

FOIA Office

FOIA / PA Officer John Livornese

100 F Street NE, Mail Stop 5100

U.S. Securities & Exchange Commission

9-04983-E

RECEIVED

JUN 2 6 2018

Office of

June 26, 2018

Dear Mr. Livornese:

Washington, DC 20549

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231,110 Stat. 3048, copies of the following agreements, based on the FOIA Request 16-00854-FOIA

Exhibit: 10.32 to Form S-1/A filled on 11/21/2003 by Xcyte Therapies Inc

Exhibit Title: License And Supply Agreement

CIK: 1130166

Sectilis will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-798-8809. Please call me or e-mail at research@sectilis.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Stella Vasconcellos Research Assistant Sectilis LLC 6931 Arlington RD. # 580 Bethesda, MD 20814



UNITED STATES SECURITIES AND EXCHANGE COMMISSION

STATION PLACE 100 F STREET, NE WASHINGTON, DC 20549-2465

Office of FOIA Services

July 25, 2018

Ms. Stella Vasconcellos Sectilis LLC 6931 Arlington Rd. # 580 Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. \S 552

Request No. 18-04983-E

Dear Ms. Vasconcellos:

This letter is in response to your request, dated and received in this office on June 26, 2018, for access to Exhibit 10.32 to Form S-1/A filed on November 21, 2003 by Xcyte Therapies Inc.

The search for responsive records has resulted in the retrieval of 27 pages of records that may be responsive to your request. They are being provided to you with this letter. Please note that Exhibit 10.32 was renumbered as Exhibit 10.33.

As shown on the enclosed invoice, the processing fee is \$45.75 in accordance with our fee schedule. You may use our Online Payment option to pay by debit or credit card. If paying by mail, checks or money orders should be made payable to the SEC and a copy of the invoice should be mailed to our payment address: Enterprise Services Center, HQ Bldg., Room 181, AMZ-341, 6500 South MacArthur Boulevard, Oklahoma City, OK 73169. Please refer to the following link for detailed instructions on how to remit payments. http://www.sec.gov/about/offices/ofm.htm

If you have any questions, please contact me at reidk@sec.gov or (202) 551-3504. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Lizzette Katilius as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

Kay Reid

Kay Reid

FOIA Lead Research Specialist

Enclosures

this exhibit. The copy filed herewith omits the information subject to the confidentiality request. Omissions are designated as [*****]. A complete version of this exhibit has been filed separately with the Securities and Exchange

Commission. LICENSE AND SUPPLY AGREEMENT



This License and Supply Agreement ("<u>Agreement</u>") is entered into as of October 15th, 1999 (the "<u>Effective Date</u>") by and between Xcyte Therapies, Inc., a Delaware corporation having a principal place of business at 2203 Airport Way South, Suite 300, Seattle, Washington 98134, United States ("<u>Xcyte</u>"), and Diaclone S.A., a French corporation having a principal place of business at 1 Boulevard Fleming, B.P. 1985 F-25020 Besancon Cedex, France ("<u>Diaclone</u>").

RECITALS

- A. Diaclone has developed and owns the Licensed Materials (as defined below).
- B. Xcyte desires to obtain, and Diaclone is willing to grant to Xcyte, an exclusive worldwide license to the Licensed Materials for the development and commercialization of Licensed Products (as defined below) within the Field (as defined below), upon the terms and subject to the conditions of this Agreement.
- C. Xcyte desires to obtain form Diaclone, and Diaclone is willing to manufacture and sell to Xcyte, the Licensed Antibody for use upon the terms and subject to the conditions of this Agreement.

Xcyte and Diaclone hereby agree as follows:

AGREEMENT

1. **Definitions**

In addition to the terms defined elsewhere in this Agreement, the following terms, whenever capitalized in this Agreement, shall have the following meanings:

- 1.1 "Affiliate" shall mean, with respect to a party, any entity that controls, is controlled by, or is under common control of a party. For this purpose, control of an entity shall mean direct or indirect ownership of fifty percent (50%) or more of the voting interest in, or a fifty percent (50%) or greater interest in the equity of, such corporation or other business entity, or the maximum percentage allowed by law in the country of the controlled entity.
- 1.2 "<u>Diaclone</u>" shall mean Diaclone S.A., a French corporation, and its Affiliates.
- 1.3 "FDA" shall mean the U.S. Food and Drug Administration or any successor agency thereof.
- 1.4 "<u>Field</u>" shall mean all ex vivo uses for (a) therapeutic purposes and (b) research applications and purposes using or relating to the Licensed Antibody or the Licensed Product.

- 1.5 "Licensed Antibody" shall mean the anti-CD28 antibody named B-T3 produced by the Licensed Cell Line, and any modifications thereof made by Xcyte or its sublicenses; provided, however, that in no event shall any antibody that is not derived from the Licensed Materials and has been made with the use of information or materials available in the public domain constitute a Licensed Antibody.
- 1.6 "<u>Licensed Cell Line</u>" shall mean the B-T3 hybridoma cell line and all progeny, clones, derivatives and modifications thereof.
- 1.7 "<u>Licensed Know-How</u>" shall mean any and all technical information, processes, compositions, formulae, data, engineering, materials, reports, analyses, know-how, trade secrets and other subject matter owned and/or controlled by Diaclone that is necessary or useful for the development, manufacture and/or commercialization of Licensed Products in the Field.
- 1.8 "<u>Licensed Materials</u>" shall mean, collectively, the Licensed Antibody and the Licensed Cell Line.
- 1.9 "<u>Licensed Product</u>" shall mean beads coated with the Licensed Antibody and made with use of the Licensed Materials.
- 1.10 "Net Sales" shall mean the gross amounts actually received by Xcyte or its sublicensees from the sale of Licensed Products to Third Parties, less (i) normal and customary rebates, and cash, quantity, trade and other discounts, actually taken, (ii) sales, use, value added and/or other similar taxes or duties actually paid, (iii) packaging, handling fees and pre-paid shipping, freight and insurance, (iv) import and/or export duties actually paid, and (v) amounts allowed or credited due to returns and the like.
- 1.11 "Third Party" shall mean a party other than Xcyte, Diaclone or their respective Affiliates.
- 1.12 "<u>Xcyte</u>" shall mean Xcyte Therapies, Inc., a Delaware corporation, and its Affiliates.

2. License

- 2.1 <u>Grant of License</u>. Diaclone hereby grants to Xcyte a worldwide, exclusive license under the Licensed Materials and Licensed Know-How, with the right to grant and authorize sublicenses, to make, have made, import, have imported, use, offer for sale, sell and otherwise distribute Licensed Products, practice any method, process or procedure, or otherwise exploit, in each case, Licensed Materials and Licensed Know-How for use in the Field (the "<u>License</u>").
- 2.2 <u>Transfer of Licensed Materials</u>. Within ninety (90) days after the Effective Date, Diaclone shall transfer to Xcyte all proprietary technical data, methods and processes, and other information (in electronic and hard copy formats) and data in the possession or control of Diaclone relating to the Licensed Materials. In addition, upon request by Xcyte, Diaclone shall

-2- [*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission.

Confidential treatment has been requested with respect to the omitted portions.

transfer to Xcyte a viable culture of the cell bank for the Licensed Cell Line, and Xcyte agrees to only use such cell bank as contemplated by and in accordance with this Agreement.

