marketing or sale of Product for use in the Prostate Cancer Field or of Fareston Product in the Breast Cancer Field in the USA (by providing to GTX relevant information, documents and data in its possession in relation to regulatory inquiries during the Regulatory Approval process for Products, necessary additional letters of cross-reference or authorization equivalent to those described in Section 7.5 to its registrations for Product in the Orion Field in the Orion Territory, and other similar assistance). Orion shall maintain the DMF filed with the U.S. FDA and all equivalent regulatory authorities outside of the USA for Product as well as its registrations for Product in the Orion Field in the Orion Territory during the Term, provided that Orion may notify GTX that Orion intends to cease maintenance of any such DMF and/or registration, in which case GTX shall have the right to maintain such filing, at GTX's expense, by notifying Orion in writing within thirty (30) days after it receives Orion's notice hereunder that it desires to maintain such filing. If GTX elects to maintain such filing, Orion shall cooperate reasonably with GTX to effect the transfer of such DMF and/or registration to GTX.

(B) Orion shall perform any stability testing for the bulk Orion Product to be manufactured and supplied by Orion to GTX that is required by regulatory authorities in any Major Country. Such testing shall be provided at no cost to GTX, except that GTX will reimburse Orion's direct costs of performing any such stability testing that must be conducted solely for the [\*] tablet of the Orion Product. Orion employees shall, at Orion's cost and expense, have the right to participate in all FDA and other regulatory agency meetings regarding the use of the Product in the Field.

(C) Orion shall have no obligation to research, develop, register, commercialize any Product or carry out any studies or testing in relation to Products, including without limitation with respect to any new or additional strength, dosage form, formulation or route of administration of the Orion Product or the Product, or provide any documentation, information or data relating to the foregoing, except as expressly provided in Section 7.1.2(a) or otherwise set forth in this Agreement, unless the Parties expressly mutually agree otherwise in writing after the Restatement Date. Other than as expressly agreed in this Agreement, Orion shall have no obligation to fund or pay for any of the costs and expenses of such activities. All studies, trials, tests, activities, documentation, data and information required by any regulatory or other governmental agency or which is necessary or useful for the research, development, registration or commercialization of the Product shall, unless otherwise expressly agreed to herein as between the Parties, be for the sole cost and responsibility of GTX.

7.1.3 AUTHORIZATION LETTERS. Any regulatory filings (including without limitation any DMFs that GTX may develop if it obtains the right to manufacture Product) compiled and filed by or on behalf of GTX shall remain the property of GTX, but GTX shall, upon request therefor by Orion, negotiate with Orion the terms under which GTX would provide appropriate authorization letters to relevant regulatory bodies to enable Orion to reference such regulatory filings for purposes of applying for and supporting Orion's applications for Regulatory Approval of products containing Toremifene outside the Field.

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

7.2 FDA FILE. As of the Restatement Date, Orion shall have transferred the Orion Product NDA and all Investigational New Drug Applications (as defined in 21 C.F.R. Section 212) for Products filed with the FDA to the name of GTX, as set forth in the Purchase Agreement.

7.3 DEVELOPMENT AND REGISTRATION COSTS. Except as otherwise expressly provided in this Agreement or otherwise mutually agreed in writing by the Parties after the Restatement Date, GTX shall bear all costs and expenses related to Product registration and regulatory activities (other than for Product for the Orion Field in the Orion Territory), including without limitation costs of filing, obtaining and maintaining all such Regulatory Approvals throughout the GTX Territory, as well as all costs and expenses for the research and development of the Product for use in the Field (other than for Product for the Orion Field in the Orion Territory), provided that GTX shall not be responsible for any costs related to the manufacture of the Orion Product (except for payments that GTX must make to Orion pursuant to Section 7.1.2(b) or Article 14 (such costs collectively referred to herein as "Manufacturing Costs"). Except for the Manufacturing Costs or as otherwise expressly provided in this Article 7, Orion shall bear no responsibility for any costs or expenses related to Product registration, regulatory, research or development activities in relation to the Product.

7.3.1 DEVELOPMENT AND REGISTRATION COSTS PRIOR TO RESTATEMENT DATE. The Parties agree that GTX shall, notwithstanding anything to the contrary in the Original Agreement or otherwise, also bear all costs and expenses related to Product research, development, registration, regulatory compliance and other activities relating to the development of Product that were incurred prior to the Amendment Date by GTX (excluding any Manufacturing Costs) (hereinafter referred to as "Incurred Costs"). Consequently, except as set forth in Section 3.1.1, GTX shall forever release and discharge Orion of any and all claims that it purports to have at the Amendment Date or may have thereafter against Orion with respect to Incurred Costs.

# 7.4 GTX DEVELOPMENT AND REGISTRATION PLAN.

7.4.1 COMPLETION OF GTX FINAL DEVELOPMENT AND REGISTRATION PLAN. The GTX Preliminary Development and Registration Plan for development and registration of Product in the Prostate Cancer Field was attached to the Original Agreement as Schedule B. GTX will prepare a GTX Final Development and Registration Plan for such activities for each Major Country in a timely fashion upon receiving approval from the appropriate regulatory authority in each Major Country of a plan for regulatory approval in that country. Immediately upon completion of the GTX Final Development and Registration Plan for each Major Country, [ \* ]. GTX shall provide a copy of such plan to Orion.

7.4.2 ORION'S RIGHT TO COMMENT ON AND OBJECT TO PLAN. Orion shall have the right to comment on each GTX Final Development and Registration Plan for Product for the Prostate Cancer Field for each Major Country. Additionally, Orion shall have the right to object to each GTX Final Development and Registration Plan for each Major Country to the extent such plan could reasonably be deemed to affect adversely Orion's development, commercialization, sales or registration of Toremifene in the Orion Field in the Orion Territory or outside the Field. GTX undertakes to change and/or amend the GTX Final Development and Registration Plan for Product for the Prostate Cancer Field for each Major Country to the extent Orion has so objected thereto as necessary to alleviate or obviate such adverse effect. Orion shall provide GTX with

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

such comments and/or objections within thirty (30) days from Orion's receipt of the GTX Final Development and Registration Plan.

7.4.3 CHANGES TO SUCH PLAN. GTX may modify the GTX Final Development and Registration Plan, as GTX deems necessary and consistent with Section 7.4.1, but shall notify Orion of such changes. Any changes to the GTX Final Development and Registration Plan for each Major Country shall also be subject to Section 7.4.2.

# 7.5 ORION DOCUMENTATION AND DATA.

7.5.1 GTX ACCESS TO ORION KNOW-HOW. Orion has provided and shall continue to provide GTX with copies of the Orion Know-How, documentation, information and data listed or referenced in the GTX Preliminary Development and Registration Plan, and GTX shall be authorized to use and reference the same in its applications for Regulatory Approval and regulatory compliance activities in relation to such Regulatory Approvals. Any Product Drug Master Files ("DMFs") compiled or owned by Orion shall remain the property of Orion, but Orion shall, upon reasonable request therefor by GTX, provide appropriate authorization letters to relevant regulatory bodies in the GTX Territory within forty-five (45) days from such request to enable GTX to reference such DMFs for purposes of GTX's applications for Regulatory Approval and regulatory compliance activities in the GTX Territory as provided for in Section 7.1. For the avoidance of doubt, neither Party is obligated to disclose the contents of its DMFs to the other Party.

7.5.2 GTX ACCESS TO DATA. During the Term, Orion shall provide GTX, within forty-five (45) days of receipt of a written request from GTX specifying in detail the documentation, information and/or data requested, access to Orion Know-How in Orion's control and possession (and freely disclosable) that GTX reasonably requires for regulatory filings for the use of Product in the Field in the GTX Territory, including any Orion Know-How concerning the use of the Product in the Orion Field in the Orion Territory to the extent such information may be reasonably required by GTX for such regulatory filings. . In instances where documentation, information and/or data requested are required by the U.S. FDA or other regulatory agency to be submitted in a time frame shorter than forty-five (45) days, GTX shall notify Orion, and GTX and Orion shall agree on a shorter time frame for provision of such materials within the time required by the FDA. In the event any of such Orion Know-How is not in the control or possession of Orion but is controlled by a Third Party, Orion and GTX shall discuss in good faith commercially reasonable efforts that Orion may, at its discretion, decide to take to assist GTX in accessing such Orion Know-How, provided that nothing herein shall obligate Orion to take steps to arrange, or incur costs, to access such Orion Know-How from such Third Party, and provided further that if requested by GTX, Orion will grant GTX the necessary authorizations to approach any such Third Party for such access. Upon GTX's request, Orion shall provide GTX with copies of such Orion Know-How referenced in the preceding sentences only in such form and content as is available to Orion, provided that, upon Orion's request, GTX shall reimburse Orion for Orion's direct out-of-pocket cost of making such copies and providing GTX with such Orion Know-How.

GTX shall also provide to Orion quarterly reports summarizing GTX's development activities for Products in the Field (excluding the Orion Field in the Orion Territory).

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

7.5.3 LETTER OF CROSS REFERENCE. Orion agrees that the Cross Reference letter dated December 10, 1999 from Orion to GTX shall remain in effect to the extent it enables GTX or its Affiliates to reference regulatory filings for the Orion Product in all countries outside of the USA. Such Cross Reference letter may not be revoked by Orion unless this Agreement is terminated. During the Term, Orion shall permit GTX, its Affiliates and the GTX Unaffiliated Sublicensees to reference, and shall provide GTX with an appropriate authorization letter to enable GTX, its Affiliates and the GTX Unaffiliated Sublicensees to reference, all applications or filings for Regulatory Approval for Orion Products for use in the Orion Field and related DMFs that are identified in Schedule E hereof (hereinafter "Orion Product Approvals") for the purpose of applying for and supporting Regulatory Approval of Products for use in the Field within the GTX Territory. Orion shall update Schedule E from time to time during the Term to set forth all Orion Product Approvals and DMFs that are owned and controlled by Orion. GTX recognizes that Orion has obtained the Orion Product Approvals solely for the purpose of its proprietary product Fareston(R), and that nothing herein shall be construed so as to obligate Orion to maintain or cause to be maintained any Orion Product Approvals solely for allowing GTX, its Affiliates and/or GTX Unaffiliated Sublicensees to refer thereto, provided that during the Term, Orion shall not withdraw such Orion Product Approvals in the absence of commercially justifiable reasons in relation to Fareston(R). Orion shall, prior to withdrawing such Orion Product Approvals, offer to GTX the right to maintain such approvals, at GTX's expense. If GTX elects to maintain such approvals, Orion shall reasonably cooperate with GTX to enable GTX to assume such responsibility.

7.5.4 ADDRESS. All requests by GTX to Orion for documentation, information or data, as agreed herein, shall be addressed only to the attention of such person(s) as is/are designated in writing or in electronic form by Orion from time to time.

7.6 GTX REGISTRATION AND MARKETING APPROVAL APPLICATIONS. GTX, its Affiliates and/or GTX Unaffiliated Sublicensees shall have the responsibility and the right to submit registration applications for Regulatory Approval and marketing and price approval of the Product for use in the Field within the GTX Territory; provided, however, that GTX shall not have the responsibility to submit such applications for approval of the Product for use in the Orion Field in the Orion Territory.

7.7 FAILURE TO FILE OR EXTEND. Orion shall have the right to terminate its obligations under Section 7.1.2(a) and its obligations to manufacture and supply to GTX Orion Product upon one hundred and eighty (180) days prior written notice to GTX, if Regulatory Approval has not been granted for the Product for use in the Prostate Cancer Field in the USA by December 31, 2009. Any such notice hereunder shall be given no later than sixty (60) days after December 31, 2009, provided that GTX shall inform Orion in writing by December 31, 2009, whether or not Regulatory Approval has been granted for the Product for use in the Prostate Cancer Field in the USA by such date. The time for Orion to provide notice to GTX of its decision to exercise its right with regard to the event described above shall be deemed to commence upon the receipt by Orion of such notice from GTX, provided that nothing shall be construed so as to prevent Orion from exercising its right hereunder if Orion discovers, either by itself or through a Third Party, that Regulatory Approval has not been granted for the Product for use in the Field in the USA by December 31, 2009. Effective upon the date that GTX receives any notice from Orion pursuant to this Section 7.7 and during the Term, Orion hereby grants GTX a contingent license under the

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Orion Patent Rights and Orion Know-How and all other patents and patent applications owned or controlled by Orion during the Term that relate to the manufacture, use or sale of Toremifene or Orion Product ("Manufacturing Patents") to make and have made Product for use in the Field in the GTX Territory (except in the Orion Field in the Orion Territory). Such license shall be exclusive and sublicensable (but only for the purposes of having manufactured the Products for GTX, its Affiliates or Unaffiliated Sublicensees). Orion shall as soon as practically possible after providing any notice to GTX pursuant to this Section 7.7 provide GTX with such then-existing manufacturing, process and quality control procedures, documentation and other relevant know-how and information to the extent reasonably necessary to enable GTX to exercise its manufacturing right pursuant to this Section 7.7 (hereinafter "Product Manufacture of Product using Orion personnel skilled in such manufacturing operations, at no charge to GTX.

7.8 REIMBURSEMENT OF ORION COSTS. Except as provided for otherwise in this Article 7, GTX shall reimburse Orion for all costs and expenses incurred by Orion in fulfilling its obligations under this Article 7 with respect to Products in the Field, subject to the following: (a) such reimbursable amounts shall include costs of assistance provided by Orion for activities relating to the Prostate Cancer Field only to the extent such costs (i) are incurred by Orion after [\*], or (ii) have been invoiced to GTX prior to [\*]; (b) such reimbursable amounts shall include costs of assistance provided by Orion for activities outside of the Prostate Cancer Field and the Breast Cancer Field, with the amounts described in this subsection (b) including Orion's [\*]; (c) such reimbursable amounts shall not include [\*]; and (d) such reimbursable amounts shall not include [\*]. Orion shall issue an invoice for all such reasonable costs and expenses so incurred that are reimbursable hereunder during each Calendar Quarter, and GTX shall effect payment of such invoice within thirty (30) days from the date of the invoice.

### 8. CONFIDENTIALITY AND PUBLICITY

8.1 CONFIDENTIALITY OBLIGATION. Each Party shall hold the other Party's Confidential Information (as defined below) of which it becomes informed in connection with this Agreement or the Original Agreement in strictest confidence and shall not disclose such Confidential Information to Third Parties or otherwise use it, except to the extent such use or disclosure is expressly permitted by the terms of this Agreement or is reasonably necessary for the performance of this Agreement.

8.2 PERMITTED DISCLOSURES. Permitted disclosures of Confidential Information hereunder include, but are not limited to: (A) disclosures to regulatory agencies to the extent required for Regulatory Approval, including but not limited to, GTX Product registrations and applications in the GTX Territory (to the extent expressly permitted hereunder), and (B) disclosures to the Parties' Affiliates, employees, agents and independent contractors (including clinical investigators, consultants and contract research organizations) who have a bona fide "need to know", and GTX Unaffiliated Sublicensees, and prospective sublicensees, provided that for such permitted disclosures under subsection (B) the disclosing Party shall obligate the recipients to maintain the confidentiality of Confidential Information under terms substantially similar to those contained in this Article 8.

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

8.3 CONFIDENTIAL INFORMATION. "Confidential Information" includes, but is not limited to, any information relating to the terms of this Agreement, the Original Agreement, the Product, the Orion Product, GTX Know-How, GTX Patent Rights, Orion Patent Rights, Orion Know-How, GTX Preliminary Development and Registration Plan, GTX Final Development and Registration Plan, clinical and non-clinical studies involving the Product, and all sales and marketing plans for the Product, as well as information concerning all other products and the business affairs, manufacturing processes and other activities of the disclosing Party that are designated as confidential in writing or orally disclosed, provided such oral disclosure is confirmed as confidential in writing within thirty (30) days thereafter. However, such obligations shall not apply to Confidential Information to the extent such information is:

(A) PUBLICLY AVAILABLE INFORMATION. Which at the time of disclosure is or later comes into public domain by publication or otherwise through no fault of the receiving Party;

(B) PREVIOUSLY KNOWN INFORMATION. Which can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure;

(C) SUBSEQUENTLY RECEIVED INFORMATION. Which is subsequently received by the receiving Party from a Third Party who is not bound by any confidentiality undertaking to the disclosing Party or to any of its Affiliates with respect to said information;

(D) INDEPENDENTLY DEVELOPED INFORMATION. Which is independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information; or

(E) LEGALLY REQUIRED DISCLOSURES OF INFORMATION. Which is legally required to be disclosed pursuant to any statute or regulation or any judicial or administrative order, including any material or information requested by the Securities and Exchange Commission (or any equivalent securities exchange) or Finnish equivalent thereof to the extent that such information cannot be treated confidential.

8.4 DURATION OF CONFIDENTIALITY OBLIGATION. The confidentiality obligations of the Parties hereunder shall remain in effect during the Term and shall survive the termination or expiration of this Agreement for any reason and be effective until the later of five (5) years after such termination or expiration, or ten (10) years after the Restatement Date.

### 8.5 PUBLICITY AND ANNOUNCEMENTS.

8.5.1 With regard to the existence and content of commercial terms and conditions of this Agreement, unless agreed upon by the Parties, neither Party shall originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, relating to this Agreement or any amendment hereto, without the approval of the other Party, except as required by law, including, without limitation, provisions regarding the disclosure requirement for publicly quoted companies, and then only to the minimum extent so required, in which event such Party shall give the other Party a

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

reasonable opportunity to review the form and content of the announcement before such legally required announcement is made.

8.5.2 GTX may originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, relating to the use of the Product in the Field provided that GTX forwards to Orion such publicity, news release or other public announcement fourteen (14) days prior to such publicity, news release or other public announcement, except as otherwise required by law or regulation, including without limitation disclosure requirements promulgated by the Securities and Exchange Commission. It is agreed that such publicity, news release or other public announcement does not require the approval of Orion, unless Orion considers such publicity, news release or other public announcement to (a) fall within the scope of Section 8.5.1; or (b) be misleading or incorrect, in which case Orion shall, within five (5) business days after receiving such publicity, news release or other public announcement, so notify GTX and provide written comments specifying changes that Orion reasonably believes will correct such inaccuracy, except as otherwise required by law or regulation. If requested by Orion, such publicity, news release or other public announcement shall include wording to the effect that Toremifene is a proprietary compound of Orion, and that Toremifene has been licensed by Orion to GTX for use in the Field.

# 9. FARESTON PRODUCT WEBSITE FOR USA

9.1 FARESTON WEBSITE. During the Term of this Agreement or as long as the Fareston Product is sold in USA (whichever period is shorter), Orion shall maintain, (including, without limitation, by renewing the applicable domain name(s)), and operate, either itself or via Third Party subcontractor(s), the internet site with the domain name www.fareston.com (or any successor site or domain name thereof). Promptly following the execution of this Agreement, Orion and GTX shall mutually agree upon a process or means whereby Orion shall provide GTX with a means to access said website in order to update and maintain web pages for the Fareston Product that are directed towards residents of the USA (the "FARESTON U.S. WEB PAGES"). The Parties acknowledge and agree that GTX shall have sole control over, and responsibility for, the content of the Fareston U.S. Web Pages, including, without limitation, the "look and feel" thereof. Orion hereby grants GTX a non-exclusive, sublicenseable license in the GTX Territory under such intellectual property rights owned or controlled by Orion during the Term that are strictly necessary for GTx, its Affiliates and Unaffiliated Sublicensees to exercise the rights granted to GTX pursuant to this Section 9.1 with respect to the Fareston U.S. Web Pages. It is understood and agreed that nothing herein shall obligate Orion to perform the foregoing tasks ]. GTX shall be responsible for ensuring that the Fareston U.S. Web Pages conform with all applicable laws and regulations. To the extent allowed by applicable laws and regulations, Orion shall have a right to build on and join and/or establish a link to the foregoing site for the Fareston Product in connection with its retained rights for Fareston Product, and to grant to its Affiliates and Unaffiliated Sublicensees such rights, at any time, at its sole discretion, with the reasonable costs thereof payable by the supplier of such link or contents. GTX shall reasonably cooperate with Orion in regard to any additions to such site. Such additions, if any, will be placed in an easily visible location on such site as agreed between the Parties.

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

### 10. TRADEMARKS

#### 10.1 TRADEMARKS.

10.1.1 GTX shall market and sell the Product for use in the Field in the GTX Territory under the Trademarks. GTX shall own and control all Trademarks (including, as provided in the Purchase Agreement, the trademark Fareston(R) in the USA). For avoidance of doubt, GTX shall not have any rights to use the trademark Fareston(R) outside of the USA. GTX shall notify Orion if GTX decides to change, alter, modify or replace the Trademark initially selected by it for a given Product.

10.1.2 If GTX exercises its right of first negotiation to obtain rights to sell Orion Product in the Orion Field under Section 2.1.6, then the Parties agree that any letter of intent and final agreement governing the terms under which GTX would obtain such rights shall provide for Orion to grant to GTX an exclusive, sublicensable license under the trademark Fareston(R) in the relevant country outside the USA (or any counterpart to such trademark that Orion is then using to market, promote, and commercialize Orion Products in the relevant country or countries) to advertise, promote, market or sell such Orion Product.

10.2 TRADEMARK FILING AND MAINTENANCE. GTX shall be responsible for filing, maintaining, prosecuting and defending the Trademarks in the GTX Territory (including, for the avoidance of doubt, the trademark Fareston(R) in the USA).

10.3 TRADEMARK DOCUMENTATION. If requested by Orion, GTX shall provide Orion with copies of all documents relating to the maintenance of the Trademark in the GTX Territory, at Orion's expense.

# 11. PATENT OWNERSHIP AND WARRANTIES

### 11.1 PATENT OWNERSHIP.

11.1.1 Subject to the license rights granted to GTX hereunder, Orion retains full ownership of all Orion Patent Rights and shall be responsible for filing, prosecuting, and maintaining Orion Patent Rights as provided for in Article 12.

11.1.2 Subject to the license rights granted to Orion hereunder, GTX retains full ownership of all GTX Patent Rights and shall be responsible for filing, prosecuting, and maintaining GTX Patent Rights as provided for in Article 12.

11.2 ORION PATENT WARRANTIES. Orion warrants and represents that, to the best of its management's knowledge as of the Effective Date: (A) Schedule B sets forth all of the Orion Patent Rights as of the Effective Date and as of the Restatement Date which are directed to the composition of matter, use or sale of the compound Toremifene per se; (B) except for the Orion Field in the Orion Territory, Orion has not and will not grant, license, convey, assign, and/or transfer to any Third Party any rights to Orion Patent Rights for use in the Field, or other rights to any Third Party, in each case inconsistent with the licenses and other rights granted to GTX hereunder, (C) based

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

upon Orion's reasonably diligent investigation, the Orion Patent Rights are (i) valid, in full force, and enforceable, and (ii) there are no existing valid Third Party patents in the GTX Territory that might be infringed by the manufacture or sale of the Orion Product by Orion to GTX under this Agreement for the Prostate Cancer Field, or in the USA for the Breast Cancer Field, and (D) the use and/or sale of Products in the Field and in the GTX Territory by GTX, its Affiliates or Unaffiliated Sublicensees pursuant to this Agreement will not, in the absence of a license from Orion, infringe any patents owned or controlled by Orion other than the Orion Patent Rights. Additionally, Orion represents and warrants to GTX that to the best of its management's knowledge as of the Restatement Date, Orion has not received any written claims or assertions from any Third Party alleging that the use of Toremifene in the Field (other than as may be for use and/or sale of Products in the Orion Field in the Orion Territory) infringes such Third Party's patent rights.

11.3 GTX PATENT WARRANTIES. GTX warrants and represents that [ \* ] as of the Effective Date: (A) Schedule A sets forth all of the GTX Patent Rights as of the Effective Date which cover the Product for use in the Prostate Cancer Field and that it had full right and authority to grant to Orion and Orion Affiliate the rights granted to it under Section 2.4; (B) subject to Section 2.1.4, GTX has not and will not grant to any Third Party any rights under the Orion Patent Rights or Orion Know-How inconsistent with GTX's licenses under this Agreement, and (C) there are no circumstances existing that render it likely that the United States Government or any agency thereof to exercise such rights as set forth and/or referenced to in Section 2.3, if GTX's development, registration and commercialization of the Product for use in the Prostate Cancer Field will be carried out as agreed herein; and (D) (i) the GTX Patent Rights are valid, in full force, and enforceable and (ii) upon GTX's reasonably diligent investigation, there are no existing valid and enforceable Third Party patents in the GTX Territory (other than any that may be owned or controlled by Shire) that might be infringed by the marketing, promotion, distribution, importation, offer for sale or sale of the Product in the Prostate Cancer Field by GTX, its Affiliates and GTX Unaffiliated Sublicensees.

### 12. PATENT PROSECUTION AND INFRINGEMENT; TRADEMARKS

12.1 ORION PATENT FILING AND PROSECUTION. Orion shall, at its sole expense, prosecute, maintain and defend Orion Patent Rights in the GTX Territory and Orion shall control all Orion Patent Rights filings and actions. Orion shall use its commercially reasonable efforts to obtain extensions in the Major Countries in the GTX Territory in which such extensions are available.

12.2 GTX PATENT FILING AND PROSECUTION. GTX shall, as its sole expense, file, prosecute, maintain and defend GTX Patent Rights in the GTX Territory and GTX shall control all GTX Patent Rights filings and actions. GTX shall use its commercially reasonable efforts to obtain GTX Patent Rights protection and commercially reasonable efforts to obtain GTX Patent Rights extensions in any countries in the GTX Territory in which such extensions are available.

12.3 NOTIFICATION OF INFRINGEMENT. The Parties shall promptly inform each other of any information that comes to their attention involving actual or apparent infringements or misappropriations of Orion Patent Rights, Orion Know-How, GTX Patent Rights, GTX Know-How, or Trademarks by any Third Party, or claims of alleged infringement made by any

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Third Party in the GTX Territory against Orion, its Affiliates, or Orion Unaffiliated Sublicensees, GTX, its Affiliates, or GTX Unaffiliated Sublicensees, resulting from the manufacture, importation, marketing, sale or use of the Product in the Field.

12.4 INFRINGEMENT OF THIRD PARTIES RIGHTS BY ORION. Orion shall, at its sole discretion, direct or defend in its own name and at its own expense any legal or other action or proceeding, including any settlement or negotiation, with respect to any alleged infringement of a Third Party patent or other proprietary right as a result of Orion's, its Affiliates', or Orion Unaffiliated Sublicensees' manufacture of Toremifene or Orion Product for use in the Field, or the use or sale of Product in the Orion Field in the Orion Territory excluding actions and proceedings covered by Section 12.5. During the time any such proceeding or any appeal thereof is pending, Royalty Income payable by GTX under Section 3.1 in the country in which such proceeding is pending shall be paid by GTX into an interest-bearing escrow account pending the outcome of such proceeding. Upon a favorable final resolution of such proceeding or any appeal thereof, GTX shall resume paying Orion the full royalties in such country, and all funds in such escrow account shall be paid to Orion. Upon an unfavorable final resolution of such proceeding or any appeal thereof, the funds in such escrow account shall be applied toward the damage award in such action, if any, and the balance, if any, shall be paid to Orion. If Orion fails to defend such proceeding or discontinues the defense, all funds in such escrow account shall be returned to GTX and GTX shall have no further obligation to pay Royalty Income in such country.

12.5 INFRINGEMENT OF THIRD PARTIES RIGHTS BY GTX. GTX shall, at its sole discretion, direct or defend in its own name and at GTX's own expense in the GTX Territory any legal or other action or proceeding, including any settlement or negotiation, with respect to any alleged infringement of a Third Party patent, trademark or other proprietary right as a result of GTX's, its Affiliates', or GTX Unaffiliated Sublicensees' making, having made, importing, marketing, distributing, using or selling the Product in GTX Territory for use in the Field, excluding actions and proceedings covered by Section 12.4.

# 12.6 INFRINGEMENT INDEMNIFICATION.

12.6.1 ORION INFRINGEMENT INDEMNIFICATION. Orion shall indemnify, defend and hold GTX (including for purposes of this Section 12.6.1, GTX Affiliates and GTX Unaffiliated Sublicensees), its and their officers, directors, and employees, and permitted successors and assigns, harmless from and against any and all liabilities, damages, claims, demands, costs and/or expenses (including reasonable attorneys' fees) (collectively, "Losses") claimed by any Third Party in any patent or proprietary right infringement suit or action which may be brought as a result of Orion's, its Affiliates', or Orion Unaffiliated Sublicensees' manufacture of Toremifene or Orion Product, except to the extent such Losses arise out of claims for which GTX shall defend, indemnify and hold Orion harmless pursuant to Section 12.6.2, and further subject to the conditions of indemnification set forth in Section 15.7.

12.6.2 GTX INFRINGEMENT INDEMNIFICATION. GTX shall indemnify, defend and hold Orion (including for purposes of this Section, Orion's Affiliates and Unaffiliated Sublicensees) its and their officers, directors, and employees, and permitted successors and assigns, harmless from and against any and all Losses claimed by any Third Party in any suits or

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

actions relating to patent, trademark or other proprietary right infringements as a result of GTX's, its Affiliates', or GTX Unaffiliated Sublicensees' making or having made, importing, marketing, using or selling the Product or Other Product under a Trademark in GTX Territory for use in the Field, except to the extent such Losses arise out of claims for which Orion shall indemnify, defend and hold GTX harmless pursuant to Section 12.6.1, and further subject to the conditions of indemnification set forth in Section 15.7.

12.7 TERMINATION FOR INFRINGEMENT OF THIRD PARTY RIGHTS. Should either Party be prevented by reason of an adverse, non-appealable court or administrative proceeding, order or judgment or arbitral award against it from manufacturing, making, using or selling the Orion Product and/ or Product in any country within the GTX Territory as required or permitted under this Agreement, then, as to such country so affected, the other Party may, upon sixty (60) days prior written notice thereof to the other Party, terminate this Agreement upon written notice to the other Party with respect to such country, and the Parties shall make a final transition accounting and settlement for outstanding bona fide costs, payments and expenses to which each Party is entitled hereunder with respect to such country.

12.8 THIRD PARTY INFRINGEMENT OF ORION PATENT RIGHTS.

12.8.1 ORION ENFORCEMENT. Orion shall have the first right but not the obligation, to commence, at its own expense, appropriate measures to enforce Orion Patent Rights [ \* ] against infringement by Third Parties relating to the Orion Patent Rights [ \* ] against infringement by Third Parties relating manufacture, use, sale, offer for sale, or import of products containing Toremifene for use in the Field within a reasonable period of time after Orion becomes aware of such infringement (including, but not limited to, by notifying the infringing Third Party of such infringement and demanding that such Third Party cease and desist from such infringement). If such infringement does not cease, Orion shall have the right to commence a legal proceeding to enforce Orion Patent Rights, if any, against such Third Party infringements within a reasonable period of time of the date Orion becomes aware of such infringement. Orion shall notify GTX promptly after Orion becomes aware of such infringement, and, upon request therefor by GTX, keep GTX reasonably informed regarding Orion's intended strategy in such situation. Additionally, if within a reasonable period of time from the date GTX becomes aware of any alleged Third Party infringement of such Orion Patent Rights, either by notice from Orion or otherwise, Orion has not commenced a legal proceeding against such infringement, or if at any time Orion discontinues the pursuit of such proceeding, GTX may, at its option, commence, continue or intervene, as the case may be, in such proceeding, provided, however, that with respect to any such proceedings in any country, GTX shall first request Orion to notify GTX whether any Third Party has a right to enforce the relevant Orion Patent Rights in the relevant countries, in which event Orion shall promptly respond to such request, and further provided that GTX' rights hereunder are subject and secondary to any rights that orion has granted to any Third Party prior to the Restatement Date in such country with respect to enforcement of the relevant Orion Patent Rights. During the time any such proceeding or any appeal thereof is pending, no Royalty Income shall be payable under Section 3.1 in the country in which such proceeding is pending. Upon a favorable final resolution of such proceeding or any appeal GTX shall resume paying Orion the full royalties in such country, and thereof GTX shall also be liable for payment of any back royalties payable for such period for which such a proceeding has been pending. Orion's commencement of such proceeding shall be at Orion's own expense, provided that Orion shall be entitled to retain all

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

recoveries in such proceeding or any appeal thereof. Such commencement by Orion shall not relieve either Party of its obligations under Section 12.6.

# 12.8.2 GTX ENFORCEMENT.

(A) GTX shall have the first right but not the obligation, to commence, at its own expense appropriate measures to enforce United States Patent Nos. [ \* ] against infringement by Third Parties, within a reasonable period of time after GTX becomes aware of such infringement (including, but not limited to, by notifying the infringing Third Party of such infringement and demanding that such Third Party cease and desist from such infringement). If such infringement does not cease, GTX shall have the right to commence a legal proceeding to enforce said Orion Patent Rights, if any, against Third Party infringements within a reasonable period of time of the date GTX becomes aware of such infringement. GTX shall notify Orion promptly after GTX becomes aware of such infringement, and, upon request therefor by Orion, keep Orion reasonably informed regarding GTX's intended strategy in such situation. Additionally, if within a reasonable period of time from the date GTX becomes aware of any alleged Third Party infringement of said Orion Patent Rights, either by notice from Orion or otherwise, GTX has not commenced a legal proceeding against such infringement, or if at any time GTX discontinues the pursuit of such proceeding, Orion may, at its option, commence, continue or intervene, as the case may be, in such proceeding, provided, however, that with respect to any such proceedings in the USA, Orion's right to commence, continue, or intervene in such proceeding are subject to and secondary to any rights that GTX has granted to any Third Party prior to the Restatement Date in such country with respect to enforcement of the relevant patent rights. During the time any such proceeding or any appeal thereof is pending, no Royalty Income shall be payable under Section 3.1 in the country in which such proceeding is pending. Upon a favorable final resolution of such proceeding or any appeal thereof, GTX shall resume paying Orion the full royalties in such country, and GTX shall also be liable for payment of any back royalties payable for such period for which such a proceeding has been pending. GTX's commencement, continuation or intervention in such proceeding shall be at GTX's own expense, provided that GTX shall be entitled to retain all recoveries in such proceeding or any appeal thereof. Such commencement, continuation or intervention by GTX shall not relieve either Party of its obligations under Section 3.1 or 12.6.

12.9 THIRD PARTY INFRINGEMENT OF GTX PATENT RIGHTS; THIRD PARTY INFRINGEMENT OF TRADEMARKS AND THE TRADEMARK FARESTON(R).

12.9.1 GTX shall have the sole right, but not the obligation, at its own expense, to commence appropriate measures to enforce GTX Patent Rights and rights to Trademarks against Third Party infringements (including, but not limited to, notifying the infringing Third Party of such infringement and demanding that such Third Party cease and desist from such infringement) and, if such infringement does not cease, commence a legal proceeding to enforce such GTX Patent Rights or rights to Trademarks, if any, against Third Party infringements. GTX's commencement of such proceeding shall be at GTX's own expense, provided that GTX shall be entitled to retain all recoveries in such proceeding or any appeal thereof. Such commencement by GTX shall not relieve either Party of its obligations under Section 12.6.

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

12.10 MUTUAL COOPERATION. In the event of any infringement litigation in the GTX Territory involving the Product or Orion Product or any Orion Patent Rights or GTX Patent Rights or a Trademark, the non-prosecuting or non-defending Party shall render such reasonable assistance as may be requested by the prosecuting or defending Party in connection with such infringement actions. If Orion requests GTX's assistance in connection with such infringement claims or actions, Orion shall reimburse GTX for such direct, documented out-of-pocket expenses as are reasonably incurred by GTX during the course of it providing such requested assistance. If GTX requests Orion's assistance in connection with such infringement claims or actions, GTX shall reimburse Orion for such direct, documented out-of-pocket expenses as are reasonably incurred by Orion during the course of it providing such requested assistance. Before incurring such expenses, the Parties shall in good faith agree in writing on the nature and extent of assistance to be rendered, and an estimate of the total expenses, which expenses shall be monitored periodically.

### 12.11 PATENT CHALLENGES.

12.11.1 If GTX, its Affiliate, or GTX Unaffiliated Sublicensee, either directly or through a contractor or agent, challenges the validity of any Orion Patent Rights in any Major Country within the GTX Territory (other than in a Major Country that is a member of the European Union) and does not cease such challenge within thirty (30) days of receipt of written notice from Orion, then such challenge shall be deemed a material breach of this Agreement and Orion shall have the right to terminate this Agreement by written notice with immediate effect, at Orion's sole discretion, in its entirety or with respect to such country.

12.11.2 If Orion challenges the validity of any GTX Patent Rights in any Major Country in the GTX Territory (other than in a Major Country that is a member of the European Union) and does not cease such challenge within thirty (30) days of receipt of written notice from GTX, then such challenge shall be deemed a material breach of this Agreement and GTX shall be entitled to terminate this Agreement by written notice with immediate effect, at GTX's sole discretion, in its entirety or with respect to such country.

### 12.12 ACTIVITIES DURING INFRINGEMENT LITIGATION.

12.12.1 In the event of any patent or trademark or other proprietary right infringement litigation involving the Product in GTX Territory in which GTX defends or prosecutes such litigation pursuant to Section 12.8 or 12.9, GTX may, at any time following one hundred eighty (180) days after the commencement of such litigation, request in writing that Orion suspend the manufacture of the Orion Product for use in the Field in the part of the GTX Territory so affected pending resolution of such litigation. If Orion elects not to comply with such request within thirty (30) days after receipt thereof, then all damages resulting from Orion's continued manufacturing of the Product for use in the Field in the part of the GTX Territory so affected (other than for the Orion Field in the Orion Territory) after Orion's receipt of such request shall be borne by Orion and be subject to Orion's indemnification obligation to GTX pursuant to Section 15.6.1.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

12.12.2 In the event of any patent or trademark or other proprietary right infringement litigation involving the Product in the GTX Territory in which Orion defends or prosecutes such litigation pursuant to Section 12.8 or 12.9, Orion may, at any time following one hundred eighty (180) days after the commencement of such litigation, request in writing that GTX suspend the import, distribution, marketing, sale and use of the Product, and suspend Orion's manufacture and supply of Orion Product for GTX hereunder, in the part of the GTX Territory so affected pending resolution of such litigation if Orion reasonably deems such action necessary or advisable to mitigate possible damages that may be incurred during the pendency of such litigation. If GTX elects not to comply with such request within thirty (30) days after receipt thereof, then all damages resulting from GTX's continued importing, distribution, marketing, sale and use of the Product in the part of the GTX and be subject to GTX's indemnification obligation to Orion pursuant to Section 15.6.2. If GTX elects to comply with such request, such compliance shall be considered a suspension of GTX's marketing and sales obligations, notwithstanding Article 6.