- 2.3 <u>Sublicensing</u>. Xcyte may grant and authorize sublicenses within the scope of the License. Upon request by Diaclone, Xcyte shall provide Diaclone with a copy, subject to the confidentiality provisions of Section 13, of the relevant terms of any sublicense agreement necessary to determine the rights granted under any Licensed Materials and the Licensed Know-How and the amounts due to Diaclone hereunder.
- 2.4 Option to Expand Field. Subject to all of the terms and conditions of this Agreement, Xcyte shall have an option (the "Option"), exercisable at any time upon written notice to Diaclone, to expand the Field hereunder to include all in vivo uses for (a) therapeutic purposes and (b) research applications and purposes using or relating to the Licensed Antibody or the Licensed Product (the "Expanded Field"). The exercise of the Option shall be subject to the payment by Xcyte of a license fee in the amount of \$75,000 and any future royalty payments pursuant to Section 6.3 with respect to the Expanded Field. Upon exercise of the Option in accordance with this Section 2.4, without further action of the parties, the Field shall automatically be amended to include the Expanded Field.
- 2.5 Right of First Refusal. In the event that, prior to the exercise of the Option by Xcyte, Diaclone shall agree with a Third Party upon the terms and conditions of a proposed license to such Third Party that would license to any extent the Licensed Materials in the Expanded Field, Diaclone shall provide written notice to Xcyte setting forth such proposed terms and conditions (the "Notice"), and Xcyte shall have a right of first refusal (the "Right of First Refusal") to enter into an agreement with Diaclone on such terms and conditions. Thereafter, Xcyte shall have a period of thirty (30) days in which to exercise the Right of First Refusal by written notice to Diaclone, during which period Diaclone shall not enter into such license with such Third Party. Upon exercise of the Right of First Refusal by Xcyte, the parties shall negotiate in good faith to enter into agreement on such terms and conditions as soon as reasonably practicable. In the event that Xcyte does not exercise the Right of First Refusal within such thirty (30)-day period, Diaclone shall have a period of sixty (60) days in which to grant such license to such Third Party of the Licensed Materials within the Expanded Field on terms no more favorable to such Third Party than those set forth in the Notice. In the event that Diaclone does not enter into such an agreement during such sixty (60)-day period, Diaclone may not enter into such an agreement without sending a new or revised Notice and complying with the terms and conditions of this Section 2.5. Upon receipt of the Notice by Xcyte, the Option shall not be exercisable by Xcyte unless and until (a) Xcyte fails to exercise the Right of First Refusal, and (b) Diaclone does not enter into such an agreement with such Third Party within such sixty (60)-day period.

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3. Manufacture and Purchase of Licensed Antibody

3.1 Manufacture

- (a) Production. Diaclone agrees to produce and test the bulk Licensed Antibody at its facilities located at 1 boulevard Fleming, B.P. 1985 F-25020 Besangon Cedex, France ("Facilities") and to sell the Licensed Antibody to Xcyte upon the terms and subject to the conditions of this Agreement. Diaclone shall manufacture and sell the Licensed Antibody for and to Xcyte on an exclusive basis for all uses within the Field, and Diaclone shall not manufacture or sell the Licensed Antibody for or to any Third Party for any use or purpose within the Field. Except as set forth in Section 4, Xcyte shall purchase the Licensed Antibody from Diaclone on an exclusive basis. All Licensed Antibody provided to Xcyte by Diaclone will be produced in accordance with the manufacturing procedures identified in Exhibit A attached hereto ("Production Protocol"), will meet the specifications identified in Exhibit B attached hereto ("Specifications") and will be manufactured in accordance with "Good Manufacturing Practices." Diaclone will qualify the Licensed Cell Line as described in Exhibit C attached hereto ("Licensed Cell Line Qualification") and comply with the process validation requirements described in Exhibit D attached hereto. Diaclone shall not use the Specifications or the Production Protocol in connection with the performance of services for any Third Party.
- (b) <u>Changes.</u> Diaclone may not make any changes to the Production Protocol, Specifications, or Licensed Cell Line Qualification without the prior written approval of Xcyte, which approval will not be unreasonably withheld. Diaclone will, however, agree to any such changes as are reasonably requested by Xcyte. Diaclone will have in place a documentation, control and change system that complies with Good Manufacturing Practices and other applicable rules, regulations and standards of the FDA, as well as any other applicable regulatory standards for the intended use of the Licensed Antibody, as such requirements may change from time to time ("<u>Regulatory Standards</u>"), and all changes made under this Section will conform to such Regulatory Standards. Any such changes will be made in writing and signed by authorized representatives of each party.
- (c) <u>Initial Quantity</u>. Diaclone shall manufacture for Xcyte an initial quantity of two (2) grams of purified bulk Licensed Antibody (the "<u>Initial Quantity</u>").

3.2 Purchase and Supply

(a) Amount. No later than _______, 1999, Diaclone will provide to Xcyte the Initial Quantity. Thereafter, Xcyte may, in its sole and absolute discretion, order additional purified bulk Licensed Antibody in amounts in excess of the Initial Quantity ("Additional Licensed Antibody") as set forth in Section 3.2(b). If Xcyte orders Additional Licensed Antibody, Diaclone will produce, sell and deliver such Additional Licensed Antibody to Xcyte in accordance with the terms of this Agreement upon delivery dates that are reasonable and mutually agreed to by the parties. Xcyte will be obligated to purchase such Additional Licensed Antibody.

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- (b) Order Procedure. Xcyte will order Licensed Antibody under this Agreement by executing and issuing to Diaclone a purchase order ("Purchase Order") which will specify the reasonable amount of Licensed Antibody ordered, reasonable delivery dates, place of delivery, pricing pursuant to Section 6.1 and any other additional terms agreed to by the parties. Each such Purchase Order will be automatically binding upon and enforceable against Diaclone upon delivery by Xcyte if in material conformity with the Specifications and the terms and conditions of this Agreement. In all other cases, a Purchase Order will be binding upon Diaclone upon (x) written acceptance by Diaclone or (y) the failure by Diaclone to object to such Purchase Order (including objection to the specified delivery dates, which shall be reasonable and mutually agreed by the parties, as set forth in Section 3.2(a)) in writing within fifteen (15) days of receipt thereof. A Purchase Order may not be amended except by a written amendment executed according to Section 13.3. Diaclone will notify Xcyte immediately if it determines that it will not be able to meet any of the terms of a Purchase Order, including, but not limited to, delivery dates. In addition, Diaclone will notify Xcyte promptly of any supply constraints (e.g., materials, third party contracts, facilities or capacity) of which it becomes aware that may affect its ability to supply the Licensed Antibody in accordance with the terms of any Purchase Order. No such notification by Diaclone or acknowledgment of such notification by Xcyte will relieve Diaclone of any liability for a breach of this Agreement or a Purchase Order.
- 3.3 <u>Production Materials</u>. As set forth in Section 6.1(d), Xcyte shall reimburse Diaclone for the purchase of certain materials to be used by Diaclone in the manufacture and production of the Licensed Antibody for Xcyte hereunder (the "<u>Production Materials</u>"); <u>provided, however</u>, that Diaclone shall not use any Production Materials for any purpose other than the manufacture and production of the Licensed Antibody for Xcyte pursuant to this Agreement, and Diaclone agrees, upon Xcyte's request and at Xcyte's expense, to deliver the Production Materials to Xcyte following any termination or expiration of this Agreement. The Production Materials and their respective estimated costs are set forth on Exhibit E attached hereto.
- 3.4 <u>Biosafety Testing</u>. Diaclone agrees to conduct, at Xcyte's expense, biosafety testing (the "<u>Biosafety Testing</u>") on all Licensed Antibody to be provided to Xcyte hereunder and under any Purchase Order. The specifications of the tests included in the Biosafety Testing, and the estimated costs therefor, are set forth in <u>Exhibit F</u> attached hereto. Diaclone shall provide to Xcyte all data, results and materials relating to the Biosafety Testing.
- 3.5 <u>Status Conferences</u>. Diaclone will, at the request of Xcyte, meet by telephone or otherwise to discuss with Xcyte the status of any Licensed Antibody ordered by Xcyte and not yet delivered by Diaclone.
- 3.6 <u>Back-up Cell Bank; Segregation of Licensed Antibody</u>. Diaclone will at all times have a back-up master cell bank for the Licensed Cell Line (minimum of five (5) vials) stored at some location other than the Facilities to minimize any risk of loss that could threaten the master cell bank located at the Facilities. If requested by Xcyte, Diaclone will, subject to space and storage limitations, segregate Licensed Antibody, including, but not limited to, the Initial Quantity, upon completion of manufacture thereof until shipment.