12.12.3 In the event either Party receives a written claim of any alleged or actual infringement of a Third Party patent or trademark or other proprietary right as a result of Orion's, its Affiliate(s) or Unaffiliated Sublicensee(s') manufacturing of or selling Orion Product to GTX, or GTX, its Affiliates, or GTX Unaffiliated Sublicensees making, having made, marketing, using or selling the Product in GTX Territory for use in the Field, each Party shall so notify the other Party and the Parties shall confer regarding the basis for such claim, and discuss how the Parties may resolve the situation. Orion shall have the right to suspend its manufacture and supply of the Orion Product in and/or to the part of the GTX Territory so affected upon twenty (20) days prior written notice to GTX pending resolution of such claim or any related infringement litigation, if necessary to mitigate damages that may be incurred. If Orion exercises its rights hereunder, the Parties shall thereafter discuss from time to time whether the situation has been resolved and, accordingly, whether Orion is in a position to resume the supply of Orion Product pursuant to this Agreement.

# 13. COMPETING PRODUCTS

13.1 OBLIGATIONS WITH RESPECT TO COMPETING PRODUCTS.

13.1.1 Beginning on the Effective Date and until the expiration of the last of the Orion Patent Rights on a country by country basis in the Major Countries, GTX and GTX Affiliates undertake not to market or sell a Competing Product in such country, excluding those countries of the Major Countries within the European Union, in which countries GTX and GTX Affiliates undertake not to market or sell any Competing Product for a period of five (5) years from the Amendment Date.

13.1.2 However, nothing contained in this Section 13.1 shall be construed as preventing either Party from conducting research and development activities relating to a Competing Product during such period or thereafter.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# 14. PRODUCT ORDERS, SUPPLY AND PAYMENTS

### 14.1 ORION SUPPLY OBLIGATIONS.

14.1.1 PRODUCT SUPPLY. During the Term, Orion shall, subject to the terms of this Article 14 and Section 7.7, supply GTX and GTX Affiliates with their requirements of Orion Product. Orion shall supply the Product in bulk tablet form.

14.1.2 PRODUCT DELIVERY. Orion shall supply Orion Product to GTX only against receipt of GTX's written purchase orders. Except as otherwise provided herein or as otherwise expressly agreed in writing by the Parties, delivery shall be within ninety (90) days from receipt and confirmation by Orion of GTX's purchase order. Orion shall confirm the delivery dates within ten (10) business days after receipt of GTX's purchase orders and, subject to the provisions of Section 14.2, Orion shall use its best reasonable efforts to fill such orders on the requested delivery dates, but shall in any event fill such orders within ninety (90) days from receipt and confirmation of GTX's purchase order. Orion shall deliver Orion Product [ \* ] to a carrier designated by GTX (with the foregoing being interpreted to effect [ \* ]. GTX shall pay shipping costs and shall assume title to and risk of loss for Orion Product purchased hereunder after such delivery to GTX's designated carrier.

14.1.3 PRODUCT SHIPPING INSTRUCTIONS. GTX shall provide Orion with appropriate instructions for each shipment of Orion Product hereunder designating the desired carrier, destination and method of transport. If Orion becomes aware that the designated carrier is unable to accept the desired shipment within the requested delivery period, Orion shall promptly notify GTX and GTX shall promptly designate another carrier or carriers.

14.2 ORION AFFILIATES AND SUBCONTRACTORS. Orion may satisfy its supply obligations under this Agreement either directly or through any Orion Affiliate (provided that such Orion Affiliate has a manufacturing site which has received all required regulatory approvals and that Orion guarantees the performance of such Affiliate), and such supply by Orion Affiliates shall not be deemed an infringement of GTX's rights hereunder.

### 14.3 GTX FORECASTS.

14.3.1 ROLLING FORECASTS. Within ninety (90) days after the Restatement Date, GTX shall inform Orion in writing of GTX's bona fide, good faith estimated requirements of Fareston Product in the GTX Territory during the year 2005. Thereafter, for the remainder of the Term, GTX shall provide to Orion by September 30 of each year a purchase forecast of GTX's estimated requirements of Orion Product for the twenty four (24) month period beginning with October 1 of the then current year, allocated for each calendar month of such period, provided that if during any calendar year GTX expects to order Product from Orion to support the launch of Product for use in the Field but outside of the Breast Cancer Field, then not later than ninety (90) days prior to GTX's anticipated first order of Orion Product from Orion to support the launch of Product for such use, GTX shall update the most recently provided purchase forecast to include GTX's good faith estimated requirements of Orion Product to support such launch (if not already included in the then-applicable forecast). GTX shall update its purchase estimates to Orion on a monthly basis by indicating by the end of each month revised estimates or confirming

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

that no revisions are necessary, which shall provide Orion with GTX's rolling twenty four (24) month forecasts.

14.3.2 EXCESS QUANTITIES. If GTX orders a quantity of Orion Product in excess of one hundred twenty-five percent (125%) of GTX's purchase forecast provided two (2) Calendar Quarters prior to such order, Orion shall deliver the quantity in excess of one hundred twenty-five percent (125%) up to one hundred fifty percent (150%) of such forecast within one hundred twenty (120) days from receipt and confirmation of GTX's purchase order. If GTX orders a quantity of Orion Product in excess of one hundred fifty percent (150%) of GTX's purchase forecast provided two (2) Calendar Quarters prior to such order, Orion shall use commercially reasonable efforts to supply the quantity in excess of one hundred fifty percent (150%) up to two hundred percent (200%) of such forecast as soon as practical, but in no event later than one hundred eighty (180) days from receipt and confirmation of GTX's purchase order. If GTX orders a quantity of Orion Product in excess of two hundred percent (200%) of GTX's purchase forecast provided two (2) Calendar Quarters prior to such Order, Orion shall use commercially reasonable efforts to supply the quantities in excess of such forecast as soon as practical.

14.3.3 MINIMUM QUANTITIES. Of the amounts of Orion Product indicated by GTX in its rolling monthly forecasts, GTX shall purchase at least one hundred percent (100%) of its estimated requirement for Orion Product for the first three (3) months of such forecast, eighty percent (80%) of its estimated requirement of Orion Product for the fourth, fifth and sixth months of such forecast, and fifty percent (50%) of its estimated requirement of Orion Product for the seventh, eighth and ninth months of such forecast. All orders and deliveries of Orion Product shall be in full batch sizes of Orion Product, as determined by Orion from time to time. Orion shall notify GTX in writing prior to the date upon which GTX must provide its first commercial order of Orion Product under this Article 14 of what the size of a full batch of Orion Product is at such time.

14.4 PRICES AND PAYMENT.

14.4.1 COMMERCIAL PRICING FORMULA. Orion's annual price of bulk Orion Product to GTX, its Affiliates or its Unaffiliated Sublicensees for commercial purposes, delivered [ \* ] (with the foregoing being interpreted to effect [ \* ]), shall be:

[\*]

14.4.2 INVOICING AND PAYMENT. Orion shall invoice GTX for commercial orders of Orion Product shipped, and GTX shall pay such invoice within thirty (30) days of receipt.

14.4.3 PRICE CHANGES. GTX may, no more than once per year, request that Orion determine whether the average cost of the raw materials set forth in Schedule C used to manufacture Product during the immediately preceding year has, in the aggregate, changed by more than five percent (5%) of the average cost thereof that applied during the year immediately preceding the date that is one year earlier than the date of GTX's request (any such change, a "Significant Cost Change"). Reasonably promptly following any such request by GTX, Orion shall make such determination and notify GTX of the result of such determination. Additionally,

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

if Orion determines that a Significant Cost Change has occurred (other than in response to such a request by GTX), it shall so notify GTX. If Orion determines that a Significant Cost Change has occurred upon GTX's request or upon Orion's own investigation, then the Parties shall (no more than once annually) adjust the price to reflect such Significant Cost Change. Such price shall apply to Orion Products purchased by GTX following the date of Orion's notice to GTX that a Significant Cost Change has occurred.

14.4.4 EXCEPTION. Notwithstanding the foregoing, GTX shall not owe Orion any payment pursuant to this Section 14.4 for any Product that is sold to a Third Party for development or commercialization of a [ \* ] as to which GTX owes Orion payments described in Section 3.1.6.

14.5 RESALE PRICES. GTX, its Affiliates and GTX Unaffiliated Sublicensees shall be free to set their own resale prices for the Product sold in the GTX Territory.

14.6 PRODUCT SUPPLY FOR TESTING AND REGISTRATION; SUPPLY OF TOREMIFENE.

14.6.1 PRODUCT SUPPLY FOR TESTING AND REGISTRATION. The supply price for the [\*] tablet of bulk Orion Product for clinical trials shall be [\*] per tablet. Orion shall supply GTX or its Affiliates with such quantities of [\*] tablets of bulk Product as GTX or its Affiliates may require of Orion Product and/or placebos for use in clinical trials of Products. The price for the [\*] tablet of bulk Orion Product for clinical trials shall be [\*] per tablet. Orion shall supply GTX with such quantities of [\*] tablets of bulk Product as GTX or its Affiliates may require of Orion Product and/or placebos for use in clinical trials of Products. The price for the [\*] tablet of bulk Product for clinical trials of Products. The price for the [\*] tablet of bulk Product for clinical trials shall be [\*] per tablet. Orion shall supply GTX with such quantities as GTX or its Affiliates may require of [\*] tablets of Orion Product and/or placebos for use in clinical trials of Products. The price for a [\*] placebo for such clinical trials shall be [\*], per tablet. All Orion Product supplied for testing and registration pursuant to this Section 14.6 shall be provided in bulk packaging. Notwithstanding the foregoing, GTX shall not owe Orion any payment pursuant to this Section 14.6 for any Product that is sold to a Third Party for development or commercialization of a [\*] as to which GTX owes Orion payments described in Section 3.1.6.

14.6.2 SUPPLY OF TOREMIFENE. For the sole purpose of aiding GTX or its Affiliates in its efforts to obtain Regulatory Approval for the Product for use in the Field in the GTX Territory, Orion shall, during the Term, upon written order thereof by GTX, provide GTX, free of charge, with up to [\*] of Toremifene in bulk powder form (the "Powder"). GTX undertakes to use such Powder only for studies necessary to support Regulatory Approval for Product for use in the Field, excluding the Orion Field in the Orion Territory. Upon ordering Powder from Orion, GTx shall provide Orion with a detailed description of such study(ies) and the expected amount of Powder needed for said study(ies).

As consideration for Orion's agreement to provide the Powder to GTX, all results, data, information, inventions, memoranda, reports, discoveries, work products and other results (including without limitation any patents(s) granted thereon), which are conceived, derived, reduced to practice, made and/or developed by or on behalf of GTX and arising out of or relating to the use of the Powder (hereinafter referred to as "Results") shall be jointly owned by GTX and

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Orion such that each Party shall have a one-half undivided interest in and to such results, without a duty of accounting to the other Party. Orion's interest in the Results, and any patent rights related thereto, shall be subject to the licenses granted to GTX pursuant to Section 2.1 to the extent such Results are included in the Orion Patent Rights or Orion Know-How. GTX hereby grants to Orion an exclusive, royalty-free, worldwide license with the right to grant sublicenses, under GTX's joint interest in the Results and any intellectual property rights relating thereto for use in developing, using, having used, selling, having sold, importing, marketing and distributing products outside of the Field and in the Orion Field in the Orion Territory. Orion hereby grants to GTX an exclusive, royalty-free, worldwide license, with the right to grant sublicenses, under Orion's joint interest in the Results and any intellectual property rights relating thereto, for use in developing, using, having used, selling, having sold, importing, marketing and distributing products in the Field (excluding in the Orion Field in the Orion Territory), to the extent such rights are not otherwise included in the Orion Patent Rights or Orion Know-How licensed to GTX pursuant to Section 2.1.1.

Any use of the Results by GTX other than for the purposes of this Agreement shall not be permitted without the express written consent of Orion, which Orion may withhold at its sole discretion.

Without prejudice to the foregoing, the Results shall be deemed both Orion's and GTX's Confidential Information and shall be used and treated for purposes of Section 8 of this Agreement as Confidential Information of the other Party. GTX shall promptly disclose to Orion all Results immediately when such Results are available.

GTX and Orion shall mutually determine whether or not any of the Results provide the basis for any patentable inventions. If both Orion and GTX consider that patents for any such inventions involving Results should be sought, then such applications shall, in accordance with what has been stated herein above, be filed in the Parties' joint name, and the Parties shall share equally all costs of filing, prosecuting and maintaining relevant patent applications and patents. The Parties shall negotiate in good faith on the division of responsibilities with regard to drafting, filing, prosecuting and maintaining the relevant patent applications and patents. If the Parties do not decide that patent application(s) should be filed for any patentable inventions included in the Results, then the Results shall continue to be treated as Confidential Information of both Parties.

14.7 AGREEMENT TERMS GOVERN. Except as otherwise agreed in writing by the Parties, the terms and conditions of this Agreement shall govern Orion and its Affiliates' sale of Orion Product to GTX, its Affiliates and GTX Unaffiliated Sublicensees during the Term, notwithstanding any conflicting terms and conditions set forth in GTX's forecast, order or purchase documents or in Orion's sale or acceptance documents and any such conflicting terms are hereby expressly rejected.

14.8 PRICE ADJUSTMENT FOR COMMERCIAL SUPPLY. It is agreed upon by the Parties that the price of the [ \* ] tablet of Orion Product to GTX, its Affiliates or Unaffiliated Sublicensees shall be reduced below [ \* ] based upon attaining certain milestone purchases of Product as follows: if GTX purchases annually an aggregate amount of [ \* ] of tablet [ \* ], the price of the tablet shall be [ \* ] per [ \* ] tablet. Similarly, (i) the price to GTX of the [ \* ] tablet of Orion

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Product shall be reduced if GTX purchases annually [ \* ] of the [ \* ] tablets such that the price per [ \* ] tablet of Orion Product shall be [ \* ], and (ii) the price to GTX of the [ \* ] tablet of Orion Product shall be reduced if GTX purchases annually [ \* ] of the [ \* ] tablets such that the price per [ \* ] tablet of Orion Product shall be [ \* ]. If a price adjustment is triggered under this Section 14.8, then the adjusted price shall apply to the entire amount of the relevant tablets purchased during the relevant year. Orion shall within thirty (30) days after the end of such year, pay to GTX an amount equal to the number of relevant tablets actually purchased during such year, multiplied by the difference between the price paid by GTX for supply of the relevant tablets and the lower price that is actually applicable due to the adjustment to be made pursuant to this Section 14.8.

14.9 TERMINATION OF PRODUCT SUPPLY. Orion shall, at its sole discretion, have the right upon providing [  $\ast$  ] prior written notice thereof, to terminate its obligations under this Article 14 relating to the manufacture and supply of Orion Product and/or Toremifene (pursuant to Section 14.6.2) in the event that Orion permanently ceases the manufacture of Toremifene and/or Orion Product. For the avoidance of doubt, the right of termination relating to the manufacture and supply of Orion Product and/or Toremifene set forth in this Section 14.9 shall not restrict or alter Orion's rights under Section 7.7. In the event that Orion so terminates such obligations, Orion shall grant GTX a contingent license under the Orion Patent Rights, Orion Know-How and the Manufacturing Patents to make and have made Product for use in the Field in the GTX Territory (except for use of the Product in the Orion Field in the Orion Territory) during the Term, with such license to be exclusive in the Field (but excluding the Orion Field in the Orion Territory) and sublicensable (but only for the purpose of having Products manufactured for GTX, its Affiliates or Unaffiliated Sublicensees). Such license shall become effective upon GTX's receipt of notice from Orion under this Section 14.9. Orion shall during such [ \* ] notice period, and as soon as practically possible after GTX's written request, provide GTX with Product Manufacturing Know-How to the extent reasonably necessary to enable GTX to exercise its back-up manufacturing right pursuant to this Section 14.9, including without limitation providing up to ten (10) person-days of technology transfer assistance at GTX's site of manufacture of Product using Orion personnel skilled in such manufacturing operations, at no charge to GTX.

### 15. PRODUCT WARRANTIES AND INDEMNIFICATION

# 15.1 PRODUCT WARRANTIES AND LIMITATIONS.

15.1.1 ORION WARRANTIES. Orion warrants and represents that the Orion Product manufactured by Orion, its Affiliate(s) or subcontractor(s), as the case may be, and delivered to GTX, its Affiliate(s) or GTX Unaffiliated Sublicensee(s) hereunder for resale shall (i) from the date of shipment until the end of the specified shelf-life conform to the Specifications (provided, however, that Orion Product has after shipment been handled and stored properly and been afforded sufficient protection against deterioration and damage) and shall have been manufactured in accordance with U.S. FDA Good Manufacturing Practices and equivalent Good Manufacturing Practices in Europe to the extent applicable to Orion, its Affiliates or subcontractors as the manufacturer(s) of Orion Product, and (ii) be transferred free and clear of any security interests, liens and encumbrances. It is expressly agreed that, except as expressly provided for in Section 11.2, no representation, warranty, commitment or obligations given,

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

made or undertaken by Orion in this Agreement shall apply with regard to any Product manufactured by a party other than Orion, its Affiliates or subcontractors, including without limitation any Product manufactured by or on behalf of GTX under its stand-by and other manufacturing rights pursuant to Section 7.7, 14.9, 16.1, 17.3.2, 17.4 or 21.2.2.

15.1.2 LIMITATIONS. Except as otherwise expressly stated herein, no warranties or representations, express or implied are made or shall be deemed to have been made by Orion, its Affiliate or subcontractor including without limitation the warranties of fitness for a particular purpose and merchantability, regarding any Product, including without limitation the Orion Product and Other Product. Subject to Orion's warranty and indemnification obligations under this Agreement for Orion Product, Orion shall have no responsibility or liability for any Product, including without limitation Orion Product and Other Product manufactured by Orion and/or used, supplied, marketed, or sold by GTX, its Affiliates or GTX Unaffiliated Sublicensees.

15.2 CERTIFICATE OF ANALYSIS. Orion shall furnish GTX with one or more certificates of analysis for each batch of Orion Product supplied hereunder, in the form required by law in each country of GTX Territory where the Orion Product is marketed, with shipment of each such batch.

## 15.3 PRODUCT INSPECTIONS.

15.3.1 GTX INSPECTION AND ANALYSIS. GTX shall inspect and analyze a representative sample of Orion Product from batches supplied by Orion promptly after receipt. If, after inspection, GTX reasonably believes the shipment does not meet the Specifications, GTX shall notify Orion in writing within thirty (30) days after GTX's receipt of any such goods. If GTX does not so notify Orion, GTX shall be deemed to have waived all claims against Orion for said quantity delivered, except for any latent defects that could not have been reasonably discovered upon such inspection, which defects shall be notified by GTX to Orion within fourteen (14) days from discovery of same. Any claims by GTX regarding goods delivered shall specify in reasonable detail the nature and basis for the claim and cite relevant Orion lot numbers or other information to enable specific identification of the goods involved. GTX shall not be required to accept Orion Product having a shelf life of less than eighty percent (80%) of the stated expiration dating on the date of shipment by Orion.

15.3.2 ORION RESPONSE. Orion shall respond to all claims made by GTX on a case-by-case basis and Orion shall have the right to first inspect any goods involved before being required to take any action with respect thereto. Orion shall review any such claim of nonconformity made by GTX within thirty (30) business days of receipt of GTX's notice under Section 15.3.1 and conduct any required testing of the goods involved as soon as possible, but in no event later than forty-five (45) days after receipt thereof, or earlier if the U.S. FDA or any corresponding regulatory authority in the GTX Territory requires an earlier response from Orion. If such review and testing by Orion (or testing by an independent laboratory as set forth below) confirms that a claimed quantity does not meet the Specifications, then, at Orion's expense, GTX shall dispose of or return such quantity involved as Orion shall direct in writing and Orion shall replace such quantity with conforming goods as soon as possible, but in no event later than sixty (60) days after testing is completed, which shall be GTX's sole and exclusive remedy for such non-conformity. If the Parties fail to agree as to whether a delivered quantity meets the

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Specifications, then the Parties shall have the batch in dispute analyzed by a mutually agreed upon independent testing laboratory located in the country in which Orion Product to which goods relate is intended for resale, or, if the Parties agree, in Finland. Such laboratory's determination shall be deemed final as to any dispute over the Specifications and the nonprevailing Party shall bear the costs of such independent laboratory's testing.

15.4 PRODUCT STORAGE. Each Party shall properly store Orion Product under conditions that will not adversely affect the quality or normal shelf life thereof.

## 15.5 GTX RESPONSIBILITIES IN GTX TERRITORY.

15.5.1 LABELING. GTX shall be responsible for packaging of the Product, and for all labeling, inserts, packaging and promotional materials and any other materials which accompany, are distributed, used or referred to in any way by GTX, its Affiliate(s) or GTX Unaffiliated Sublicensee(s) in connection with the Product and GTX shall ensure that same shall conform to all legal requirements in each country of the GTX Territory in which the Product is sold. Subject to applicable legal and regulatory requirements and space limitations, all Product labeling, packaging, inserts and promotional materials shall indicate that the Product is marketed by GTX. GTX shall, upon written request therefore by Orion, provide Orion with copies of representative samples of materials which GTX, its Affiliates and GTX Unaffiliated Sublicensees intend to use in connection with the marketing, promotion and sale of the Product thirty (30) days prior to their first use thereof, provided that nothing herein or otherwise, including without limitation any request by Orion to be furnished with such materials or review of same, shall be construed as Orion assuming any liability or responsibility for such materials or their conformity to all legal requirements in any country of the GTX Territory in which the Product is sold and such request and/or review by Orion of such materials shall be without prejudice to the first sentence of this Section 15.5. GTX, its Affiliates, or GTX Unaffiliated Sublicensee shall register, promote, market and sell the Product in the GTX Territory only for the indications for which relevant Regulatory Approvals have been obtained and only in accordance with applicable legal and governmental authority requirements.

15.5.2 NOTIFICATION. GTX shall also be responsible for notifying, reporting or registering this Agreement or the business relationship created hereby with any government authorities in the GTX Territory to the extent legally required. Orion shall provide GTX with such assistance as GTX may reasonably request in connection therewith.

## 15.6 RECIPROCAL INDEMNIFICATION PROVISIONS.

15.6.1 ORION INDEMNIFICATION. Orion shall defend, indemnify and hold GTX, its Affiliates, GTX Unaffiliated Sublicensees, and its and their officers, directors and employees, harmless from and against any and all liabilities, damages, claims, demands, costs, or expenses (including reasonable attorneys' fees) Losses claimed by any Third Party for any property or other economic loss or damage or injury or death suffered by it to the extent the same is determined to have been caused by (A) the negligence, fault, willful wrongdoing or any other act or omission in relation to the manufacture by Orion, its Affiliates or subcontractor(s) of the Orion Product, or a material breach of this Agreement by Orion, its Affiliate(s) or Unaffiliated Sublicensee(s), or (B) or a breach by Orion of the warranties set forth in Section 15.1 and/or

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

20.1(i), or (C) the manufacture, use, sale, importation, distribution and/or marketing of the Product for use in the Orion Field and in the Orion Territory by Orion, its Affiliates or Unaffiliated Sublicensees, except with respect to each of (A) and (B) to the extent that such Losses are caused by activities for which GTX must defend, indemnify and hold harmless pursuant to Section 15.6.2.

15.6.2 GTX INDEMNIFICATION. GTX shall defend, indemnify and hold Orion, its Affiliates, and its and their the officers, directors and employees harmless from and against any and all Losses claimed by any Third Party for any property or other economic loss or damage, injury or death suffered by it to the extent the same is determined to have been caused by (A) a breach by GTX of [\*](i); (B) the negligence, fault, willful wrongdoing or any other act or omission, or material breach of this Agreement by GTX, its Affiliates or Unaffiliated Sublicensees; (C) the manufacture, use, sale, importation, distribution, and/or marketing of the Product by GTX, its Affiliates or Unaffiliated Sublicensees in the Field in the GTX Territory, including without limitation any product liability claim for property or other economic loss or damage, injury or death suffered by a Third Party arising out of or relating to the Product or Other Product or use thereof, except with respect to each of (B) and (C) to the extent that such Losses are caused by activities for which Orion must defend, indemnify and hold harmless GTX pursuant to Section 15.6.1.

15.7 CONDITIONS FOR INDEMNIFICATION. With respect to any indemnification obligations of either Party to the other Party under this Agreement, the following conditions must be met for such indemnification obligations to become applicable: (A) the indemnified Party shall notify the indemnifying Party promptly in writing of any claim which may give rise to an obligation on the part of the indemnifying Party hereunder; (B) the indemnifying Party shall be allowed to timely undertake the sole control of the defense of any such action and claim, including all negotiations for the settlement, or compromise of such claim or action at its sole expense; and (C) the indemnified Party shall render reasonable assistance, information, cooperation and authority to permit the indemnifying Party to defend such action, it being agreed that any out-of-pocket expenses or other expenses incurred by the indemnified Party in rendering the same shall be borne or reimbursed promptly by the indemnifying Party. Neither Party shall consent to the entry of any judgment or settle or otherwise compromise any such action or suit in a way that adversely affects the other Party's intellectual property rights or other rights, obligations or interests with respect to Products, or imposes obligations on such other Party, without such other Party's prior written consent.

15.8 LIABILITY INSURANCE. GTX shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies commercializing products of similar nature that present similar liability risks. It is understood that such insurance shall not be construed to create a limit of GTX's liability with respect to its any of its obligations hereunder, including without limitation its indemnification and compensation obligations under this Agreement. GTX shall provide Orion with written evidence of such insurance (including without limitation financial information that describes the amounts available under such insurance) upon request. This Section 15.8 shall survive the termination expiration of this Agreement for ten (10) years for whatsoever reason.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

## 16. STANDBY MANUFACTURING RIGHTS; INVENTORY MAINTENANCE

16.1 INABILITY TO MANUFACTURE OR SUPPLY. If Orion is unable to supply or manufacture Orion Product, as ordered pursuant to Sections 14.1.2 and 14.3.2, for ninety (90) or more consecutive days after the agreed delivery time for any reason (including but not limited to a Force Majeure event), save as for reasons arising from acts or omissions of GTX, its Affiliates and/or its Unaffiliated Sublicensees, including without limitation failure by GTX, its Affiliates and/or its Unaffiliated Sublicensees to notify Orion of Orion's failure to deliver Orion Product ordered pursuant to Sections 14.1.2 and 14.3.2, then GTX may, at its option, responsibility and expense, elect to manufacture or have a Third Party manufacture Toremifene and/or Orion Product for use in manufacturing and selling the Product for use in the Field anywhere in the GTX Territory (except for use in the Orion Field in the Orion Territory) until such time as Orion can demonstrate to GTX's reasonable satisfaction that Orion is capable of resuming the manufacture of Toremifene and/or Orion Product, as applicable. To the extent necessary to implement such standby manufacturing rights, Orion hereby grants GTX a contingent license under the Orion Patent Rights, Orion Know-How and Manufacturing Patents to make and have made Toremifene and/or Orion Product for use in the Field in the GTX Territory (except for use in the Orion Field in the Orion Territory). Such license shall be exclusive and sublicensable (but only for the purpose of having Products manufactured for GTX, its Affiliates or Unaffiliated Sublicensees), with such license to become effective only under the circumstances specified in the preceding sentence. In such case, Orion shall as soon as practically possible provide GTX with Product Manufacturing Know-How to the extent reasonably necessary to enable GTX to exercise its back-up manufacturing right pursuant to this Section 16.1, including without limitation providing up to ten (10) person-days of technology transfer assistance at GTX's site of manufacture of Product using Orion personnel skilled in such manufacturing operations, at no charge to GTX. Orion shall promptly notify GTX in writing of any circumstances rendering it unable to manufacture Product and the estimated duration of such circumstances. GTX's standby-manufacturing rights under this Section 16.1 shall be GTX's sole and exclusive remedy for Orion's failure to manufacture or have manufactured Orion Product for supply to GTX under Article 14.

16.2 BACK-UP MANUFACTURING RIGHT. GTX shall have the right to require Orion to qualify and maintain the qualification for, at GTX's expense (as described below), a back-up facility(ies) for use in manufacturing Product for supply to GTX pursuant to Article 14 at any time after GTX's good faith forecasted Net Sales of Products provided pursuant to Section 14.3 [\*] in a given Year, or actual Net Sales for Product in any given Year [\*]. GTX shall exercise such right by written notice to Orion. Promptly after receiving such notice, Orion and GTX shall meet to discuss the manner in which Orion proposes to qualify and maintain the qualification for such back-up manufacturing facility(ies) (for example, by qualify as site owned by Orion or by engaging a Third Party manufacturer to qualify another facility), the timing for qualifying such facility(ies) (which costs may include, by way of example, Orion's costs of obtaining Regulatory Approvals necessary to enable the sale in the Territory of Product manufactured at such site). Orion shall promptly thereafter, subject to agreement on reimbursement by GTX of Orion's related costs and expenses, qualify such back-up facility and maintain the qualification for such back-up facility and maintain the qualify such back-up facility and maintain the qualify such back-up facility and for orion's related costs incurred directly in connection with qualifying such facility (ies) (which costs may include, by way of example, Orion's costs of obtaining Regulatory Approvals necessary to enable the sale in the Territory of Product manufactured at such site). Orion shall promptly thereafter, subject to agreement on reimbursement by GTX of Orion's related costs and expenses, qualify such back-up facility and maintain the qualification for such facility (including obtaining relevant Regulatory Approvals

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

and making appropriate regulatory filings) to assure continued supply of Product in the event Orion is unable to supply Products in the amounts ordered pursuant to Article 14. GTX shall reimburse Orion for [ \* ], or [ \* ] the Parties. Nothing in this Section 16.2 shall be deemed to limit Orion's obligations under Article 14, or to prevent GTX from seeking any remedies available to it under law or in equity for any breach by Orion under such Sections.

16.3 MAINTENANCE OF INVENTORY. Orion shall, at all times during the Term, maintain or have maintained, either itself or through a subcontractor, an amount of Toremifene and other raw materials critical for the manufacture of Products containing such Toremifene sufficient to manufacture the amount of Product forecasted to be ordered by GTX pursuant to Section 14.3 during the subsequent [\*] period of time. The Parties will agree upon an appropriate amount of reserve supplies to be maintained by Orion during the [\*] following the First Commercial Sale of Product in the Prostate Cancer Field at the time GTX provides an update to its forecasted requirements to support launch of Product in such field pursuant to Section 14.1. Such supplies shall serve as a reserve supply to be used by Orion solely to manufacture Product for GTX if any shortfall in the amount of Product supplied by Orion pursuant to Article 14 occurs or is reasonably anticipated to occur. Nothing in this Section 16.3 shall be deemed to limit Orion's obligations under Article 14.

## 17. MANUFACTURING INSPECTIONS AND CHANGES

17.1 REGULATORY INSPECTIONS. Each Party shall allow representatives of the U.S. FDA and any other regulatory agency or authority with jurisdiction over the manufacture, marketing and distribution of the Product to tour and inspect all facilities utilized by such Party in the manufacture, testing, packaging, storage, and shipment of Product sold under this Agreement, and shall co-operate with such representatives in every reasonable manner. Upon notification by the U.S. FDA or any other regulatory agency of such agency's intent to conduct an inspection, the Party receiving such notification will immediately inform the other Party of such inspection with such advance notice as to allow the other Party to have representatives present during such inspection (to the extent such presence is allowed by such regulatory agency). Each Party shall also provide the other Party with a copy of any U.S. FDA Form 483 notices of adverse findings, regulatory letters or similar notifications it receives from any other governmental authority setting forth adverse findings or non compliance with any applicable laws, regulations or standards relating to the Product within five (5) days of its own receipt thereof. Each Party shall also provide the other Party with a copy of its proposed written response to such governmental authority before submission and shall incorporate any changes thereto which the other Party may reasonably request.

17.2 ORION-INITIATED MANUFACTURING CHANGES. Save as for changes required under applicable laws and regulations or by any competent regulatory or other authority, during the Term, Orion shall not make any material changes to its manufacturing operations for Toremifene or Orion Product to be supplied to GTX pursuant to this Agreement, without informing GTX prior to such changes; provided that if such changes would require GTX to make additional filings with regulatory authorities or to seek additional Regulatory Approvals for Orion Product, then Orion shall not make such change without GTX's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

## 17.3 GTX-INITIATED MANUFACTURING CHANGES.

17.3.1 GTX REQUEST FOR MANUFACTURING CHANGES. Prior to Orion providing GTX with notice pursuant to Section 14.9, GTX may, from time to time during the Term and as agreed in this Section 17.3, make a written and detailed request for changes in Orion's manufacturing operations, or the Specifications, for Toremifene or Orion Product. Such changes that are required and mandatory under applicable laws and regulations in a Major Country shall be deemed "Required Manufacturing Changes", and such changes that are intended to promote quality control/quality assurance, and/or to achieve greater efficiency or cost savings in the manufacturing process but are not so required and mandatory shall be deemed "Other Manufacturing Changes".

17.3.2 REQUIRED MANUFACTURING CHANGES. Provided that GTX furnishes Orion with evidence of Required Manufacturing Changes, Orion shall commence the implementation of Required Manufacturing Changes as soon as practicable, but in no event later than (i) ninety (90) days after receipt of GTX's request (or within such other longer time period as may be mutually agreed upon by the Parties if implementation within ninety (90) days is impossible or reasonably impractical, such agreement not to be unreasonably withheld, conditioned or delayed by GTX) or (ii) earlier if required by the U.S. FDA or any corresponding regulatory authority in a Major Country. If Orion does not commence the implementation of Required Manufacturing Changes within the time period referenced in the preceding sentence or does not notify GTX in writing that Orion disputes whether GTX's requested changes are Required Manufacturing Changes, then GTX shall have the option to exercise standby manufacturing rights for Toremifene and Product pursuant to Section 16.1 until such time as Orion implements such Required Manufacturing Changes. If Orion notifies GTX in writing that Orion disputes whether GTX's requested changes are Required Manufacturing Changes, the Parties shall resolve such dispute by reference to a mutually agreed upon independent Third Party regulatory expert as soon as possible for a binding determination of whether the requested changes are Required Manufacturing Changes. If such independent Third Party regulatory expert determines that GTX's requested changes are Required Manufacturing Changes, Orion shall implement such changes as soon as possible. Any modification to the Specifications that is necessary to implement or reflect a Required Manufacturing Change shall be deemed to be included in the Specifications, and any Products manufactured thereunder by Orion shall be deemed Orion Products.

17.3.3 OTHER MANUFACTURING CHANGES. Orion shall give due consideration to making Other Manufacturing Changes proposed by GTX. Orion shall within sixty (60) days from receipt of GTX's written request for Other Manufacturing Changes provide GTX a written response to such request indicating whether it would be willing to discuss, and as appropriate, negotiate the terms and conditions under which Orion would be willing to implement such Other Manufacturing Changes.

17.4 NEW DOSAGE STRENGTHS AND FORMULATIONS. Upon written request by GTX, the Parties shall meet in person or by teleconference to discuss, and as appropriate, negotiate the terms under which Orion would be willing to manufacture and supply to GTX any dosage strengths or formulations of the Product other than those that are available as an Orion Product as of the Restatement Date (including without limitation any combination Product containing

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Toremifene and another active ingredient) or any Product otherwise having specifications different from Orion Product Specifications (such Products, collectively "Other Product(s)"), as provided in this Section 17.4.

The Parties shall conduct such discussions during a sixty (60) day period following GTX's written request setting forth in sufficient detail the changes proposed by GTX, or any mutually agreed extension of such time period ("Evaluation Period"). If Orion would be willing to manufacture such Other Product, Orion shall within the Evaluation Period notify GTX of the terms and conditions under which it would be willing to do so, and the Parties shall negotiate a written amendment to this Agreement to include the applicable terms and conditions under which Orion would manufacture and supply such Other Product, including without limitation the supply price of such Other Product. Upon execution of such amendment, such Other Product shall be deemed to be an Orion Product. Such negotiation shall be conducted for up to one hundred twenty (120) days following GTX's receipt of Orion's notice of such terms and conditions ("Negotiation Period"). It is expressly agreed that Orion shall have no obligation to manufacture and supply any Other Product unless a mutually acceptable definitive written amendment to this Agreement, if any, in relation to such Other Product is executed by duly authorized representatives of both Parties.

In the event Orion notifies GTX within the Evaluation Period that it will not be interested in supplying such Other Product, or the Parties do not amend this Agreement during the Negotiation Period to specify applicable terms for, or execute another agreement governing, Orion's supply of such Other Product for use in the Field (other than use in the Orion Field in the Orion Territory), then if GTX has a good faith basis for requiring supply of such Other Product including but not limited to its desire to develop a dosage strength of Product other than one which is in clinical development by or on behalf of GTX as of the Restatement Date and in which an Orion Product is available, or a formulation of Product that incorporates a new technology or another active ingredient in order to optimize the pharmacokinetic properties of Product, improve the competitive position of Product in the market, or to increase the efficiency or safety of Products, GTX shall have the right to manufacture, or engage a Third Party subcontractor to manufacture, such Other Product for sale and use in the Field only. GTX shall exercise such right to manufacture or have manufactured an Other Product for sale and use in the Field (except for use in the Orion Field in the Orion Territory) pursuant to this Section 17.4 in good faith only, and not for the purpose of obtaining the right to manufacture Product by, for example, proposing minor changes to the Product formulation that do not present a commercially reasonable basis for development. To the extent reasonably contingent license under Orion's Patent Right, Orion Know-How, Manufacturing Patents, and Product Manufacturing Know-How to make and have made the relevant Other Product for use in the Field in the GTX Territory (except for use in the Orion Field in the Orion Territory). Such license shall be exclusive and sublicensable but only for the purpose of having Products manufactured for GTX, its Affiliates and Unaffiliated Sublicensees), and shall become effective only under the circumstances specified in this Section 17.4.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

#### 18. PRODUCT RECALLS

18.1 RECALL NOTIFICATION. Each Party shall promptly notify the other Party in writing of any facts relating to the advisability of the recall, destruction or withholding from the market of the Product anywhere in the GTX Territory (any of the foregoing, a "Recall").

18.2 RECALL IMPLEMENTATION IN GTX TERRITORY. If at any time (A) any governmental or regulatory authority in the GTX Territory issues a request, directive or order for a Recall; (B) a court of competent jurisdiction orders a Recall in the GTX Territory; or (C) GTX determines, following consultation with Orion (except in emergency situations in which there is insufficient time for such consultation), that a Recall in the GTX Territory is necessary or advisable, GTX shall take all appropriate corrective actions to effect the Recall and Orion shall provide GTX with such cooperation in connection with the Recall as GTX may reasonably request.