- Ownership of Equipment and Materials. Any tooling, test equipment or other equipment or material provided directly by Xcyte to Diaclone, or purchased by Diaclone for purposes of performing its obligations hereunder and paid for by Xcyte will remain at all times the sole property of Xcyte, will be clearly marked and at all times identified as Xcyte's property by Diaclone and will be returned to Xcyte at Xcyte's cost upon Xcyte's request at any time or upon the termination of this Agreement. While in Diaclone's possession, such equipment or material (a) may not be transferred to any third party without Xcyte's prior written consent, (b) may be used only for the purpose of producing the Licensed Antibody or other products produced by Diaclone for Xcyte as agreed by the parties and (c) will be controlled, protected, preserved, maintained in good working order and repaired by Diaclone, all subject to Xcyte's instructions. Diaclone will reimburse Xcyte for any loss or damage to such equipment and material, excluding normal wear and tear. All such equipment and material will be included, to the extent applicable, in Diaclone' calibration and document control programs, subject to Xcyte's prior written authorization.
- 3.8 Ownership of Licensed Antibody. The parties acknowledge and agree that Xcyte is the sole owner of all Licensed Antibody provided to Xcyte by Diaclone pursuant to this Agreement. Diaclone agrees to take any action deemed by Xcyte to be necessary or appropriate to vest such ownership position in Xcyte and to transfer and assign all right, title and interest held by Diaclone in such Licensed Antibody to Xcyte.

4. Third Party Supply.

Failure to Supply. If (a) Diaclone materially fails to comply with the Regulatory Standards for a period of six (6) months or some lesser time as reasonably determined by Xcyte based on the severity of the violation, (b) Diaclone cannot (or does not wish to) produce Licensed Antibody of the quality, in the quantity or within the time frame reasonably required by Xcyte (with the applicable time frame being within thirty (30) days of the delivery date specified in the applicable Purchase Order, or within ninety (90) days in the case of a force majeure event as described in Section 11, provided that Diaclone is in compliance with the provisions of Section 11), (c) Diaclone either does not have or loses the right to use any of the technology required to produce and test the Licensed Antibody in accordance with the Specifications, the Production Protocol and any other specifications agreed upon by the parties, including, without limitation, use of viral inactivation technology acceptable to Xcyte and in compliance with the Regulatory Standards, or (d) one or more parties (other than parties that currently have an ownership interest in Diaclone) obtains the ability, through on ownership interest in the capital stock or assets of Diaclone or by other means, to influence existing or future terms of this Agreement or Diaclone's performance hereunder, then Xcyte may, in addition to all other remedies it may have under this Agreement or otherwise, at its sole option, elect to have one or more Third Parties manufacture and supply the Licensed Antibody and/or produce the Licensed Antibody itself.

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- 4.2 <u>Phase III Clinical Trials</u>. At such time as Xcyte is preparing for the commencement of Phase III Clinical Trials relating to the Licensed Materials or Licensed Product, Xcyte may, at its sole option, elect to have one or more Third Parties manufacture and supply the Licensed Antibody and/or produce the Licensed Antibody itself.
- Assistance. In the event that Xcyte shall elect to have one or more Third Parties manufacture and supply the Licensed Antibody and/or produce the Licensed Antibody itself pursuant to Section 4.1 or Section 4.2, Diaclone shall, upon Xcyte's request, promptly transfer a minimum of five (5) vials of the master cell bank for the Licensed Cell Line to Xcyte or any such Third Party. In addition, Diaclone shall provide to Xcyte and/or any such Third Party all necessary information and cooperation to enable Xcyte or such Third Party to manufacture the Licensed Antibody in accordance with the Specifications and the Production Protocol. If requested by Xcyte, Diaclone will assist Xcyte in locating an appropriate Third Party manufacturer to produce the Licensed Antibody.

5. Quality Control, Legal, Regulatory Standards

- 5.1 Release and Stability Testing. Diaclone will perform release testing for X each lot of bulk Licensed Antibody supplied to Xcyte hereunder in accordance with Diaclone's standard operating procedures as approved by Xcyte. No Licensed Antibody will be released that X does not meet the Specifications.
- 5.2 <u>Compliance with Law and Regulation</u>. Diaclone will comply with all international, national, state and local laws, ordinances, rules and regulations applicable to the conduct of its business, including, but not limited to, the Regulatory Standards, in performing its obligations hereunder and will maintain, during the term of this Agreement, a manufacturing facility, personnel and quality control and quality assurance programs that comply with the Regulatory Standards. In the event that regulatory certification is required for the manufacture, sale or distribution of Licensed Materials, Diaclone will ensure that such certification is met at its own expense.
- 5.3 <u>Contacts with Regulatory Bodies</u>. Diaclone will advise Xcyte of all contacts with any regulatory agency concerning the Licensed Antibody and, upon request, will provide Xcyte with copies of all materials regarding the Licensed Antibody that it submits to any regulatory agency or that are provided by any regulatory agency to Diaclone.
- Since the Licensed Antibody is considered by Xcyte to impact the performance, safety or efficacy of an Xcyte product, Diaclone will be subject to qualification activities including verbal or written surveys or on site quality system audits. Xcyte will have reasonable access at reasonable times during normal business hours, subject to the parties' mutual agreement, to visit Diaclone's facilities for the purpose of inspecting Diaclone's testing and manufacturing processes or reviewing any documents relating to the Licensed Antibody. Access for such purposes will not be unreasonably withheld, Further, the Licensed Antibody will be incorporated into products which will be subject to inspection by applicable regulatory authorities (including the FDA). Diaclone hereby agrees that such inspections will be permitted, that Xcyte may, at its option, be present at the Facilities for such

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inspections and that Diaclone will provide documents relating to the Licensed Antibody as requested by such regulatory authorities. Further, Diaclone shall advise Xcyte immediately if Diaclone receives notice of an impending inspection or if an authorized agent of the FDA or other governmental agency visits the Facilities concerning the Licensed Materials. Diaclone shall furnish to Xcyte any report including any FDA Form 483 notices (or comparable notices of other agencies), regulatory letters or similar documents received from such agency and the application of such report to the Licensed Materials, if any, within seven (7) days of Diaclone's receipt of such report.

- 5.5 Records Retention. All records relating to the manufacture of the Licensed Antibody and the fulfillment of each Purchase Order, including all Lot History Records, will be retained for a period of at least five (5) years from the date of manufacture. Prior to the destruction of any such records, written notice will be provided to Xcyte, and Xcyte will have the right to request and retain them.
- 5.6 <u>Changes to Facilities</u>. Diaclone will notify Xcyte in writing not less than ninety (90) days prior to making any change in the Facilities if, as a result of such change, the Licensed Antibody would fail to meet the Specifications or Diaclone would be in violation of Regulatory Standards. No such change will be made by Diaclone without Xcyte's prior written approval, which approval may be granted or withheld in Xcyte's sole discretion.
- 5.7 <u>Product Recall.</u> Xcyte and Diaclone each will notify the other promptly if the Licensed Antibody or a Licensed Product alleged or proven to be the subject or a recall, market withdrawal or correction and the parties will cooperate in the handling and disposition of any such recall, market withdrawal or correction; <u>provided</u>, <u>however</u>, that in the event of a disagreement as to any matter related to such recall, market withdrawal or correction, Xcyte will have final authority.
- Sometimes of the Scyte access to its regulatory submissions, clinical samples, and any necessary reference testing material to the extent necessary to facilitate any FDA or other regulatory body submissions undertaken by Xcyte and will, no later than December 1, 1999, or at such other time or times as may be requested by Xcyte, provide to Xcyte all cooperation, information and materials that may be reasonably requested by Xcyte in connection with any IND or similar filing or filings undertaken by Xcyte. Additionally, Diaclone agrees to provide Xcyte with any assistance reasonably requested by Xcyte in obtaining such governmental approvals, including, without limitation, the furnishing of all technical information, processes, formulae, data, engineering, materials, know-how and trade secrets owned or controlled by Diaclone that are relevant to the development and manufacture of the Licensed Materials available to Diaclone and its Affiliates.

6. Supply Pricing; Licensee Fee; Royalties

6.1 Supply Pricing.

- (a) <u>Price Per Gram</u>. Subject to the provisions of this Section 6.1, the price to be paid for purchase of Licensed Antibody during the term of this Agreement shall be Fifteen Thousand Dollars (\$15,000) per gram of Licensed Antibody.
- (b) <u>Initial Quantity</u>. Xcyte shall pay to Diaclone Thirty Thousand Dollars (\$30,000) within thirty (30) days of acceptance by Xcyte of the Initial Quantity. Such payments shall be non-refundable, except as set forth in Section 8.1(c).
- (c) <u>Production Materials</u>. Xcyte shall reimburse Diaclone for all purchases of Production Materials by Diaclone that are approved in writing in advance by Xcyte (provided that Xcyte shall also approve the price of such Production Materials in the event that the price therefor materially differs from the price set forth on <u>Exhibit E</u> attached hereto) within forty-five (45) days of receipt of an undisputed invoice with respect thereto from Diaclone.
- (d) <u>Biosafety Testing</u>. Diaclone shall conduct and pay for the Biosafety Testing in accordance with <u>Exhibit F</u> attached hereto (provided that Xcyte shall preapprove any costs that materially differ from the estimated costs set forth in <u>Exhibit F</u> attached hereto) and invoice Xcyte for reimbursement. Xcyte shall pay all undisputed amounts on such invoice within forty-five (45) days of receipt thereof.
- (e) <u>Cell Banks</u>. Within forty-five (45) days of receipt of an invoice from Diaclone with respect thereto, Xcyte shall reimburse Diaclone for its out-of-pocket costs incurred in connection with the preparation of the qualified master and working cell banks for the Licensed Cell Line. The parties acknowledge and agree that Xcyte has already reimbursed Diaclone for \$2,500 of such costs (and Diaclone acknowledges receipt of such reimbursement), the parties anticipate that the remainder of such costs will be an additional amount of approximately \$2,500.
- (f) Invoicing for Licensed Antibody. Diaclone will invoice Xcyte, in duplicate, accompanied (if applicable) by a bill of lading or airway bill, for all Licensed Antibody purchased hereunder promptly upon delivery of such Licensed Antibody pursuant to Section 8. The price per gram set forth in Section 6.1(a) is inclusive of all costs payable by Xcyte for purchase of the Licensed Antibody. Xcyte will, under no circumstances, be responsible for any costs in addition to such amounts, including, without limitation, costs for activities performed by Biotest AG or any other Affiliate of Diaclone. Diaclone will indemnify Xcyte for any such additional costs.
- 6.2 <u>License Fee</u>. In consideration of the License, Xcyte shall pay the following fees to Diaclone at the following times: (a) Twenty Thousand Dollars (\$20,000) within ten (10) days of the Effective Date; (b) Twenty-Five Thousand Dollars (\$25,000) within thirty (30) days of the satisfaction by Diaclone of its obligations under Section 2.2; and (c) Thirty

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Thousand Dollars (\$30,000) within six (6) months of the receipt by Diaclone of the payment set forth in the preceding clause (b).

6.3 Royalties

- (a) Royalties on Net Sales. Subject to the other provisions of this Section 6.3, Xcyte shall pay to Diaclone, on a product-by-product basis, a royalty equal to two percent (2%) of Net Sales. Following the first approval by the FDA or its foreign equivalent of a Licensed Product for therapeutic uses, the amount payable to Diaclone by Xcyte under this Section 6.3 for all Licensed Products used for therapeutic uses shall be, at a minimum, (i) \$10,000 in each year for the first two (2) years following such first approval, (ii) \$20,000 in each of the third and fourth years following such first approval and (iii) \$30,000 during each year thereafter during the remainder of the term of this Agreement. By way of clarification, such minimum annual amounts shall not be reduced in any manner by the provisions of Sections 6.3(b) or 6.3(c) below.
- (b) <u>Combination Products</u>. In the event that a Licensed Product is used or sold by Xcyte in combination as a single product with one or more other product(s) or service(s) which are not Licensed Products, Net Sales from such sales and/or use for purposes of calculating the amounts due under Section 6.3(a) above shall be calculated by multiplying the Net Sales of that combination by the fraction A/(A + B), where A is the gross selling price of then Licensed Product sold separately and B is the gross selling price of the other product or service sold separately. In the event that no such separate sales or use are made by Xcyte, Net Sales for royalty determination shall be as reasonably allocated by Xcyte between such Licensed Product and such other product or service, based upon their relative importance and proprietary protection. It is understood and agreed that Xcyte intends to use Licensed Products in connection with products and services which do not entail the use of the Licensed Materials, and that such Licensed Products shall be subject to this Section 6.3(b).
- (c) Third Party Offsets. In the event that Xcyte enters into any license or other agreement with a third party with respect to intellectual property or inputs protected by intellectual property which is necessary or useful for the manufacture, use or sale of a Licensed Product, Xcyte may offset any amounts paid to such third party thereunder against royalties otherwise due Diaclone pursuant to this Section 6.3; provided, however, that the royalties that would otherwise be due to Diaclone may not be reduced by more than fifty percent (50%) in any quarter.
- (d) One Royalty. For purposes of clarity, the parties acknowledge and agree that no more than one royalty payment shall be due with respect to a sale of a particular Licensed Product. In addition, no royalty shall be payable under this Section 6.3 with respect to Licensed Products distributed for use in research and/or development, in clinical trials or as promotional samples.