18.3 RECALL COSTS AND EXPENSES IN GTX TERRITORY. GTX shall bear the costs and expenses of any Recall in the GTX Territory, provided that Orion shall bear all costs and expenses of any Recall in the GTX Territory to the extent such Recall is the result of a breach in the warranties set forth in Section 15.1.

## 19. ADVERSE DRUG EXPERIENCES

19.1 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS.

(A) To ensure that all relevant safety information for Toremifene is shared between the Parties, the following information will be exchanged: (i) GTX will provide to Orion all regulatory safety updates (e.g. 120-day safety updates, annual reports, and post-authorization safety updates) concerning Product and information regarding all serious adverse events from clinical studies and all spontaneous adverse reactions, including reports from literature concerning the Product coming to the knowledge of GTX; and (ii) Orion will provide to GTX Periodic Safety Update Reports prepared in accordance with ICH E2C or equivalent guidelines as adopted by the European Medicines Evaluation Agency (EMEA) relevant to Product for use in the Orion Field in the Orion Territory, and information regarding all serious adverse events from clinical studies and all spontaneous adverse reactions, including reports from literature concerning Product, coming to the knowledge of Orion. All of the above mentioned safety information shall be exchanged reasonably in advance of any applicable regulatory deadlines or upon release of such information. In addition, any safety information which may negatively affect the benefit-risk ratio of Products or that may have consequences regarding the product information (e.g. labeling, data sheets, instruction leaflets) or may require immediate safety measures to be taken by either Party shall be forwarded to the other Party without any delay. Each Party is responsible for any regulatory safety reporting requirements with respect to maintaining its own Regulatory Approval applications and complying with regulatory requirements for Products that it has the right to sell pursuant to this Agreement according to applicable laws, rules and regulations.

(B) The intent of Section 19.1(a) is to enable each Party to comply with regulatory requirements for Toremifene products, which requirements may change from

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

time to time. Concurrently with the execution of this Agreement, the Parties shall execute an agreement setting forth a mutually acceptable detailed procedure generally consistent with the intent of Section 19.1(a) that enables each Party to comply with such regulatory requirements with respect to such Products. Under such agreement, from time to time after the Restatement Date, the Parties shall meet upon request by either Party to discuss and agree upon any modifications to such detailed procedure necessary to ensure that each Party is in compliance with regulatory reputing requirements for Products that it has the right to develop and sell pursuant to this Agreement.

This Article 19 shall survive the expiration or termination of this  $\ensuremath{\mathsf{Agreement}}$  .

20. REPRESENTATIONS AND WARRANTIES

20.1 REPRESENTATIONS AND WARRANTIES OF THE PARTIES. Each Party hereby represents and warrants to the other Party as follows:

(A) CORPORATE STATUS. It is a corporation duly organized and validly existing under the laws of its state or other jurisdiction of incorporation or formation;

(B) AUTHORITY. It has the power and authority to execute and deliver this Agreement, and to perform its obligations hereunder;

(C) NO CONFLICTS. The execution, delivery and performance by it of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) any loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter documents or by-laws; or (iii) any order, whit, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(D) NO APPROVALS. Except for the regulatory filings and approvals for the Product referenced herein, no authorization, consent or approval of any governmental authority or Third Party is required for the execution, delivery or performance by it of this Agreement, and the execution, delivery or performance of this Agreement will not violate any law, rule or regulation applicable to such party;

(E) ENFORCEABILITY. This Agreement has been duly authorized, executed and delivered and constitutes its legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles;

(F) COMPLIANCE WITH LAWS. It shall comply with all applicable local, state, national, regional and governmental laws and regulations relating to its activities under this Agreement; and

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(G) NEGATIVE DATA OR INFORMATION. It has, to the best of its management's knowledge, no knowledge of negative data or information regarding the Product, which, to the best of its reasonable belief, would have a material effect on the regulatory approval process and/or on the commercialization of the Product in the Field.

(H) NO DEBARMENT. It has not been and will not be debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 335a(a) or (b). In the event that such Party becomes aware of, or receives notice of, the debarment of any individual, corporation, partnership, or association performing activities which relate to the Products, it shall notify the other Party immediately and address the issue as directed by the other Party.

(I) NO IMPROPER CONTENT ON FARESTON U.S. WEB PAGES. It has not and will not place any links or information on the Fareston U.S. Web Pages pursuant to Article 9 that would: (A) infringe on the intellectual property rights of any Third Party; (B) violate any law, statute, ordinance or regulation; (C) be defamatory, trade libelous, unlawfully threatening or unlawfully harassing; or (D) contain any viruses or other computer programming routines that damage, detrimentally interfere with, surreptitiously intercept or expropriate any system, data or personal information.

20.2 REPRESENTATION BY ORION. Orion hereby represents and warrants to GTX that:

(A) As of the Restatement Date, Orion has entered into the Fareston Repurchase Agreement pursuant to which Orion has terminated its agreement with Shire dated 6 September, 1999, as amended, under which Shire had been granted licenses or other rights to develop and/or commercialize Products in the USA in the Breast Cancer Field.

20.3 REPRESENTATION BY GTX. GTX hereby represents and warrants to Orion that:

(A) As of the Restatement Date, GTX has acquired sufficient rights and licenses from The University of Tennessee Research Foundation to the patent applications included in the GTX Patent Rights that are listed in Part II of Schedule A that are necessary for the purpose of performing its obligations under this Agreement.

## 21. TERM AND EARLY TERMINATION RIGHTS

21.1 TERM. The Term shall extend for the period provided in Section 1.51.

21.2 TERMINATION FOR CAUSE. Either Party shall have the right, without prejudice to any other rights or remedies available to it, either to terminate this Agreement or the license rights granted to a Party under this Agreement on a country-by-country basis for cause as described in this Section 21.2 as follows:

21.2.1 BANKRUPTCY. Either Party shall have the right to terminate this Agreement and same shall terminate upon expiry of a sixty (60) days notice period, if the other Party becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

the event an involuntary bankruptcy action is filed against the other Party and not dismissed within ninety (90) days, or if the other Party becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business.

21.2.2 MATERIAL BREACH. If either Party commits a material breach of this Agreement and if the Party alleged to be in breach of this Agreement fails to (i) cure such breach or (ii) commence bona fide dispute resolution proceedings under Section 25.2 contesting whether a breach has occurred and/or whether such breach is a material breach, in either case within sixty (60) days after receipt of written notice from the Party asserting the breach, then the Party asserting the breach may terminate this Agreement in its entirety (if such breach is a material breach, other than as specified in Sections 6.4.2 and 12.11.1 or 12.11.2), or, if such breach is by GTX and is described in Section 6.4.2 or in Section 12.11.1, then Orion may terminate its supply obligations as set forth under Article 14 and terminate the license granted to GTX pursuant to Section 2.1, in each case with respect to the Major Country in relation to which such material breach occurred under Section 6.4.2 or 12.11.1. If the Agreement is terminated either in its entirety or with regard to a particular Major Country, as the case may be, then if GTX is the breaching Party, GTX shall grant to Orion a nonexclusive, royalty-bearing license, with the right to grant sublicenses, under the GTX Patent Rights, the Trademarks, the Regulatory Approvals (by means of assignment or transfer of, or authorization to cross-reference, relevant Regulatory Approval(s)) and the GTX Know-How to make, have made, develop, use, sell, offer for sale, market and promote, and import Products in the country(ies) in which GTX's license terminates, or, if Orion is the breaching Party, then the license granted to GTX shall be expanded to include an exclusive, sublicensable license under the Orion Patent Rights, Orion Know-How, and Manufacturing Patents to make and have made Products for use in the Field in the GTX Territory, (except for use in the Orion Field in the Orion Territory). In the event of termination of the Agreement due to Orion's breach, Orion shall as soon as practically possible provide GTX with Product Manufacturing Know-How to the extent reasonably necessary to enable GTX to exercise its manufacturing right pursuant to this Section, including without limitation providing up to ten (10) person-days of technology transfer assistance at GTX's site of Manufacture or Product using Orion personnel skilled in such manufacturing operations, at no charge to GTX.

(A) If the non-breaching Party obtains a license under this Agreement as provided in Section 21.2.2, it shall pay to the other Party a running royalty equal to [\*] of Net Sales of Product by the non-breaching Party, its Affiliates or Unaffiliated Sublicensees. Furthermore, if GTX is the breaching Party, GTX shall promptly transfer to Orion, at GTX's expense, all Regulatory Approvals and registration filings for the Product in the territory in which Orion obtains such license, together with such documentation, information and data in its possession as Orion may need for regulatory compliance in the course of exercising its rights in such territory with respect to Product.

21.3 TERMINATION BY MUTUAL AGREEMENT. The Parties may terminate this Agreement at any time by drafting and executing a mutually acceptable written agreement. The written agreement shall specify the consequences of such termination.

21.4 TERMINATION BY GTX FOR SAFETY OR EFFICACY REASONS. If at any time during the Term: (i) GTX decides not to file an application for Regulatory Approval in any country or decides to withdraw such application due to documented adverse reactions or other safety issues

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

with the Product or the Product's lack of efficacy or limited efficacy (collectively, "Safety or Efficacy Issues"); (ii) GTX's application(s) for Regulatory Approval in any country is rejected due to Safety or Efficacy Issues; (iii) GTX's application(s) for Regulatory Approval in any country is subsequently withdrawn because of Safety or Efficacy Issues; or (iv) the Product is withdrawn or recalled from the market in any country because of Safety or Efficacy Issues, then GTX may, at its option, terminate this Agreement with respect to such country upon thirty (30) days prior written notice to Orion. GTX must exercise this right of termination within the later of (a) sixty (60) days of the occurrence of the event giving rise to such right or (b) thirty (30) days of GTX's last meeting, if any, with the relevant regulatory authorities, provided that GTX uses reasonable diligence to schedule such meeting and that Orion is providing reasonable co-operation to GTX in connection with such meeting. GTX may, at its option, exercise its right of termination under this Section 21.4 on a country-by-country basis, and, if GTX does so, GTX's termination notice shall specify the country or countries of the GTX Territory affected. GTX shall transfer to Orion, at Orion's expense, all Regulatory Approvals and registration filings for the Product in the country for which it terminates its license, together with such documentation, information and data in its possession as Orion may need for regulatory compliance in the course of any further development of Product in such country Orion may elect to conduct thereafter.

21.5 EFFECT OF TERMINATION. Termination or expiration of this Agreement through any means and for any reason shall not relieve the Parties of any obligations accruing prior thereto and shall be without prejudice to the rights and remedies of either Party with respect to any prior breach of any of the provisions of this Agreement.

#### 22. NOTICES

22.1 MANNER OF GIVING NOTICES. All notices required or permitted in connection with this Agreement shall be writing and may be given by personal delivery, prepaid registered or certified airmail letter, courier, facsimile, addressed to the Party to receive the same at its address set forth below, or to such other address as it shall later designate by like notice to the other Party. Notice of termination of this Agreement if given by facsimile shall be confirmed by prepaid registered or certified airmail letter dated and posted within twenty-four (24) hours. The effective date of receipt of any notice if served by facsimile shall be deemed the first business day in the city of destination following the transmission or dispatch thereof and, if served by courier shall deemed the second business day in the city of destination following the dispatch thereof unless earlier received. Notice by personal delivery shall be effective as of the date of such delivery.

22.2 ADDRESSES FOR NOTICES.

Notices to Orion shall be sent to:

Orion Corporation Orion Pharma Attn: President of Orion Pharma Orionintie 1, P.O. Box 65 FIN-02101 Espoo

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Finland Facsimile: 358-9-429-3044

With a copy to:

Orion Corporation Orion Pharma Attn: Legal Counsel Orionintie 1, P.O. Box 65 FIN-02101 Espoo Finland Facsimile: 358-9-429-4088

Notices to GTX shall be sent to:

GTx, Inc. Attn: President, with a copy to the General Counsel 3 North Dunlap Avenue Van Vleet Building, Third Floor Memphis, Tennessee 38163 U.S.A. Telephone: 1-901-523-9700 x107 Facsimile: 1-901-523-9772

With a copy to: Cooley Godward LLP Five Palo Alto Square 3000 El Camino Real Palo Alto, CA 94306-2155

Attention: Robert Jones, Esq. Telephone: (650) 843-5034 Facsimile: (650) 849-7400

## 23. INTEGRATION

This Agreement represents the entire Agreement between the Parties relating to the subject matter hereof and supersedes all prior arrangements, understandings, correspondence, notes, minutes and agreements between the Parties (or their predecessors in interest) whether written or oral. No supplement, modification or amendment of this Agreement shall be binding unless executed by the Parties in writing and signed by the duly authorized representatives of both Parties.

## 24. ASSIGNMENT

Neither Party may assign this Agreement or any of its rights hereunder, nor delegate any of its duties or obligations hereunder, to any Third Party without the prior written consent of the

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

other Party, except (i) to an Affiliate in accordance with the terms of this Agreement, in which case notification thereof shall be provided to the other Party prior to such assignment to an Affiliate, or (ii) in connection with a merger, consolidation or similar reorganization. For clarity, this Agreement shall survive any such merger, consolidation or reorganization of either Party with or into, another party and no consent for such merger, consolidation or reorganization shall be provided promptly after a request is made) to any contemplated assignment if such contemplated assignment is in connection with the sale by either Party of all or substantially all of its assets to a Third Party. Any assignment of this Agreement to an Affiliate of the assigning Party shall not relieve the assigning Party of its responsibilities and obligations hereunder.

## 25. GOVERNING LAW AND DISPUTE RESOLUTION

25.1 GOVERNING LAW. This Agreement, including the validity, construction, interpretation and performance thereof, shall be governed entirely by the laws of Sweden. It is the specific intent and agreement of the Parties that the United Nations Convention on the International Sale of Goods shall not apply to this Agreement.

25.2 DISPUTE RESOLUTION. All disputes arising out of or in connection with this Agreement (except those involving actions commenced by or involving Third Parties and affecting or involving only one of the Parties) shall be resolved with the following mechanism:

25.2.1 ATTEMPTED AMICABLE RESOLUTION. The Parties shall promptly give each other written notice of any disputes requiring resolution hereunder, which written notice shall specify the Section(s) of this Agreement the other Party is alleged to have breached and shall briefly state the initiating Party's claims, and the Parties shall use reasonable efforts to resolve any such disputes in an amicable manner.

Any disputes arising in connection with this Agreement which cannot be resolved in an amicable manner by representatives of the Parties shall be referred, not later than thirty (30) days after initiation of dispute resolution proceedings under this Section 25.2.1, to the following corporate officers of the Parties for resolution:

For GTX: Chief Executive Officer (or his or her designee)

For Orion: President of Orion-Pharma (or his or her designee)

Such officers (or their designees) shall attempt to resolve the dispute and shall communicate with each other by facsimile or telephone or in personal meetings in an effort to resolve the dispute.

25.2.2 ARBITRATION. Any disputes (excluding any dispute, controversy or claim arising out of or relating to the validity, enforceability, scope or infringement of patent or trademark rights) arising in connection with this Agreement which cannot be resolved by the Parties within forty-five (45) days after initiation of dispute resolution proceedings under Section 25.2.1 shall be finally settled by binding arbitration under the Rules of the Arbitration Institute of the Stockholm Chamber of Commerce, Stockholm, Sweden in accordance with said

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Rules then in effect with proceedings to be held in Stockholm, Sweden in the English language. Reasonable submission of evidence shall be permitted in any such proceeding to the extent permitted under and consistent with such Rules. Judgment upon any award rendered by the arbitrator(s) in such proceedings may be issued and enforced by any court having competent jurisdiction. Any disputes arising out of or relating to the validity, enforceability, scope or infringement of patent or trademark rights shall be submitted for resolution by a court of competent jurisdiction.

25.3 EFFECT OF COMMENCING DISPUTE RESOLUTION. If either Party in good faith commences dispute resolution proceedings under Section 25.2, (A) any applicable notice periods or cure periods hereunder (including but not limited to the periods referenced in Sections 21.2 and 21.4) shall be temporarily suspended pending the outcome of such dispute resolution proceedings and (B) the non-breaching Party may, at its option, pay any amounts payable to the other Party that are in dispute into an interest-bearing escrow account pending the outcome of such dispute resolution proceedings.

## 26. LIMITATION OF DAMAGES

Except for indirect damages resulting from breach of Article 8, in no event shall either Party be liable to the other Party for any indirect, consequential or punitive damages in connection with the performance of this Agreement or any breach of this Agreement (excluding such damages payable to a Third Party which are subject to the indemnification obligations of the Parties set forth in this Agreement.

#### 27. FORCE MAJEURE

Neither Party shall be held in breach of this Agreement for failure to perform any of its obligations hereunder to the extent and for the time period such performance is prevented in whole or in part by reason of any Force Majeure event, including but not limited to industrial disputes, strikes, lockouts, riots, mobs, fires, floods, and other natural disasters and Acts of God, wars declared or undeclared, civil strife, embargo, delays in delivery or defects or shortages of raw materials from suppliers, loss or breakdown of any production equipment, losses or shortage of power, damage to or loss of gods in transit, currency restrictions, or events caused by reason of laws, regulations or orders by any government, governmental agency or instrumentality or by any other supervening unforeseeable circumstances whatsoever beyond the control of the Party so affected. The Party so affected shall (A) give prompt written notice to the other Party of the nature and date of commencement of the Force Majeure event and its expected duration and (B) use its reasonable efforts to avoid or remove the Force Majeure event as soon as possible to the extent it is so able to do.

#### 28. RELATIONSHIP OF PARTIES

The relationship of the Parties under this Agreement is that of independent contractors. Nothing contained in this Agreement shall be construed so as to constitute the Parties as partners, joint venturers or agents of the other. Neither Party has any express or implied right or authority under this Agreement to assume or create any obligations or make any warranties and representations on behalf of or in the name of the other Party, or to bind the other Party to any

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

contract, agreement or undertaking with any Third Party, and no conduct of the Parties pursuant to the terms of this Agreement shall be deemed to establish such right or authority. Neither Party shall make any representation to Third Parties that the relationship created hereby constitutes a partnership, joint venture or agency relationship.

#### 29. SEVERABILITY

In case one or more of the provisions contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, but this Agreement shall be construed by limiting such invalid, illegal or unenforceable provision, if such is not possible, by deleting such provision from this Agreement.

#### 30. NON-WAIVER

The failure by either Party at any time to enforce any of the terms or provisions or conditions of this Agreement or exercise any right hereunder shall not constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same. No waiver of any of the provisions of this Agreement shall be deemed binding unless executed in writing by the Party to be bound by it.

#### 31. HEADINGS

The headings in this Agreement are for convenience of reference only and shall not be used in the interpretation of any provisions hereof.

## 32. GOVERNING LANGUAGE

The English language version of this Agreement shall be controlling in all respects regardless of whether any translations into any other languages are made.

## 33. EXECUTION

This Agreement shall be executed by the Parties in two (2) original counterparts, one (1) original counterpart being retained by each Party and either of which shall be deemed sufficient to prove the existence and terms and conditions hereof. This Agreement may be executed by the Parties by the exchange of facsimile signature pages, with signed original counterparts of the Agreement to be exchanged by the Parties promptly thereafter.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

IN WITNESS WHEREOF, the Parties' duly authorized representatives hereto have executed this Agreement as of the Restatement Date.

ORION	CORPORATION	GTX, I	NC.
By:		By:	Mitchell Steiner, M.D.
Title:	Orion Corporation Orion Pharma	Title:	Vice-Chairman and CEO GTx, Inc.
By:	Timo Lappalainen	By:	Marc Hanover
Title:	Orion Corporation Orion Pharma	Title:	President and COO GTx, Inc.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

COUNTRY/JURISDICTION	TITLE	INVENTORS	PATENT NO.	ISSUE DATE	STATUS
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER		6,265,448	July 24, 2001	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	<ol> <li>MITCHELLS S. STENIER</li> <li>SHARAN RAGHAW</li> </ol>	6,413,534	July 2, 2002	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER		6,410,043	June 2, 2002	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	<ol> <li>MITCHELLS S. STENIER</li> <li>SHARAN RAGHAW</li> </ol>	6,413,535	June 2, 2002	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	1. MITCHELL S. STEINER 2. SHARAN RAGHOW (THE UNIVERSITY OF TENNESSEE RESEARCH CORPORATION)	6,413,533	July 2, 2002	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	<ol> <li>MITCHELL S. STEINER</li> <li>SHARAN RAGHOW</li> <li>(THE UNIVERSITY OF TENNESSEE RESEARCH CORPORATION)</li> </ol>	6,632,447	Oct 14, 2003	Issued

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE A: PART II

APPLICATIONS FILED IN THE UNITED STATES

[\*]

APPLICATIONS FILED IN FOREIGN JURISDICTIONS

[\*]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# TITLE: NOVEL ALKANE AND ALKENE DERIVATIVES AND THEIR PREPARATION AND USE (TOREMIFENE)

Country		Patent No	Expiry
AU	Australia	556608	May 25, 2008 *
BG	Bulgaria	98379	May 20, 2003
CA	Canada	1185977	May, 20, 2003
CN	China	A-FI96091019	December 20, 2003
DK	Denmark	170927	December 21, 2003 *
EP	Europe	95875	December 21, 2003 *
СН	Switzerland	95875	May 19, 2008 *
IT	Italy	95875	February 14, 2008 *
SE	Sweden	95875	May 20, 2008 *
FI	Finland	77839	December 21, 2003 *
ΗK	Hong Kong	83/89	May 20, 2003
HU	Hungary	193536	May 26, 2003
HU	Hungary	200742	May 26, 2003
IE	Ireland	55023	December 21, 2003 *
IL	Israel	68784	May 25, 2003
JP	Japan	2105540	May 25, 2003
JP	Japan	1739006	June 29, 2005 *
JP	Japan	1959197	May 25, 2003
JP	Japan	1867986	May 25, 2003
LV	Latvia	5066	May 26, 2003
NO	Norway	156164	December 21, 2003 *
NZ	New Zealand	204349	May 25, 2003
R0	Romania	C-20106 **	December 29, 2004
SG	Singapore	654/88	May 20, 2003
SU	Russia	1508955	May 26, 2003
US	USA	4696949	September 29, 2009 *
US	USA	5491173	September 29, 2004
US	USA	4996225	February 17, 2008
ZA	South Africa	833803	May 25, 2003

EP = Germany, Belgium, Austria, Italy, Sweden, Netherlands, Switzerland, Lichtenstein, Luxemburg, Great Britain, France

\* Patent term extension

\*\* Pipe-line protection based on US 4696949

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE B: PART II. ORION PATENT APPLICATIONS

TITLE: NOVEL ALKANE AND ALKENE DERIVATIVES AND THEIR PREPARATION AND USE (TOREMIFENE)

Country Patent Appln. No

[\*]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# SPECIFICATIONS FOR [ \* ] TABLETS

	SP	ECIFICATION	
TEST	[*]	[*]	[*]
CHARACTERS Colour Shape Score Code Coating	[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]
[ * ] [ * ]	[*]	[*]	[*]
[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ]
[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE D: GTX'S MSR OBLIGATION

## (TO BE COMPLETED PURSUANT TO SECTION 6.1.1)

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. REGISTRATION STATUS 27.9.2001 ORION PHARMA

Status: Approved, Pending Submission types: Marketing authorizations (2 PAGES)

Sent Date	Appl. Date	Product	Country	Decision Date	Decision	M.A. holder
N=39						
[ * ] [ * ] [ * ] [ * ] [ * ] 30.12.87 27.12.88	[ * ] 30.12.87	[ * ] [ * ] [ * ] [ * ] [ * ] [ * ] Fareston 20 mg tablet Fareston 60 mg tablet	[ * ] [ * ] [ * ] [ * ] [ * ] Finland Russia	21.12.88 12.12.89	[ * ] [ * ] [ * ] [ * ] [ * ] Approved Approved	[ * ] [ * ] [ * ] [ * ] [ * ] Orion-yhtyma Oy Farmos Orion Corporation
27.12.88 26.02.93 26.02.93 26.05.92 10.11.93 10.11.93 14.11.94	30.11.94	Fareston 20 mg tablet Fareston 60 mg tablet Fareston 20 mg tablet Fareston 60 mg tablet Fareston 60 mg tablet Fareston 20 mg tablet Fareston 60 mg tablet	Russia Latvia Latvia Norway Ukraine Ukraine Sweden	12.12.89 20.05.93 20.05.93 31.07.95 02.02.96 02.02.96 14.02.96	Approved Approved Approved Approved Approved Approved Approved	Orion Corporation Orion-yhtyma Oy Farmos Orion-yhtyma Oy Farmos Orion Corporation Orion Corporation Orion Corporation Orion Corporation
14.11.94 14.11.94 27.11.94 27.11.94	30.11.94 30.11.94 30.11.94 30.11.94	Fareston 60 mg tablet Fareston 60 mg tablet Fareston 60 mg tablet Fareston 60 mg tablet	Sweden Finland United Kingdom Spain	14.02.96 14.02.96 14.02.96 14.02.96	Approved Approved Approved Approved	Orion Corporation Orion Corporation Orion Corporation Orion Corporation
27.11.94 27.11.94 27.11.94 27.11.94	30.11.94 29.11.94 29.11.94 28.11.94	Fareston 60 mg tablet Fareston 60 mg tablet Fareston 60 mg tablet Fareston 60 mg tablet	Portugal Netherlands Luxembourg Italy	14.02.96 14.02.96 14.02.96 14.02.96	Approved Approved Approved Approved	Orion Corporation Orion Corporation Orion Corporation Orion Corporation
27.11.94 27.11.94 27.11.94 27.11.94 27.11.94	29.11.94 01.12.94 28.11.94 30.11.94	Fareston 60 mg tablet Fareston 60 mg tablet Fareston 60 mg tablet Fareston 60 mg tablet	Ireland Greece Germany France	14.02.96 14.02.96 14.02.96 14.02.96 14.02.96	Approved Approved Approved Approved	Orion Corporation Orion Corporation Orion Corporation Orion Corporation
27.11.94 27.11.94 17.11.92 27.11.94 31.03.96 31.03.96	30.11.94	Fareston 60 mg tablet Fareston 20 mg tablet	Belgium Austria Denmark Uzbekistan Uzbekistan	14.02.96 14.02.96 14.02.96 14.02.96 16.09.96 16.09.96	Approved Approved Approved Approved Approved	Orion Corporation Orion Corporation Orion Corporation Orion Corporation Orion Corporation
19.12.94	03.01.95	Fareston 60 mg tablet	United States of America	29.05.97	Approved	Orion Corporation

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Sent Date	Appl. Date	Product	Country	Decision Date	Decision	M.A. holder
10.04.95	15.07.96	Fareston 60 mg tablet	Hungary	14.01.98	Approved	Orion Corporation
01.08.97	01.0897	Fareston 60 mg tablet	Cyprus	23.04.98	Approved	Orion Corporation
10.07.96		Fareston 60 mg tablet	Taiwan, R.O.C.	29.09.98	Approved	Orion Corporation
31.03.95		Fareston 60 mg tablet	Dominican Republic	29.12.98	Approved	Orion Corporation
10.11.95	26.04.96	Fareston 60 mg tablet	China	13.02.99	Approved	Orion Corporation
30.07.01		Fareston 60 mg tablet	Georgia	30.07.01	Approved	Orion Corporation
30.07.01		Fareston 20 mg tablet	Georgia	30.07.01	Approved	Orion Corporation

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

### EXHIBIT C

#### PHARMACOVIGILANCE AGREEMENT

SCHEDULE PHARMACOVIGILANCE DATA EXCHANGE AGREEMENT	SUPERSEDES	VALID FROM Signature date		
PARTIES:				
ORION CORPORATION (HEREINAFTER ORION)				
- GTX, INC. (HEREINAFTER GTX)				
Draft Dec 10, 2004				

#### 1. PURPOSE

The purpose of this Agreement is to describe the procedures and define the responsibilities which the Parties, Orion and GTX, shall adopt to ensure compliance with the regulatory requirements for pharmacovigilance and to satisfy the business interests of Orion and GTX with regard to safety issues of the Product.

This Agreement is made pursuant to the Amended and Restated License and Supply Agreement dated January 1, 2005 between Orion and GTX, and the Purchase Agreement between Orion and GTX dated December 13, 2005 (together, the "Other Agreements"). All capitalized terms not defined herein shall have the meaning given in the Other Agreements. This Agreement is entered into pursuant to Section 19.1 of the Amended and Restated License and Supply Agreement, and is not intended to supercede or alter the Parties obligations under either of the Other Agreements. In the event of any conflict between this Agreement and the Other Agreements, the Other Agreements shall govern. Additionally, any information exchanged between the Parties shall be deemed Confidential Information of the disclosing Party under the Amended and Restated License and Supply Agreement. Any disputes arising hereunder shall be resolved as provided in Section 25 of the Amended and Restated License and Supply Agreement.

2. LANGUAGE OF ALL EXCHANGE, CONTACT PERSONS AND TERMINOLOGY

The language of all exchange shall be English.

The contact person(s) for each of the Parties are identified in Appendix 1. Each Party may change its contact persons and shall notify the other Party thereof in writing.

Throughout this document terms and definitions of terms as adopted by the International Conference on Harmonisation of the Technical Requirements of Pharmaceuticals for Human Use ("ICH") are used.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE SUPERSEDES VALID FROM PHARMACOVIGILANCE DATA - N/A Signature date EXCHANGE AGREEMENT

PARTIES:

- - ORION CORPORATION (HEREINAFTER ORION)

- - GTX, INC. (HEREINAFTER GTX)

- -----

Draft Dec 10, 2004

-----

3. GLOBAL SAFETY DATABASE

3.1 ORION FIELD [ \* ]

Orion shall be responsible for the maintenance and consistency of a complete safety database for spontaneous (including literature) adverse event ("AE") reports as well as clinical study serious adverse event ("SAE") reports concerning the Product in the Orion FIELD. GTX shall keep a secondary safety database for all reports from such events occurring in the USA, and any other reports it receives with respect to Product in the Orion Field. Duplicate reports within the Orion and GTX databases shall be identified and deleted from the databases by the Parties.

GTX shall be responsible for forwarding all reports received with respect to the USA to Orion within the timeframes defined in Section 4 in order to enable the entry of such reports into the Orion database.

Orion will within [  $\ast$  ] of the date of this Agreement transfer or assure the transfer to GTX of the current database containing the spontaneously reported AEs that have been received to date since the marketing of the Product in the USA.

Orion, at the reasonable request of GTX, shall perform queries of the complete safety database for spontaneous reports for use in regulatory filings in the USA in a timely manner to allow GTX to fulfill regulatory requirements related to maintenance of the NDA in the USA and related documents.

3.2 FIELD (EXCLUDING THE ORION FIELD)

GTX shall be responsible for the maintenance and consistency of a complete safety database for spontaneous (including literature) AE reports as well as clinical study SAE reports concerning the Product in the Field (outside of the Orion Field). Orion shall keep a secondary safety database if considered necessary by Orion for reports concerning the Product in the Field (outside of the Orion Field).

4. EXCHANGE OF INDIVIDUAL AE REPORTS

4.1 GENERAL

Exchange of individual AE and SAE reports shall be between the central pharmacovigilance units of Orion and GTX, Orion Pharma Drug Safety ("DS") and GTX Drug Safety Department, which shall collect and distribute the data in their own safety networks according to their own Standard Operating Procedures ("SOPs").

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

-----SCHEDULE SUPERSEDES VALID FROM PHARMACOVIGILANCE DATA - N/A Signature of Signature date EXCHANGE AGREEMENT PARTTES: ORION CORPORATION (HEREINAFTER ORION) - -GTX, INC. (HEREINAFTER GTX) - -\_\_\_\_\_ Draft Dec 10, 2004 4.2 SPONTANEOUS REPORTS FROM GTX TO ORION GTX shall provide information of spontaneous reports originating from the GTX Territory in writing, using the FDA form 3500A within the timeframes defined below. Serious spontaneous reports are to be sent to Orion no later than [ \* ] after receipt by GTX. Non-serious spontaneous reports are to be sent to Orion no later than [ \* ] after receipt by GTX. FROM ORION TO GTX Orion DS shall provide information of spontaneous reports with respect to the Orion Territory in writing, using the CIOMS I form within the timeframes defined below. Serious spontaneous reports are to be sent to GTX no later than [ \* ] after receipt by Orion. Non-serious spontaneous reports: to be discussed, usually in Periodic - -Safety Update reports only. 4.3 REPORTS FROM CLINICAL STUDIES From clinical studies sponsored by Orion or GTX, the investigator shall report all SAEs to the respective company according to each company's SOPs. FROM GTX TO ORTON GTX shall provide to Orion all clinical study SAEs originating from the  $\ensuremath{\mathsf{GTX}}$ Territory in writing, using FDA form 3500A within the timeframes defined below. Death and life-threatening SAEs within [  $^{\ast}$  ] after receipt by GTX. All other SAEs within [ \* ] after receipt by GTX - -Non-serious AEs are not in the scope of this Agreement. - -FROM ORION TO GTX - -Orion shall provide to GTX all clinical study SAEs originating from any territory outside of the Orion Territory coming to the knowledge of Orion in writing, using the CIOMS I form within the timeframes defined below: Death and life-threatening SAEs within [ \* ] after receipt by Orion. - -All other SAEs within [ \* ] after receipt by Orion. - -Non-serious AEs are not in the scope of this Agreement. - -[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED. C-3

SCHEDULE SUPERSEDES VALID FROM PHARMACOVIGILANCE DATA - N/A Signature date EXCHANGE AGREEMENT PARTIES:

- - ORION CORPORATION (HEREINAFTER ORION)

- - GTX, INC. (HEREINAFTER GTX)

Draft Dec 10, 2004

4.4 FOLLOW-UP INFORMATION

The Party first notified of an AE is responsible for obtaining follow-up information required for a proper assessment of the AE. This information shall be exchanged as described in Section 4.

## 5. ASSESSMENT OF INDIVIDUAL REPORTS

Each Party shall be responsible for its own medical assessment of the reported AEs when entering the report into its database according to their internal SOPs. The global safety database concerning the Orion Field shall reflect Orion's assessment, while the global safety database concerning the Field (but excluding the Orion Field) shall reflect GTX's assessment. In the event that there is a difference in seriousness or causality assessments of a case received from either Party and entered into a database, discussion between the Parties shall take place and agreement reached to allow timely reporting. Any resultant action must be communicated between the Parties.

## 5.1 SPONTANEOUS REPORTS

In general, the principle of the implied positive causality shall be applied to all spontaneously reported AEs received by Orion. Orion shall assess expectedness, labeling and listedness issues for each report according to Orion internal SOPs.

GTX will make a reasonable assessment of causality for each spontaneously reported AE received. In accordance with 21 CFR 310.305, GTX will submit all spontaneously reported AEs to FDA that are serious and unexpected (unlabeled) regardless of causality according to FDA regulations. In general, GTX will provide the GTX assessment of causality in the submission as further information for FDA.

5.2 REPORTS FROM CLINICAL STUDIES

The assessment of causality of the Product with respect to the SAE occurring in a clinical study shall be made by the responsible investigator and the sponsor of the clinical study according to the procedure in the study protocol and the sponsor's applicable guideline/SOP, respectively. For clinical study reports the causality scales of the Parties are attached in Appendix 2.

Assessment of labelling (expectedness) shall be made by the Parties according to their applicable guideline/SOP using a common Investigator's Brochure and/or Core Data Sheet and approved national labelling.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE SUPERSEDES VALID FROM PHARMACOVIGILANCE DATA - N/A Signature date EXCHANGE AGREEMENT - ORION CORPORATION (HEREINAFTER ORION)

- - GTX, INC. (HEREINAFTER GTX)

Draft Dec 10, 2004

6. LITERATURE REVIEW

Orion shall be responsible for reviewing, processing and exchanging individual reports from the world-wide literature concerning the Product in Orion Field. GTX shall assist by notifying Orion of reports observed in the GTX Territory.

GTX shall be responsible for reviewing, processing and exchanging individual reports from the world-wide literature concerning the Product in Field excluding Orion Field. Orion stall assist by notifying GTX of reports observed in the Orion Territory.

Individual reports identified in literature shall be exchanged as individual AE reports (Section 4).

7. PERIODIC SAFETY REPORTS

7.1 ORION FIELD [ \* ]

Orion shall be responsible for preparing global PSURs according to the ICH E2C Guideline as adopted by the European Union Committee for Proprietary Medicinal Products Pharmacovigilance Working Party relevant to Product for use in the Orion Field in the Orion Territory. The periodicity of PSURs is based on the European Birth Date of the Product. Orion may change the periodicity, if considered necessary.

GTX is responsible for providing Orion with the necessary information for the PSUR as defined in the above CPMP Guidelines and as needed by Orion for the preparation of PSURs. GTX shall provide this information as soon as possible and at least within [\*] of the data lock point (the last day of that PSUR period, or "DLP"). This information shall include at least the following:

- Update of regulatory authority or Marketing Authorisation Holder actions taken for safety reasons;
- Patient exposure in clinical studies conducted by GTX during the PSUR period;
- Short discussion of all GTX ongoing and completed studies (non-clinical, clinical and epidemiological), studies specifically planned or in progress and published studies;
- addressing safety issues or yielding safety information with potential impact on Product information.

Final PSUR shall be provided by Orion to GTX upon issuance.

GTX shall be responsible for preparation of any periodic reports relevant to Product for use in the Orion Field to maintain its NDA in the USA. The NDA annual report for NDA [ \* ] is due on [ \* ] of each year and the database lock for the annual report will be [ \* ] of each year. GTX will send a request for information on or shortly after [ \* ] that will include at least the following information:

- A summary of the spontaneous reports of serious adverse events during the reporting period;
- - Update of regulatory authority or Marketing Authorisation Holder actions taken for safety reasons during the reporting period;

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

-----SCHEDULE SUPERSEDES VALID FROM PHARMACOVIGILANCE DATA - N/A Signature d Signature date EXCHANGE AGREEMENT PARTTES: ORION CORPORATION (HEREINAFTER ORION) - -GTX, INC. (HEREINAFTER GTX) - -- -----Draft Dec 10, 2004 \_\_\_\_\_ Patient exposure in clinical studies conducted by Orion during the reporting period; A summary of the on-going, completed and published studies (nonclinical, clinical and epidemiological) during the reporting period; A summary of the planned studies (nonclinical, clinical and epidemiological) specifically planned to be conducted with estimated timelines, including start dates and expected completion dates (if known). 7.2 FIELD (EXCLUDING ORION FIELD) GTX shall be responsible for all regulatory safety updates concerning the Product for use outside the Orion Field. Final annual reports shall be provided by GTX to Orion upon issuance. 8. STANDARD REFERENCE DOCUMENTS 8.1 PRODUCT LABELING Orion Field [ \* ] Orion shall be responsible for maintaining the Company Core Safety Information (CCSI) for the Product in Orion Field [\*]. Orion will provide to GTX of any planned changes related to product safety to the CCSI prior to implementation with sufficient time for GTX to review and comment on the proposed changes. GTX shall be responsible for maintaining the labeling in the USA for the Product in Orion Field. GTX will provide to Orion any planned changes related to Product safety to the labeling in the USA prior to implementation with sufficient time for Orion to review and comment on the proposed changes. Field (excluding Orion Field) - - $\ensuremath{\mathsf{GTX}}$  shall be responsible for maintaining the labeling in the USA and CCSI for the Product in Field, excluding Orion Field.