7. Payment; Reports and Records

- 7.1 <u>Timing of Royalty Payments; Payment Method</u>. Xcyte agrees to pay all royalties due to Diaclone within sixty (60) days of the last day of the calendar quarter in which such royalties accrue.
- 7.2 <u>Royalty Reports</u>. Xcyte shall deliver to Diaclone within ninety (90) days after the end of each calendar quarter in which Licensed Products are sold a report setting forth in reasonable detail the calculation of the royalties payable to Diaclone for such calendar quarter, including the Licensed Products sold in each country, the Net Sales thereof, and all amounts received from sublicensees for sales of Licensed Products. Such reports shall be Confidential Information of Xcyte subject to Section 13.
- 7.3 <u>Currency</u>; <u>Foreign Payments</u>. All payments due hereunder shall be paid in United States dollars. If any currency conversion shall be required in connection with the payment of any royalties hereunder, such conversion shall be made by using the exchange rate for the purchase of U.S. Dollars reported by the Bank of America on the last business day of the calendar quarter to which such royalty payments relate. If at any time legal restrictions prevent the prompt remittance of any royalties owed with respect to Net Sales in any jurisdiction, Xcyte may notify Diaclone and make such payments by depositing the amount thereof in local currency in a bank account or other depository in such country in the name of Diaclone, and Xcyte shall have no further obligations under this Agreement with respect thereto.
- Inspection of Books and Records. Xcyte shall maintain accurate books and records which enable the calculation of royalties payable hereunder to be verified. Xcyte shall retain the books and records for each quarterly period for three (3) years after the submission of the corresponding report under Section 7.2. Upon thirty (30) days prior notice to Xcyte, independent accountants selected by Diaclone and reasonably acceptable to Xcyte, after entering into a confidentiality agreement with Xcyte, may have access to Xcyte's books and records to conduct a review or audit once per calendar year, for the sole purpose of verifying the accuracy of Xcyte's payments and compliance with this Agreement. The accounting firm shall report to Diaclone only whether there has been a royalty underpayment and, if so, the amount thereof. Such access shall be permitted during Xcyte's normal business hours during the term of this Agreement and for two (2) years after the expiration or termination of this Agreement. Any such inspection or audit shall be at Diaclone' expense; provided, however, that in the event that an inspection reveals an underpayment of ten percent (10%) or more in any audit period, Xcyte shall x pay the costs of such inspection and promptly pay to Diaclone any underpayment.
- 7.5 <u>Taxes</u>. All royalty amounts required to be paid to Diaclone pursuant to this Agreement may be paid with deduction for withholding for or on account of any taxes (other than taxes imposed on or measured by net income) or similar government charge imposed by a jurisdiction other than the United States ("<u>Withholding Taxes</u>"). At Diaclone's request, Xcyte shall provide Diaclone a certificate evidencing payment of any Withholding Taxes hereunder and shall reasonably assist Diaclone to obtain the benefit of any applicable tax treaty.

Purchase Order are stated in United States Dollars, and do not include sales, use, excise or any other similar taxes imposed by international, federal, state or local governments, or shipping charges. Such prices are inclusive of handling and all other charges unless otherwise specifically provided in the Pricing Schedule or Purchase Order. Taxes and shipping charges will be itemized separately in each invoice. Unless otherwise provided in the Purchase Order, terms of payment will be net forty-five (45) days from Xcyte's receipt of the Licensed Antibody or invoice, whichever occurs later, subject to Xcyte's acceptance of the Licensed Antibody and the resolution of any good faith disputes relating to the invoiced amount. No payment of an invoice will be deemed to constitute acceptance of the Licensed Antibody by Xcyte. If Xcyte disputes any invoice, Xcyte will, within forty-five (45) days of receipt of such invoice, notify Diaclone that it disputes the accuracy or appropriateness of such invoice and provide the basis for such dispute.

8. Delivery; Acceptance

8.1 Documentation, Inspection

- Xcyte under this Agreement or any Purchase Order, Diaclone will send a copy of the lot history record, a copy of the certificate of analysis or compliance certifying that such Licensed Antibody meets the Specifications and a report that includes: (i) manufacturing data and batch identification; (ii) any special observations made during production; (iii) information on the type and number of batch samples taken (references to other documents that contain the foregoing information will be sufficient); and (iv) data, results and information with respect to the status of the Biosafety Testing. In addition, Diaclone will provide a material safety data sheet for the Licensed Antibody and any other documentation required by the Specifications or requested by Xcyte. Any substitution, reprocessing or reworking of the Licensed Antibody must be reported to and approved by Xcyte before any Licensed Antibody subject to such variances may be shipped. Any substituted, reprocessed or reworked Licensed Antibody must be accompanied by variance and nonconformance data in addition to the documentation described above.
- (b) <u>Acceptance and Rejection</u> All Licensed Antibody delivered under this Agreement will be inspected and tested by Xcyte or its designee using Xcyte's standard testing procedures. Xcyte will give notice by facsimile of its rejection or acceptance of any Licensed Antibody within sixty (60) days of receipt thereof.
- (c) <u>Non-Conformance</u>. Notwithstanding the completion of such inspection or the passing of the date for notice of rejection under Section 8.1 (b), if any Licensed Antibody is found at any time by Xcyte, or its customers or users of the Licensed Antibody or a Xcyte product in which the Licensed Antibody was incorporated, to be defective or not in conformity with the Specifications, or if Xcyte is not satisfied with the results of the Biosafety Testing, Xcyte may, at its option: (i) reject such Licensed Antibody, require Diaclone to replace such Licensed Antibody at Diaclone's expense (other than costs of Biosafety Testing and Production Materials, which shall be borne by Xcyte in accordance with Sections 3.3 and 3.4) and provide notice to Xcyte that any Licensed Antibody delivered is replacement Licensed

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Antibody, provided that if Diaclone is unable to replace such Licensed Antibody within the time period specified in Section 4.1, or such other time period as may be agreed by the parties, then Xcyte may exercise its option for the manufacturing rights set forth in Section 4, or (ii) notwithstanding anything to the contrary in this Agreement, request a refund of all amounts paid to Diaclone hereunder in connection with such Licensed Antibody (other than payments made with respect to Biosafety Testing and Production Materials in accordance with Sections 3.3 and 3.4), in which case Diaclone will promptly refund such amounts; provided, however, that Diaclone shall be entitled to retain \$15,000 with respect to each two (2) grams of such Licensed Antibody if such Licensed Antibody is not defective.

8.2 Shipping and Delivery

- (a) Shipping. Unless otherwise specified in the Purchase Order, all freight expenses for delivery of the Licensed Antibody will be prepaid by Diaclone and added to Diaclone's invoice to Xcyte for payment by Xcyte. Xcyte will obtain permits for importation of the Licensed Antibody into the United States and other countries as appropriate. No Licensed Antibody may be shipped to Xcyte's designated destination until the appropriate import permits have been obtained, and Diaclone shall assist Xcyte, upon request of Xcyte, in obtaining approvals of regulatory agencies in the applicable jurisdictions for importation of the Licensed Antibody. Diaclone shall be responsible for exporting the Licensed Antibody from France or such other location in which Diaclone may manufacture the Licensed Antibody in accordance with this Agreement and shall obtain any necessary export licenses or approvals required for such export.
- (b) <u>Delivery</u>. Unless otherwise specified in the Purchase Order, the FOB point will be the location designated by Xcyte in the Purchase Order for delivery of the Licensed Antibody. Diaclone will bear all risk of loss or damages to the Licensed Antibody, and title to the Licensed Antibody will not transfer to Xcyte until delivery of the Licensed Antibody (including any Licensed Antibody segregated in accordance with Section 3.6 prior to shipment) to Xcyte's designated location.
- 9. Representations and Warranties. In addition to all other express or implied warranties, Diaclone represents and warrants that it has the right (a) to use all technology it employs in the production, use and sale of the Licensed Antibody hereunder, (b) to grant all licenses granted or to be granted hereunder and (c) to perform all of its other obligations under this Agreement. Diaclone further represents and warrants that its Facilities will be maintained as required herein and that the Licensed Antibody (i) will meet the Specifications, (ii) will be manufactured in accordance with the Production Protocol and "Good Manufacturing Practices," (iii) will be free from all liens and security interests such that full ownership rights vest in Xcyte, and (iv) has been developed, labeled, packaged, manufactured, tested, stored, supplied and sold in accordance with the terms of this Agreement and the Regulatory Standards. Diaclone represents and warrants that (A) the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which Diaclone is a party (B) Diaclone has not received written notice that the Licensed Materials infringe upon the intellectual property rights of any third party, (C) there are no threatened or pending actions, suits, investigations, claims or proceedings in any way relating to the Licensed Materials to which Diaclone is a party

[*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission.

Confidential treatment has been requested with respect to the omitted portions.

or of which Diaclone is aware, and (D) it is the exclusive owner of all right, title and interest in the Licensed Materials.