9. SUBMISSION TO REGULATORY AUTHORITIES

9.1 FDA

GTX shall be responsible for maintaining the NDA and for submitting all applicable reports to FDA.

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

-----SCHEDULE SUPERSEDES VALID FROM PHARMACOVIGILANCE DATA - N/A Signature of Signature date EXCHANGE AGREEMENT \_\_\_\_\_ PARTTES: ORION CORPORATION (HEREINAFTER ORION) - -GTX, INC. (HEREINAFTER GTX) - -\_\_\_\_\_ Draft Dec 10, 2004 9.2 RA REQUESTS FOR ADDITIONAL SAFETY INFORMATION Responses to all pharmacovigilance-related requests from the RAs shall be the responsibility of the Party to which the questions are addressed.

Coordination of the response to an additional safety information request is the responsibility of the Party receiving the request. Depending on the nature of the request there may be a need to discuss and mutually agree between the Parties, if global safety database need to be queried.

10. SIGNAL IDENTIFICATION

Each Party shall notify the other in writing of any potential safety signals identified and discuss and agree any proposed actions, including safety changes in the relevant labeling reference documents.

Both Parties shall identify the representatives needed to evaluate and agree on the necessary actions.

## 11. AMENDMENTS TO THIS AGREEMENT

Any amendments to this Agreement, except those made to Appendix 1 and 2, require signatures of both Orion and GTX.

## 12. MEETINGS

The Parties shall meet to discuss pharmacovigilance issues and/or changes to this Agreement at the reasonable request of either of the Parties.

#### 13. MISCELLANEOUS

Neither Party may assign this Agreement or any of its rights hereunder, nor delegate any of its duties or obligations hereunder, to any third party without the prior written consent of the other Party, except (i) to an affiliate in accordance with the terms of this Agreement, in which case notification thereof shall be provided to the other Party prior to such assignment to an affiliate, or (ii) in connection with a merger, consolidation or similar reorganization. Neither Party may assign its rights hereunder where permitted except in connection with a permitted assignment of such Party's rights under the Amended and Restated License and Supply Agreement. For clarity, this Agreement shall survive any such merger, consolidation or reorganization of either Party with or into, another Party and no consent for such merger, consolidation or reorganization shall be needed. Neither Party shall unreasonably withhold its consent (which

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

-----SCHEDULE SUPERSEDES VALID FROM PHARMACOVIGILANCE DATA - N/A Signature of Signature date EXCHANGE AGREEMENT \_\_\_\_\_ PARTTES: ORION CORPORATION (HEREINAFTER ORION) - -GTX, INC. (HEREINAFTER GTX) - -\_\_\_\_\_ Draft Dec 10, 2004 shall be provided promptly after a request is made) to any contemplated assignment if such contemplated assignment is in connection with the sale by either Party of all or substantially all of its assets to a third party. Any assignment of this Agreement to an affiliate of the assigning Party shall not

relieve the assigning Party of its responsibilities and obligations hereunder. This Agreement, including the validity, construction, interpretation and performance thereof, shall be governed entirely by the laws of Sweden.

The relationship of the Parties under this Agreement is that of independent contractors. Nothing contained in this Agreement shall be construed so as to constitute the Parties as partners, joint venturers or agents of the other. Neither Party has any express or implied right or authority under this Agreement to assume or create any obligations or make any warranties and representations on behalf of or in the name of the other Party, or to bind the other Party to any contract, agreement or undertaking with any third party, and no conduct of the Parties pursuant to the terms of this Agreement shall be deemed to establish such right or authority. Neither Party shall make any representation to third parties that the relationship created hereby constitutes a partnership, joint venture or agency relationship.

In case one or more of the provisions contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, but this Agreement shall be construed by limiting such invalid, illegal or unenforceable provision, if such is not possible, by deleting such provision from this Agreement.

This Agreement, together with the Amended and Restated License and Supply Agreement dated January 1, 2005, represents the entire agreement between the Parties relating to the subject matter hereof and except as provided below supersedes all prior arrangements, understandings, correspondence, notes, minutes and as between the Parties (or their predecessors in interest) whether written or oral. Notwithstanding the foregoing, nothing herein is intended to supersede or affect the Parties' rights under the Purchase Agreement dated December 13, 2004, and the Amended and Restated License and Supply Agreement dated January 1, 2005.

The failure by either Party at any time to enforce any of the terms or provisions or conditions of this Agreement or exercise any right hereunder shall not constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same. No waiver of any of the provisions of this Agreement shall be deemed binding unless executed in writing by the Party to be bound by it.

This Agreement shall be executed by the Parties in two (2) original counterparts, one (1) original counterpart being retained by each Party and either of which shall be deemed

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

----------SCHEDULESUPERSEDESVALID FROMPHARMACOVIGILANCE DATA- N/ASignature d Signature date EXCHANGE AGREEMENT PARTIES: ORION CORPORATION (HEREINAFTER ORION) - -GTX, INC. (HEREINAFTER GTX) - -...... - -----Draft Dec 10, 2004 sufficient to prove the existence and terms and conditions hereof. This

Agreement may be executed by the Parties by the exchange of facsimile signature pages, with signed original counterparts of the Agreement to be exchanged by the Parties promptly thereafter.

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE PHARMACOVIGILANCE DATA EXCHANGE AGREEMENT	SUPERSEDES - N/A	VALID FROM Signature date			
PARTIES:					
ORION CORPORATION	(HEREINAFTER 0	RION)			
GTX, INC. (HEREIN	,				
Draft Dec 10, 2004					
THIS AGREEMENT HAS BEEN AGREED UPON AND ADOPTED BY ORION AND GTX AND WILL BECOME EFFECTIVE JANUARY 1, 2005.					
ORION CORPORATION		GTX Inc.			
Date:		Date:			
[*]					
L J Date:		Date:			
		Juce.			
[*]					
[ * ] = CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY					

[ ^ ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

- ----------SCHEDULE SUPERSEDES VALID FROM PHARMACOVIGILANCE DATA - N/A Signature of Signature date EXCHANGE AGREEMENT PARTIES: - -ORION CORPORATION (HEREINAFTER ORION) GTX, INC. (HEREINAFTER GTX) - -..... - -----Draft Dec 10, 2004 -----APPENDIX 1: LIST OF CONTACT PERSONS ORION: INDIVIDUAL REPORTS/TRANSMISSION RELATED ISSUES: [\*] GENERAL MEDICAL ISSUES: [\*] OVERALL RESPONSIBILITY FOR INTERNATIONAL PHARMACOVIGILANCE: [\*] GTX: [\*] [\*] [ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

```
C-11
```

APPENDIX 2: COMPANY CAUSALITY FOR CLINICAL STUDY REPORTS (IF NEEDED)

# [\*]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

#### EXHIBIT D

#### QUALITY ASSURANCE AGREEMENT

#### QUALITY ASSURANCE AGREEMENT

This agreement is entered into between ORION CORPORATION, a corporation organized and existing under the laws of Finland, established at Orionintie 1, P.O. Box 65, FIN-02101 Espoo, Finland (hereinafter referred to as "ORION") and GTX, INC., a corporation organized and existing under the laws of the State of Delaware, U.S.A. and having its principal office at 3 North Dunlap Avenue, Van Vleet Building, Memphis, Tennessee 38163, USA (hereinafter referred to as "GTX").

This agreement applies to the Product named in the Appendix 1 (hereinafter referred to as "the Product").

In order to establish the division of responsibilities relating to the quality assurance procedures determined in the "Good Manufacturing Practice for Medicinal Products in the European Community (Commission Directive 91/356/EEC, Medicinal Products for Human Use)", equivalent to US, GMP as defined in Part 11 of Chapter 21 of the Code of Federal Regulations, the parties agree as follows:

- 1. When performing its obligations under this agreement, ORION shall at all times comply with the requirements of the applicable regional GMPs for which the Product is intended.
- 2. The detailed responsibilities of the parties for the Product are listed in Appendix 1.

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

- Release activities shall follow the general format outlined in Appendix 2: "Release Procedures and Responsibilities for Fareston 60mg tablets".
- 4. In the event ORION shall desire to make any change in the manufacturing location, it shall do so in accordance with the applicable provisions of the applicable agreement executed between the parties.
- 5. ORION shall perform its manufacturing and quality control obligations in accordance with the requirements set forth in the registration approval(s) granted by the relevant regulatory authorities for the Product.
- 6. ORION shall send to GTx the certificate of analysis with each batch of the Products delivered. Furthermore, GTx may also request the full batch documentation concerning a particular batch. ORION agrees to deliver to GTx such documentation within [ \* ] from GTx's request.
- Upon prior notification to ORION, GTx is entitled to inspect the manufacturing and quality control facilities related to the Product.
- The person appointed responsible for the quality assurance of the Product within GTx is [ \* ] and within ORION [ \* ]. A listing of responsible personnel is in Appendix 3.
- 9. Neither party may assign this agreement or any of its rights hereunder, nor delegate any of its duties or obligations hereunder, to any third party without the prior written consent of the other party, except (i) to an affiliate in accordance with the terms of this agreement, in which case notification thereof shall be provided to the other party prior to such assignment to an affiliate, or (ii) in connection with a merger, consolidation or similar reorganization. For clarity, this agreement shall survive any such merger, consolidation or reorganization of either party with or into, another party and

no consent for such merger, consolidation or reorganization shall be needed. Neither party shall unreasonably withhold its consent (which shall be provided promptly after a request is made) to any contemplated assignment if such contemplated assignment is in connection with the sale by either party of all or substantially all of its assets to a third party. Any assignment of this agreement to an affiliate of the assigning party shall not relieve the assigning party of its responsibilities and obligations hereunder.

- 10. This agreement, including the validity, construction, interpretation and performance thereof, shall be governed entirely by the laws of Sweden. It is the specific intent and agreement of the parties that the United Nations Convention on the International Sale of Goods shall not apply to this agreement.
- 11. The relationship of the parties under this agreement is that of independent contractors. Nothing contained in this agreement shall be construed so as to constitute the parties as partners, joint venturers or agents of the other. Neither party has any express or implied right or authority under this agreement to assume or create any obligations or make any warranties and representations on behalf of or in the name of the other party, or to bind the other party to any contract, agreement or undertaking with any third party, and no conduct of the parties pursuant to the terms of this agreement shall be deemed to establish such right or authority. Neither party shall make any representation to third parties that the relationship created hereby constitutes a partnership, joint venture or agency relationship.
- 12. In case one or more of the provisions contained in this agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this agreement, but this agreement shall be construed by limiting such

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

invalid, illegal or unenforceable provision, if such is not possible, by deleting such provision from this agreement.

- 13. This agreement represents the entire agreement between the parties relating to the subject matter hereof and supersedes all prior arrangements, understandings, correspondence, notes, minutes and agreements between the parties (or their predecessors in interest) whether written or oral. No supplement, modification or amendment of this agreement shall be binding unless executed by the parties in writing and signed by the duly authorized representatives of both parties. Nothing herein is intended to supersede or affect the parties' rights under the Purchase Agreement dated December 13, 2004, and the Amended and Restated License and Supply Agreement dated January 1, 2005.
- 14. The failure by either party at any time to enforce any of the terms or provisions or conditions of this agreement or exercise any right hereunder shall not constitute a waiver of the same or affect that party's rights thereafter to enforce or exercise the same. No waiver of any of the provisions of this agreement shall be deemed binding unless executed in writing by the party to be bound by it.
- 15. The English language version of this agreement shall be controlling in all respects regardless of whether any translations into any other languages are made.
- 16. This agreement shall be executed by the parties in two (2) original counterparts, one (1) original counterpart being retained by each party and either of which shall be deemed sufficient to prove the existence and terms and conditions hereof. This agreement may be executed by the parties by the exchange of facsimile signature pages, with signed original counterparts of the agreement to be exchanged by the parties promptly thereafter.

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Date:		Date:
ORION (	CORPORATION	GTx
ENCLS	Appendix 1	Product/Division of Responsibilities
	Appendix 2	Product Release
	Appendix 3	Responsible Personnel

PRODUCT:

Name:	Fareston(TM) Tablets, 60 MG
Active Ingredient:	Toremifene Citrate
Strength:	60 mg
Dosage form:	Tablets
Packaging size:	Bulk containers

The following responsibilities will be assumed by the agreeing parties.

#### DIVISION OF RESPONSIBILITIES:

ITEM	ORION	GTX	THIRD PARTY VENDOR
	TY * ] [ * ] * ] * ] * ] * ] * ] * ] * ] * ] * ]		[ * ] [ * ] [ * ] [ * ] [ * ] [ * ]
	NUFACTURER       OF       FINISHED       PROE         *       [       *       ]       [       *       ]         *       ]       [       *       ]       [       *       ]         *       ]       [       *       ]       [       *       ]         *       ]       [       *       ]       [       *       ]         *       ]       [       [       *       ]       [       *       ]         *       ]       [       [       *       ]       [       *       ]         *       ]       [       [       *       ]       [       *       ]         *       ]       [       [       *       ]       [       *       ]         *       ]       [       [       ]       [       *       ]       [       *       ]         *       ]       [       [       ]       [       *       ]       [       *       ]         *       ]       [       [       ]       [       *       ]       [       *       ]       ]       ]	UCT)	[ * ] [ * ]

GMP COMPLIANCE

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

ITEM	ORION	GTX	THIRD PARTY VENDOR	
[ * ] [ * ] [ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ] [ * ]		[ * ] [ * ] [ * ] [ * ] [ * ] [ * ]	
Date:	Date:			
ORION CORPORATION				

APPENDIX 2

This procedure applies to Fareston 60 mg tablet.

- 1. Orion will supply product to GTx that has been manufactured, packaged and tested under cGMP.
- The product will be manufactured, packaged and tested in accordance with NDA [ \* ] and all approved supplements, and any compendial monographs which may exist in the future.

GTx will not distribute any Fareston without first receiving a "Final Release Certificate" from Orion stating the following:

- The batch number of the bulk drug tablets being released.
- The expiration date of the batch being released.
- A statement confirming the batch meets all Regulatory requirements as defined in NDA [\*], subsequent amendments, and any compendial monographs, which may exist in the future, and is released by Orion for distribution in the United States.
- 3. GTx or its agent (hereinafter referred to as "GTx") will receive this product into a cGMP warehouse either owned by GTx or an appropriately qualified contract facility (hereinafter referred as the "GTx Distribution Center") operating in compliance with GMP, as defined by the US Food and Drug Administration. Such GTx Distribution Center will include, without limitation, temperature controls including recording devices and appropriate record keeping.
- 4. GTx will select a transportation agent and provide the information to Orion for use.
- The GTx Distribution Center will be in compliance with cGMP. This will include but not be limited to a [\*].
- 6. GTx will perform an incoming inspection of the released batch to verify quantity of bulk drug product received and a visual inspection confirming the presence of the appropriate batch number and expiration date. Should a batch fail the above inspection, GTx will place the batch on hold pending the conclusion of an appropriate investigation. GTx will notify both the Head of Quality Assurance of Orion and the Head of Quality Assurance or designee of the authorized packaging site of this deficiency.
- 7. GTx will maintain an appropriate Customer Complaints program in compliance with 21 Code of Federal Regulations. Customer complaints regarding Fareston will be forwarded to the appropriate Quality Assurance Manager at Orion for

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

investigations. Orion will also provide an investigation report to the Director of GTx's Corporate Quality Unit within [  $^{*}$  ].

8. Should a US Recall of Fareston become necessary, GTx Quality Assurance will notify the Director of Orion's Corporate Quality Unit immediately. GTx will coordinate the Recall in accordance to its procedures and applicable Regulations. GTx will update Orion, as appropriate.

Date: Date: Orion Corporation GTx, Inc. [\*] [\*] [\*]

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

APPENDIX 3 RESPONSIBLE PERSONNEL

# COMPANY NAME: ORION PHARMA

Responsible Contacts: [ \* ]

[\*]

COMPANY NAME: GTX, INC.

Responsible Contacts: [ \* ]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

## EXHIBIT E

# SALES AND MARKETING PLAN

# [\*]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# EXHIBIT F

# [ \* ] SPECIFICATIONS

# SPECIFICATIONS FOR [ \* ] TABLETS

	SP	ECIFICATION	
TEST	[*]	[*]	[*]
CHARACTERS Colour Shape Score Code Coating	[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]
[ * ] [ * ]	[*]	[*]	[*]
[ * ] [ * ]	[ * ] [ * ]	[ * ] [ * ]	[ * ] [ * ]

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

F-1

## EXHIBIT G

#### LETTER OF TRANSFER OF OWNERSHIP OF NDA

January 1, 2005

Richard Pazdur, M.D., Director Division of Oncology Drug Products, HFD-150 Center for Drug Evaluation and Research Food and Drug Administration Woodmont Office Complex 2, Room 2055 1451 Rockville Pike Rockville, MD 20852

Dear Dr. Pazdur:

RE: FARESTON(R) (TOREMIFENE CITRATE) TABLETS NDA [ \* ] TRANSFER OF NDA

Reference is made to New Drug Application [ \* ], approved on 29 May 1997. This letter is to acknowledge that effective January 1, 2005, GTx, Inc., rather than Orion Corporation, will act as the sponsor of NDA [ \* ] for FARESTON(R) (toremifene citrate) Tablets and fulfill the obligations set forth in 21 CFR 314.

The primary point of contact is now:

[\*]

Please amend your records accordingly.

Sincerely,

ORION PHARMA SIGNATURE

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

G-1

## EXHIBIT H

#### GTX FDA LETTER

January 1, 2005

Richard Pazdur, M.D., Director Division of Oncology Drug Products, HFD-150 Center for Drug Evaluation and Research Food and Drug Administration Woodmont Office Complex 2, Room 2055 1451 Rockville Pike Rockville, MD 20852

Dear Dr. Pazdur:

RE: FARESTON(R) (TOREMIFENE CITRATE) TABLETS
NDA [ \* ]
TRANSFER OF OWNERSHIP OF NDA

Reference is made to New Drug Application [ \* ], approved on 29 May 1997. This correspondence and attached signed Form FDA 356h serve as notification of the change in ownership of this NDA. The new sponsor of the application is GTx, Inc. The sponsor contact information is:

[\*]

This change in ownership becomes effective upon the Agency's receipt of the letter of transfer from Orion Corporation dated January 1, 2005. Pursuant to the provisions in 21 CFR 314.72, all rights and responsibilities associated with the subject New Drug Application have been transferred to GTx, Inc. In addition, all documentation relevant to NDA [ \* ] for FARESTON(R) (toremifene citrate) Tablets has been transferred to GTx, Inc.

Should you have any questions regarding this submission, please contact me at [  $^{\ast}$  ].

Sincerely,

[\*]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

H-1

PART 1.1(D):

As of the Date of Agreement, no Assumed Contracts or Restricted Contracts are known to either Party; however, if the Parties identify any contracts to be transferred to GTx pursuant to this Agreement, they will update this Disclosure Schedule to include such contract(s).

```
PART 2.6:
```

NONE

- PART 2.7:
- [\*]
- PART 3.3:

## NONE

 $[\ *\ ]$  = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# PAGE

1.	PURCHAS	E AND SALE OF ASSETS; RELATED AGREEMENTS	1
	1.1	Assets to be Transferred	1
	1.2	Intellectual Property License to Purchased Assets	2
	1.3	Liabilities to be Assumed	2
	1.4	Liabilities Not to be Assumed	3
	1.5	Deposit; Purchase Price	3
	1.6	Other Agreements	3
	1.7	Allocation of Purchase Price	3
	1.8	Further Action	3
	1.9	Closing	4
2.	REPRESE	NTATIONS AND WARRANTIES OF ORION	4
	2.1	Due Organization	4
	2.2	Right to Assign Purchased Assets; Title to Purchased Assets	4
	2.3	Contracts	4
	2.4	Proceedings; Orders	5
	2.5	Authority; Binding Nature of Agreements	5
	2.6	Consents	5
	2.7	No Debarment; Compliance with Laws	5
	2.8	Filings	6
3.	REPRESE	NTATIONS AND WARRANTIES OF GTX	6
	3.1	Due Organization	6
	3.2	Authority; Binding Nature of Agreement	6
	3.3	Consents	7
	3.4	Proceedings; Orders	7
	3.5	No Debarment	7
4.	PRE-CLOSING COVENANTS OF ORION		
	4.1	Fareston Repurchase Agreement	7
	4.2	Operation Of Business	7
	4.3	Filings and Consents	7
	4.4	Best Efforts	8

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

-i-

			PAGE
	4.5	Confidentiality	8
5.	PRE-CL	OSING COVENANTS OF GTX	8
	5.1	Filings and Consents	8
	5.2	Best Efforts	8
	5.3	Confidentiality	8
6.	CONDIT	IONS PRECEDENT TO GTX'S OBLIGATION TO CLOSE	8
	6.1	Accuracy Of Representations	8
	6.2	Performance Of Obligations	9
	6.3	Additional Documents	9
	6.4	No Proceedings	9
7.	CONDIT	IONS PRECEDENT TO ORION'S OBLIGATION TO CLOSE	9
	7.1	Accuracy Of Representations	9
	7.2	GTx's Performance	10
	7.3	No Proceedings	10
	7.4	[*]	10
8.	INDEMN	IFICATION, ETC	10
	8.1	Survival of Representations	10
	8.2	Indemnification by Orion	11
	8.3	Limitations	11
	8.4	Indemnification by GTx	12
	8.5	Limitations	12
	8.6	Indemnification Procedures; Defense of Third Party Claims	13
	8.7	Other Claims	13
9.	P0ST-C	LOSING COVENANTS	14
	9.1	Transfer of NDA; Access	14
	9.2	Marketing Plan	14
	9.3	Letters Regarding NDA	15
10.	CONFID	ENTIALITY	15
	10.1	Confidential Information	15
11.	MISCEL	LANEOUS PROVISIONS	15

-ii-

		PAGE
11.1	Further Assurances	15
11.2	Fees and Expenses	15
11.3	Notices	15
11.4	Publicity	16
11.5	Headings	17
11.6	Counterparts	17
11.7	Governing Law; Dispute Resolution	17
11.8	Effect of Commencing Dispute Resolution	18
11.9	Successors and Assigns; Assignment	18
11.10	Waiver	18
11.11	Amendments	19
11.12	Severability	19
11.13	Parties in Interest	19
11.14	Independent Contractors	19
11.15	Entire Agreement	19
11.16	Disclosure Schedule	19
FIELD. "FIELD		2

-iii-

EXHIBIT 10.2

#### AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT

THIS AMENDED AND RESTATED LICENSE AND SUPPLY AGREEMENT (this "Agreement") is entered into and made effective as of this 1st day of January, 2005 (the "Restatement Date") by and between ORION CORPORATION, a corporation organized and existing under the laws of Finland and having its principal office at Orionintie 1 FIN-02200 Espoo, Finland ("Orion"), and GTX, INC., (fka Genotherapeutics, Inc.) a corporation organized and existing under the laws of the State of Delaware, U.S.A. and having its principal office at 3 North Dunlap Avenue, Van Vleet Building, Third Floor, Memphis, Tennessee 38163, USA ("GTX").

WHEREAS, Orion and GTX entered into a Toremifene License and Supply Agreement effective as of March 30, 2000 (the "Effective Date"), to govern the Parties' rights and obligations with respect to the research, development, commercialization and manufacture of Product (as defined in said agreement) (the "Original Agreement");

WHEREAS, Orion and GTX amended and restated the Original Agreement on October 22, 2001 (the "Amendment Date"), and then amended the Original Agreement on March 5, 2003 (the "First Amendment"), and on December 29, 2003 (the "Second Amendment");

WHEREAS, Shire and Orion have entered into an agreement wherein Orion will acquire all of Shire's rights and interests to Toremifene for the breast cancer indication in the United States;

WHEREAS, GTX desires to expand its license to include all of Orion's other rights and interests in Toremifene for human use, except for the use of Toremifene for the prevention and treatment of breast cancer in countries outside of the United States and use of Toremifene in the animal health field worldwide, and Orion desires to grant to GTX such licenses;

WHEREAS, the Parties desire with this Agreement to supercede and replace the Original Agreement, First Amendment and Second Amendment effective as of the Restatement Date to provide that GTX shall have the sole responsibility for researching, developing, registering and commercializing the Product (as defined below) within the Field (as defined below) worldwide, except for the use of Toremifene either for the prevention and treatment of breast cancer in countries outside of the United States or for animal health; and

WHEREAS, Orion shall have no monetary or other responsibilities for researching, developing, registering or commercializing Product, but shall remain responsible for manufacturing Orion Product (as defined below), as agreed herein;

NOW THEREFORE for and in consideration of the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, Orion and GTX (hereinafter individually a "Party"; and collectively the "Parties") hereto agree as follows:

#### 1. DEFINITIONS

For purposes of this Agreement, the following terms shall be defined as set forth below. Additional terms used in specific Sections of this Agreement shall be defined in such Sections.

1.1 "ADDITIONAL PRODUCT" shall have the meaning set forth in Section 2.1.5.

1.2 "AFFILIATE" shall mean any business entity controlled by a Party, or which controls a Party, or which is under common control with a Party. "Control" herein means the direct or indirect ownership of more than fifty percent (50%) of the authorized issued voting shares in such entity, or such other relationship as in fact legally results in effective control over the management, business and affairs of such entity or Party, as the case may be.

1.3 "ANNUAL NET SALES" shall mean Net Sales (as defined below) in any calendar year.

1.4 "BREAST CANCER FIELD" shall mean the prevention and treatment of breast cancer.

1.5 "CALENDAR QUARTER" shall mean each of the three (3) month periods beginning on January 1, April 1, July 1 and October 1 of each year during the Term (as defined below).

1.6 "COMPETING PRODUCT" shall mean any pharmaceutical product containing a SERM as a therapeutically active ingredient as well as any salt thereof, which product is licensed, sold and/or marketed for use in the Field, including, but not limited to, other dosage forms licensed, sold and/or marketed for use in the Field. Competing Product does not include Orion Product, but includes any generic form of the Product.

1.7 "CORRECTION FACTOR" shall have the meaning set forth in Section 3.1.3(b).

1.8 "DMF" shall have the meaning provided in Section 7.5.

1.9 "EUROPEAN UNION" shall include Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, United Kingdom, Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, Slovenia, and any such other country or territory that may become part of the European Union after the Restatement Date.

1.10 "FARESTON PRODUCT" shall mean the Orion Product in 60 mg tablet form containing Toremifene that was promoted in the USA under the brand name "Fareston" by Shire prior to the Restatement Date for use in the Breast Cancer Field.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.11 "FARESTON REPURCHASE AGREEMENT" shall mean the Repurchase Agreement entered by and between Shire and Orion dated December 13, 2004.

1.12 "FARESTON U.S. WEB PAGES" shall have the meaning set forth in Article 9.

1.13 "FIELD" shall mean all uses of a Product in humans. The Parties expressly acknowledge that the use of Product in the field of animal health is excluded from the scope of this Agreement.

1.14 "FIRST COMMERCIAL SALE" means in each country, the date the Product is first sold, marketed, or publicly made available for sale for use in a given portion of the Field by GTX, its Affiliate or a GTX Unaffiliated Sublicensee. Product for use in a given portion of the Field, distributed or used for clinical trial purposes shall not be considered sold, marketed or made publicly available for sale and shall not constitute First Commercial Sale.

1.15 "GENERIC PRODUCT" shall mean a generic pharmaceutical product for human use containing Toremifene as an active ingredient sold by an entity other than GTX, its Affiliate or its Unaffiliated Sublicensee and which can be substituted by the prescriber or dispenser for a Product for use in the Field (excluding Products sold by or on behalf of Orion, in the Orion Territory in the Orion Field or outside the Field).

1.16 "GTX FINAL DEVELOPMENT AND REGISTRATION PLAN" shall mean the final product development and registration plan for each Product in the Prostate Cancer Field prepared by GTX, its Affiliate or a GTX Unaffiliated Sublicensee, as the same may be modified from time to time pursuant to Section 7.4.

1.17 "GTX KNOW-HOW" shall mean such non-patented and unpublished non-clinical, pre-clinical and clinical documentation, information, and data including information and data in U.S. IND [ \* ], U.S. IND [ \* ], and all resulting marketing applications worldwide relating to the use of Toremifene or any SERM in the Field, that is owned or controlled by, and disclosable by and available to, GTX and its Affiliates as of the Effective Date or at any time during the Term, including but not limited to all registration materials for the Effective Date or at any time during the Term, and all non-patented and unpublished documentation, information and data relating to the formulation, manufacture and/or quality control of the Product that is owned or controlled by GTX and/or its Affiliates as of the Effective Date or at any time during the Term, and all non-patented and unpublished documentation, information and data relating to the formulation, manufacture and/or quality control of the Product that is owned or controlled by GTX and/or its Affiliates as of the Effective Date or at any time during the Term.

1.18 "GTX PATENTS" shall mean the patents issued from GTX Patent Applications as of the Effective Date and other patents owned or controlled by GTX and its Affiliates that are issued at any time during the Term, and that claim technology used for the manufacture, sale or use of any SERM for use in the Prostate Cancer Field (including any divisions, continuations, continuations-in-part, re-examinations, reissues, additions, renewals and extensions thereof). GTX Patents in existence as of the Restatement Date are set forth in Part I of Schedule A. For purposes of this Agreement, the Parties acknowledge that GTX Patents shall include United States Patents as set forth on Schedule A, which claims the use of Product in the Prostate Cancer Field, which patents are in the name of and owned by The University of Tennessee Research Foundation. GTX represents and warrants that it has acquired sufficient

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

rights and licenses from The University of Tennessee Research Foundation to said patents for the purpose of performing its obligations under this Agreement.

1.19 "GTX PATENT APPLICATIONS" shall mean patent applications of the University of Tennessee Research Foundation or GTX, as applicable, and/or Affiliates of GTX pending as of the Effective Date, and patent applications owned or controlled by the University of Tennessee Research Foundation and/or GTX, as applicable, and/or Affiliates of GTX, that are filed at any time during the Term, in each case that claim technology used for the manufacture, sale or use of any SERM for use in the Prostate Cancer Field (including any divisions, continuations, continuations-in-part, re-examinations, reissues, additions, renewals and extensions thereof). GTX Patent Applications in existence as of the Restatement Date are set forth in Part II of Schedule A.

1.20 "GTX PATENT RIGHTS" shall mean GTX Patents and GTX Patent Applications.

1.21 "GTX PRELIMINARY DEVELOPMENT AND REGISTRATION PLAN" shall mean the preliminary product development plan for the development of the Product in the Prostate Cancer Field prepared by GTX which has been provided to Orion prior to Effective Date, and which was attached to the Original Agreement.

1.22 "GTX TERRITORY" shall mean all countries or territories worldwide.

1.23 "GTX UNAFFILIATED SUBLICENSEE" shall mean any sublicensee of GTX other than a GTX Affiliate. For avoidance of doubt, Orion shall not be a GTX Unaffiliated Sublicensee.

1.24 "MAJOR COUNTRY" shall mean the United States of America including its fifty states, the District of Columbia, Puerto Rico, and all other USA territories and possessions ("USA"), Canada, Japan, Great Britain, France, Germany, Spain and Italy.

 $1.25\ "MANUFACTURING\ COSTS"$  shall have the meaning set forth in Section 7.3.

 $\ensuremath{\texttt{1.26}}$  "MANUFACTURING PATENTS" shall have the meaning provided in Section 7.7.

1.27 "MAT NET SALES OF FARESTON PRODUCT" shall mean the certain moving annual total sales of the Fareston Product as defined in Section 3.1.3(b).

1.28 "NET SALES" shall mean the invoiced gross sales of the Product to a Third Party which is not a GTX Unaffiliated Sublicensee, less: (A) credits and allowances or adjustments (consistent with generally accepted accounting principles), granted to such customers on account of rejections, recalls or returns of the Product previously sold; (B) any customary and reasonable trade and cash discounts, rebates, including government rebates, granted in connection with sale of Product to such customers; (C) sales, tariff duties and/or use taxes directly imposed and with reference to particular sales; and (D) outbound transportation prepaid or allowed, amounts allowed or credited on returns, export licenses, import duties, value added tax, and prepaid freight.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

 $\ensuremath{\texttt{1.29}}$  "ORION FIELD" shall mean the use of Toremifene in the Breast Cancer Field.

1.30 "ORION KNOW-HOW" shall mean such non-patented and unpublished non-clinical, pre-clinical and clinical documentation, information, and data relating to the Orion Product that is owned or controlled by, and disclosable by and available to, Orion and its Affiliates as of the Effective Date or at any time during the Term which is necessary for the development by GTX of Product for use in the Field (including without limitation filing an application for Regulatory Approval for the Product for use in the Field), including information and data in the Orion Product NDA relating to Fareston Product, registration materials for the Orion Product, documentation, information and data relating to the formulation and/or quality control of the Orion Product. Except as otherwise provided in Sections 7.7, 14.9, 16.1, 17.3.2, 17.4 and 21.2, Orion Know-How shall exclude information relating to Orion's manufacture of Toremifene (as defined below) and Orion Product (as defined below).

1.31 "ORION PATENTS" shall mean the patents owned or controlled by Orion that are directed to the compound Toremifene per se, and relate to the use or sale of Toremifene and all other patents issued from Orion Patent Applications during the Term (including any divisions, continuations, continuations-in-part, re-examinations, reissues, additions, renewals and extensions thereof). Orion Patents in existence as of the Restatement Date are set forth in Part I of Schedule B. Schedule B shall be amended by Orion from time to time during the Term to include future Orion Patents.

1.32 "ORION PATENT APPLICATIONS" shall mean patent applications owned or controlled by Orion and its Affiliates that are pending as of the Effective Date, and patent applications owned or controlled by Orion and its Affiliates that are filed at any time during the Term, in each case that are directed to the compound Toremifene per se and relate to the use or sale of Toremifene (including any divisions, continuations, continuations-in-part, re-examinations, reissues, additions, renewals and extensions thereof). Orion Patent Applications in existence as of the Restatement Date are set forth in Part II of Schedule B. Schedule B shall be amended by Orion from time to time during the Term to include future Orion Patent Applications.

 $1.33\ "ORION PATENT RIGHTS" shall mean Orion Patents and Orion Patent Applications.$ 

1.34 "ORION PRODUCT" shall mean tablets containing [ \* ] of Toremifene respectively, that are manufactured by Orion and are commercially available as of the Restatement Date, and such other dosage strength or formulation of Toremifene as a therapeutically active ingredient as Orion may agree to manufacture pursuant to Section 17.4.

1.35 "ORION PRODUCT NDA" shall mean U.S. NDA [ \* ].

1.36 "ORION TERRITORY" shall mean all countries and territories worldwide, except for the USA.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.37 "ORION UNAFFILIATED SUBLICENSEE" shall mean any licensee or sublicensee under the Orion Patent Rights, other than an Orion Affiliate, GTX, a GTX Affiliate or a GTX Unaffiliated Sublicensee.

1.38 "OTHER PRODUCT" shall have the meaning set forth in Section 17.4.

1.39 "PREMIUM" shall mean, with respect to an equity investment by a Third Party in GTX, an amount equal to the difference between the total consideration paid for the purchase of shares of GTX stock and the fair market value of such stock, as defined herein. Such fair market value shall be equal to the trading price of a share of GTX common stock on the date such Third Party investment is made (or, if such date is not a trading day, the price of a share of GTX common stock on the most recent trading day prior to the date of such investment, and if such Third Party investment occurs concurrent with the initial public offering, then the price per share at which stock is offered to the public), multiplied by the number of shares issued to such Third Party investor.

1.40 "PRODUCT" shall mean any pharmaceutical product for human use within the Field containing Toremifene as a therapeutically active ingredient.

1.41 "PRODUCT ROYALTY ADJUSTMENT DATE" shall have the meaning set forth in Section 3.1.3(a).

1.42 "PROSTATE CANCER FIELD" shall mean the prevention and treatment of prostate cancer, which shall mean for the purposes of hereof: preventing prostate carcinogenesis; suppressing or inhibiting prostate cancer; reducing the risk of developing prostate cancer; increasing the survival rate of a subject with prostate cancer; and treating prostate cancer. Furthermore, the Prostate Cancer Field shall include the prevention and/or treatment of osteoporosis, gynecomastia, hot flashes, and other side effects induced by chemical or surgical androgen deprivation therapy in the treatment of prostate cancer.

1.43 "PURCHASE AGREEMENT" shall mean the agreement between Orion and GTX dated December 13, 2004.

1.44 "REGULATORY APPROVAL" shall mean all governmental approvals required to import, market, promote and sell the Product for use in the Field in any given country or territory in the GTX Territory, including but not limited to, product registrations, medical approvals and price and marketing approvals.

 $1.45\ "ROYALTY\ INCOME"$  shall have the meaning set forth in Section 3.1.5.

1.46 "SALES OF GENERIC PRODUCT" shall mean the documented sale and use of a Generic Product.

1.47 "[ \* ]" shall have the meaning set forth in Section 3.1.6.

1.48 "SERM" shall mean Toremifene (as described in the Orion Patent Rights), including its isomers, metabolites, derivatives or analogs having either antiestrogenic or estrogenic pharmacological properties.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.49 "SHIRE" shall mean Shire US, Inc., a corporation duly organized and existing under the laws of New Jersey, USA, and having its principal offices in Wayne, Pennsylvania, which had rights to Product in the USA in the Breast Cancer Field prior to the Restatement Date.

1.50 "SPECIFICATIONS" shall mean the current specifications (as of the Restatement Date) for the Orion Product, as such specifications are, with regard to [\*] containing Toremifene, set forth in the Orion Product NDA, and with regard to [\*] and [\*] tablet of Orion Product set forth in Schedule C (Copies of such current specifications are set forth in Schedule C attached hereto and made a part hereof.) The Specifications shall also include any other modified or additional specifications applicable to Orion Product which may be manufactured by Orion, pursuant to Section 17.3 or 17.4. Schedule C may be amended from time to time as necessary to reflect modifications to the Specifications for any Other Product that Orion may agree to manufacture pursuant to Section 17.4.

1.51 "TERM" shall mean the period commencing on the effective date of the Original Agreement and continuing, on a country by country basis until the later of (a) the date of expiration or invalidation of the last to expire or be invalidated of the GTX Patent Rights, or (b) the expiration or termination of the last to expire of the marketing or regulatory exclusivity granted by the FDA, the European Medicines Agency or other equivalent regulatory authority for Product, each of (a) and (b) herein as subject to earlier termination under Article 21.

1.52 "THIRD PARTY" or "THIRD PARTIES" shall mean any party or parties other than GTX, Orion, an Affiliate of GTX, or an Affiliate of Orion.

1.53 "TOREMIFENE" shall mean [ \* ].

1.54 "TRADEMARKS" shall mean the trademarks GTX selects and registers for the Product in the GTX Territory in accordance with Article 10 of this Agreement, and the trademark Fareston(R) in the USA used by Shire prior to the Restatement Date for the Fareston Product.

 $1.55\ "USA"$  shall mean the United States of America including its fifty states, the District of Columbia, Puerto Rico, and all its territories and possessions.

1.56 "U.S. FDA" shall mean the United States Food and Drug Administration and any successor regulatory agency.

 $1.57\ \mbox{"U.S.}$  IND" shall mean an Investigational New Drug Application filed with the U.S. FDA.

 $\rm 1.58$  "U.S. NDA" shall mean a New Drug Application filed with the U.S. FDA.

1.59 "UPFRONT AND MILESTONE INCOME" shall have the meaning provided in Section 3.1.1(c).

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

1.60 "VALID CLAIM" shall mean a claim of an issued patent which has not expired and which has not been held revoked, invalid or unenforceable by decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed with the time allowed for appeal having expired, and which has not been admitted to be invalid through reissue or disclaimer or otherwise.

#### 2. GRANT AND SCOPE OF RIGHTS GRANTED

2.1 ORION GRANTS TO GTX.

2.1.1 LICENSE GRANTS. Orion hereby grants to GTX for the Term:

(I) an exclusive right and license, with the right to grant sublicenses as provided in Section 2.1.4, under Orion Patent Rights and Orion Know-How, to develop, use, have used, sell, have sold, import, market and distribute the Product in the Field in the GTX Territory, except in the Orion Field in the Orion Territory; and

(II) a non-exclusive right and license, with the right to grant sublicenses as provided in Section 2.1.4, under the Orion Patents and Orion Know-How, to perform research and preclinical development activities in accordance with Section 2.5 using the Powder (as defined in Section 14.6.2) to be provided to GTX pursuant to Section 14.6.2, except in the Orion Field in the Orion Territory.

For the avoidance of doubt, nothing herein shall limit or restrict or be construed to limit or restrict Orion from using, and GTX acknowledges that Orion may use, Toremifene and Product (i) as a reference compound and reference product in its research and development activities for the Field and for uses outside the Field, and (ii) in conducting business activities in the Orion Field in and for the Orion Territory, as well as in the field of animal health.

Licenses under Section 2.1.1(i) may be expanded to include the right to make and have made Products as provided in Sections 7.7, 14.9, 16.1, 17.3.2, 17.4 and 21.2.2 on such terms as are set forth in such Sections.

2.1.2 MANUFACTURING RIGHTS RESERVED. Except as otherwise provided in Sections 7.7, 14.9, 16.1, 17.3.2, 17.4 and 21.2.2, Orion retains the exclusive right to manufacture or have manufactured Toremifene, Orion Product and Product including, without limitation, any Toremifene and Orion Product to be supplied to GTX under this Agreement and subject to Sections 7.7, 14.9, 16.1, 17.3.2, 17.4 and 21.2.2 herein, during the Term GTX undertakes to purchase all its requirement of Product exclusively from Orion.

2.1.3 USE OF ORION KNOW-HOW. Under the license granted pursuant to Section 2.1.1(i), GTX shall, subject to the terms and conditions of this Agreement, including without limitation Article 8, have the right to use and reference Orion Know-How in support of GTX's clinical trials and applications for Regulatory Approval within the Field for the Product in the GTX Territory. Subject to the license rights granted hereunder, Orion retains full ownership rights to all Orion Know-How.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

2.1.4 SUBLICENSING. GTX shall have the right to sublicense its rights received under this Agreement in the GTX Territory to any Third Party except that GTX shall not have the right to grant sublicenses to any Third Party to market, sell or offer for sale the Fareston Product for use in the Breast Cancer Field in the USA. For any permitted sublicense granted by GTX, GTX shall notify Orion within fifteen (15) days after execution of an agreement between GTX and a GTX Unaffiliated Sublicensee. GTX shall endeavor to include in its agreement with each GTX Unaffiliated Sublicensee a provision stating that, upon termination of this Agreement, such Unaffiliated Sublicensee and Orion shall discuss, and as appropriate, negotiate the terms and conditions under which Orion and such sublicensee would be willing to collaborate with regard to the further development and/or commercialization of the Product for use in the field in which GTX and such sublicensee were previously developing and/or commercializing Products, provided that any such further development and/ or commercialization of the Product by Orion and such sublicensee shall be subject to and conditioned by a definite written agreement, if any, accepted and signed by duly authorized representatives of Orion. GTX shall forward to Orion a complete copy of each sublicense agreement. No sublicense shall relieve GTX of any of its obligations or commitments under this Agreement and GTX shall cause its Affiliates and GTX Unaffiliated Sublicensees to comply with all of GTX obligations and commitments under this Agreement.

GTX shall remain jointly and severally liable to Orion with its Affiliate(s) and GTX Unaffiliated Sublicensee(s) that obtain a sublicense under the licenses granted to GTX pursuant to Section 2.1.1 for performance of GTX's obligations under this Agreement. GTX shall be responsible for complying and ensuring that such of its Affiliates and GTX Unaffiliated Sublicensees, as applicable, comply with all relevant laws, regulations and requirements relating to the importation, packaging, distribution, marketing, promotion, sale and use of Product in the GTX Territory.

Orion shall have the right to propose to GTX one or more potential sub-licensees under GTX's rights to the Product for use in the Field (other than in the Orion Field) in South Korea and China (including, for the purpose of this Agreement, the People's Republic of China and Taiwan). GTX shall consider such proposal(s) in good faith when appointing such a sub-licensee for the Product for use in the Field (other than in the Orion Field) for South Korea and China.

2.1.5 GTX RIGHTS OF FIRST NEGOTIATION. Orion grants GTX, on a country by country basis, the right of first negotiation to negotiate further agreements under commercially reasonable terms and conditions regarding the further development, registration, promotion, marketing, sales and distribution of a pharmaceutical product for human use within the Prostate Cancer Field containing SERMs as the active ingredient (a) which is covered by a Valid Claim within the GTX Patent Rights in such country; and (b) for which Orion has both a license or other right to develop and commercialize such products and has commenced, within five (5) years after the Amendment Date, a Phase I clinical trial for such product anywhere in the world for a primary indication falling within the Prostate Cancer Field (a product fulfilling (a) and (b), hereinafter referred to as "Additional Product"). If Orion decides to offer to any Third Party the opportunity to participate in the development or commercialization of such Additional Product, it shall so notify GTX in writing. [\*] after GTX's receipt of such notice from Orion regarding commercially

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

reasonable terms and conditions for obtaining rights in and to such Additional Product, GTX shall notify Orion in writing if it wishes to enter into negotiations with respect to such Additional Product. Should GTX elect to exercise such right, the Parties agree to negotiate in good faith the commercially reasonable terms and conditions for a letter of intent to be completed [ \* ] of receipt by Orion of such notification from GTX. Any deadlines may be extended by mutual written agreement. Should GTX fail to provide written notification to Orion by the end of [ \* ], or GTX notifies Orion that it does not wish to enter into negotiations; or the Parties, despite conducting good faith negotiations, are unable to finalize the commercial terms of the letter of intent [ \* ], GTX shall have no further rights in the SERM, and Orion shall be free to contract with a Third Party concerning same or itself further pursue the development, registration, promotion, marketing, sales and distribution of such Additional Product.

2.1.6 GTX RIGHTS TO NEGOTIATE FOR RIGHTS IN THE ORION FIELD IN THE ORION TERRITORY. With respect to the development and commercialization of Products in the Orion Field in the Orion Territory, GTX shall have the following rights:

(A) As of the Restatement Date, Orion has Third Party licensees that have rights to develop and/or commercialize the Product in the Orion Field and in the Orion Territory. If any such sublicense terminates at any time during the Term after the Restatement Date, and if Orion desires to seek another Third Party sublicensee under such rights, then Orion shall so notify GTX and GTX shall have a right to negotiate with Orion the terms under which GTX may obtain such rights to such Product in the Orion Field and in the Orion Territory, on the following basis:

(B) If GTX is interested in negotiating with Orion for such rights to Product in the Orion Field and in the Orion Territory, it shall notify Orion thereof in writing within thirty (30) days of receiving Orion's notice. The Parties shall negotiate in good faith for a period of ninety (90) days after Orion receives GTX's notice of interest on the terms of an agreement governing such rights and during said period Orion shall not grant such rights to any Third Party. If the Parties fail within such ninety (90) day period to execute such an agreement, then Orion shall thereafter be free to contract with any Third Party with respect to the rights in guestion.

2.2 NO IMPLIED LICENSES. Any rights not expressly granted by either Party to the other Party in this Agreement are expressly reserved by the Party owning or controlling such rights and, accordingly, no licenses other than those specified herein shall be deemed granted by this Agreement by implication, estoppel or otherwise.

2.3 UNITED STATES GOVERNMENT RIGHTS. In the event it is determined that any GTX Patent Rights were developed with the support of the United States Government or any agency thereof (the "Government"), the Government will retain rights in the GTX Patent Rights as set forth in Title 35 U.S.C. Section 200 et seq. All rights herein granted to GTX are subject to any such rights held by the Government and further subject to any restrictions or obligations that may be imposed by the Government pursuant to such rights, at such time that it is determined.

2.4 ORION'S RIGHT OF FIRST NEGOTIATION.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

2.4.1 Whereas Orion has considerable knowledge and experience in the marketing, sales and distribution of pharmaceutical products in, inter alia, Scandinavia (which term shall for purpose of this Section 2.4 comprise the countries of Denmark, Finland, Norway and Sweden), GTX undertakes to regard Orion as its preferential partner for the marketing, sales and distribution of the Product in Scandinavia for use in the Field (other than in the Orion Field in the Orion Territory), subject to this Section 2.4.1. Consequently, GTX grants, and shall cause its Affiliates and Unaffiliated Sublicensees who receive a sublicense under the license granted to GTX pursuant to Section 2.1.1 in Scandinavia to grant, to Orion a right of first negotiation to negotiate in good faith an agreement(s) under commercially reasonable terms and conditions regarding the marketing, sales and/or distribution by Orion of the Product in Scandinavia for use in the Field (other than in the Orion Field in the Orion Territory), with the express understanding that such commercially reasonable terms and conditions shall not comprise an obligation to develop and register the Product for use in the Field in any country of Scandinavia.

2.4.2 Within thirty (30) days after Orion's receipt of a first written offer from GTX regarding commercially reasonable terms and conditions governing such rights, Orion shall notify GTX in writing if it wishes to negotiate the terms and conditions under which Orion could obtain the rights contemplated in this Section 2.4. Should Orion so exercise such right, the Parties shall negotiate exclusively with each other and in good faith the commercially reasonable terms and conditions for a license and distribution agreement for the marketing, sales and distribution by Orion of the Product in Scandinavia for use in the Field (excluding the Orion Field in the Orion Territory), such negotiations to be completed within one hundred and eighty (180) days from the date of Orion's notification to GTX. Any deadlines may be extended by mutual agreement upon reasonable request. If Orion fails to provide written notification to GTX by the end of the thirty (30) day period; Orion notifies GTX that it does not wish to enter into negotiations; or the Parties despite conducting good faith negotiations, are unable to finalize the material commercial terms of agreement within such one hundred and eighty (180) day period (any such event, a "Termination of the Orion Right"), Orion shall have no further right under this Agreement to market, sell and distribute the Product in Scandinavia and GTX shall be free to offer to or enter into an agreement with any Third Party or any GTX Affiliate with respect to such activities after the Termination of the Orion Right occurs.

2.4.3 In the event that GTX's Unaffiliated Sublicensee for Product for use in the Field in the USA does not obtain the right and license to sell, have sold, import, market and distribute the Product in the Field in Europe at the time of execution of the sublicense agreement for the Product for use in the Field in the USA, then Orion shall, on the terms and conditions of Sections 2.4.1 and 2.4.2, have a right of first negotiation to negotiate in good faith an agreement(s) under commercially reasonable terms and conditions regarding the marketing, sales, and/or distribution of the Product for use in the Field in Europe.

2.5 USE OF TOREMIFENE BY GTX FOR RESEARCH. Subject to Sections 2.1.1(ii) and 14.6.2, GTX may use the Powder provided to it pursuant to Section 14.6.2 to perform stability studies and other activities with respect to Products for use in the Field that are necessary for supporting Regulatory Approval of Products or expanding the indications for Products within the Field. GTX shall, upon Orion's request therefor, provide Orion with written updates of any and all activities undertaken by or on behalf of it pursuant to this Section 2.5, and with the results thereof in reasonable detail.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

2.6 PROHIBITED ACTIONS. During the Term of this Agreement, Orion shall not grant any rights to any Third Party that are inconsistent with the licenses granted to GTX pursuant to Section 2.1.1.

3. PAYMENTS

3.1 TYPES OF PAYMENTS. For the rights, privileges and licenses granted hereunder, GTX shall pay Orion in the manner provided as follows:

3.1.1 In the event GTX or its Affiliate receives Upfront and Milestone Income (as defined in Section 3.1.1(c)), GTX shall pay Orion as follows:

(A) Any Upfront and Milestone Income for the sublicensing of Product rights in the Prostate Cancer Field shall first be applied to [ \* ] both prior to and after the Effective Date with respect to the [ \* ] and also for the [ \* ].

(B) Upon full reimbursement of such [\*] pursuant to Section 3.1.1(a), any remaining Upfront and Milestone Income (the "Net Upfront and Milestone Income") shall then be paid by GTX to Orion as follows:

(I) GTX shall pay Orion [  $^{\ast}$  ] of the portion of Net Upfront and Milestone Income that is [  $^{\ast}$  ]; and

(II) [  $^{\ast}$  ] of the portion of the Net Upfront and Milestone Income that is [  $^{\ast}$  ].

(C) For the purposes of this Agreement, "Upfront and Milestone Income" shall mean any bona fide consideration (either in cash or non-cash form) received by GTX or its Affiliate from a GTX Unaffiliated Sublicensee for sublicensing GTX's rights in and to the Product for use in the Prostate Cancer Field in the GTX Territory excluding: (i) Royalty Income (as defined in Section 3.1.5); (ii) cost of goods payments for supply of Product manufactured by Orion and supplied at the prices set forth in Article 14 herein below, or payments to reimburse GTX's fully burdened costs of manufacturing or having manufactured Product by or on behalf of GTX as permitted under this Agreement; (iii) in the form of a loan; or (iv) for the purchase of an equity interest in GTX (except to the extent such purchase price is a Premium over the fair market value of such stock, in which case the Premium, but not the portion of such price that is at the fair market value of such stock, shall be included in Upfront and Milestone Income). Notwithstanding the foregoing, if GTX receives Upfront and Milestone Income received in the form described in (ii) or (iii) [ \* ]. For example and without limitation, [ \* ].

3.1.2 If GTX is Acquired prior to the first Regulatory Approval of Product for use in the Prostate Cancer Field, then GTX shall pay to Orion an amount equal to the lesser of one million dollars (\$1,000,000) or one percent (1%) of the fair market value of GTX at the time of such acquisition. "Acquired" means that GTX either (i) sells all or substantially all of its assets to a Third Party, or (ii) is merged with or consolidated or reorganized into a Third Party, or becomes a subsidiary of a Third Party, and, as a result of such transaction, the stockholders of

[ \* ] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

GTX immediately prior to such transaction own less than fifty percent (50%) of the surviving parent entity.

3.1.3 ROYALTIES PAYABLE ON COMMERCIAL SALES OF FARESTON PRODUCT UNTIL PRODUCT ROYALTY ADJUSTMENT DATE.

(A) For commercial sales of the Fareston Product by GTX or its Affiliates after the Restatement Date, until the earlier to occur of (y) the [\*] or (z) the [\*] of a Product for use in the Prostate Cancer Field (any such Product in the Prostate Cancer Field, hereinafter referred to as a "New Product", and the date that is the earlier to occur of (y) or (z), hereinafter referred to as the "Product Royalty Adjustment Date"), GTX shall pay to Orion a running royalty on Net Sales of Fareston Product by GTX, its Affiliate or its Unaffiliated Sublicensee, as follows:

(I) Up until the end of the calendar month immediately preceding the month in which the [  $\ast$  ] occurs, the royalty due to Orion with respect to Net Sales of the Fareston Product by GTX, its Affiliates and/or Unaffiliated Sublicensees in the USA shall be [  $\ast$  ] of Net Sales of Fareston Product.

(II) Commencing upon the first day of the calendar month in which the [ \* ] occurs, and for the [ \* ] the royalty due to Orion with respect to Net Sales of the Fareston Product shall be [ \* ] of Net Sales of Fareston Product by GTX, its Affiliates and/or Unaffiliated Sublicensees during such period of time, or (B) [ \* ] of the MAT Net Sales of Fareston Product (as calculated and defined in Section 3.1.3(b)).

(III) Upon the first day of the [ \* ] occurs, and for the [ \* ] the royalty due to Orion with respect to Net Sales of Fareston Product by GTX, its Affiliates and Unaffiliated Sublicensees shall be [ \* ] of Net Sales of Fareston Product by GTX, its Affiliates and Unaffiliated Sublicensees during such period of time, or (B) [ \* ] of [ \* ] MAT Net Sales of Fareston Product.

(B) The Parties have agreed to use a moving annual total ("MAT") of sales of Fareston Product in the USA in calculating royalties due on Net Sales of Fareston Product in the USA during [\*] of the first New Product, which MAT takes into account and reflects [\*] during such period of time. Such MAT shall be based upon (i) the [\*] of such New Product and (ii) the actual Net Sales of the Fareston Product in the USA during the [\*] as follows: First, the "Correction Factor" shall be calculated, which shall be equal to the Net Sales of Fareston Product by GTX, its Affiliates and/or Unaffiliated Sublicensees in the USA during the [\*] occurs, divided by the Net Sales of Fareston Product during the [\*]. Then, the "MAT Net Sales of Fareston Product" shall be calculated, which shall be equal to the Correction Factor be [\*]. Then, the "MAT Net Sales of Fareston Product" shall be calculated, which shall be equal to the Correction Factor multiplied by actual Net Sales of the Fareston Product during [\*] occurs.

(C) For example and without limitation, if the Net Sales of the Fareston Product have been [ \* ] for [ \* ] prior to the [ \* ] occurs, and [ \* ] for [ \* ] preceding the beginning of the [ \* ] occurs, then the Correction Factor would be [ \* ]. Accordingly, the MAT

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Net Sales of Fareston Product would be [  $^{\ast}$  ] of the actual Net Sales of the Fareston Product during the [  $^{\ast}$  ].

(D) Commencing upon the Product Royalty Adjustment Date, the royalty for Fareston Product shall be paid pursuant to Section 3.1.4 and shall no longer be due pursuant to Sections 3.1.3(a) and (b).

(E) For clarity, sales of any New Product shall not be included in the calculation of Net Sales of Fareston Product under this Section 3.1.3, but shall instead be subject to the royalty due pursuant to Section 3.1.4, no matter when such sales occur.

3.1.4 ROYALTIES PAYABLE ON OTHER COMMERCIAL SALES OF PRODUCT. Except as provided for the Fareston Product prior to the Product Royalty Adjustment Date in Section 3.1.3, GTX shall pay to Orion a royalty on Net Sales of Product by GTX or its Affiliates, equal to [ \* ] of Net Sales of such Products, on a country by country basis, subject to the provisions of Sections 3.1.8 and 21.2.2.

3.1.5 Subject to the provisions of Sections 3.1.8 and 21.2.2, and except as provided for the Fareston Product prior to the Product Royalty Adjustment Date in Section 3.1.3, in the event GTX receives running royalty income from GTX Unaffiliated Sublicensees for sublicensing GTX's rights in and to any Product and/or based upon sales by GTX Unaffiliated Sublicensees of any Product in the GTX Territory ("Royalty Income"), GTX shall pay Orion the lesser of, on a country by country basis, either (a) [\*] of such Royalty Income; or (b) [\*] of such Product by such GTX Unaffiliated Sublicensees provided, however, that in no event shall the amounts due to Orion pursuant to this Section 3.1.5 be [\*] of Net Sales of such Product by such GTX Unaffiliated Sublicensees.

3.1.6 Notwithstanding Sections 3.1.3 through 3.1.5, if GTX enters into an agreement with a Third Party to [ \* ] and GTX is [ \* ] (a [ \* ]), then in lieu of the payments to Orion under Sections 3.1.3 through 3.1.5, GTX shall pay to Orion [ \* ] of [ \* ] Additionally, GTX shall not be obligated to pay Orion any amounts under Sections 14.4 or 14.6 for Product supplied to GTX for the purpose of [ \* ], as the Parties have agreed that the amounts due to Orion pursuant to this Section 3.1.6 shall be in lieu of any payments that would otherwise be due to Orion for the supply of such Product if this Section 3.1.6 were not applicable.

3.1.7 As of December 31, 2000, an upfront license fee of four hundred thousand dollars (\$400,000) (the "Upfront License Fee"), was paid in full by GTX to Orion. This payment shall be creditable by GTX against fees or payments due to Orion with respect to Upfront and Milestone Income pursuant to Section 3.1.1.

3.1.8 If a Generic Product is sold in any Major Country of the GTX Territory, and, for two (2) succeeding Calendar Quarters the Sales of Generic Product in that country [ \* ] of the sales of Product (calculated on a unit basis) in that country by GTX, its Affiliates and Unaffiliated Sublicensees, then the royalty on Net Sales owed by GTX to Orion under Section 3.1.4 and the payments due to Orion on Royalty Income pursuant to Section 3.1.5, respectively, shall be reduced to [ \* ] of the amount otherwise due to Orion pursuant to either

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Section 3.1.4 or 3.1.5, as applicable, with regard to such country with such reduction to be applicable to the immediately succeeding Calendar Quarter only.

3.1.9 For clarity, in no event shall a royalty be due with respect to the sale of a given unit of Fareston Product pursuant to more than one of Sections 3.1.3, 3.1.4 or 3.1.5.

3.2 NON-REFUNDABILITY. All milestone payments GTX makes to Orion pursuant to Section 3.1.1 shall be non-refundable once paid. However, if this Agreement is terminated for any reason prior to a given milestone payment becoming due or if the events specified for a given milestone payment do not occur, then GTX shall have no obligation to make such milestone payment.

3.3 ROYALTY REPORTS AND PAYMENTS. Commencing with the first Calendar Quarter in which GTX, its Affiliates or a GTX Unaffiliated Sublicensees make the First Commercial Sale of a Product, GTX shall provide Orion with a written report of Net Sales and Royalty Income on a country-by-country basis within forty-five (45) days after the last day of March, June, September and December for Royalty Income accruing on Net Sales during the three (3) preceding calendar months. Concurrently with the submission of each such written report, GTX shall pay or cause to be paid to Orion the total amount of royalties shown to be due thereon.

3.4 CURRENCY. GTX shall make all Upfront and Milestone Income and royalty payments to Orion pursuant to Section 3.1 in U.S. Dollars except that GTX shall make all cost of goods payments to Orion pursuant to Article 14 in euros. Where royalty payments are made, payments earned shall be first determined by GTX in the currency of the country where the Net Sales on the sales giving rise to payments were made and then converted directly to its equivalent in U.S. dollars. The rates of exchange for converting the currencies involved to U.S. dollars shall be the Foreign Exchange Rates quoted in the Wall Street Journal rate on the last business day of the quarterly period in which the royalty payments were earned.

 $3.5~\rm NO$  ROYALTIES PAYABLE BETWEEN AFFILIATES. No royalties shall be payable to a Party on sales between the other Party, its Affiliates or between the Party's Affiliates.

3.6 NO MULTIPLE ROYALTIES. No multiple royalties shall be payable because the Product, its manufacture, use or sale is or shall be covered by multiple patents.

#### 4. LIAISON

Representatives of the Parties shall meet bi-annually or as otherwise agreed to review the development, sales and marketing activities for Product conducted by GTX, its Affiliates or its Unaffiliated Sublicensees for use in the Field in the GTX Territory, with the exact dates and locations of such meetings to be mutually agreed upon. Such meetings shall alternate between GTX's and Orion's offices or be at other mutually agreed upon locations, with each Party to be responsible for the travel and living costs and expenses of its own representatives attending such meetings.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

5.

5.1 METHOD OF PAYMENT. In the event of any required tax withholding, the paying Party will provide the receiving Party with any relevant certificates or documents required for national, state or local tax credit and reporting purposes. Payments hereunder shall not be creditable against any other amounts payable by a Party under this Agreement, except as otherwise expressly stated herein. All payments shall be made by bank wire transfer (e.g., "SWIFT" or other comparable electronic transfer method) to such account(s) as the receiving Party shall designate beforehand in writing to the paying Party. Payments shall be deemed paid once funds are freely available to the receiving Party at such account(s).

5.2 LATE PAYMENTS. The Party entitled to payment hereunder reserves the right to charge the paying Party interest on any amounts owing from the paying Party which are overdue by more than fourteen (14) business days at a rate of [\*] per annum, or the maximum rate allowed by law, whichever is lower, calculated from the date any payment was due and payable.

5.3 RECORD KEEPING AND AUDIT RIGHTS. Each Party shall keep or cause to be kept accurate records relating to Net Sales, royalties, development and any other costs and expenses subject to payment, deduction or reimbursement by either Party to the other Party in sufficient detail to enable the amounts payable hereunder to be determined. Upon the written request of either Party (but not more frequently than once in any calendar year), the requesting Party may retain an independent certified public accountant, subject to approval by the other Party (which approval shall not be unreasonably withheld), to review such records to verify the accuracy of the payments made or payable hereunder. Such accountant shall be required to execute a confidentiality agreement in a form reasonably acceptable to the audited Party and shall report to the auditing Party only the amount of any underpayment or overcharge. Within ten (10) business days after completion of such review, the Parties shall reconcile any underpayment or overcharge. The auditing Party shall pay the cost of any review of records conducted at its request under this Section. However, if the review establishes underpayment or overcharge by the audited Party of over three percent (3%) during the period of the review, the audited Party shall promptly reimburse the auditing Party for the fees and expenses of the accountant. Such audit rights may be exercised by the Parties only with respect to records for the current calendar year and the preceding two (2) calendar years.

6. GTX PRODUCT MARKETING AND SALES ACTIVITIES

#### 6.1 MINIMUM SALES REQUIREMENTS FOR USA.

6.1.1 LEVELS OF MSRS. GTX shall have annual minimum sales requirements for Product for use in the Prostate Cancer Field ("MSRs") in the second year and fourth year after Product Launch in the USA for the Prostate Cancer Field equal to [ \* ] of GTX's annual Product Sales Projections (as defined below) in the USA for the Prostate Cancer Field. To establish such projections for the purpose of the foregoing sentence, GTX shall provide to Orion quarterly Product Sales Projections in the USA for the Prostate Cancer Field, within ninety (90) days after GTX, its Affiliate or Unaffiliated Sublicensee completes the last pivotal clinical trial as provided in the GTX Final Development and Registration Plan for Product in the Prostate Cancer Field in

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

the USA. The Parties shall set forth in Schedule D GTX'S MSR obligations within sixty (60) days after GTX provides such projections, and such MSRs shall be made a part hereof. Beginning with the [ \* ] year after Product Launch in USA for use in the Prostate Cancer Field until the end of the Term, GTX shall have an annual MSR equal to [ \* ] of the average of GTX'S Actual Product Sales (as defined below) in the USA for Product in the Prostate Cancer Field for the [ \* ]. "Product Sales Projections" means GTX's good faith estimates of the target patient population in a given year for Products in the Prostate Cancer Field in the USA, multiplied by the price per tablet of Product for use in the Prostate Cancer Field in the USA that GTX plans to be able to charge during the [ \* ] after Product Launch. "Actual Product Sales of Product in the Prostate Cancer Field so ra GTX Unaffiliated Sublicensee's actual Net Sales of Product in the Prostate Cancer Field during a given year in the USA.

For example, in year [ \* ] if the target patient population in the USA is [ \* ] subjects in the Prostate Cancer Field and the Product would be consumed by such patients [ \* ] for the Prostate Cancer Field at a hypothetical price of [ \* ], GTX's Product Sales Projections for the USA would [ \* ]. The hypothetical price for a tablet set forth above is hypothetical and was only used for the sole purpose of explaining the mechanism for calculating the Product Sales Projections and MSRs. Nothing contained in such example shall be so construed to deny the right of GTX to freely set its resale price of the Product.

6.1.2 PRODUCT LAUNCH DATE. "Product Launch in USA" shall be determined by the date on which the Product has received Regulatory Approval and is commercially available in the USA as follows: (i) if such date occurs during the first six (6) months of any calendar year (i.e., January 1-June 30), Product Launch in USA shall be deemed to have occurred on January 1 of such calendar year, and (ii) if such date occurs during the last six (6) months of any calendar year (i.e., July 1-December 31), Product Launch in USA shall be deemed to have occurred on January 1 of the following calendar year.

6.1.3 ADJUSTMENT. GTX's annual Product Sales Projections for the Prostate Cancer Field in the USA shall be subject to adjustment by written agreement of the Parties, with a corresponding adjustment in the MSRs, in the event of government intervention in given markets (including, but not limited to, government mandated health care reforms, rebates or regulatory changes), failure to obtain (or delay in obtaining) approval for a Product indication in the Prostate Cancer Field, or other events or causes affecting the market for the Product for use in the Prostate Cancer Field beyond the control of GTX, including but not limited to lower than anticipated pricing approvals measured on an aggregate basis throughout USA; GTX Patent Rights and/or Orion Patent Rights invalidation, infringement or expiration; Product safety and/or efficacy issues and/or major therapeutic advances materially affecting the market potential for the Product for use in the Prostate Cancer Field (including but not limited to new surgical procedures or introduction of new competitive products with superior safety and/or efficacy profiles); or a Force Majeure event (as described in Article 27).

6.1.4 FAILURE TO ACHIEVE MSRS. If GTX's annual Product Sales in USA for the Prostate Cancer Field are less than the MSRs in any applicable calendar year, GTX shall, without prejudice to its payment obligations under Section 3.1, pay Orion royalties corresponding to the "shortfall" between the actual royalties paid by GTX for such year and the royalties which would have been payable pursuant to Section 3.1 had GTX achieved the MSRs during such year,

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

subject to Section 6.1.3. GTX's payment of such "shortfall" hereunder shall be Orion's sole and exclusive remedy for GTX's failure to achieve MSRs in USA for such year. However, if GTX fails to pay such "shortfall," then Orion may, without prejudice to its right to such shortfall, also terminate this Agreement pursuant to Section 21.2.2.

6.2 NO MINIMUM SALES REQUIREMENTS OUTSIDE OF USA; NO MINIMUM SALES REQUIREMENTS FOR SALES OF FARESTON PRODUCT. GTX shall not have any minimum sales requirements with respect to sale of Product in any countries in the GTX Territory outside of the USA. GTX shall not have any MSRs with respect to any sales of Fareston Product or for any Product for use outside the Prostate Cancer Field. GTx agrees that it will continue to sell Fareston Product in the Breast Cancer Field in the USA until at least the Royalty Adjustment Date. If GTX desires, after such date, to cease commercialization of the Fareston Product in the Breast Cancer Field in the USA, then it may so notify Orion in writing. In such case, the Parties shall discuss the reasons why GTX desires to cease such commercialization activities. If Orion approves such proposal by GTX to cease commercializing the Fareston Product in the Breast Cancer Field in the USA (such approval not to be unreasonably withheld), then GTX may cease such activities. Without limiting the foregoing, Orion may not withhold its approval of a proposal by GTX under this Section 6.2 if GTX would be incurring, or based on GTX's reasonable projections would be likely to incur, a loss if it continues to commercialize Fareston Product in the Breast Cancer Field in the USA.

6.3 MARKETING AND SALES EFFORTS IN THE MAJOR COUNTRIES.

6.3.1 COMMERCIALLY REASONABLE OBLIGATION. On a country by country basis, subject to Sections 6.3 and 6.4, during the period commencing with Regulatory Approval in a Major Country, and for the remainder of the Term, GTX, its Affiliate and/or a GTX Unaffiliated Sublicensee shall use commercially reasonable efforts to promote, market, distribute and sell the Product for use in the Prostate Cancer Field in such Major Country. For purposes of this Section 6.3, "commercially reasonable" shall mean using, in the relevant Major Countries, an equivalent degree of effort as GTX, its Affiliate or a GTX Unaffiliated Sublicensee would use to promote, market, distribute and sell a product of its own that is of comparable market potential in such Major Country during the same time period (as determined by consideration of, without limitation, potential market, patent protection, and availability of competitive products), including but not limited to, engaging in the following activities (subject to any applicable U.S. FDA restrictions or other applicable legal restrictions):

(A) Using reasonable diligence to establish and maintain good business relationships with hospitals, health systems, doctors and other medical professionals in accordance with standard and customary practices in such Major Country;

(B) Using commercially reasonable efforts to establish and maintain an adequate capacity of sales personnel consisting of reasonably qualified personnel who have been certified, as trained by GTX, its Affiliate or a GTX Unaffiliated Sublicensee, to promote and market the Product for use in the Prostate Cancer Field in such Major Country, and to provide such sales force with adequate sales and promotional materials for the Product;

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(C) Promoting and detailing the Product for use in the Prostate Cancer Field throughout such Major Country, provided that GTX, its Affiliate or a GTX Unaffiliated Sublicensee may, in its discretion use relatively greater promotional and detailing efforts (i) in some Major Countries than it uses in other of such countries, and (ii) in some parts of each Major Country than in other parts thereof, consistent with its overall marketing plan; and further provided, however, that the foregoing shall in no event be deemed to limit GTX's its Affiliate or a GTX Unaffiliated Sublicensee overall obligations under the first paragraph of this Section 6.3.1.

(D) Advertising the Product for use in the Prostate Cancer Field in professional journals and publications and sponsoring or attending appropriate symposia, trade exhibitions and medical education programs in a manner equivalent to that used for GTX's, its Affiliate's or a GTX Unaffiliated Sublicensee's, as applicable, own products of comparable market potential in such Major Country; and

(E) Formulating and using reasonable efforts to implement annual sales and marketing plans for the Product for use in the Prostate Cancer Field in such Major Country and providing copies of such plans to Orion for review and comment, provided that Orion shall not have approval rights with respect to such plans.

6.3.2 SALES OBJECTIVES AND OTHER FACTORS FOR THE USA. GTX and Orion shall agree in writing upon annual target sales objectives for the Product for use in the Prostate Cancer Field in the USA, commencing with the fourth calendar year after First Commercial Sale of the Product for use in the Prostate Cancer Field in the USA, provided that such annual target sales objectives shall not be considered MSRs for any purposes, but instead shall be used by the Parties for informational and planning purposes and shall be one (1) factor, among others, to be considered in assessing whether GTX has complied with its commercially reasonable obligations hereunder. GTX's level of sales and marketing expenses for the Product for use in the Prostate Cancer Field in the USA and events or causes affecting the market for the Product for use in the Prostate Cancer Field beyond the control of GTX shall also be among the factors to be considered in assessing whether GTX has complied with its commercially reasonable obligations hereunder.

6.4 PRODUCT LAUNCH.

6.4.1 TIMING OF LAUNCH. GTX shall use commercially reasonable efforts to launch the Product for use in a given indication in the Prostate Cancer Field as soon as practical in every Major Country of the GTX Territory where GTX, its Affiliates and/or GTX Unaffiliated Sublicensees have obtained Regulatory Approval for such indication. Notwithstanding the foregoing, GTX, its Affiliate or a GTX Unaffiliated Sublicensee may, acting in good faith in the exercise of its reasonable business judgment, determine either to delay the launch of the Product for use in a given indication in the Prostate Cancer Field or not to launch the Product for use in a given indication in the Field in any given country in the GTX Territory other than a Major Country, which decision to delay or not to launch shall not be deemed a failure to use commercially reasonable efforts. Further, GTX's, its Affiliates' or a GTX Unaffiliated Sublicensee's decision to delay the launch of the Product for use in the Prostate Cancer Field in any Major Country for up to six (6) months after GTX or its Affiliates have obtained Regulatory

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Approval in such country, shall not be deemed a failure to use commercially reasonable efforts pursuant to Section 6.3 to the extent that GTX can demonstrate that such delay was attributable to bona fide business reasons affecting the Product.

6.4.2 DECISIONS NOT TO LAUNCH. GTX shall promptly notify Orion in writing if GTX, its Affiliate or a GTX Unaffiliated Sublicensee, as applicable, determines to delay the launch of the Product for use in a given indication in the Prostate Cancer Field in any Major Country after obtaining Regulatory Approval of Product therefor. If such decision is due to any reasons other than the potential for, or the existence of, adverse business effects in such Major Country, then such decision shall be deemed a material breach of this Agreement pursuant to Section 21.2.2 and GTX shall be subject to the provisions of such Section within thirty days (30) after GTX's decision not to launch in such Major Country.

6.5 MARKETING COSTS AND EXPENSES. Except as otherwise provided herein or as otherwise mutually agreed by the Parties, GTX, its Affiliate or a GTX Unaffiliated Sublicensee shall bear all costs and expenses connected with its marketing and sales activities for the Product for use in the Field and its performance under this Agreement.

6.6 MARKETING PLANS AND REPORTS.

6.6.1 MARKETING PLANS. GTX shall develop and provide to Orion by October 31 of each year during the Term marketing and sales plans for the Product for each Major Country for the following calendar year, commencing with the calendar year in which Regulatory Approval is obtained in each respective country. Such plans shall include the projected Annual Net Sales and the projected advertising and promotion budgets for such year, and shall not be applicable to the calculation of MSRs in connection with the sale of Products in the Prostate Cancer Field in the USA pursuant to Section 6.1, for which GTX shall separately provide information.