10. Term and Termination

- 10.1 <u>Term</u>. The initial term of this Agreement will begin on the Effective Date and will continue, subject to early termination as provided in Section 7.2, a period of seven (7) years.
 - 10.2 <u>Termination</u>. This Agreement may be terminated as follows:
- (a) Xcyte may terminate this Agreement at any time upon thirty (30) days written notice to Diaclone;
- (b) Either party may terminate this Agreement in the event of a material breach by the other party provided that the defaulting party fails to cure such breach within thirty (30) days after receipt of notice of such breach, or in the case of a breach that is not capable of cure within thirty (30) days, if the defaulting party fails to begin cure within thirty (30) days after receipt of notice of such breach or to continue to pursue such cure diligently thereafter;
- (c) Either party may terminate in the event of (i) the making by either party of any general assignment for the benefit of creditors, (ii) the filing by or against either party of a petition for reorganization or arrangement under any law relating to bankruptcy (unless, in the case of a petition filed against such party, the same is dismissed within sixty (60) days), (iii) the appointment if a trustee or receiver to take possession of substantially all of either party's assets, where possession is not restored to such party within sixty (60) days, or (iv) the attachment, execution or other judicial seizure of substantially all of either party's assets, where such seizure is not discharged within sixty (60) days; or
 - (d) This Agreement may be terminated as set forth in Section 8.3.
- 10.3 <u>Effect of Termination</u>. Neither party will be relieved of any obligations incurred under this Agreement prior to the date of such termination or expiration by the termination or expiration thereof, and the provisions of Sections 1, 2.1, 3.6, 3.8, 4, 5.8, 7.4, 9, 10, 12, 13, 14, 15 and 16 will survive any such termination or expiration.

11. Force Majeure

11.1 No Liability. Neither party will be liable for any failure to fulfill any term or condition of this Agreement, other than the payment of amounts owed hereunder, nor will such failure constitute a breach of or default under this Agreement, if fulfillment has been delayed, hindered or prevented by an event of force majeure, including any war, riot, strike, acts of the elements, acts or compliance with any order of any government or agency thereof (including the enactment of any new laws, rules or regulations), sabotage or industrial accident, where the failure to perform is beyond the reasonable control and not caused by the negligence or intentional misconduct of the non-performing party, and the non-performing party has exerted all reasonable efforts to avoid or remedy the force majeure.

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- 11.2 <u>Notice of Force Majeure</u>. Promptly following the date any event of force majeure occurs, the party so affected will advise the other party in writing of the date and nature of the event and the period of time such event is expected to continue. During the existence of such event, the duties and obligations of the parties under this Agreement will be suspended and the parties will take all reasonable action to ensure resumption of normal performance under this Agreement as soon as possible.
- 11.3 <u>Termination Right</u>. If, as a result of any such force majeure event, a party is unable to fully perform its obligations hereunder for a period of ninety (90) days, the other party will have the right to terminate this Agreement upon written notice, effective the date of such notice.

12. Indemnification; Limitation of Liability

- 12.1 <u>By Diaclone</u>. Diaclone will defend, indemnify and hold harmless Xcyte and its officers, directors, employees and agents (collectively, "<u>Indemnitee</u>") from and against any and all losses, damages, liability, settlement costs, defense costs, other expenses and attorneys' fees (a "<u>Liability</u>") resulting from a Third Party claim or suit related to or arising out of the development, labeling, packaging, manufacturing, storage, testing, or supply of Licensed Antibody or any breach of this Agreement by Diaclone, including, without limitation, breach of any representation or warranty contained herein.
- 12.2 <u>By Xcyte</u>. Xcyte shall defend, indemnify and hold harmless Diaclone and its officers, directors, employees and agents (collectively, "<u>Indemnitee</u>") from and against any and all Liabilities resulting from a Third Party claim or suit relating to or arising out of the development, labeling, packaging, manufacturing, storage, testing or sale of any Licensed Product by Xcyte or any breach of this Agreement by Xcyte, including, without limitation, breach of any representation or warranty contained herein.
- 12.3 <u>Procedure</u>. In the event that any Indemnitee intends to claim indemnification under this Section 12 it shall promptly notify the indemnifying party in writing of such alleged Liability. The indemnifying party shall have the right to control the defense and settlement thereof. The Indemnities shall cooperate with the indemnifying party and its legal representatives in the investigation of any action, claim or liability covered by this Section 12. The Indemnitee shall not, except at its own cost, voluntarily make any payment or incur any expense with respect to any claim or suit without the prior written consent of the indemnifying party, which the indemnifying party shall not be required to give.
- 12.4 <u>LIMITATION OF LIABILITY</u>. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY.

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13. **Confidentiality**

be limited to, any information marked as confidential Information" will include, but not be limited to, any information marked as confidential and all know-how, formulas, specifications, processes, product ideas, inventions and technical, business and financial plans, forecasts and strategies, and any information derived therefrom disclosed by either party to the other. Each party will hold in confidence and not use or disclose to others, except as specifically authorized by this Agreement, the Confidential Information of the other. Each party will protect the other party's Confidential Information by using the same degree of care, but not less than a reasonable degree of care, used to protect its own Confidential Information. Diaclone acknowledges that the Specifications, the Production Protocol, the quantity of the Licensed Antibody ordered or used by Xcyte and the quantity of Xcyte's product sold by Xcyte are Confidential Information of Xcyte.

This restriction does not apply to the extent it can be established by the receiving party that the information:

- (a) was known to the receiving party at the time of disclosure;
- (b) was part of the public domain at the time of disclosure or later entered the public domain through no fault of the receiving party;
- (c) was made known to the receiving party from another source under no obligation to the disclosing party; or
- (d) was independently developed by the receiving party without the use of the disclosing party's Confidential Information.

Notwithstanding the above, each party may disclose the other party's Confidential Information: (i) to employees or agents to the extent necessary to accomplish the purposes of this Agreement, provided that each such individual is first bound by an obligation of confidentiality equivalent to that described herein, (ii) to the extent necessary to comply with applicable laws, judicial orders or governmental regulations provided that each party agrees to give reasonable advance notice to the other of any such intended disclosure, and to minimize such disclosure to the extent possible, and (iii) to governmental agencies to obtain approval for commercial sale of the Licensed Antibody or any of Xcyte's products. Each party's Confidential Information will remain the property of that party, and the disclosure of Confidential Information hereunder does not constitute a grant of any right or license to such Information. The restrictions described in this Section 13 will remain in effect for five (5) years after termination of this Agreement.

13.2 <u>Test Results</u>. Diaclone specifically agrees that the results of any tests performed on the Licensed Cell Line or Licensed Antibody that are paid for by Xcyte belong solely to Xcyte, are part of Xcyte's Confidential Information and are subject to the protections described in this section. Diaclone further agrees that such information will not be used by Diaclone for any purpose other than to produce Licensed Antibody for Xcyte as described in this Agreement, or be used by or for the benefit of any third party without Xcyte prior consent.

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13.3 Equitable Relief. The parties agree that due to the unique nature of the Confidential Information, there can be no adequate remedy at law for any breach of the receiving party's obligations under this Agreement, thereby resulting in irreparable harm to the disclosing party. Therefore, notwithstanding Section 16.6 hereof, upon any such breach of this Section 13 or any threat thereof, the disclosing party shall be entitled to seek appropriate mandatory or negative injunctive relief.