6.6.2 MARKETING AND SALES REPORTS FOR PRODUCT. GTX shall provide to Orion, within forty-five (45) days after the end of each calendar year, a written marketing activities and sales report for each of the Major Countries in which Product is launched. The report shall include at least a description of sales, marketing and promotion activities and a list of scientific conferences or other events involving the particular Product or its therapeutic area, accompanied by a general description of the nature and extent of GTX's participation in such conferences or events.

7. GTX PRODUCT DEVELOPMENT AND REGISTRATIONS

7.1 GTX DEVELOPMENT AND REGISTRATION ACTIVITIES.

7.1.1 GTX ACTIVITIES. In accordance with the GTX Preliminary Development and Registration Plan and the GTX Final Development and Registration Plan, GTX shall undertake development and registration activities for the Product for use in the Prostate Cancer Field in the GTX Territory, including but not limited to, conducting or sponsoring, and completing or having completed in accordance with U.S. FDA regulations and Good Clinical Practice regulations under the European Union legislation and directives requirements, all

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

clinical studies and other activities required for Regulatory Approval under the GTX Final Development and Registration Plan. Without limiting the provisions of Section 7.7, GTX shall use its commercially reasonable efforts to pursue such development and registration activities under the GTX Final Development and Registration Plan with the objective of filing applications for Regulatory Approval in all Major Countries throughout the GTX Territory in the Prostate Cancer Field according to the anticipated filing dates set forth in the GTX Final Development and Registration Plan timetable [ \* ]. GTX's Regulatory Approvals in the GTX Territory shall be owned solely by GTX.

## 7.1.2 ORION ACTIVITIES.

(A) Orion shall use its commercially reasonable efforts to assist GTX in obtaining and maintaining the U.S. FDA Regulatory Approval of Products in the Prostate Cancer Field and of the Fareston Product in the Breast Cancer Field in the USA (including obtaining and/or maintaining the Orion Product NDA and all related U.S. INDs filed with the U.S. FDA for such Products, and any other required Regulatory Approvals in the Major Countries of the GTX Territory relating to the manufacture, use, marketing or sale of Product for use in the Prostate Cancer Field or of Fareston Product in the Breast Cancer Field in the USA (by providing to GTX relevant information, documents and data in its possession in relation to regulatory inquiries during the Regulatory Approval process for Products, necessary additional letters of cross-reference or authorization equivalent to those described in Section 7.5 to its registrations for Product in the Orion Field in the Orion Territory, and other similar assistance). Orion shall maintain the DMF filed with the U.S. FDA and all equivalent regulatory authorities outside of the USA for Product as well as its registrations for Product in the Orion Field in the Orion Territory during the Term, provided that Orion may notify GTX that Orion intends to cease maintenance of any such DMF and/or registration, in which case GTX shall have the right to maintain such filing, at GTX's expense, by notifying Orion in writing within thirty (30) days after it receives Orion's notice hereunder that it desires to maintain such filing. If GTX elects to maintain such filing, Orion shall cooperate reasonably with GTX to effect the transfer of such DMF and/or registration to GTX.

(B) Orion shall perform any stability testing for the bulk Orion Product to be manufactured and supplied by Orion to GTX that is required by regulatory authorities in any Major Country. Such testing shall be provided at no cost to GTX, except that GTX will reimburse Orion's direct costs of performing any such stability testing that must be conducted solely for the [\*] tablet of the Orion Product. Orion employees shall, at Orion's cost and expense, have the right to participate in all FDA and other regulatory agency meetings regarding the use of the Product in the Field.

(C) Orion shall have no obligation to research, develop, register, commercialize any Product or carry out any studies or testing in relation to Products, including without limitation with respect to any new or additional strength, dosage form, formulation or route of administration of the Orion Product or the Product, or provide any documentation, information or data relating to the foregoing, except as expressly provided in Section 7.1.2(a) or otherwise set forth in this Agreement, unless the Parties expressly mutually agree otherwise in writing after the Restatement Date. Other than as expressly agreed in this Agreement, Orion shall have no obligation to fund or pay for any of the costs and expenses of such activities. All

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

studies, trials, tests, activities, documentation, data and information required by any regulatory or other governmental agency or which is necessary or useful for the research, development, registration or commercialization of the Product shall, unless otherwise expressly agreed to herein as between the Parties, be for the sole cost and responsibility of GTX.

7.1.3 AUTHORIZATION LETTERS. Any regulatory filings (including without limitation any DMFs that GTX may develop if it obtains the right to manufacture Product) compiled and filed by or on behalf of GTX shall remain the property of GTX, but GTX shall, upon request therefor by Orion, negotiate with Orion the terms under which GTX would provide appropriate authorization letters to relevant regulatory bodies to enable Orion to reference such regulatory filings for purposes of applying for and supporting Orion's applications for Regulatory Approval of products containing Toremifene outside the Field.

7.2 FDA FILE. As of the Restatement Date, Orion shall have transferred the Orion Product NDA and all Investigational New Drug Applications (as defined in 21 C.F.R. Section 212) for Products filed with the FDA to the name of GTX, as set forth in the Purchase Agreement.

7.3 DEVELOPMENT AND REGISTRATION COSTS. Except as otherwise expressly provided in this Agreement or otherwise mutually agreed in writing by the Parties after the Restatement Date, GTX shall bear all costs and expenses related to Product registration and regulatory activities (other than for Product for the Orion Field in the Orion Territory), including without limitation costs of filing, obtaining and maintaining all such Regulatory Approvals throughout the GTX Territory, as well as all costs and expenses for the research and development of the Product for use in the Field (other than for Product for the Orion Field in the Orion Territory), provided that GTX shall not be responsible for any costs related to the manufacture of the Orion Product (except for payments that GTX must make to Orion pursuant to Section 7.1.2(b) or Article 14 (such costs collectively referred to herein as "Manufacturing Costs"). Except for the Manufacturing Costs or as otherwise expressly provided in this Article 7, Orion shall bear no responsibility for any costs or expenses related to Product registration, regulatory, research or development activities in relation to the Product.

7.3.1 DEVELOPMENT AND REGISTRATION COSTS PRIOR TO RESTATEMENT DATE. The Parties agree that GTX shall, notwithstanding anything to the contrary in the Original Agreement or otherwise, also bear all costs and expenses related to Product research, development, registration, regulatory compliance and other activities relating to the development of Product that were incurred prior to the Amendment Date by GTX (excluding any Manufacturing Costs) (hereinafter referred to as "Incurred Costs"). Consequently, except as set forth in Section 3.1.1, GTX shall forever release and discharge Orion of any and all claims that it purports to have at the Amendment Date or may have thereafter against Orion with respect to Incurred Costs.

7.4 GTX DEVELOPMENT AND REGISTRATION PLAN.

7.4.1 COMPLETION OF GTX FINAL DEVELOPMENT AND REGISTRATION PLAN. The GTX Preliminary Development and Registration Plan for development and registration of Product in the Prostate Cancer Field was attached to the Original Agreement as Schedule B. GTX will prepare a GTX Final Development and Registration Plan for such activities for each

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Major Country in a timely fashion upon receiving approval from the appropriate regulatory authority in each Major Country of a plan for regulatory approval in that country. Immediately upon completion of the GTX Final Development and Registration Plan for each Major Country, [\*] GTX shall provide a copy of such plan to Orion.

7.4.2 ORION'S RIGHT TO COMMENT ON AND OBJECT TO PLAN. Orion shall have the right to comment on each GTX Final Development and Registration Plan for Product for the Prostate Cancer Field for each Major Country. Additionally, Orion shall have the right to object to each GTX Final Development and Registration Plan for each Major Country to the extent such plan could reasonably be deemed to affect adversely Orion's development, commercialization, sales or registration of Toremifene in the Orion Field in the Orion Territory or outside the Field. GTX undertakes to change and/or amend the GTX Final Development and Registration Plan for Product for the Prostate Cancer Field for each Major Country to the extent Orion has so objected thereto as necessary to alleviate or obviate such adverse effect. Orion shall provide GTX with such comments and/or objections within thirty (30) days from Orion's receipt of the GTX Final Development and Registration Plan.

7.4.3 CHANGES TO SUCH PLAN. GTX may modify the GTX Final Development and Registration Plan, as GTX deems necessary and consistent with Section 7.4.1, but shall notify Orion of such changes. Any changes to the GTX Final Development and Registration Plan for each Major Country shall also be subject to Section 7.4.2.

7.5 ORION DOCUMENTATION AND DATA.

7.5.1 GTX ACCESS TO ORION KNOW-HOW. Orion has provided and shall continue to provide GTX with copies of the Orion Know-How, documentation, information and data listed or referenced in the GTX Preliminary Development and Registration Plan, and GTX shall be authorized to use and reference the same in its applications for Regulatory Approval and regulatory compliance activities in relation to such Regulatory Approvals. Any Product Drug Master Files ("DMFs") compiled or owned by Orion shall remain the property of Orion, but Orion shall, upon reasonable request therefor by GTX, provide appropriate authorization letters to relevant regulatory bodies in the GTX Territory within forty-five (45) days from such request to enable GTX to reference such DMFs for purposes of GTX's applications for Regulatory Approval and regulatory compliance activities in the GTX Territory as provided for in Section 7.1. For the avoidance of doubt, neither Party is obligated to disclose the contents of its DMFs to the other Party.

7.5.2 GTX ACCESS TO DATA. During the Term, Orion shall provide GTX, within forty-five (45) days of receipt of a written request from GTX specifying in detail the documentation, information and/or data requested, access to Orion Know-How in Orion's control and possession (and freely disclosable) that GTX reasonably requires for regulatory filings for the use of Product in the Field in the GTX Territory, including any Orion Know-How concerning the use of the Product in the Orion Field in the Orion Territory to the extent such information may be reasonably required by GTX for such regulatory filings. In instances where documentation, information and/or data requested are required by the U.S. FDA or other regulatory agency to be submitted in a time frame shorter than forty-five (45) days, GTX shall notify Orion, and GTX and Orion shall agree on a shorter time frame for provision of such

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

materials within the time required by the FDA. In the event any of such Orion Know-How is not in the control or possession of Orion but is controlled by a Third Party, Orion and GTX shall discuss in good faith commercially reasonable efforts that Orion may, at its discretion, decide to take to assist GTX in accessing such Orion Know-How, provided that nothing herein shall obligate Orion to take steps to arrange, or incur costs, to access such Orion Know-How from such Third Party, and provided further that if requested by GTX, Orion will grant GTX the necessary authorizations to approach any such Third Party for such access. Upon GTX's request, Orion shall provide GTX with copies of such Orion Know-How referenced in the preceding sentences only in such form and content as is available to Orion, provided that, upon Orion's request, GTX shall reimburse Orion for Orion's direct out-of-pocket cost of making such copies and providing GTX with such Orion Know-How.

GTX shall also provide to Orion quarterly reports summarizing GTX's development activities for Products in the Field (excluding the Orion Field in the Orion Territory).

7.5.3 LETTER OF CROSS REFERENCE. Orion agrees that the Cross Reference letter dated December 10, 1999 from Orion to GTX shall remain in effect to the extent it enables GTX or its Affiliates to reference regulatory filings for the Orion Product in all countries outside of the USA. Such Cross Reference letter may not be revoked by Orion unless this Agreement is terminated. During the Term, Orion shall permit GTX, its Affiliates and the GTX Unaffiliated Sublicensees to reference, and shall provide GTX with an appropriate authorization letter to enable GTX, its Affiliates and the GTX Unaffiliated Sublicensees to reference, all applications or filings for Regulatory Approval for Orion Products for use in the Orion Field and related DMFs that are identified in Schedule E hereof (hereinafter "Orion Product Approvals") for the purpose of applying for and supporting Regulatory Approval of Products for use in the Field within the GTX Territory. Orion shall update Schedule E from time to time during the Term to set forth all Orion Product Approvals and DMFs that are owned and controlled by Orion. GTX recognizes that Orion has obtained the Orion Product Approvals solely for the purpose of its proprietary product Fareston(R), and that nothing herein shall be construed so as to obligate Orion to maintain or cause to be maintained any Orion Product Approvals solely for allowing GTX, its Affiliates and/or GTX Unaffiliated Sublicensees to refer thereto, provided that during the Term, Orion shall not withdraw such Orion Product Approvals in the absence of commercially justifiable reasons in relation to Fareston(R). Orion shall, prior to withdrawing such Orion Product Approvals, offer to GTX the right to maintain such approvals, at GTX's expense. If GTX elects to maintain such approvals, Orion shall reasonably cooperate with GTX to enable GTX to assume such responsibility.

7.5.4 ADDRESS. All requests by GTX to Orion for documentation, information or data, as agreed herein, shall be addressed only to the attention of such person(s) as is/are designated in writing or in electronic form by Orion from time to time.

7.6 GTX REGISTRATION AND MARKETING APPROVAL APPLICATIONS. GTX, its Affiliates and/or GTX Unaffiliated Sublicensees shall have the responsibility and the right to submit registration applications for Regulatory Approval and marketing and price approval of the Product for use in the Field within the GTX Territory; provided, however, that GTX shall not have the responsibility to submit such applications for approval of the Product for use in the Orion Field in the Orion Territory.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

7.7 FAILURE TO FILE OR EXTEND. Orion shall have the right to terminate its obligations under Section 7.1.2(a) and its obligations to manufacture and supply to GTX Orion Product upon one hundred and eighty (180) days prior written notice to GTX, if Regulatory Approval has not been granted for the Product for use in the Prostate Cancer Field in the USA by December 31, 2009. Any such notice hereunder shall be given no later than sixty (60) days after December 31, 2009, provided that GTX shall inform Orion in writing by December 31, 2009, whether or not Regulatory Approval has been granted for the Product for use in the Prostate Cancer Field in the USA by such date. The time for Orion to provide notice to GTX of its decision to exercise its right with regard to the event described above shall be deemed to commence upon the receipt by Orion of such notice from GTX, provided that nothing shall be construed so as to prevent Orion from exercising its right hereunder if Orion discovers, either by itself or through a Third Party, that Regulatory Approval has not been granted for the Product for use in the Field in the USA by December 31, 2009. Effective upon the date that GTX receives any notice from Orion pursuant to this Section 7.7 and during the Term, Orion hereby grants GTX a contingent license under the Orion Patent Rights and Orion Know-How and all other patents and patent applications owned or controlled by Orion during the Term that relate to the manufacture, use or sale of Toremifene or Orion Product ("Manufacturing Patents") to make and have made Product for use in the Field in the GTX Territory (except in the Orion Field in the Orion Territory). Such license shall be exclusive and sublicensable (but only for the purposes of having manufactured the Products for GTX, its Affiliates or Unaffiliated Sublicensees). Orion shall as soon as practically possible after providing any notice to GTX pursuant to this Section 7.7 provide GTX with such then-existing manufacturing, process and quality control procedures, documentation and other relevant know-how and information to the extent reasonably necessary to enable GTX to exercise its manufacturing right pursuant to this Section 7.7 (hereinafter "Product Manufacturing Know-How"), including without limitation providing up to ten (10) person-days of technology transfer assistance at GTX's site of manufacture of Product using Orion personnel skilled in such manufacturing operations, at no charge to GTX.

7.8 REIMBURSEMENT OF ORION COSTS. Except as provided for otherwise in this Article 7, GTX shall reimburse Orion for all costs and expenses incurred by Orion in fulfilling its obligations under this Article 7 with respect to Products in the Field, subject to the following: (a) such reimbursable amounts shall include costs of assistance provided by Orion for activities relating to the Prostate Cancer Field only to the extent such costs (i) are incurred by Orion after [ \* ] or (ii) have been invoiced to GTX prior to [ \* ]; (b) such reimbursable amounts shall include costs of assistance provided by Orion for activities outside of the Prostate Cancer Field and the Breast Cancer Field, with the amounts described in this subsection (b) including Orion's [ \* ]; (c) such reimbursable amounts shall not include [ \* ] and (d) such reimbursable amounts shall not include [ \* ] and (d) such reimbursable amounts costs and expenses so incurred that are reimbursable hereunder during each Calendar Quarter, and GTX shall effect payment of such invoice within thirty (30) days from the date of the invoice.

## 8. CONFIDENTIALITY AND PUBLICITY

8.1 CONFIDENTIALITY OBLIGATION. Each Party shall hold the other Party's Confidential Information (as defined below) of which it becomes informed in connection with this Agreement or the Original Agreement in strictest confidence and shall not disclose such Confidential Information to Third Parties or otherwise use it, except to the extent such use or

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

disclosure is expressly permitted by the terms of this Agreement or is reasonably necessary for the performance of this Agreement.

8.2 PERMITTED DISCLOSURES. Permitted disclosures of Confidential Information hereunder include, but are not limited to: (A) disclosures to regulatory agencies to the extent required for Regulatory Approval, including but not limited to, GTX Product registrations and applications in the GTX Territory (to the extent expressly permitted hereunder), and (B) disclosures to the Parties' Affiliates, employees, agents and independent contractors (including clinical investigators, consultants and contract research organizations) who have a bona fide "need to know", and GTX Unaffiliated Sublicensees, and prospective sublicensees, provided that for such permitted disclosures under subsection (B) the disclosing Party shall obligate the recipients to maintain the confidentiality of Confidential Information under terms substantially similar to those contained in this Article 8.

8.3 CONFIDENTIAL INFORMATION. "Confidential Information" includes, but is not limited to, any information relating to the terms of this Agreement, the Original Agreement, the Product, the Orion Product, GTX Know-How, GTX Patent Rights, Orion Patent Rights, Orion Know-How, GTX Preliminary Development and Registration Plan, GTX Final Development and Registration Plan, clinical and non-clinical studies involving the Product, and all sales and marketing plans for the Product, as well as information concerning all other products and the business affairs, manufacturing processes and other activities of the disclosing Party that are designated as confidential in writing or orally disclosed, provided such oral disclosure is confirmed as confidential in writing within thirty (30) days thereafter. However, such obligations shall not apply to Confidential Information to the extent such information is:

(A) PUBLICLY AVAILABLE INFORMATION. Which at the time of disclosure is or later comes into public domain by publication or otherwise through no fault of the receiving Party;

(B) PREVIOUSLY KNOWN INFORMATION. Which can be demonstrated by documentation or other competent proof to have been in the receiving Party's possession prior to disclosure;

(C) SUBSEQUENTLY RECEIVED INFORMATION. Which is subsequently received by the receiving Party from a Third Party who is not bound by any confidentiality undertaking to the disclosing Party or to any of its Affiliates with respect to said information;

(D) INDEPENDENTLY DEVELOPED INFORMATION. Which is independently developed by or for the receiving Party without reference to the disclosing Party's Confidential Information; or

(E) LEGALLY REQUIRED DISCLOSURES OF INFORMATION. Which is legally required to be disclosed pursuant to any statute or regulation or any judicial or administrative order, including any material or information requested by the Securities and Exchange Commission (or any equivalent securities exchange) or Finnish equivalent thereof to the extent that such information cannot be treated confidential.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

8.4 DURATION OF CONFIDENTIALITY OBLIGATION. The confidentiality obligations of the Parties hereunder shall remain in effect during the Term and shall survive the termination or expiration of this Agreement for any reason and be effective until the later of five (5) years after such termination or expiration, or ten (10) years after the Restatement Date.

## 8.5 PUBLICITY AND ANNOUNCEMENTS.

8.5.1 With regard to the existence and content of commercial terms and conditions of this Agreement, unless agreed upon by the Parties, neither Party shall originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, relating to this Agreement or any amendment hereto, without the approval of the other Party, except as required by law, including, without limitation, provisions regarding the disclosure requirement for publicly quoted companies, and then only to the minimum extent so required, in which event such Party shall give the other Party a reasonable opportunity to review the form and content of the announcement before such legally required announcement is made.

8.5.2 GTX may originate any publicity, news release or other public announcement, written or oral, whether to the public press, stockholders or otherwise, relating to the use of the Product in the Field provided that GTX forwards to Orion such publicity, news release or other public announcement fourteen (14) days prior to such publicity, news release or other public announcement, except as otherwise required by law or regulation, including without limitation disclosure requirements promulgated by the Securities and Exchange Commission. It is agreed that such publicity, news release or other public announcement does not require the approval of Orion, unless Orion considers such publicity, news release or other public announcement to (a) fall within the scope of Section 8.5.1; or (b) be misleading or incorrect, in which case Orion shall, within five (5) business days after receiving such publicity, news release or other public announcement, so notify GTX and provide written comments specifying changes that Orion reasonably believes will correct such inaccuracy, except as otherwise required by law or regulation. If requested by orion, such publicity, news release or other public announcement shall include wording to the effect that Toremifene is a proprietary compound of Orion, and that Toremifene has been licensed by Orion to GTX for use in the Field.

# 9. FARESTON PRODUCT WEBSITE FOR USA

9.1 FARESTON WEBSITE. During the Term of this Agreement or as long as the Fareston Product is sold in USA (whichever period is shorter), Orion shall maintain, (including, without limitation, by renewing the applicable domain name(s)), and operate, either itself or via Third Party subcontractor(s), the internet site with the domain name www.fareston.com (or any successor site or domain name thereof). Promptly following the execution of this Agreement, Orion and GTX shall mutually agree upon a process or means whereby Orion shall provide GTX with a means to access said website in order to update and maintain web pages for the Fareston Product that are directed towards residents of the USA (the "FARESTON U.S. WEB PAGES"). The Parties acknowledge and agree that GTX shall have sole control over, and responsibility for, the content of the Fareston U.S. Web Pages, including, without limitation, the "look and feel" thereof. Orion hereby grants GTX a non-exclusive, sublicenseable license in the GTX Territory under such intellectual property rights owned or controlled by Orion during the Term that are

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

strictly necessary for GTX, its Affiliates and Unaffiliated Sublicensees to exercise the rights granted to GTX pursuant to this Section 9.1 with respect to the Fareston U.S. Web Pages. It is understood and agreed that nothing herein shall obligate Orion to perform the foregoing tasks [\*] GTX shall be responsible for ensuring that the Fareston U.S. Web Pages conform with all applicable laws and regulations. To the extent allowed by applicable laws and regulations, Orion shall have a right to build on and join and/or establish a link to the foregoing site for the Fareston Product in connection with its retained rights for Fareston Product, and to grant to its Affiliates and Unaffiliated Sublicensees such rights, at any time, at its sole discretion, with the reasonable costs thereof payable by the supplier of such link or contents. GTX shall reasonably cooperate with Orion in regard to any additions to such site as agreed between the Parties.

#### 10. TRADEMARKS

#### 10.1 TRADEMARKS.

10.1.1 GTX shall market and sell the Product for use in the Field in the GTX Territory under the Trademarks. GTX shall own and control all Trademarks (including, as provided in the Purchase Agreement, the trademark Fareston(R) in the USA). For avoidance of doubt, GTX shall not have any rights to use the trademark Fareston(R) outside of the USA. GTX shall notify Orion if GTX decides to change, alter, modify or replace the Trademark initially selected by it for a given Product.

10.1.2 If GTX exercises its right of first negotiation to obtain rights to sell Orion Product in the Orion Field under Section 2.1.6, then the Parties agree that any letter of intent and final agreement governing the terms under which GTX would obtain such rights shall provide for Orion to grant to GTX an exclusive, sublicensable license under the trademark Fareston(R) in the relevant country outside the USA (or any counterpart to such trademark that Orion is then using to market, promote, and commercialize Orion Products in the relevant country or countries) to advertise, promote, market or sell such Orion Product.

10.2 TRADEMARK FILING AND MAINTENANCE. GTX shall be responsible for filing, maintaining, prosecuting and defending the Trademarks in the GTX Territory (including, for the avoidance of doubt, the trademark Fareston(R) in the USA).

10.3 TRADEMARK DOCUMENTATION. If requested by Orion, GTX shall provide Orion with copies of all documents relating to the maintenance of the Trademark in the GTX Territory, at Orion's expense.

## 11. PATENT OWNERSHIP AND WARRANTIES

11.1 PATENT OWNERSHIP.

11.1.1 Subject to the license rights granted to GTX hereunder, Orion retains full ownership of all Orion Patent Rights and shall be responsible for filing, prosecuting, and maintaining Orion Patent Rights as provided for in Article 12.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

11.1.2 Subject to the license rights granted to Orion hereunder, GTX retains full ownership of all GTX Patent Rights and shall be responsible for filing, prosecuting, and maintaining GTX Patent Rights as provided for in Article 12.

11.2 ORION PATENT WARRANTIES. Orion warrants and represents that, to the best of its management's knowledge as of the Effective Date: (A) Schedule  ${\tt B}$ sets forth all of the Orion Patent Rights as of the Effective Date and as of the Restatement Date which are directed to the composition of matter, use or sale of the compound Toremifene per se; (B) except for the Orion Field in the Orion Territory, Orion has not and will not grant, license, convey, assign, and/or transfer to any Third Party any rights to Orion Patent Rights for use in the Field, or any rights to manufacture the Product or Toremifene for use in the Field, or other rights to any Third Party, in each case inconsistent with the licenses and other rights granted to GTX hereunder, (C) based upon Orion's reasonably diligent investigation, the Orion Patent Rights are (i) valid, in full force, and enforceable, and (ii) there are no existing valid Third Party patents in the GTX Territory that might be infringed by the manufacture or sale of the Orion Product by Orion to GTX under this Agreement for the Prostate Cancer Field, or in the USA for the Breast Cancer Field, and (D) the use and/or sale of Products in the Field and in the GTX Territory by GTX, its Affiliates or Unaffiliated Sublicensees pursuant to this Agreement will not, in the absence of a license from Orion, infringe any patents owned or controlled by Orion other than the Orion Patent Rights. Additionally, Orion represents and warrants to GTX that to the best of its management's knowledge as of the Restatement Date, Orion has not received any written claims or assertions from any Third Party alleging that the use of Toremifene in the Field (other than as may be for use and/or sale of Products in the Orion Field in the Orion Territory) infringes such Third Party's patent rights.

11.3 GTX PATENT WARRANTIES. GTX warrants and represents that [\*] as of the Effective Date: (A) Schedule A sets forth all of the GTX Patent Rights as of the Effective Date which cover the Product for use in the Prostate Cancer Field and that it had full right and authority to grant to Orion and Orion Affiliate the rights granted to it under Section 2.4; (B) subject to Section 2.1.4, GTX has not and will not grant to any Third Party any rights under the Orion Patent Rights or Orion Know-How inconsistent with GTX's licenses under this Agreement, and (C) there are no circumstances existing that render it likely that the United States Government or any agency thereof to exercise such rights as set forth and/or referenced to in Section 2.3, if GTX's development, registration and commercialization of the Product for use in the Prostate Cancer Field will be carried out as agreed herein; and (D) (i) the GTX Patent Rights are valid, in full force, and enforceable and (ii) upon GTX's reasonably diligent investigation, there are no existing valid and enforceable Third Party patents in the GTX Territory (other than any that may be owned or controlled by Shire) that might be infringed by the marketing, promotion, distribution, importation, offer for sale or sale of the Product in the Prostate Cancer Field by GTX, its Affiliates and GTX Unaffiliated Sublicensees.

## 12. PATENT PROSECUTION AND INFRINGEMENT; TRADEMARKS

12.1 ORION PATENT FILING AND PROSECUTION. Orion shall, at its sole expense, prosecute, maintain and defend Orion Patent Rights in the GTX Territory and Orion shall control all Orion Patent Rights filings and actions. Orion shall use its commercially reasonable efforts to

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

obtain extensions in the Major Countries in the GTX Territory in which such extensions are available.

12.2 GTX PATENT FILING AND PROSECUTION. GTX shall, as its sole expense, file, prosecute, maintain and defend GTX Patent Rights in the GTX Territory and GTX shall control all GTX Patent Rights filings and actions. GTX shall use its commercially reasonable efforts to obtain GTX Patent Rights protection and commercially reasonable efforts to obtain GTX Patent Rights extensions in any countries in the GTX Territory in which such extensions are available.

12.3 NOTIFICATION OF INFRINGEMENT. The Parties shall promptly inform each other of any information that comes to their attention involving actual or apparent infringements or misappropriations of Orion Patent Rights, Orion Know-How, GTX Patent Rights, GTX Know-How, or Trademarks by any Third Party, or claims of alleged infringement made by any Third Party in the GTX Territory against Orion, its Affiliates, or Orion Unaffiliated Sublicensees, GTX, its Affiliates, or GTX Unaffiliated Sublicensees, resulting from the manufacture, importation, marketing, sale or use of the Product in the Field.

12.4 INFRINGEMENT OF THIRD PARTIES RIGHTS BY ORION. Orion shall, at its sole discretion, direct or defend in its own name and at its own expense any legal or other action or proceeding, including any settlement or negotiation, with respect to any alleged infringement of a Third Party patent or other proprietary right as a result of Orion's, its Affiliates', or Orion Unaffiliated Sublicensees' manufacture of Toremifene or Orion Product for use in the Field, or the use or sale of Product in the Orion Field in the Orion Territory excluding actions and proceedings covered by Section 12.5. During the time any such proceeding or any appeal thereof is pending, Royalty Income payable by GTX under Section 3.1 in the country in which such proceeding is pending shall be paid by GTX into an interest-bearing escrow account pending the outcome of such proceeding. Upon a favorable final resolution of such proceeding or any appeal thereof, GTX shall resume paying Orion the full royalties in such country, and all funds in such escrow account shall be paid to Orion. Upon an unfavorable final resolution of such proceeding or any appeal thereof, the funds in such escrow account shall be applied toward the damage award in such action, if any, and the balance, if any, shall be paid to Orion. If Orion fails to defend such proceeding or discontinues the defense, all funds in such escrow account shall be returned to GTX and GTX shall have no further obligation to pay Royalty Income in such country.

12.5 INFRINGEMENT OF THIRD PARTIES RIGHTS BY GTX. GTX shall, at its sole discretion, direct or defend in its own name and at GTX's own expense in the GTX Territory any legal or other action or proceeding, including any settlement or negotiation, with respect to any alleged infringement of a Third Party patent, trademark or other proprietary right as a result of GTX's, its Affiliates', or GTX Unaffiliated Sublicensees' making, having made, importing, marketing, distributing, using or selling the Product in GTX Territory for use in the Field, excluding actions and proceedings covered by Section 12.4.

## 12.6 INFRINGEMENT INDEMNIFICATION.

12.6.1 ORION INFRINGEMENT INDEMNIFICATION. Orion shall indemnify, defend and hold GTX (including for purposes of this Section 12.6.1, GTX Affiliates and GTX

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Unaffiliated Sublicensees), its and their officers, directors, and employees, and permitted successors and assigns, harmless from and against any and all liabilities, damages, claims, demands, costs and/or expenses (including reasonable attorneys' fees) (collectively, "Losses") claimed by any Third Party in any patent or proprietary right infringement suit or action which may be brought as a result of Orion's, its Affiliates', or Orion Unaffiliated Sublicensees' manufacture of Toremifene or Orion Product, except to the extent such Losses arise out of claims for which GTX shall defend, indemnify and hold Orion harmless pursuant to Section 12.6.2, and further subject to the conditions of indemnification set forth in Section 15.7.

12.6.2 GTX INFRINGEMENT INDEMNIFICATION. GTX shall indemnify, defend and hold Orion (including for purposes of this Section, Orion's Affiliates and Unaffiliated Sublicensees) its and their officers, directors, and employees, and permitted successors and assigns, harmless from and against any and all Losses claimed by any Third Party in any suits or actions relating to patent, trademark or other proprietary right infringements as a result of GTX's, its Affiliates', or GTX Unaffiliated Sublicensees' making or having made, importing, marketing, using or selling the Product or Other Product under a Trademark in GTX Territory for use in the Field, except to the extent such Losses arise out of claims for which Orion shall indemnify, defend and hold GTX harmless pursuant to Section 12.6.1, and further subject to the conditions of indemnification set forth in Section 15.7.

12.7 TERMINATION FOR INFRINGEMENT OF THIRD PARTY RIGHTS. Should either Party be prevented by reason of an adverse, non-appealable court or administrative proceeding, order or judgment or arbitral award against it from manufacturing, making, using or selling the Orion Product and/ or Product in any country within the GTX Territory as required or permitted under this Agreement, then, as to such country so affected, the other Party may, upon sixty (60) days prior written notice thereof to the other Party, terminate this Agreement upon written notice to the other Party with respect to such country, and the Parties shall make a final transition accounting and settlement for outstanding bona fide costs, payments and expenses to which each Party is entitled hereunder with respect to such country.

12.8 THIRD PARTY INFRINGEMENT OF ORION PATENT RIGHTS.

12.8.1 ORION ENFORCEMENT. Orion shall have the first right but not the obligation, to commence, at its own expense, appropriate measures to enforce Orion Patent Rights [\*] against infringement by Third Parties relating to the manufacture, use, sale, offer for sale, or import of products containing Toremifene for use in the Field within a reasonable period of time after Orion becomes aware of such infringement (including, but not limited to, by notifying the infringing Third Party of such infringement and demanding that such Third Party cease and desist from such infringement). If such infringement does not cease, Orion shall have the right to commence a legal proceeding to enforce Orion Patent Rights, if any, against such Third Party infringements within a reasonable period of time of the date Orion becomes aware of such infringement. Orion shall notify GTX promptly after Orion becomes aware of such infringement, and, upon request therefor by GTX, keep GTX reasonably informed regarding Orion's intended strategy in such situation. Additionally, if within a reasonable period of time from the date GTX becomes aware of any alleged Third Party infringement of such Orion Patent Rights, either by notice from Orion or otherwise, Orion has not commenced a legal proceeding against such infringement, or if at any time Orion discontinues the pursuit of such proceeding,

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

GTX may, at its option, commence, continue or intervene, as the case may be, in such proceeding, provided, however, that with respect to any such proceedings in any country, GTX shall first request Orion to notify GTX whether any Third Party has a right to enforce the relevant Orion Patent Rights in the relevant countries, in which event Orion shall promptly respond to such request, and further provided that GTX' rights hereunder are subject and secondary to any rights that Orion has granted to any Third Party prior to the Restatement Date in such country with respect to enforcement of the relevant Orion Patent Rights. During the time any such proceeding or any appeal thereof is pending, no Royalty Income shall be payable under Section 3.1 in the country in which such proceeding is pending. Upon a favorable final resolution of such proceeding or any appeal thereof, GTX shall resume paying Orion the full royalties in such country, and GTX shall also be liable for payment of any back royalties payable for such period for which such a proceeding has been pending. Orion's commencement of such proceeding shall be at Orion's own expense, provided that Orion shall be entitled to retain all recoveries in such proceeding or any appeal thereof. Such commencement by Orion shall not relieve either Party of its obligations under Section 12.6.

12.8.2 GTX ENFORCEMENT.

(A) GTX shall have the first right but not the obligation, to commence, at its own expense appropriate measures to enforce United States Patent Nos. [ \* ] against infringement by Third Parties, within a reasonable period of time after GTX becomes aware of such infringement (including, but not limited to, by notifying the infringing Third Party of such infringement and demanding that such Third Party cease and desist from such infringement). If such infringement does not cease, GTX shall have the right to commence a legal proceeding to enforce said Orion Patent Rights, if any, against Third Party infringements within a reasonable period of time of the date GTX becomes aware of such infringement. GTX shall notify Orion promptly after GTX becomes aware of such infringement, and, upon request therefor by Orion, keep Orion reasonably informed regarding GTX's intended strategy in such situation. Additionally, if within a reasonable period of time from the date GTX becomes aware of any alleged Third Party infringement of said Orion Patent Rights, either by notice from Orion or otherwise, GTX has not commenced a legal proceeding against such infringement, or if at any time GTX discontinues the pursuit of such proceeding, Orion may, at its option, commence, continue or intervene, as the case may be, in such proceeding, provided, however, that with respect to any such proceedings in the USA, Orion's right to commence, continue, or intervene in such proceeding are subject to and secondary to any rights that GTX has granted to any Third Party prior to the Restatement Date in such country with respect to enforcement of the relevant patent rights. During the time any such proceeding or any appeal thereof is pending, no Royalty Income shall be payable under Section 3.1 in the country in which such proceeding is pending. Upon a favorable final resolution of such proceeding or any appeal thereof, GTX shall resume paying Orion the full royalties in such country, and GTX shall also be liable for payment of any back royalties payable for such period for which such a proceeding has been pending. GTX's commencement, continuation or intervention in such proceeding shall be at GTX's own expense, provided that GTX shall be entitled to retain all recoveries in such proceeding or any appeal thereof. Such commencement, continuation or intervention by GTX shall not relieve either Party of its obligations under Section 3.1 or 12.6.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# 12.9 THIRD PARTY INFRINGEMENT OF GTX PATENT RIGHTS; THIRD PARTY INFRINGEMENT OF TRADEMARKS AND THE TRADEMARK FARESTON(R).

12.9.1 GTX shall have the sole right, but not the obligation, at its own expense, to commence appropriate measures to enforce GTX Patent Rights and rights to Trademarks against Third Party infringements (including, but not limited to, notifying the infringing Third Party of such infringement and demanding that such Third Party cease and desist from such infringement) and, if such infringement does not cease, commence a legal proceeding to enforce such GTX Patent Rights or rights to Trademarks, if any, against Third Party infringements. GTX's commencement of such proceeding shall be at GTX's own expense, provided that GTX shall be entitled to retain all recoveries in such proceeding or any appeal thereof. Such commencement by GTX shall not relieve either Party of its obligations under Section 12.6.

12.10 MUTUAL COOPERATION. In the event of any infringement litigation in the GTX Territory involving the Product or Orion Product or any Orion Patent Rights or GTX Patent Rights or a Trademark, the non-prosecuting or non-defending Party shall render such reasonable assistance as may be requested by the prosecuting or defending Party in connection with such infringement actions. If Orion requests GTX's assistance in connection with such infringement claims or actions, Orion shall reimburse GTX for such direct, documented out-of-pocket expenses as are reasonably incurred by GTX during the course of it providing such requested assistance. If GTX requests Orion's assistance in connection with such infringement claims or actions, GTX shall reimburse Orion for such direct, documented out-of-pocket expenses as are reasonably incurred by Orion during the course of it providing such requested assistance. Before incurring such expenses, the Parties shall in good faith agree in writing on the nature and extent of assistance to be rendered, and an estimate of the total expenses, which expenses shall be monitored periodically.