14. Intellectual Property.

- Property" will mean all intellectual property, tangible or intangible including, without limitation, any and all data, techniques, inventions, discoveries, ideas, processes, know-how, patents, patent applications, trade secrets, and other proprietary information. Except as expressly stated herein, neither party grants any right or license to any of its Intellectual Property to the other party, and the disclosure of Confidential Information by either party to the other will not obligate the disclosing party to grant rights in or to the subject matter of such Confidential Information to the receiving party.
- 14.2 Ownership. All Intellectual Property pertaining to the development, manufacture or use of the Licensed Materials will be owned by the inventor as determined under United States patent law. Any such Intellectual Property which is invented jointly by the parties ("Joint Intellectual Property") will be jointly owned by the parties. All patent applications on the Joint Intellectual Property will be agreed to by each of the parties and filed, prosecuted and maintained jointly by the parties at their joint expense. Any such Joint Intellectual Property may be used (or sublicensed) by either Diaclone or Xcyte worldwide for any purpose without accounting to the other. If for any reason Diaclone or Xcyte declines to participate in the filing, prosecution, or maintenance of any patent application or patent on the Joint Intellectual Property, (other than Joint Intellectual Property governed by Section 14.3), the other party will be entitled to assume responsibility for such activities at its sole expense, and such patent application or patent will become the sole property of such party.
- 14.3 <u>Assignment</u>. Notwithstanding the above, any Intellectual Property developed by Diaclone at Xcyte's expense will belong solely to Xcyte regardless of whether it would otherwise have been solely or jointly owned by Diaclone, and Diaclone will take any action necessary to confirm Xcyte's ownership of and assign all such Intellectual Property to Xcyte upon Xcyte's request. Xcyte will have the exclusive right to apply for or register patents and other proprietary protections in such assigned Intellectual Property and Diaclone agrees to execute such documents, render such assistance and take such other action as Xcyte may reasonably request, at Xcyte's expense, to apply for, register, perfect, confirm and protect Xcyte's rights therein.
- 15. <u>Communications and Notices</u>. All, notices hereunder will be in wiriting and will be deemed given if delivered personally or by facsimile transmission (receipt verified), telexed, or sent by express courier service to the parties at the following addresses (or to such other address as specified by either party):

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If to Xcyte, addressed to:

Xcyte Therapies, Inc.

2203 Airport Way South, Suite 300

Seattle, Washington 98134

United States

Attn: Business Development

Fax: (206) 328-7316

With a copy to:

Venture Law Group 4750 Carillon Point

Kirkland, Washington 98033

United States

Attn: William W. Ericson Fax: (425) 739-8750

If to Diaclone:

Diaclone, S.A.

1 boulevard Fleming, B.P. 1985

F-25020 Besancon Cedex

France

Attn: Dr. John Wijdenes

Fax:

16. Miscellaneous.

Assignment. This Agreement is binding on successors and assigns of the parties provided that this Agreement may not be assigned to a third party without the prior written consent of the other party, which consent will not be unreasonably withheld; provided, however, that Xcyte may assign this Agreement to an acquiror of all or substantially all of its assets or the resulting entity in a merger or consolidation, or in connection with any other transaction resulting in the transfer of at least fifty percent (50%) of its voting power, without the consent of Diaclone.

- Orders and, where applicable, Xcyte's Purchasing Standard Terms and Conditions ("<u>Ts & Cs</u>"), constitutes the entire Agreement between the parties regarding this subject matter and supersedes all such prior understandings between the parties. Any amendment to this Agreement must be in writing and signed by an authorized representative of each party. If there is any conflict between the terms of this Agreement and the Ts & Cs or a Purchase Order, the terms of this Agreement will prevail. If there is any conflict between the Ts & Cs and a Purchase Order, the Purchase Order will prevail.
- 16.3 <u>Independent Contractor</u>. Diaclone will be an independent contractor and not an agent, partner or co-venturer of Xcyte. Neither party will have the authority to bind the other by contract or otherwise. This Agreement will not be deemed or construed as creating a partnership between Diaclone and Xcyte for any purpose.

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- 16.4 <u>Attorney's Fees</u>. The prevailing party in any lawsuit or arbitration based on or arising out of this Agreement will be entitled to recover from the other party its costs and expenses (including attorney's fees) reasonably incurred in connection with such lawsuit or arbitration.
- 16.5 <u>Arbitration</u>. Any and all disputes relating to or arising from this Agreement will be resolved by binding arbitration to be held in Seattle, Washington under the American Arbitration Association Rules.
- 16.6 <u>No Conflict</u>. Each party represents and warrants that it is authorized to enter into this Agreement and that the terms of this Agreement do not create a conflict with any right, obligation or agreement that it has with any third party.
- 16.7 <u>Waiver</u>. Xcyte's failure to enforce any provision of this Agreement or a Purchase Order will not be a construed as a waiver of such provision and will not affect Xcyte's right to enforce each and every provision of this Agreement.
- 16.8 <u>Severability</u>. If any term or provision of this Agreement is held invalid or unenforceable, the remaining terms will be valid and enforced to the fullest extent permitted by applicable law.
- 16.9 Governing Law. This Agreement will be governed by and construed in accordance with the laws of the State of Washington, USA, without regard to its conflict of law rules, and not by the provisions of the 1980 U.N. Convention of Contracts for the International Sale of Goods. Except as set forth in Section 16.6, the parties hereby irrevocable submit to the jurisdiction of the state and federal courts located in King County, Washington.
- 16.10 <u>Counterparts</u>. This Agreement may be executed in two or more counterparts, each of which shall constitute an original, and all of which together shall constitute one and the same instrument.

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IN WITNESS WHEREOF, each of the parties has caused this Agreement to be executed by its duly authorized representative as of the date first set forth above.

DIACLONE:	
DIACLONE, S.A.	
By: /s/: John Loydenes	
Name: John Loydenes	
Title: President and CEO	
XCYTE:	
XCYTE THERAPIES, INC.	
By: /s/: Ronald Jay Berenson	M. 2-1
Name: Ronald Jay Berenson	
Title: President and CEO	

EXHIBIT A

PRODUCTION PROTOCOL

Scheme for bioreactor production of B-T3

Adaptation: Adaptation of the cells to ferum free media (by reduction of serum). Freezing of adapted cells. Viral tests on the master cell bank (MCB).

Diaclone will reserve 50 vials of the MCB for Xcyte and prepare a 100 Vial working cell bank (WCB) to be used exclusively for producing Antibody for Xcyte.

WCB: Ampoule of the WCB in liquid nitrogen. Thaw at 37°C.

Transfer cells into the environment of the culture (MSS) Washing and centrifugation (200 x g) of the cellular suspension

INOCULUM: Start with an adjusted cell concentration at $>1-5 \times 10^5$ cells/mL in a flask.

Transfer culture into roller bottles (500 mL working volume) 37°C, 5% CO₂

PRODUCTION: Inoculate the bioreactor with a concentration of $> 2 \times 10^5$ cells/mL Production is performed in either a perfusion process or a stir tank process to be agreed upon by the sponsor and Diaclone

Increase the volume at 37°C, 20% pO₂, pH 7.2 Cell concentration 1-2 x 10⁶ cells/mL up to working volume (Perfusion) Cell concentration 8 x 10⁵ cells/mL up to working volume (35L Stir Tank Fed-Batch)

Harvest-Feeding Culture:

Perfusion

Add new media and harvest the supernatant (SN), and continue with tangential filtration, so that the volume of the bioreactor is constant; maximum cell concentration is gained under these conditions. Stationary phase: 10-20 x 10⁶ cells/mL 37°C, 20% pO₂ pH>6.8 infusion: 2d⁻¹. Harvest of the SN continuing with tangential filtration.

Collection and pool the SN in bags of 100 L; concentration of mAb 50-200 ug/mL Store at 2° to 8°C

Concentration of the SN (200-500 L) by tangential ultrafiltration (10 to 15 times) Store at 2° to 8°C

> Harvest-Feeding Culture: Stir Tank Fed-Batch

> > [*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Harvest the supernatant (SN) daily, and replace with fresh medium, so that the volume of the bioreactor is constant; and cell concentration is reduced to 3-4 x. 10⁵ cells/mL. Before Harvest, the cell density is typically 6-8 x 10⁶ cells/mL. Maintain culture at 37°C, 20% pO₂ pH 7 –7.2.

Pool the collection of three (3) days SN and filter by tangential flow to eliminate cell debris. Sterile Filter pool on Pall 0.2 μm filter unit,

Store at 2° to 8°C

Concentration of the SN pools by tangential ultrafiltration (15 to 20 times) and filter on Pall 0.2

µm filter unit

Store at 2° to 8°C

II. Scheme for purification of B-T3

PURIFICATION: Diafiltration of the concentrate against 22 mM TRIS buffer, pH 7.5 and adjust protein concentration to 1-2 mg/mL

Q-SEPHAROSE FF chromatography: Elution of mAb with 22mM TRIS, 0.15 M NaCl, pH 7.5

Diafiltration against 20 mM NaAcetate, pH 7.0 buffer

VIRAL INACTIVATION: following the NYBC method (0.3% TNBP, 1% Tween-80, 16 h at 25°C +/- 0.5°C)

S-SEPHAROSE FF chromatography: Elution with 20m M NaAcetate, 0.075 M NaCl, pH 7

Diafiltration against buffer 100 mM KH₂PO₄, pH 7.0

Add 1.3 M of Ammonium Sulphate (SA) before application to the column

POLYPROPYL-A chromatography (HIC): Elution of mAb 1 M +/- 0.1 M SA

Diafiltration against Phosphate Saline Buffer (PBS), pH 7.4

Store in sterile, apyrogenic bottles (1L) at 2°C to 8°C, and analyze

FINAL BULK PRODUCT

Ampoules ≥ 2 mg/mL, 10 mg each (5 mL) at -4°C; Analyze

*Diaclone will use dedicated chromatography media in production columns for the antibody purification.

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 -2- separately with the Securities & Exchange Commission.
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EXHIBIT B

SPECIFICATIONS

Test*	Unprocessed Bulk	Purified Bulk	
Sterility	Pass (C)	Pass (C)	
Virus testing:			
In Vitro, 5 indicator cell lines	Negative (C)	N.T	
Negative Stain EM	Report Value. (particle concentration not to exceed 5 log validated viral clearance safety factor) (C)	N.T	
Residual DNA (P32 hybridization)	Report Value (C)	<100 pg/mg protein (C)	
LAL (Endotoxin)	Report value (B)	≤ 5 EU/mg protein (B)	
Isotype testing for IgG2a, heavy and light chain specific	IgG2a Only (C)	IgG2a Only (B)	
Protein Concentration (Bradford)	Report Value (D)	≥ 2 mg/mL (B)	
Protein concentration using specific extinction coefficient of 1.4 at A 280nm	Report Value (D)	≥ 2 mg/mL (B)	
IgG Concentration by ELISA or Protein A HPLC	Report Value (D)	Report Value (B)	
Fill Volume	N.T.	≥5 mL (B)	
рН	N.T.	7.3 – 7.5 (B)	
Appearance	N.T.	Clear, slight precipitate may be present (B)	
IEF (isoelectric points, pI)	N.T.	Report values; (T.B.D.): provide photograph & densitometer tracing (B)	
SDS-PAGE (stained with Coomassie Blue under reducing and non-reducing conditions)	N.T.	Report value (T.B.D.): provide photograph & densitometer tracing (B)	
Tween-80	N.T.	<30µg/ml (B)	
TNBP	N.T.	<10μg/ml (B)	
Lipid	N.T.	<0.1mg/ml (B)	
SE-HPLC Purity and Aggregate	N.T.	≥95% monomer (B)	
Antigen binding assay	Titration on positive and negative cell lines using flow cytometry (D)	Titration by flow on positive and negative cell lines using flow cytometry (D)	

N.T. = Not Tested

B=Biotest

C=CLB

D=Diaclone

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^{*}Copies of Standard Operating Procedures and Test Methods to be provided for review.

EXHIBIT C

CELL LINE QUALIFICATION

I. Requirements for regulatory submission:

- Source, name and characterization of parent cell line
- Species, characterization, tissue origin of immune cell
- Immortalization procedures
- Identification of immunogen (ie: source of immunogen)
- Description of immunization scheme
- Description of screening procedures used
- Description of cell cloning procedures
- Description of seed lot system and preparation of cell banks

II. Cell line testing: MCB, WCB, if applicable, and end of production cells (EOPC).

Provide documentation and report results for the following"

- Sterility
- Isoenzyme Analysis
- Mycoplasma
- Virus testing results to be supplied to Xcyte and subjected to review for meeting Regulatory Standards (See Biosafety Testing). Additional viral testing may be required.
- DNA Fingerprint
- MAP Test
- Confirmation of species of origin and lack of cross contamination by other cell lines
- Precautions used to prevent contamination of cell line (e.g., change over procedures, cleaning, facilities)
- * All documents to be provided in English.

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EXHIBIT D

REGULATORY SUBMISSIONS

I. Process Validation and Production Records:

- Diaclone will provide existing summary validation reports for virus removal, DNA removal and removal of other process specific materials, etc.
- Diaclone will provide full reports for submission to regulatory authorities, if required.
- Diaclone will provide a complete set Batch Records for the Production of the B-T3 Master X Cell Bank, Working Cell Bank, Bulk Supernatant, Purified Bulk Antibody, and Filling Record.

II. Facilities and Equipment:

• Diaclone will provide documentation of its Facilities, Equipment, and Operational procedures as requested by Xcyte or Regulatory Agency for support of regulatory submissions

III. Product Testing:

- Diaclone will provide copies of all relevant Standard Operating Procedures, Test Methods and Study Protocols used in the testing of the B-T3 cell line, bulk supernatant, and Lot Release of purified immunoglobulin.
- Diaclone will provide full reports of results for submission to regulatory authorities, as requested by Xcyte or Regulatory Agency.

^[*] Certain information on this page has been omitted and filed separately with the Securities & Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

EXHIBIT E

PRODUCTION MATERIALS

The following materials are to be dedicated to the manufacture of B-T3 antibody for Xcyte:

Q-Sepharose 1.5-litres S-Sepharose 1.5 litres 2 Diafiltration cassettes Polypropyl - A Column

Hollow fiber module

TOTAL

815 US\$ 815 US\$ 2790 US\$ 6710 US\$ 990 US\$

12,120 US\$

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EXHIBIT F

BIOSAFETY TESTING

Cell Line: BT3 (murine IgG2a monoclonal anti-Human CD28 Antibody) **Test Method** Specification MCB WCB EOP Sterility Negative C C D Mycoplasma (PTC/CPMP) Absent C C D Ab Production/Concentration via HPLC or Report Only D D D ELISA EOP=MCB Karyology (genetic stability) Not being performed. CLB indicates coverage under DNA fingerprinting and isoenzyme analysis Identify via Isoenzyme Analysis Murine only C C Identify via DNA Fingerprint EOP=MCB, murine only C C Cell Viability: post freeze/thaw >85% D D D Cell Density Report Only D D D Mouse Antibody Production (MAP) w/ Negative C C LCMV chanllenge (CLB to substitute serological test only for LCMV) In Vitro Adventious Virus, 5 cell lines Negative C C InVivo Adventious Virus, embryonated Negative C C eggs, adult & suckling mice, guinea pigs Reverse Transcriptase Report Only (Inherent C C

C = CLB, P.O. Box 9190, 1006 AD Amsterdam, Plesmanlaan 125, 1066 CX Amsterdam, The Netherlands D= Diaclone

Murine Retrovirus Only)

Murine Retrovirus Only)

Murine Retrovirus Only)

Murine Retrovirus Only)

Report Only (Inherent

Report Only (Inherent

Report Only (Inherent

C

C

C

C

C

C

S+L - Focus Assay, amplified

XC Plaque Assay, amplified

Transmission EM, 100 cells minimum

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