### 12.11 PATENT CHALLENGES.

12.11.1 If GTX, its Affiliate, or GTX Unaffiliated Sublicensee, either directly or through a contractor or agent, challenges the validity of any Orion Patent Rights in any Major Country within the GTX Territory (other than in a Major Country that is a member of the European Union) and does not cease such challenge within thirty (30) days of receipt of written notice from Orion, then such challenge shall be deemed a material breach of this Agreement and Orion shall have the right to terminate this Agreement by written notice with immediate effect, at Orion's sole discretion, in its entirety or with respect to such country.

12.11.2 If Orion challenges the validity of any GTX Patent Rights in any Major Country in the GTX Territory (other than in a Major Country that is a member of the European Union) and does not cease such challenge within thirty (30) days of receipt of written notice from GTX, then such challenge shall be deemed a material breach of this Agreement and GTX shall be entitled to terminate this Agreement by written notice with immediate effect, at GTX's sole discretion, in its entirety or with respect to such country.

# 12.12 ACTIVITIES DURING INFRINGEMENT LITIGATION.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

12.12.1 In the event of any patent or trademark or other proprietary right infringement litigation involving the Product in GTX Territory in which GTX defends or prosecutes such litigation pursuant to Section 12.8 or 12.9, GTX may, at any time following one hundred eighty (180) days after the commencement of such litigation, request in writing that Orion suspend the manufacture of the Orion Product for use in the Field in the part of the GTX Territory so affected pending resolution of such litigation if GTX reasonably deems such action necessary or advisable to mitigate possible damages that may be incurred during the pendency of such litigation. If Orion elects not to comply with such request within thirty (30) days after receipt thereof, then all damages resulting from Orion's continued manufacturing of the Product for use in the Field in the part of the GTX Territory so affected (other than for the Orion Field in the Orion Territory) after Orion's receipt of such request shall be borne by Orion and be subject to Orion's indemnification obligation to GTX pursuant to Section 15.6.1.

12.12.2 In the event of any patent or trademark or other proprietary right infringement litigation involving the Product in the GTX Territory in which Orion defends or prosecutes such litigation pursuant to Section 12.8 or 12.9, Orion may, at any time following one hundred eighty (180) days after the commencement of such litigation, request in writing that GTX suspend the import, distribution, marketing, sale and use of the Product, and suspend Orion's manufacture and supply of Orion Product for GTX hereunder, in the part of the GTX Territory so affected pending resolution of such litigation if Orion reasonably deems such action necessary or advisable to mitigate possible damages that may be incurred during the pendency of such litigation. If GTX elects not to comply with such request within thirty (30) days after receipt thereof, then all damages resulting from GTX's continued importing, distribution, marketing, sale and use of the Product in the part of the GTX Territory so affected after GTX's receipt of such request shall be borne by GTX and be subject to GTX's indemnification obligation to Orion pursuant to Section 15.6.2. If GTX elects to comply with such request, such compliance shall be considered a suspension of GTX's marketing and sales obligations, notwithstanding Article 6.

12.12.3 In the event either Party receives a written claim of any alleged or actual infringement of a Third Party patent or trademark or other proprietary right as a result of Orion's, its Affiliate(s) or Unaffiliated Sublicensee(s') manufacturing of or selling Orion Product to GTX, or GTX, its Affiliates, or GTX Unaffiliated Sublicensees making, having made, marketing, using or selling the Product in GTX Territory for use in the Field, each Party shall so notify the other Party and the Parties shall confer regarding the basis for such claim, and discuss how the Parties may resolve the situation. Orion shall have the right to suspend its manufacture and supply of the Orion Product in and/or to the part of the GTX Territory so affected upon twenty (20) days prior written notice to GTX pending resolution of such claim or any related infringement litigation, if necessary to mitigate damages that may be incurred. If Orion exercises its rights hereunder, the Parties shall thereafter discuss from time to time whether the situation has been resolved and, accordingly, whether Orion is in a position to resume the supply of Orion Product pursuant to this Agreement.

# 13. COMPETING PRODUCTS

13.1 OBLIGATIONS WITH RESPECT TO COMPETING PRODUCTS.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

13.1.1 Beginning on the Effective Date and until the expiration of the last of the Orion Patent Rights on a country by country basis in the Major Countries, GTX and GTX Affiliates undertake not to market or sell a Competing Product in such country, excluding those countries of the Major Countries within the European Union, in which countries GTX and GTX Affiliates undertake not to market or sell any Competing Product for a period of five (5) years from the Amendment Date.

13.1.2 However, nothing contained in this Section 13.1 shall be construed as preventing either Party from conducting research and development activities relating to a Competing Product during such period or thereafter.

## 14. PRODUCT ORDERS, SUPPLY AND PAYMENTS

#### 14.1 ORION SUPPLY OBLIGATIONS.

14.1.1 PRODUCT SUPPLY. During the Term, Orion shall, subject to the terms of this Article 14 and Section 7.7, supply GTX and GTX Affiliates with their requirements of Orion Product. Orion shall supply the Product in bulk tablet form.

14.1.2 PRODUCT DELIVERY. Orion shall supply Orion Product to GTX only against receipt of GTX's written purchase orders. Except as otherwise provided herein or as otherwise expressly agreed in writing by the Parties, delivery shall be within ninety (90) days from receipt and confirmation by Orion of GTX's purchase order. Orion shall confirm the delivery dates within ten (10) business days after receipt of GTX's purchase orders and, subject to the provisions of Section 14.2, Orion shall use its best reasonable efforts to fill such orders on the requested delivery dates, but shall in any event fill such orders within ninety (90) days from receipt and confirmation of GTX's purchase order. Orion shall deliver Orion Product [ \* ] to a carrier designated by GTX (with the foregoing being interpreted to effect [ \* ]. GTX shall pay shipping costs and shall assume title to and risk of loss for Orion Product purchased hereunder after such delivery to GTX's designated carrier.

14.1.3 PRODUCT SHIPPING INSTRUCTIONS. GTX shall provide Orion with appropriate instructions for each shipment of Orion Product hereunder designating the desired carrier, destination and method of transport. If Orion becomes aware that the designated carrier is unable to accept the desired shipment within the requested delivery period, Orion shall promptly notify GTX and GTX shall promptly designate another carrier or carriers.

14.2 ORION AFFILIATES AND SUBCONTRACTORS. Orion may satisfy its supply obligations under this Agreement either directly or through any Orion Affiliate (provided that such Orion Affiliate has a manufacturing site which has received all required regulatory approvals and that Orion guarantees the performance of such Affiliate), and such supply by Orion Affiliates shall not be deemed an infringement of GTX's rights hereunder.

14.3 GTX FORECASTS.

14.3.1 ROLLING FORECASTS. Within ninety (90) days after the Restatement Date, GTX shall inform Orion in writing of GTX's bona fide, good faith estimated requirements of

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Fareston Product in the GTX Territory during the year 2005. Thereafter, for the remainder of the Term, GTX shall provide to Orion by September 30 of each year a purchase forecast of GTX's estimated requirements of Orion Product for the twenty four (24) month period beginning with October 1 of the then current year, allocated for each calendar month of such period, provided that if during any calendar year GTX expects to order Product from Orion to support the launch of Product for use in the Field but outside of the Breast Cancer Field, then not later than ninety (90) days prior to GTX's anticipated first order of Orion Product from Orion to support the launch of Product from Orion to support the launch of Product for such use, GTX shall update the most recently provided purchase forecast to include GTX's good faith estimated requirements of Orion Product to support such launch (if not already included in the then-applicable forecast). GTX shall update its purchase estimates to Orion on a monthly basis by indicating by the end of each month revised estimates or confirming that no revisions are necessary, which shall provide Orion with GTX's rolling twenty four (24) month forecasts.

14.3.2 EXCESS QUANTITIES. If GTX orders a quantity of Orion Product in excess of one hundred twenty-five percent (125%) of GTX's purchase forecast provided two (2) Calendar Quarters prior to such order, Orion shall deliver the quantity in excess of one hundred twenty-five percent (125%) up to one hundred fifty percent (150%) of such forecast within one hundred twenty (120) days from receipt and confirmation of GTX's purchase order. If GTX orders a quantity of Orion Product in excess of one hundred fifty percent (150%) of GTX's purchase forecast provided two (2) Calendar Quarters prior to such order Orion shall use commercially reasonable efforts to supply the quantity in excess of one hundred fifty percent (150%) up to two hundred percent (200%) of such forecast as soon as practical, but in no event later than one hundred eighty (180) days from receipt and confirmation of GTX's purchase order. If GTX orders a quantity of Orion Product in excess of two hundred percent (200%) of GTX's purchase forecast provided two (2) Calendar Quarters prior to such Order, Orion shall use commercially reasonable efforts to supply the quantities in excess of such forecast as soon as practical.

14.3.3 MINIMUM QUANTITIES. Of the amounts of Orion Product indicated by GTX in its rolling monthly forecasts, GTX shall purchase at least one hundred percent (100%) of its estimated requirement for Orion Product for the first three (3) months of such forecast, eighty percent (80%) of its estimated requirement of Orion Product for the fourth, fifth and sixth months of such forecast, and fifty percent (50%) of its estimated requirement of Orion Product for the seventh, eighth and ninth months of such forecast. All orders and deliveries of Orion Product shall be in full batch sizes of Orion Product, as determined by Orion from time to time. Orion shall notify GTX in writing prior to the date upon which GTX must provide its first commercial order of Orion Product is at such time.

14.4 PRICES AND PAYMENT.

14.4.1 COMMERCIAL PRICING FORMULA. Orion's annual price of bulk Orion Product to GTX, its Affiliates or its Unaffiliated Sublicensees for commercial purposes, delivered [  $\ast$  ] (with the foregoing being interpreted to effect [  $\ast$  ], shall be:

[\*]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

14.4.2 INVOICING AND PAYMENT. Orion shall invoice GTX for commercial orders of Orion Product shipped, and GTX shall pay such invoice within thirty (30) days of receipt.

14.4.3 PRICE CHANGES. GTX may, no more than once per year, request that Orion determine whether the average cost of the raw materials set forth in Schedule C used to manufacture Product during the immediately preceding year has, in the aggregate, changed by more than five percent (5%) of the average cost thereof that applied during the year immediately preceding the date that is one year earlier than the date of GTX's request (any such change, a "Significant Cost Change"). Reasonably promptly following any such request by GTX, Orion shall make such determination and notify GTX of the result of such determination. Additionally, if Orion determines that a Significant Cost Change has occurred (other than in response to such a request by GTX), it shall so notify GTX. If Orion determines that a Significant Cost Change has occurred upon GTX's request or upon Orion's own investigation, then the Parties shall (no more than once annually) adjust the price to reflect such Significant Cost Change. Such price shall apply to Orion Products purchased by GTX following the date of Orion's notice to GTX that a Significant Cost Change has occurred.

14.4.4 EXCEPTION. Notwithstanding the foregoing, GTX shall not owe Orion any payment pursuant to this Section 14.4 for any Product that is sold to a Third Party for development or commercialization of a [ \* ] as to which GTX owes Orion payments described in Section 3.1.6.

14.5 RESALE PRICES. GTX, its Affiliates and GTX Unaffiliated Sublicensees shall be free to set their own resale prices for the Product sold in the GTX Territory.

14.6 PRODUCT SUPPLY FOR TESTING AND REGISTRATION; SUPPLY OF TOREMIFENE.

14.6.1 PRODUCT SUPPLY FOR TESTING AND REGISTRATION. The supply price for the [ \* ] tablet of bulk Orion Product for clinical trials shall be [ \* ] per tablet. Orion shall supply GTX or its Affiliates with such quantities of [ \* ] tablets of bulk Product as GTX or its Affiliates may require of Orion Product and/or placebos for use in clinical trials of Products. The price for the [ \* ] tablet of bulk Orion Product for clinical trials shall be [ \* ] per tablet. Orion shall supply GTX with such quantities of [ \* ] tablets of bulk Product as GTX or its Affiliates may require of Orion Product and/or placebos for use in clinical trials of Products. The price for the [ \* ] tablet of bulk Product for clinical trials shall be [ \* ] per tablet. Orion shall supply GTX with such quantities as GTX or its Affiliates may require of [ \* ] tablet of bulk Product for clinical trials shall be [ \* ] per tablet. Orion shall supply GTX with such quantities as GTX or its Affiliates may require of [ \* ] tablets of Orion Product and/or placebos for use in clinical trials of Products. The price for a [ \* ] placebo for such clinical trials shall be [ \* ], per tablet. All Orion Product supplied for testing and registration pursuant to this Section 14.6 shall be provided in bulk packaging. Notwithstanding the foregoing, GTX shall not owe Orion any payment pursuant to this Section 14.6 for any Product that is sold to a Third Party for development or commercialization of a [ \* ] as to which GTX owes Orion payments described in Section 3.1.6.

14.6.2 SUPPLY OF TOREMIFENE. For the sole purpose of aiding GTX or its Affiliates in its efforts to obtain Regulatory Approval for the Product for use in the Field in the GTX Territory, Orion shall, during the Term, upon written order thereof by GTX, provide GTX, free of charge, with up to [ \* ] of Toremifene in bulk powder form (the "Powder"). GTX

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

undertakes to use such Powder only for studies necessary to support Regulatory Approval for Product for use in the Field, excluding the Orion Field in the Orion Territory. Upon ordering Powder from Orion, GTx shall provide Orion with a detailed description of such study(ies) and the expected amount of Powder needed for said study(ies).

As consideration for Orion's agreement to provide the Powder to GTX, all results, data, information, inventions, memoranda, reports, discoveries, work products and other results (including without limitation any patents(s) granted thereon), which are conceived, derived, reduced to practice, made and/or developed by or on behalf of GTX and arising out of or relating to the use of the Powder (hereinafter referred to as "Results") shall be jointly owned by GTX and Orion such that each Party shall have a one-half undivided interest in and to such results, without a duty of accounting to the other Party. Orion's interest in the Results, and any patent rights related thereto, shall be subject to the licenses granted to GTX pursuant to Section 2.1 to the extent such Results are included in the Orion Patent Rights or Orion Know-How. GTX hereby grants to Orion an exclusive, royalty-free, worldwide license with the right to grant sublicenses, under GTX's joint interest in the Results and any intellectual property rights relating thereto for use in developing, using, having used, selling, having sold, importing, marketing and distributing products outside of the Field and in the Orion Field in the Orion Territory Orion hereby grants to GTX an exclusive, royalty-free, worldwide license, with the right to grant sublicenses, under Orion's joint interest in the Results and any intellectual property rights relating thereto, for use in developing, using, having used, selling, having sold, importing, marketing and distributing products in the Field (excluding in the Orion Field in the Orion Territory), to the extent such rights are not otherwise included in the Orion Patent Rights or Orion Know-How licensed to GTX pursuant to Section 2.1.1.

Any use of the Results by GTX other than for the purposes of this Agreement shall not be permitted without the express written consent of Orion, which Orion may withhold at its sole discretion.

Without prejudice to the foregoing, the Results shall be deemed both Orion's and GTX's Confidential Information and shall be used and treated for purposes of Section 8 of this Agreement as Confidential Information of the other Party. GTX shall promptly disclose to Orion all Results immediately when such Results are available.

GTX and Orion shall mutually determine whether or not any of the Results provide the basis for any patentable inventions. If both Orion and GTX consider that patents for any such inventions involving Results should be sought, then such applications shall, in accordance with what has been stated herein above, be filed in the Parties' joint name, and the Parties shall share equally all costs of filing, prosecuting and maintaining relevant patent applications and patents. The Parties shall negotiate in good faith on the division of responsibilities with regard to drafting, filing, prosecuting and maintaining the relevant patent applications and patents. If the Parties do not decide that patent application(s) should be filed for any patentable inventions included in the Results, then the Results shall continue to be treated as Confidential Information of both Parties.

14.7 AGREEMENT TERMS GOVERN. Except as otherwise agreed in writing by the Parties, the terms and conditions of this Agreement shall govern Orion and its Affiliates' sale of

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Orion Product to GTX, its Affiliates and GTX Unaffiliated Sublicensees during the Term, notwithstanding any conflicting terms and conditions set forth in GTX's forecast, order or purchase documents or in Orion's sale or acceptance documents and any such conflicting terms are hereby expressly rejected.

14.8 PRICE ADJUSTMENT FOR COMMERCIAL SUPPLY. It is agreed upon by the Parties that the price of the [\*] tablet of Orion Product to GTX, its Affiliates or Unaffiliated Sublicensees shall be reduced below [\*] based upon attaining certain milestone purchases of Product as follows: if GTX purchases annually an aggregate amount of [\*] of tablet [\*] the price of the tablet shall be [\*] per [\*] tablet. Similarly, (i) the price to GTX of the [\*] tablet of Orion Product shall be reduced if GTX purchases annually [\*] of the [\*] tablets such that the price per [\*] tablet of Orion Product shall be [\*]. If a price adjustment is triggered under this Section 14.8, then the adjusted price shall apply to the entire amount of the relevant tablets purchased during the relevant year. Orion shall within thirty (30) days after the end of such year, pay to GTX an amount equal to the number of relevant tablets actually purchased during such year, multiplied by the difference between the price paid by GTX for supply of the relevant tablets and the lower price that is actually applicable due to the adjustment to be made pursuant to this Section 14.8.

14.9 TERMINATION OF PRODUCT SUPPLY. Orion shall, at its sole discretion, have the right upon providing [  $^{*}$  ] prior written notice thereof, to terminate its obligations under this Article 14 relating to the manufacture and supply of Orion Product and/or Toremifene (pursuant to Section 14.6.2) in the event that Orion permanently ceases the manufacture of Toremifene and/or Orion Product. For the avoidance of doubt, the right of termination relating to the manufacture and supply of Orion Product and/or Toremifene set forth in this Section 14.9 shall not restrict or alter Orion's rights under Section 7.7. In the event that Orion so terminates such obligations, Orion shall grant GTX a contingent license under the Orion Patent Rights, Orion Know-How and the Manufacturing Patents to make and have made Product for use in the Field in the GTX Territory (except for use of the Product in the Orion Field in the Orion Territory) during the Term, with such license to be exclusive in the Field (but excluding the Orion Field in the Orion Territory) and sublicensable (but only for the purpose of having Products manufactured for GTX, its Affiliates or Unaffiliated Sublicensees). Such license shall become effective upon GTX's receipt of notice from Orion under this Section 14.9. Orion shall during such [ \* ] notice period, and as soon as practically possible after GTX's written request, provide GTX with Product Manufacturing Know-How to the extent reasonably necessary to enable GTX to exercise its back-up manufacturing right pursuant to this Section 14.9, including without limitation providing up to ten (10) person-days of technology transfer assistance at GTX's site of manufacture of Product using Orion personnel skilled in such manufacturing operations, at no charge to GTX.

## 15. PRODUCT WARRANTIES AND INDEMNIFICATION

15.1 PRODUCT WARRANTIES AND LIMITATIONS.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

15.1.1 ORION WARRANTIES. Orion warrants and represents that the Orion Product manufactured by Orion, its Affiliate(s) or subcontractor(s), as the case may be, and delivered to GTX, its Affiliate(s) or GTX Unaffiliated Sublicensee(s) hereunder for resale shall (i) from the date of shipment until the end of the specified shelf-life conform to the Specifications (provided, however, that Orion Product has after shipment been handled and stored properly and been afforded sufficient protection against deterioration and damage) and shall have been manufactured in accordance with U.S. FDA Good Manufacturing Practices and equivalent Good Manufacturing Practices in Europe to the extent applicable to Orion, its Affiliates or subcontractors as the manufacturer(s) of Orion Product, and (ii) be transferred free and clear of any security interests, liens and encumbrances. It is expressly agreed that, except as expressly provided for in Section 11.2, no representation, warranty, commitment or obligations given, made or undertaken by Orion in this Agreement shall apply with regard to any Product manufactured by a party other than Orion, its Affiliates or subcontractors, including without limitation any Product manufactured by or on behalf of GTX under its stand-by and other manufacturing rights pursuant to Section 7.7, 14.9, 16.1, 17.3.2, 17.4 or 21.2.2.

15.1.2 LIMITATIONS. Except as otherwise expressly stated herein, no warranties or representations, express or implied are made or shall be deemed to have been made by Orion, its Affiliate or subcontractor including without limitation the warranties of fitness for a particular purpose and merchantability, regarding any Product, including without limitation the Orion Product and Other Product. Subject to Orion's warranty and indemnification obligations under this Agreement for Orion Product, Orion shall have no responsibility or liability for any Product, including without limitation Orion Product and Other Product manufactured by Orion and/or used, supplied, marketed, or sold by GTX, its Affiliates or GTX Unaffiliated Sublicensees.

15.2 CERTIFICATE OF ANALYSIS. Orion shall furnish GTX with one or more certificates of analysis for each batch of Orion Product supplied hereunder, in the form required by law in each country of GTX Territory where the Orion Product is marketed, with shipment of each such batch.

#### 15.3 PRODUCT INSPECTIONS.

15.3.1 GTX INSPECTION AND ANALYSIS. GTX shall inspect and analyze a representative sample of Orion Product from batches supplied by Orion promptly after receipt. If, after inspection, GTX reasonably believes the shipment does not meet the Specifications, GTX shall notify Orion in writing within thirty (30) days after GTX's receipt of any such goods. If GTX does not so notify Orion, GTX shall be deemed to have waived all claims against Orion for said quantity delivered, except for any latent defects that could not have been reasonably discovered upon such inspection, which defects shall be notified by GTX to Orion within fourteen (14) days from discovery of same. Any claims by GTX regarding goods delivered shall specify in reasonable detail the nature and basis for the claim and cite relevant Orion lot numbers or other information to enable specific identification of the goods involved. GTX shall not be required to accept Orion Product having a shelf life of less than eighty percent (80%) of the stated expiration dating on the date of shipment by Orion.

15.3.2 ORION RESPONSE. Orion shall respond to all claims made by GTX on a case-by-case basis and Orion shall have the right to first inspect any goods involved before being

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

required to take any action with respect thereto. Orion shall review any such claim of nonconformity made by GTX within thirty (30) business days of receipt of GTX's notice under Section 15.3.1 and conduct any required testing of the goods involved as soon as possible, but in no event later than forty-five (45) days after receipt thereof, or earlier if the U.S. FDA or any corresponding regulatory authority in the GTX Territory requires an earlier response from Orion. If such review and testing by Orion (or testing by an independent laboratory as set forth below) confirms that a claimed quantity does not meet the Specifications, then, at Orion's expense, GTX shall dispose of or return such quantity involved as Orion shall direct in writing and Orion shall replace such quantity with conforming goods as soon as possible, but in no event later than sixty (60) days after testing is completed, which shall be GTX's sole and exclusive remedy for such non-conformity. If the Parties fail to agree as to whether a delivered quantity meets the Specifications, then the Parties shall have the batch in dispute analyzed by a mutually agreed upon independent testing laboratory located in the country in which Orion Product to which goods relate is intended for resale, or, if the Parties agree, in Finland. Such laboratory's determination shall be deemed final as to any dispute over the Specifications and the nonprevailing Party shall bear the costs of such independent laboratory's testing.

15.4 PRODUCT STORAGE. Each Party shall properly store Orion Product under conditions that will not adversely affect the quality or normal shelf life thereof.

# 15.5 GTX RESPONSIBILITIES IN GTX TERRITORY.

15.5.1 LABELING. GTX shall be responsible for packaging of the Product, and for all labeling, inserts, packaging and promotional materials and any other materials which accompany, are distributed, used or referred to in any way by GTX, its Affiliate(s) or GTX Unaffiliated Sublicensee(s) in connection with the Product and GTX shall ensure that same shall conform to all legal requirements in each country of the GTX Territory in which the Product is sold. Subject to applicable legal and regulatory requirements and space limitations, all Product labeling, packaging, inserts and promotional materials shall indicate that the Product is marketed by GTX. GTX shall, upon written request therefore by Orion, provide Orion with copies of representative samples of materials which GTX, its Affiliates and GTX Unaffiliated Sublicensees intend to use in connection with the marketing, promotion and sale of the Product thirty (30) days prior to their first use thereof, provided that nothing herein or otherwise, including without limitation any request by Orion to be furnished with such materials or review of same, shall be construed as Orion assuming any liability or responsibility for such materials or their conformity to all legal requirements in any country of the GTX Territory in which the Product is sold and such request and/or review by Orion of such materials shall be without prejudice to the first sentence of this Section 15.5. GTX, its Affiliates, or GTX Unaffiliated Sublicensee shall register, promote, market and sell the Product in the GTX Territory only for the indications for which relevant Regulatory Approvals have been obtained and only in accordance with applicable legal and governmental authority requirements.

15.5.2 NOTIFICATION. GTX shall also be responsible for notifying, reporting or registering this Agreement or the business relationship created hereby with any government authorities in the GTX Territory to the extent legally required. Orion shall provide GTX with such assistance as GTX may reasonably request in connection therewith.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

#### 15.6 RECIPROCAL INDEMNIFICATION PROVISIONS.

15.6.1 ORION INDEMNIFICATION. Orion shall defend, indemnify and hold GTX, its Affiliates, GTX Unaffiliated Sublicensees, and its and their officers, directors and employees, harmless from and against any and all liabilities, damages, claims, demands, costs, or expenses (including reasonable attorneys' fees) Losses claimed by any Third Party for any property or other economic loss or damage or injury or death suffered by it to the extent the same is determined to have been caused by (A) the negligence, fault, willful wrongdoing or any other act or omission in relation to the manufacture by Orion, its Affiliates or subcontractor(s) of the Orion Product, or a material breach of this Agreement by Orion, its Affiliate(s) or Unaffiliated Sublicensee(s), or (B) or a breach by Orion of the warranties set forth in Section 15.1 and/or 20.1(i), or (C) the manufacture, use, sale, importation, distribution and/or marketing of the Product for use in the Orion Field and in the Orion Territory by Orion, its Affiliates or Unaffiliated Sublicensees, except with respect to each of (A) and (B) to the extent that such Losses are caused by activities for which GTX must defend, indemnify and hold harmless pursuant to Section 15.6.2.

15.6.2 GTX INDEMNIFICATION. GTX shall defend, indemnify and hold Orion, its Affiliates, and its and their the officers, directors and employees harmless from and against any and all Losses claimed by any Third Party for any property or other economic loss or damage, injury or death suffered by it to the extent the same is determined to have been caused by (A) a breach by GTX of [ \* ]; (B) the negligence, fault, willful wrongdoing or any other act or omission, or material breach of this Agreement by GTX, its Affiliates or Unaffiliated Sublicensees; (C) the manufacture, use, sale, importation, distribution, and/or marketing of the Product by GTX, its Affiliates or Unaffiliated Sublicensees in the Field in the GTX Territory, including without limitation any product liability claim for property or other economic loss or damage, injury or death suffered by a Third Party arising out of or relating to the Product or Other Product or use thereof, except with respect to each of (B) and (C) to the extent that such Losses are caused by activities for which Orion must defend, indemnify and hold harmless GTX pursuant to Section 15.6.1.

15.7 CONDITIONS FOR INDEMNIFICATION. With respect to any indemnification obligations of either Party to the other Party under this Agreement, the following conditions must be met for such indemnification obligations to become applicable: (A) the indemnified Party shall notify the indemnifying Party promptly in writing of any claim which may give rise to an obligation on the part of the indemnifying Party hereunder; (B) the indemnifying Party shall be allowed to timely undertake the sole control of the defense of any such action and claim, including all negotiations for the settlement, or compromise of such claim or action at its sole expense; and (C) the indemnified Party shall render reasonable assistance, information, cooperation and authority to permit the indemnifying Party to defend such action, it being agreed that any out-of-pocket expenses or other expenses incurred by the indemnified Party in rendering the same shall be borne or reimbursed promptly by the indemnifying Party. Neither Party shall consent to the entry of any judgment or settle or otherwise compromise any such action or suit in a way that adversely affects the other Party's intellectual property rights or other rights, obligations or interests with respect to Products, or imposes obligations on such other Party, without such other Party's prior written consent.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

15.8 LIABILITY INSURANCE. GTX shall procure and maintain insurance, including product liability insurance, adequate to cover its obligations hereunder and which are consistent with normal business practices of prudent companies commercializing products of similar nature that present similar liability risks. It is understood that such insurance shall not be construed to create a limit of GTX's liability with respect to its any of its obligations hereunder, including without limitation its indemnification and compensation obligations under this Agreement. GTX shall provide Orion with written evidence of such insurance (including without limitation financial information that describes the amounts available under such insurance) upon request. This Section 15.8 shall survive the termination expiration of this Agreement for ten (10) years for whatsoever reason.

# 16. STANDBY MANUFACTURING RIGHTS; INVENTORY MAINTENANCE

16.1 INABILITY TO MANUFACTURE OR SUPPLY. If Orion is unable to supply or manufacture Orion Product, as ordered pursuant to Sections 14.1.2 and 14.3.2, for ninety (90) or more consecutive days after the agreed delivery time for any reason (including but not limited to a Force Majeure event), save as for reasons arising from acts or omissions of GTX, its Affiliates and/or its Unaffiliated Sublicensees, including without limitation failure by GTX, its Affiliates and/or its Unaffiliated Sublicensees to notify Orion of Orion's failure to deliver Orion Product ordered pursuant to Sections 14.1.2 and 14.3.2, then GTX may, at its option, responsibility and expense, elect to manufacture or have a Third Party manufacture Toremifene and/or Orion Product for use in manufacturing and selling the Product for use in the Field anywhere in the GTX Territory (except for use in the Orion Field in the Orion Territory) until such time as Orion can demonstrate to GTX's reasonable satisfaction that Orion is capable of resuming the manufacture of Toremifene and/or Orion Product, as applicable. To the extent necessary to implement such standby manufacturing rights, Orion hereby grants GTX a contingent license under the Orion Patent Rights, Orion Know-How and Manufacturing Patents to make and have made Toremifene and/or Orion Product for use in the Field in the GTX Territory (except for use in the Orion Field in the Orion Territory). Such license shall be exclusive and sublicensable (but only for the purpose of having Products manufactured for GTX, its Affiliates or Unaffiliated Sublicensees), with such license to become effective only under the circumstances specified in the preceding sentence. In such case, Orion shall as soon as practically possible provide GTX with Product Manufacturing Know-How to the extent reasonably necessary to enable GTX to exercise its back-up manufacturing right pursuant to this Section 16.1, including without limitation providing up to ten (10) person-days of technology transfer assistance at GTX's site of manufacture of Product using Orion personnel skilled in such manufacturing operations, at no charge to GTX. Orion shall promptly notify GTX in writing of any circumstances rendering it unable to manufacture Product and the estimated duration of such circumstances. GTX's standby-manufacturing rights under this Section 16.1 shall be GTX's sole and exclusive remedy for Orion's failure to manufacture or have manufactured Orion Product for supply to GTX under Article 14.

16.2 BACK-UP MANUFACTURING RIGHT. GTX shall have the right to require Orion to qualify and maintain the qualification for, at GTX's expense (as described below), a back-up facility(ies) for use in manufacturing Product for supply to GTX pursuant to Article 14 at any time after GTX's good faith forecasted Net Sales of Products provided pursuant to Section 14.3 [\*] in a given Year, or actual Net Sales for Product in any given Year [\*]. GTX shall exercise

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

such right by written notice to Orion. Promptly after receiving such notice, Orion and GTX shall meet to discuss the manner in which Orion proposes to qualify and maintain the qualification for such back-up manufacturing facility(ies) (for example, by qualifying a site owned by Orion or by engaging a Third Party manufacturer to qualify another facility), the timing for qualifying such facility(ies), and Orion's estimated costs incurred directly in connection with qualifying such facility(ies) (which costs may include, by way of example, Orion's costs of obtaining Regulatory Approvals necessary to enable the sale in the Territory of Product manufactured at such site). Orion shall promptly thereafter, subject to agreement on reimbursement by GTX of Orion's related costs and expenses, qualify such back-up facility and maintain the qualification for such facility (including obtaining relevant Regulatory Approvals and making appropriate regulatory filings) to assure continued supply of Product in the event Orion is unable to supply Products in the amounts ordered pursuant to Article 14. GTX shall reimburse Orion for [ \* ] or [ \* ] the Parties. Nothing in this Section 16.2 shall be deemed to limit Orion's obligations under Article 14, or to prevent GTX from seeking any remedies available to it under law or in equity for any breach by Orion under such Sections.

16.3 MAINTENANCE OF INVENTORY. Orion shall, at all times during the Term, maintain or have maintained, either itself or through a subcontractor, an amount of Toremifene and other raw materials critical for the manufacture of Products containing such Toremifene sufficient to manufacture the amount of Product forecasted to be ordered by GTX pursuant to Section 14.3 during the subsequent [\*] period of time. The Parties will agree upon an appropriate amount of reserve supplies to be maintained by Orion during the first [\*] following the First Commercial Sale of Product in the Prostate Cancer Field at the time GTX provides an update to its forecasted requirements to support launch of Product in such field pursuant to Section 14.1. Such supplies shall serve as a reserve supply to be used by Orion solely to manufacture Product for GTX if any shortfall in the amount of Product supplied by Orion pursuant to Article 14 occurs or is reasonably anticipated to occur. Nothing in this Section 16.3 shall be deemed to limit Orion's obligations under Article 14.

# 17. MANUFACTURING INSPECTIONS AND CHANGES

17.1 REGULATORY INSPECTIONS. Each Party shall allow representatives of the U.S. FDA and any other regulatory agency or authority with jurisdiction over the manufacture, marketing and distribution of the Product to tour and inspect all facilities utilized by such Party in the manufacture, testing, packaging, storage, and shipment of Product sold under this Agreement, and shall co-operate with such representatives in every reasonable manner. Upon notification by the U.S. FDA or any other regulatory agency of such agency's intent to conduct an inspection, the Party receiving such notification will immediately inform the other Party of such inspection with such advance notice as to allow the other Party to have representatives present during such inspection (to the extent such presence is allowed by such regulatory agency). Each Party shall also provide the other Party with a copy of any U.S. FDA Form 483 notices of adverse findings, regulatory letters or similar notifications it receives from any other governmental authority setting forth adverse findings or non compliance with any applicable laws, regulations or standards relating to the Product within five (5) days of its own receipt thereof. Each Party shall also provide the other Party with a copy of is proposed written response to such governmental authority before submission and shall incorporate any changes thereto which the other Party may reasonably request.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

17.2 ORION-INITIATED MANUFACTURING CHANGES. Save as for changes required under applicable laws and regulations or by any competent regulatory or other authority, during the Term, Orion shall not make any material changes to its manufacturing operations for Toremifene or Orion Product to be supplied to GTX pursuant to this Agreement, without informing GTX prior to such changes; provided that if such changes would require GTX to make additional filings with regulatory authorities or to seek additional Regulatory Approvals for Orion Product, then Orion shall not make such change withhout GTX's prior written consent, such consent not to be unreasonably withheld, conditioned or delayed.

## 17.3 GTX-INITIATED MANUFACTURING CHANGES.

17.3.1 GTX REQUEST FOR MANUFACTURING CHANGES. Prior to Orion providing GTX with notice pursuant to Section 14.9, GTX may, from time to time during the Term and as agreed in this Section 17.3, make a written and detailed request for changes in Orion's manufacturing operations, or the Specifications, for Toremifene or Orion Product. Such changes that are required and mandatory under applicable laws and regulations in a Major Country shall be deemed "Required Manufacturing Changes", and such changes that are intended to promote quality control/quality assurance, and/or to achieve greater efficiency or cost savings in the manufacturing Changes".

17.3.2 REQUIRED MANUFACTURING CHANGES. Provided that GTX furnishes Orion with evidence of Required Manufacturing Changes, Orion shall commence the implementation of Required Manufacturing Changes as soon as practicable, but in no event later than (i) ninety (90) days after receipt of GTX's request (or within such other longer time period as may be mutually agreed upon by the Parties if implementation within ninety (90) days is impossible or reasonably impractical, such agreement not to be unreasonably withheld, conditioned or delayed by GTX) or (ii) earlier if required by the U.S. FDA or any corresponding regulatory authority in a Major Country. If Orion does not commence the implementation of Required Manufacturing Changes within the time period referenced in the preceding sentence or does not notify GTX in writing that Orion disputes whether GTX's requested changes are Required Manufacturing Changes, then GTX shall have the option to exercise standby manufacturing rights for Toremifene and Product pursuant to Section 16.1 until such time as Orion implements such Required Manufacturing Changes. If Orion notifies GTX in writing that Orion disputes whether GTX's requested changes are Required Manufacturing Changes, the Parties shall resolve such dispute by reference to a mutually agreed upon independent Third Party regulatory expert as soon as possible for a binding determination of whether the requested changes are Required Manufacturing Changes. If such independent Third Party regulatory expert determines that GTX's requested changes are Required Manufacturing Changes, Orion shall implement such changes as soon as possible. Any modification to the Specifications that is necessary to implement or reflect a Required Manufacturing Change shall be deemed to be included in the Specifications, and any Products manufactured thereunder by Orion shall be deemed Orion Products.

17.3.3 OTHER MANUFACTURING CHANGES. Orion shall give due consideration to making Other Manufacturing Changes proposed by GTX. Orion shall within sixty (60) days from receipt of GTX's written request for Other Manufacturing Changes provide GTX a written

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

response to such request indicating whether it would be willing to discuss, and as appropriate, negotiate the terms and conditions under which Orion would be willing to implement such Other Manufacturing Changes.

17.4 NEW DOSAGE STRENGTHS AND FORMULATIONS. Upon written request by GTX, the Parties shall meet in person or by teleconference to discuss, and as appropriate, negotiate the terms under which Orion would be willing to manufacture and supply to GTX any dosage strengths or formulations of the Product other than those that are available as an Orion Product as of the Restatement Date (including without limitation any combination Product containing Toremifene and another active ingredient) or any Product otherwise having specifications different from Orion Product Specifications (such Products, collectively "Other Product(s)"), as provided in this Section 17.4.

The Parties shall conduct such discussions during a sixty (60) day period following GTX's written request setting forth in sufficient detail the changes proposed by GTX, or any mutually agreed extension of such time period ("Evaluation Period"). If Orion would be willing to manufacture such Other Product, Orion shall within the Evaluation Period notify GTX of the terms and conditions under which it would be willing to do so, and the Parties shall negotiate a written amendment to this Agreement to include the applicable terms and conditions under which Orion would manufacture and supply such Other Product, including without limitation the supply price of such Other PRODUCT. Upon execution of such amendment, such Other Product shall be deemed to be an Orion Product. Such negotiation shall be conducted for up to one hundred twenty (120) days following GTX's receipt of Orion's notice of such terms and conditions ("Negotiation Period"). It is expressly agreed that Orion shall have no obligation to manufacture and supply any Other Product unless a mutually acceptable definitive written amendment to this Agreement, if any, in relation to such Other Product is executed by duly authorized representatives of both Parties.

In the event Orion notifies GTX within the Evaluation Period that it will not be interested in supplying such Other Product, or the Parties do not amend this Agreement during the Negotiation Period to specify applicable terms for, or execute another agreement governing, Orion's supply of such Other Product for use in the Field (other than use in the Orion Field in the Orion Territory), then if GTX has a good faith basis for requiring supply of such Other Product, including but not limited to its desire to develop a dosage strength of Product other than one which is in clinical development by or on behalf of GTX as of the Restatement Date and in which an Orion Product is available, or a formulation of Product that incorporates a new technology or another active ingredient in order to optimize the pharmacokinetic properties of Product, improve the competitive position of Product in the market, or to increase the efficiency or safety of Products, GTX shall have the right to manufacture, or engage a Third Party subcontractor to manufacture, such Other Product for sale and use in the Field only. GTX shall exercise such right to manufacture or have manufactured an Other Product for sale and use in the Field (except for use in the Orion Field in the Orion Territory) pursuant to this Section 17.4 in good faith only, and not for the purpose of obtaining the right to manufacture Product by, for example, proposing minor changes to the Product formulation that do not present a commercially reasonable basis for development. To the extent reasonably necessary to implement such manufacturing right, Orion hereby grants GTX a contingent license under Orion's Patent Rights, Orion Know-How, Manufacturing Patents, and Product Manufacturing Know-How to make and

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

have made the relevant Other Product for use in the Field in the GTX Territory (except for use in the Orion Field in the Orion Territory). Such license shall be exclusive and sublicensable but only for the purpose of having Products manufactured for GTX, its Affiliates and Unaffiliated Sublicensees), and shall become effective only under the circumstances specified in this Section 17.4.

# 18. PRODUCT RECALLS

18.1 RECALL NOTIFICATION. Each Party shall promptly notify the other Party in writing of any facts relating to the advisability of the recall, destruction or withholding from the market of the Product anywhere in the GTX Territory (any of the foregoing, a "Recall").

18.2 RECALL IMPLEMENTATION IN GTX TERRITORY. If at any time (A) any governmental or regulatory authority in the GTX Territory issues a request, directive or order for a Recall; (B) a court of competent jurisdiction orders a Recall in the GTX Territory; or (C) GTX determines, following consultation with Orion (except in emergency situations in which there is insufficient time for such consultation), that a Recall in the GTX Territory is necessary or advisable, GTX shall take all appropriate corrective actions to effect the Recall and Orion shall provide GTX with such cooperation in connection with the Recall as GTX may reasonably request.

18.3 RECALL COSTS AND EXPENSES IN GTX TERRITORY. GTX shall bear the costs and expenses of any Recall in the GTX Territory, provided that Orion shall bear all costs and expenses of any Recall in the GTX Territory to the extent such Recall is the result of a breach in the warranties set forth in Section 15.1.

# 19. ADVERSE DRUG EXPERIENCES

19.1 ADVERSE EVENTS AND SERIOUS ADVERSE EVENTS.

(A) To ensure that all relevant safety information for Toremifene is shared between the Parties, the following information will be exchanged: (i) GTX will provide to Orion all regulatory safety updates (e.g. 120-day safety updates, annual reports, and post-authorization safety updates) concerning Product and information regarding all serious adverse events from clinical studies and all spontaneous adverse reactions, including reports from literature concerning the Product coming to the knowledge of GTX; and (ii) Orion will provide to GTX Periodic Safety Update Reports prepared in accordance with ICH E2C or equivalent guidelines as adopted by the European Medicines Evaluation Agency (EMEA) relevant to Product for use in the Orion Field in the Orion Territory, and information regarding all serious adverse events from clinical studies and all spontaneous adverse reactions, including reports from literature concerning Product, coming to the knowledge of Orion. All of the above mentioned safety information shall be exchanged reasonably in advance of any applicable regulatory deadlines or upon release of such information. In addition, any safety information which may negatively affect the benefit-risk ratio of Products or that may have consequences regarding the product information (e.g. labeling, data sheets, instruction leaflets) or may require immediate safety measures to be taken by either Party shall be forwarded to the other Party without any delay. Each Party is responsible for any regulatory safety reporting requirements

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

with respect to maintaining its own Regulatory Approval applications and complying with regulatory requirements for Products that it has the right to sell pursuant to this Agreement according to applicable laws, rules and regulations.

(B) The intent of Section 19.1(a) is to enable each Party to comply with regulatory requirements for Toremifene products, which requirements may change from time to time. Concurrently with the execution of this Agreement, the Parties shall execute an agreement setting forth a mutually acceptable detailed procedure generally consistent with the intent of Section 19.1(a) that enables each Party to comply with such regulatory requirements with respect to such Products. Under such agreement, from time to time after the Restatement Date, the Parties shall meet upon request by either Party to discuss and agree upon any modifications to such detailed procedure necessary to ensure that each Party is in compliance with regulatory reporting requirements for Products that it has the right to develop and sell pursuant to this Agreement.

This Article 19 shall survive the expiration or termination of this  $\ensuremath{\mathsf{Agreement}}$  .

## 20. REPRESENTATIONS AND WARRANTIES

20.1 REPRESENTATIONS AND WARRANTIES OF THE PARTIES. Each Party hereby represents and warrants to the other Party as follows:

 (A) CORPORATE STATUS. It is a corporation duly organized and validly existing under the laws of its state or other jurisdiction of incorporation or formation;

(B) AUTHORITY. It has the power and authority to execute and deliver this Agreement, and to perform its obligations hereunder;

(C) NO CONFLICTS. The execution, delivery and performance by it of this Agreement and its compliance with the terms and provisions hereof does not and will not conflict with or result in a breach of any of the terms and provisions of or constitute a default under (i) any loan agreement, guaranty, financing agreement, agreement affecting a product or other agreement or instrument binding or affecting it or its property; (ii) the provisions of its charter documents or by-laws; or (iii) any order, whit, injunction or decree of any court or governmental authority entered against it or by which any of its property is bound;

(D) NO APPROVALS. Except for the regulatory filings and approvals for the Product referenced herein, no authorization, consent or approval of any governmental authority or Third Party is required for the execution, delivery or performance by it of this Agreement, and the execution, delivery or performance of this Agreement will not violate any law, rule or regulation applicable to such party;

(E) ENFORCEABILITY. This Agreement has been duly authorized, executed and delivered and constitutes its legal, valid and binding obligation enforceable against it in accordance with its terms subject, as to enforcement, to bankruptcy, insolvency, reorganization and other laws of general applicability relating to or affecting creditors' rights and to the availability of particular remedies under general equity principles;

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

(F) COMPLIANCE WITH LAWS. It shall comply with all applicable local, state, national, regional and governmental laws and regulations relating to its activities under this Agreement; and

(G) NEGATIVE DATA OR INFORMATION. It has, to the best of its management's knowledge, no knowledge of negative data or information regarding the Product, which, to the best of its reasonable belief, would have a material effect on the regulatory approval process and/or on the commercialization of the Product in the Field.

(H) NO DEBARMENT. It has not been and will not be debarred under Section 306 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. 335a(a) or (b). In the event that such Party becomes aware of, or receives notice of, the debarment of any individual, corporation, partnership, or association performing activities which relate to the Products, it shall notify the other Party immediately and address the issue as directed by the other Party.

(I) NO IMPROPER CONTENT ON FARESTON U.S. WEB PAGES. It has not and will not place any links or information on the Fareston U.S. Web Pages pursuant to Article 9 that would: (A) infringe on the intellectual property rights of any Third Party; (B) violate any law, statute, ordinance or regulation; (C) be defamatory, trade libelous, unlawfully threatening or unlawfully harassing; or (D) contain any viruses or other computer programming routines that damage, detrimentally interfere with, surreptitiously intercept or expropriate any system, data or personal information.

20.2 REPRESENTATION BY ORION. Orion hereby represents and warrants to GTX that:

(A) As of the Restatement Date, Orion has entered into the Fareston Repurchase Agreement pursuant to which Orion has terminated its agreement with Shire dated 6 September, 1999, as amended, under which Shire had been granted licenses or other rights to develop and/or commercialize Products in the USA in the Breast Cancer Field.

 $$20.3\ REPRESENTATION$  BY GTX. GTX hereby represents and warrants to Orion that:

(A) As of the Restatement Date, GTX has acquired sufficient rights and licenses from The University of Tennessee Research Foundation to the patent applications included in the GTX Patent Rights that are listed in Part II of Schedule A that are necessary for the purpose of performing its obligations under this Agreement.

21. TERM AND EARLY TERMINATION RIGHTS

 $\ensuremath{\text{21.1}}$  TERM. The Term shall extend for the period provided in Section 1.51.

21.2 TERMINATION FOR CAUSE. Either Party shall have the right, without prejudice to any other rights or remedies available to it, either to terminate this Agreement or the license rights granted to a Party under this Agreement on a country-by-country basis for cause as described in this Section 21.2 as follows:

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

21.2.1 BANKRUPTCY. Either Party shall have the right to terminate this Agreement and same shall terminate upon expiry of a sixty (60) days notice period, if the other Party becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, or in the event an involuntary bankruptcy action has been omitted and filed separately against the other Party and not dismissed within ninety (90) days, or if the other Party becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business.

21.2.2 MATERIAL BREACH. If either Party commits a material breach of this Agreement and if the Party alleged to be in breach of this Agreement fails to (i) cure such breach or (ii) commence bona fide dispute resolution proceedings under Section 25.2 contesting whether a breach has occurred and/or whether such breach is a material breach, in either case within sixty (60) days after receipt of written notice from the Party asserting the breach, then the Party asserting the breach may terminate this Agreement in its entirety (if such breach is a material breach, other than as specified in Sections 6.4.2 and 12.11.1 or 12.11.2), or, if such breach is by GTX and is described in Section 6.4.2 or in Section 12.11.1, then Orion may terminate its supply obligations as set forth under Article 14 and terminate the license granted to GTX pursuant to Section 2.1, in each case with respect to the Major Country in relation to which such material breach occurred under Section 6.4.2 or 12.11.1. If the Agreement is terminated either in its entirety or with regard to a particular Major Country, as the case may be, then if GTX is the breaching Party, GTX shall grant to Orion a nonexclusive, royalty-bearing license, with the right to grant sublicenses, under the GTX Patent Rights, the Trademarks, the Regulatory Approvals (by means of assignment or transfer of, or authorization to cross-reference, relevant Regulatory Approval(s)) and the GTX Know-How to make, have made, develop, use, sell, offer for sale, market and promote, and import Products in the country(ies) in which GTX's license terminates, or, if Orion is the breaching Party, then the license granted to GTX shall be expanded to include an exclusive, sublicensable license under the Orion Patent Rights, Orion Know-How, and Manufacturing Patents to make and have made Products for use in the Field in the GTX Territory, (except for use in the Orion Field in the Orion Territory). In the event of termination of the Agreement due to Orion's breach, Orion shall as soon as practically possible provide GTX with Product Manufacturing Know-How to the extent reasonably necessary to enable GTX to exercise its manufacturing right pursuant to this Section, including without limitation providing up to ten (10) person-days of technology transfer assistance at GTX's site of Manufacture or Product using Orion personnel skilled in such manufacturing operations, at no charge to GTX.

(A) If the non-breaching Party obtains a license under this Agreement as provided in Section 21.2.2, it shall pay to the other Party a running royalty equal to [\*] of Net Sales of Product by the non-breaching Party, its Affiliates or Unaffiliated Sublicensees. Furthermore, if GTX is the breaching Party, GTX shall promptly transfer to Orion, at GTX's expense, all Regulatory Approvals and registration filings for the Product in the territory in which Orion obtains such license, together with such documentation, information and data in its possession as Orion may need for regulatory compliance in the course of exercising its rights in such territory with respect to Product.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

21.3 TERMINATION BY MUTUAL AGREEMENT. The Parties may terminate this Agreement at any time by drafting and executing a mutually acceptable written agreement. The written agreement shall specify the consequences of such termination.

21.4 TERMINATION BY GTX FOR SAFETY OR EFFICACY REASONS. If at any time during the Term: (i) GTX decides not to file an application for Regulatory Approval in any country or decides to withdraw such application due to documented adverse reactions or other safety issues with the Product or the Product's lack of efficacy or limited efficacy (collectively, "Safety or Efficacy Issues"); (ii) GTX's application(s) for Regulatory Approval in any country is rejected due to Safety or Efficacy Issues; (iii) GTX's application(s) for Regulatory Approval in any country is subsequently withdrawn because of Safety or Efficacy Issues; or (iv) the Product is withdrawn or recalled from the market in any country because of Safety or Efficacy Issues, then GTX may, at its option, terminate this Agreement with respect to such country upon thirty (30) days prior written notice to Orion. GTX must exercise this right of termination within the later of (a) sixty (60) days of the occurrence of the event giving rise to such right or (b) thirty (30) days of GTX's last meeting, if any, with the relevant regulatory authorities, provided that GTX uses reasonable diligence to schedule such meeting and that Orion is providing reasonable co-operation to GTX in connection with such meeting. GTX may, at its option, exercise its right of termination under this Section 21.4 on a country-by-country basis, and, if GTX does so, GTX's termination notice shall specify the country or countries of the GTX Territory affected. GTX shall transfer to Orion, at Orion's expense, all Regulatory Approvals and registration filings for the Product in the country for which it terminates its license, together with such documentation, information and data in its possession as Orion may need for regulatory compliance in the course of any further development of Product in such country Orion may elect to conduct thereafter.

21.5 EFFECT OF TERMINATION. Termination or expiration of this Agreement through any means and for any reason shall not relieve the Parties of any obligations accruing prior thereto and shall be without prejudice to the rights and remedies of either Party with respect to any prior breach of any of the provisions of this Agreement.

# 22. NOTICES

22.1 MANNER OF GIVING NOTICES. All notices required or permitted in connection with this Agreement shall be writing and may be given by personal delivery, prepaid registered or certified airmail letter, courier, facsimile, addressed to the Party to receive the same at its address set forth below, or to such other address as it shall later designate by like notice to the other Party. Notice of termination of this Agreement if given by facsimile shall be confirmed by prepaid registered or certified airmail letter dated and posted within twenty-four (24) hours. The effective date of receipt of any notice if served by facsimile shall be deemed the first business day in the city of destination following the transmission or dispatch thereof and, if served by courier shall deemed the second business day in the city of destination following the transmissed or an of the dispatch thereof unless earlier received. Notice by personal delivery shall be effective as of the date of such delivery.

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

22.2 ADDRESSES FOR NOTICES.

Notices to Orion shall be sent to:

Orion Corporation Orion Pharma Attn: President of Orion Pharma Orionintie 1, P.O. Box 65 FIN-02101 Espoo Finland Facsimile: 358-9-429-3044

With a copy to:

Orion Corporation Orion Pharma Attn: Legal Counsel Orionintie 1, P.O. Box 65 FIN-02101 Espoo Finland Facsimile: 358-9-429-4088 Notices to GTX shall be sent to: GTx, Inc. Attn: President, with a copy to the General Counsel 3 North Dunlap Avenue Van Vleet Building, Third Floor Memphis, Tennessee 38163 U.S.A. Telephone: 1-901-523-9700 x107 Facsimile: 1-901-523-9772 With a copy to: Cooley Godward LLP Five Palo Alto Square 3000 El Camino Real Palo Alto, CA 94306-2155

Attention: Robert Jones, Esq. Telephone: (650) 843-5034 Facsimile: (650) 849-7400

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

#### 23. INTEGRATION

This Agreement represents the entire Agreement between the Parties relating to the subject matter hereof and supersedes all prior arrangements, understandings, correspondence, notes, minutes and agreements between the Parties (or their predecessors in interest) whether written or oral. No supplement, modification or amendment of this Agreement shall be binding unless executed by the Parties in writing and signed by the duly authorized representatives of both Parties.

## 24. ASSIGNMENT

Neither Party may assign this Agreement or any of its rights hereunder, nor delegate any of its duties or obligations hereunder, to any Third Party without the prior written consent of the other Party, except (i) to an Affiliate in accordance with the terms of this Agreement, in which case notification thereof shall be provided to the other Party prior to such assignment to an Affiliate, or (ii) in connection with a merger, consolidation or similar reorganization. For clarity, this Agreement shall survive any such merger, consolidation or reorganization of either Party with or into, another party and no consent for such merger, consolidation or reorganization shall be needed. Neither Party shall unreasonably withhold its consent (which shall be provided promptly after a request is made) to any contemplated assignment if such contemplated assignment is in connection with the sale by either Party of all or substantially all of its assets to a Third Party. Any assignment of this Agreement to an Affiliate of the assigning Party shall not relieve the assigning Party of its responsibilities and obligations hereunder.

## 25. GOVERNING LAW AND DISPUTE RESOLUTION

25.1 GOVERNING LAW. This Agreement, including the validity, construction, interpretation and performance thereof, shall be governed entirely by the laws of Sweden. It is the specific intent and agreement of the Parties that the United Nations Convention on the International Sale of Goods shall not apply to this Agreement.

25.2 DISPUTE RESOLUTION. All disputes arising out of or in connection with this Agreement (except those involving actions commenced by or involving Third Parties and affecting or involving only one of the Parties) shall be resolved with the following mechanism:

25.2.1 ATTEMPTED AMICABLE RESOLUTION. The Parties shall promptly give each other written notice of any disputes requiring resolution hereunder, which written notice shall specify the Section(s) of this Agreement the other Party is alleged to have breached and shall briefly state the initiating Party's claims, and the Parties shall use reasonable efforts to resolve any such disputes in an amicable manner.

Any disputes arising in connection with this Agreement which cannot be resolved in an amicable manner by representatives of the Parties shall be referred, not later than thirty (30) days after initiation of dispute resolution proceedings under this Section 25.2.1, to the following corporate officers of the Parties for resolution:

For GTX: Chief Executive Officer (or his or her designee)

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Such officers (or their designees) shall attempt to resolve the dispute and shall communicate with each other by facsimile or telephone or in personal meetings in an effort to resolve the dispute.

25.2.2 ARBITRATION. Any disputes (excluding any dispute, controversy or claim arising out of or relating to the validity, enforceability, scope or infringement of patent or trademark rights) arising in connection with this Agreement which cannot be resolved by the Parties within forty-five (45) days after initiation of dispute resolution proceedings under Section 25.2.1 shall be finally settled by binding arbitration under the Rules of the Arbitration Institute of the Stockholm Chamber of Commerce, Stockholm, Sweden in accordance with said Rules then in effect with proceedings to be held in Stockholm, Sweden in the English language. Reasonable submission of evidence shall be permitted in any such proceeding to the extent permitted under and consistent with such Rules. Judgment upon any award rendered by the arbitrator(s) in such proceedings may be issued and enforced by any court having competent jurisdiction. Any disputes arising out of or relating to the validity, enforceability, scope or infringement of patent or trademark rights shall be submitted for resolution by a court of competent jurisdiction.

25.3 EFFECT OF COMMENCING DISPUTE RESOLUTION. If either Party in good faith commences dispute resolution proceedings under Section 25.2, (A) any applicable notice periods or cure periods hereunder (including but not limited to the periods referenced in Sections 21.2 and 21.4) shall be temporarily suspended pending the outcome of such dispute resolution proceedings and (B) the non-breaching Party may, at its option, pay any amounts payable to the other Party that are in dispute into an interest-bearing escrow account pending the outcome of such dispute resolution proceedings.

#### 26. LIMITATION OF DAMAGES

Except for indirect damages resulting from breach of Article 8, in no event shall either Party be liable to the other Party for any indirect, consequential or punitive damages in connection with the performance of this Agreement or any breach of this Agreement (excluding such damages payable to a Third Party which are subject to the indemnification obligations of the Parties set forth in this Agreement.

#### 27. FORCE MAJEURE

Neither Party shall be held in breach of this Agreement for failure to perform any of its obligations hereunder to the extent and for the time period such performance is prevented in whole or in part by reason of any Force Majeure event, including but not limited to industrial disputes, strikes, lockouts, riots, mobs, fires, floods, and other natural disasters and Acts of God, wars declared or undeclared, civil strife, embargo, delays in delivery or defects or shortages of raw materials from suppliers, loss or breakdown of any production equipment, losses or shortage of power, damage to or loss of goods in transit, currency restrictions, or events caused by reason of laws, regulations or orders by any government, governmental agency or instrumentality or by any other supervening unforeseeable circumstances whatsoever beyond the control of the Party

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

so affected. The Party so affected shall (A) give prompt written notice to the other Party of the nature and date of commencement of the Force Majeure event and its expected duration and (B) use its reasonable efforts to avoid or remove the Force Majeure event as soon as possible to the extent it is so able to do.

### 28. RELATIONSHIP OF PARTIES

The relationship of the Parties under this Agreement is that of independent contractors. Nothing contained in this Agreement shall be construed so as to constitute the Parties as partners, joint venturers or agents of the other. Neither Party has any express or implied right or authority under this Agreement to assume or create any obligations or make any warranties and representations on behalf of or in the name of the other Party, or to bind the other Party to any contract, agreement or undertaking with any Third Party, and no conduct of the Parties pursuant to the terms of this Agreement shall be deemed to establish such right or authority. Neither Party shall make any representation to Third Parties that the relationship created hereby constitutes a partnership, joint venture or agency relationship.

### 29. SEVERABILITY

In case one or more of the provisions contained in this Agreement shall, for any reason, be held invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Agreement, but this Agreement shall be construed by limiting such invalid, illegal or unenforceable provision, if such is not possible, by deleting such provision from this Agreement.

### 30. NON-WAIVER

The failure by either Party at any time to enforce any of the terms or provisions or conditions of this Agreement or exercise any right hereunder shall not constitute a waiver of the same or affect that Party's rights thereafter to enforce or exercise the same. No waiver of any of the provisions of this Agreement shall be deemed binding unless executed in writing by the Party to be bound by it.

### 31. HEADINGS

The headings in this Agreement are for convenience of reference only and shall not be used in the interpretation of any provisions hereof.

### 32. GOVERNING LANGUAGE

The English language version of this Agreement shall be controlling in all respects regardless of whether any translations into any other languages are made.

### 33. EXECUTION

This Agreement shall be executed by the Parties in two (2) original counterparts, one (1) original counterpart being retained by each Party and either of which shall be deemed sufficient to prove the existence and terms and conditions hereof. This Agreement may be

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

executed by the Parties by the exchange of facsimile signature pages, with signed original counterparts of the Agreement to be exchanged by the Parties promptly thereafter.

IN WITNESS WHEREOF, the Parties' duly authorized representatives hereto have executed this Agreement as of the Restatement Date.

ORION CO	DRPORATION	GTX, INC.		
By:	/s/ Pekka Kaivola	By:	/s/ Mitchell S. Steiner	
			Mitchell Steiner, M.D.	
Title:	Director Orion Corporation Orion Pharma	Title:	Vice-Chairman and CEO GTx, Inc.	
By:	/s/ Timo Lappalainen  Timo Lappalainen	By:	/s/ Marc Hanover  Marc Hanover	
Title:	Senior Vice President Orion Corporation Orion Pharma	Title:	President and COO GTx, Inc.	

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

COUNTRY/JURISDICTION	TITLE	INVENTORS	PATENT NO.	ISSUE DATE	STATUS
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	<ol> <li>MITCHELLS S. STENIER</li> <li>SHARAN RAGHAW</li> </ol>	6,265,448	July 24, 2001	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	<ol> <li>MITCHELLS S. STENIER</li> <li>SHARAN RAGHAW</li> </ol>	6,413,534	July 2, 2002	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	<ol> <li>MITCHELLS S. STENIER</li> <li>SHARAN RAGHAW</li> </ol>	6,410,043	June 2, 2002	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	<ol> <li>MITCHELLS S. STENIER</li> <li>SHARAN RAGHAW</li> </ol>	6,413,535	June 2, 2002	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	1. MITCHELL S. STEINER 2. SHARAN RAGHOW (THE UNIVERSITY OF TENNESSEE RESEARCH CORPORATION)	6,413,533	July 2, 2002	Issued
UNITED STATES	METHOD FOR CHEMOPREVENTION OF PROSTATE CANCER	1. MITCHELL S. STEINER 2. SHARAN RAGHOW (THE UNIVERSITY OF TENNESSEE RESEARCH CORPORATION)	6,632,447	Oct 14, 2003	Issued

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE A: PART II

APPLICATIONS FILED IN THE UNITED STATES
[ \* ]
APPLICATIONS FILED IN FOREIGN JURISDICTIONS
[ \* ]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

### TITLE: NOVEL ALKANE AND ALKENE DERIVATIVES AND THEIR PREPARATION AND USE (TOREMIFENE)

Country		Patent No	
AU	Australia	556608	May 25, 2008 *
BG	Bulgaria	98379	May 20, 2003
CA	Canada	1185977	May, 20, 2003
CN	China	A-FI96091019	December 20, 2003
DK	Denmark	170927	December 21, 2003 *
EP	Europe	95875	December 21, 2003 *
СН	Switzerland	95875	May 19, 2008 *
IT	Italy	95875	February 14, 2008 *
SE	Sweden	95875	May 20, 2008 *
FI	Finland	77839	December 21, 2003 *
HK	Hong Kong	83/89	May 20, 2003
HU	Hungary	193536	May 26, 2003
HU	Hungary	200742	May 26, 2003
IE	Ireland	55023	December 21, 2003 *
IL	Israel	68784	May 25, 2003
JP	Japan	2105540	May 25, 2003
JP	Japan	1739006	June 29, 2005 *
JP	Japan	1959197	May 25, 2003
JP	Japan	1867986	May 25, 2003
LV	Latvia	5066	May 26, 2003
NO	Norway	156164	December 21, 2003 *
NZ	New Zealand	204349	May 25, 2003
RO	Romania	C-20106 **	December 29, 2004
SG	Singapore	654/88	May 20, 2003
SU	Russia	1508955	May 26, 2003
US	USA	4696949	September 29, 2009 *
US	USA	5491173	September 29, 2004
US	USA	4996225	February 17, 2008
ZA	South Africa	833803	May 25, 2003

EP = Germany, Belgium, Austria, Italy, Sweden, Netherlands, Switzerland, Lichtenstein, Luxemburg, Great Britain, France

\* Patent term extension
 \*\* Pipe-line protection based on US 4696949

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

SCHEDULE B: PART II. ORION PATENT APPLICATIONS

TITLE: NOVEL ALKANE AND ALKENE DERIVATIVES AND THEIR PREPARATION AND USE (TOREMIFENE)

Country Patent Appln. No

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# SPECIFICATIONS FOR [ \* ] TABLETS

SPECIFICATION		
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
[*]	[*]	[*]
	[ * ] [ * ]	[*]       [*]       [*]         [*]       [*]       [*]

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

з.

## SCHEDULE D: GTX'S MSR OBLIGATION

(TO BE COMPLETED PURSUANT TO SECTION 6.1.1)

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

REGISTRATION STATUS 27.9.2001 ORION PHARMA

Status: Approved, Pending Submission types: Marketing authorizations (2 PAGES)

Sent Date	Appl. Date	Product	Country	Decision Date	Decision	M.A. holder
N=39						
[ * ] [ * ] [ * ] [ * ] [ * ]	[*]	[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]		[ * ] [ * ] [ * ] [ * ] [ * ]	[ * ] [ * ] [ * ] [ * ] [ * ]
30.12.87	30.12.87	Fareston 20 mg tablet	Finland	21.12.88	Approved	Ōrion-yhtyma Oy
27.12.88 27.12.88 26.02.93		Fareston 60 mg tablet Fareston 20 mg tablet Fareston 60 mg tablet	Russia Russia Latvia	12.12.89 12.12.89 20.05.93	Approved Approved Approved	Farmos Orion Corporation Orion Corporation Orion-yhtyma Oy Farmos
26.02.93		Fareston 20 mg tablet	Latvia	20.05.93	Approved	Orion-yhtyma Oy Farmos
26.05.92 10.11.93 10.11.93 14.11.94 14.11.94 27.11.94 27.11.94 27.11.94 27.11.94 27.11.94 27.11.94 27.11.94 27.11.94 27.11.94	30.11.94 30.11.94 30.11.94 30.11.94 30.11.94 29.11.94 29.11.94 29.11.94 29.11.94 29.11.94	Fareston 60 mg tablet Fareston 60 mg tablet Fareston 20 mg tablet Fareston 60 mg tablet	Norway Ukraine Sweden Finland United Kingdom Spain Portugal Netherlands Luxembourg Italy Ireland Gracea	$\begin{array}{c} 31.07.95\\ 02.02.96\\ 14.02.96\\$	Approved Approved Approved Approved Approved Approved Approved Approved Approved Approved Approved	Orion Corporation Orion Corporation
27.11.94 27.11.94 27.11.94 27.11.94 17.11.92 27.11.94 31.03.96 31.03.96 10.04.95 01.08.97	01.12.94 28.11.94 30.11.94 30.11.94 15.07.96 01.0897	Fareston 60 mg tablet Fareston 20 mg tablet Fareston 60 mg tablet Fareston 60 mg tablet	Greece Germany France Belgium Austria Denmark Uzbekistan Uzbekistan Hungary Cyprus	14.02.9614.02.9614.02.9614.02.9614.02.9614.02.9616.09.9616.09.9614.01.9823.04.98	Approved Approved Approved Approved Approved Approved Approved Approved Approved	Orion Corporation Orion Corporation Orion Corporation Orion Corporation Orion Corporation Orion Corporation Orion Corporation Orion Corporation Orion Corporation Orion Corporation

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

Sent Date	Appl. Date	Product	Country	Decision Date	Decision	M.A. holder
10.07.96 31.03.95		Fareston 60 mg tablet Fareston 60 mg tablet	Taiwan, R.O.C. Dominican	29.09.98 29.12.98	Approved Approved	Orion Corporation Orion Corporation
10.11.95 30.07.01 30.07.01	26.04.96	Fareston 60 mg tablet Fareston 60 mg tablet Fareston 20 mg tablet	Republic China Georgia Georgia	13.02.99 30.07.01 30.07.01	Approved Approved Approved	Orion Corporation Orion Corporation Orion Corporation

[\*] = 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 24B-2 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED.

# TOREMIFENE LICENSE AND SUPPLY AGREEMENT

BY AND BETWEEN

ORION CORPORATION

# ESPOO, FINLAND

AND

## GTX INC.,

TENNESSEE, U.S.A.

DEFINI	TIONS2
1.1	"Additional Product"2
1.2	"Affiliate"2
1.3	"Annual Net Sales"2
1.4	"Breast Cancer Field"2
1.5	"Calendar Quarter"2
1.6	"Competing Product"2
1.7	"Correction Factor"2
1.8	"DMF"2
1.9	"European Union"2
1.10	"Fareston Product"2
1.11	"Fareston Repurchase Agreement"3
1.12	"Fareston U.S. Web Pages"3
1.13	"Field"3
1.14	"First Commercial Sale"3
1.15	"Generic Product"3
1.16	"GTX Final Development and Registration Plan"3
1.17	"GTX Know-How"3
1.18	"GTX Patents"3
1.19	"GTX Patent Applications"4
1.20	"GTX Patent Rights"4
1.21	"GTX Preliminary Development and Registration Plan"4
1.22	"GTX Territory"4
1.23	"GTX Unaffiliated Sublicensee"4
1.24	"Major Country"4
1.25	"Manufacturing Costs"4
1.26	"Manufacturing Patents"4
1.27	"MAT Net Sales of Fareston Product"4
1.28	"Net Sales"4
1.29	"Orion Field"5
1.30	"Orion Know-How"5
1.31	"Orion Patents"5

1.

-i-

1.32	"Orion Patent Applications"5
1.33	"Orion Patent Rights"5
1.34	"Orion Product"5
1.35	"Orion Product NDA"5
1.36	"Orion Territory"5
1.37	"Orion Unaffiliated Sublicensee"6
1.38	"Other Product"6
1.39	"Premium"6
1.40	"Product"6
1.41	"Product Royalty Adjustment Date"6
1.42	"Prostate Cancer Field"6
1.43	"Purchase Agreement"6
1.44	"Regulatory Approval"6
1.45	"Royalty Income"6
1.46	"Sales of Generic Product"6
1.47	"[ * ]"6
1.48	"SERM"
1.49	"Shire"7
1.50	"Specifications"7
1.51	"Term"7
1.52	"Third Party" or "Third Parties"7
1.53	"Toremifene"7
1.54	"Trademarks"7
1.55	"USA"7
1.56	"U.S. FDA"7
1.57	"U.S. IND"7
1.58	"U.S. NDA"7
1.59	"Upfront and Milestone Income"7
1.60	"Valid Claim"8

-ii-

2.	GRANT	AND SCOPE OF RIGHTS GRANTED8
	2.1	Orion Grants to GTX8
	2.2	No Implied Licenses10
	2.3	United States Government Rights10
	2.4	Orion's Right of First Negotiation10
	2.5	Use of Toremifene by GTX for Research11
	2.6	Prohibited Actions12
3.	PAYMEN	ITS12
	3.1	Types of Payments12
	3.2	Non-Refundability15
	3.3	Royalty Reports and Payments15
	3.4	Currency
	3.5	No Royalties Payable Between Affiliates15
	3.6	No Multiple Royalties15
4.	LIAISO	)N15
5.	PAYMEN	IT, RECORD KEEPING AND AUDIT RIGHTS16
	5.1	Method of Payment16
	5.2	Late Payments16
	5.3	Record Keeping and Audit Rights16
6.	GTX PF	RODUCT MARKETING AND SALES ACTIVITIES16
	6.1	Minimum Sales Requirements for USA16
	6.2	No Minimum Sales Requirements Outside of USA; No Minimum Sales Requirements for Sales of Fareston Product
	6.3	Marketing and Sales Efforts in the Major Countries18
	6.4	Product Launch
	6.5	Marketing Costs and Expenses20
	6.6	Marketing Plans and Reports20
7.	GTX PF	RODUCT DEVELOPMENT AND REGISTRATIONS20
	7.1	GTX Development and Registration Activities20
	7.2	FDA File22
	7.3	Development and Registration Costs22

# -iii-

	7.4	GTX Development and Registration Plan22
	7.5	Orion Documentation and Data23
	7.6	GTX Registration and Marketing Approval Applications23
	7.7	Failure to File or Extend25
	7.8	Reimbursement of Orion Costs25
8.	CONFIDE	ENTIALITY AND PUBLICITY25
	8.1	Confidentiality Obligation25
	8.2	Permitted Disclosures26
	8.3	Confidential Information26
	8.4	Duration of Confidentiality Obligation27
	8.5	Publicity and Announcements27
9.	FAREST	ON PRODUCT WEBSITE FOR USA27
	9.1	Fareston Website27
10.	TRADEM	ARKS
	10.1	Trademarks
	10.2	Trademark Filing and Maintenance28
	10.3	Trademark Documentation28
11.	PATENT	OWNERSHIP AND WARRANTIES
	11.1	Patent Ownership28
	11.2	Orion Patent Warranties29
	11.3	GTX Patent Warranties29
12.	PATENT	PROSECUTION AND INFRINGEMENT; TRADEMARKS29
	12.1	Orion Patent Filing and Prosecution29
	12.2	GTX Patent Filing and Prosecution
	12.3	Notification of Infringement30
	12.4	Infringement of Third Parties Rights by Orion
	12.5	Infringement of Third Parties Rights by GTX
	12.6	Infringement Indemnification
	12.7	Termination for Infringement of Third Party Rights31
	12.8	Third Party Infringement of Orion Patent Rights31

## -iv-

	12.9	Third Party Infringement of GTX Patent Rights; Third Party Infringement of Trademarks and the Trademark Fareston(R)33
	12.10	Mutual Cooperation33
	12.11	Patent Challenges
	12.12	Activities During Infringement Litigation33
13.	COMPET	ING PRODUCTS
	13.1	Obligations With Respect to Competing Products
14.	PRODUC	T ORDERS, SUPPLY AND PAYMENTS35
	14.1	Orion Supply Obligations35
	14.2	Orion Affiliates and Subcontractors35
	14.3	GTX Forecasts
	14.4	Prices and Payment
	14.5	Resale Prices
	14.6	Product Supply for Testing and Registration; Supply of Toremifene
	14.7	Agreement Terms Govern
	14.8	Price Adjustment for Commercial Supply
	14.9	Termination of Product Supply
15.	PRODUC	T WARRANTIES AND INDEMNIFICATION
	15.1	Product Warranties and Limitations
	15.2	Certificate of Analysis40
	15.3	Product Inspections40
	15.4	Product Storage41
	15.5	GTX Responsibilities in GTX Territory41
	15.6	Reciprocal Indemnification Provisions42
	15.7	Conditions for Indemnification42
	15.8	Liability Insurance43
16.	STANDB	Y MANUFACTURING RIGHTS; INVENTORY MAINTENANCE43
	16.1	Inability to Manufacture or Supply43
	16.2	Back-up Manufacturing Right43
	16.3	Maintenance of Inventory44

- V -

17.	MANUFA	CTURING INSPECTIONS AND CHANGES44
	17.1	Regulatory Inspections44
	17.2	Orion-initiated Manufacturing Changes45
	17.3	GTX-Initiated Manufacturing Changes45
	17.4	New Dosage Strengths and Formulations46
18.	PRODUC	T RECALLS
	18.1	Recall Notification47
	18.2	Recall Implementation in GTX Territory47
	18.3	Recall Costs and Expenses in GTX Territory47
19.	ADVERS	E DRUG EXPERIENCES47
	19.1	Adverse Events and Serious Adverse Events47
20.	REPRES	ENTATIONS AND WARRANTIES48
	20.1	Representations and Warranties of the Parties48
	20.2	Representation by Orion49
	20.3	Representation by GTX49
21.	TERM A	ND EARLY TERMINATION RIGHTS49
	21.1	Term
	21.2	Termination for Cause49
	21.3	Termination by Mutual Agreement51
	21.4	Termination by GTX for Safety or Efficacy Reasons51
	21.5	Effect of Termination51
22.	NOTICE	S51
	22.1	Manner of Giving Notices51
	22.2	Addresses for Notices52
23.	INTEGR	ATION53
24.	ASSIGN	MENT53
25.	GOVERN	ING LAW AND DISPUTE RESOLUTION53
	25.1	Governing Law53
	25.2	Dispute Resolution53
	25.3	Effect of Commencing Dispute Resolution54

## -vi-

26.	LIMITATION OF DAMAGES
27.	FORCE MAJEURE
28.	RELATIONSHIP OF PARTIES
29.	SEVERABILITY
30.	NON-WAIVER
31.	HEADINGS
32.	GOVERNING LANGUAGE
33.	EXECUTION

vii