18-02532-E

foiapa

From: Mark Edwards <medwards@biosciadvisors.com>

Sent: Friday, February 16, 2018 7:29 PM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibits 4.7, 4.11 and 4.12 to the 3/31/03 Form 20-F, filed by Protherics PLC on 9/30/2003. Confidential treatment was sought as to certain portions when initially filed with the Commission.

In the event that confidential treatment has not expired or has been extended, I further request that you send me the expiration date(s) from the relevant CT order(s) so I will know when I should resubmit my request.

I authorize up to $61 in search and retrieval fees. Please send the exhibit(s) by PDF if possible.

Sincerely,

Mark
Mark G Edwards
Managing Director
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598
medwards@biosciadvisors.com
925 954-1397

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

March 19, 2018

Mr. Mark G. Edwards
Bioscience Advisors
2855 Mitchell Dr., Suite 103
Walnut Creek, CA 94598

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02532-E

Dear Mr. Edwards:

This letter is in response to your request, dated February 16, 2018 and received in this office on February 20, 2018, for access to Exhibits 4.7, 4.11 and 4.12 to the March 31, 2003 Form 20-F, filed by Protherics PLC on September 30, 2003.

The search for responsive records has resulted in the retrieval of 71 pages of records that may be responsive to your request. They are being provided to you with this letter.

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

Confidential treatment requested 4.7

AMENDMENT NO. 3
TO
DISTRIBUTION AGREEMENT

THIS AMENDMENT NO. 3 TO DISTRIBUTION AGREEMENT (this "Amendment") is made and entered into as of the ____ day of February, 2002, and is by and among Protherics Inc., a Delaware corporation located in Nashville, Tennessee ("Protherics") and Altana, Inc., a New York corporation located in Melville, New York ("Altana"). Terms used and not defined in this Amendment shall have the meanings given to such terms in the Distribution Agreement, dated as of October 11, 1997 (the "Distribution Agreement").

W I T N E S S E T H:

WHEREAS, Altana and Therapeutic Antibodies Inc., a Delaware corporation ("TAb") entered into the Distribution Agreement, effective as of October 11, 1997, which agreement was amended on each of October 25, 1999 and September 12, 2000.

WHEREAS, TAb merged with and into a wholly-owned subsidiary of Proteus International PLC effective as of September 15, 1999 (the "Merger") and, as a result of the Merger, Proteus International PLC changed its name to "Protherics PLC," and the wholly-owned subsidiary into which TAb was merged changed its name to "Protherics Inc.";

WHEREAS, as a result of the Merger, Protherics Inc. assumed all of the rights and obligations of TAb, including all of TAb's rights and obligations under the Distribution Agreement;

WHEREAS, Protherics and Altana desire to amend the Distribution Agreement as and to the extent set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, covenants and undertakings hereinafter contained, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereto agree as follows:

1. Altana Sales Representatives. Protherics and Altana hereby agree to modify the requirement that at least 85% of Altana's Savage Laboratories division sales representatives be assigned to the Products. Altana represents to Protherics that notwithstanding such modification, Altana will be able to perform its marketing and sales obligations under the Agreement at substantially the same level as it would be able to perform in the absence of such modification. Accordingly, Section 7.11 of the Distribution Agreement shall be amended by deleting the first sentence thereof and substituting therefor the following:

> "Altana shall assign responsibility for the promotion, distribution and sale of the Products to not less than 10 dedicated field sales representatives at all times following the initial Commencement Date."

2. Distribution to Zoos and Military. Protherics and Altana hereby agree to eliminate the restriction that Altana may not market and distribute CroFab ™ to zoos and military purchasers. Accordingly, the following sections of the Distribution Agreement shall be amended as follows:

(i) Section 6.1 is hereby amended to delete the proviso clause at the end of the first sentence.

(ii) Section 6.3 shall be amended to read as follows:

"Altana agrees that it shall not advertise, promote, distribute, sell or otherwise utilize the Products and/or Trademarks outside of the Territory, and Protherics agrees that it will not authorize any of its distributors to supply the Products into the Territory. Protherics shall take such reasonable measures as Altana requests to ensure that its designees and customers do not sell Products within the Territory."

(iii) Section 14.3 shall be amended by deleting the last sentence thereof and substituting therefor the following:

"Altana's right to use any Trademarks developed by Protherics for use with the Products shall be non-assignable and non-exclusive as to distribution of any Product outside the Territory."

(iv) The first section of Schedule 8.1 (with respect to CroFab™ (formerly CroTAb®)) is hereby amended by deleting Section (10) thereof in its entirety.

3. DigiFab™ Royalties. The second section of Schedule 8.1 (with respect to DigiFab™ (formerly DigiTAb™)) is hereby amended by deleting the second paragraph of Section 1 thereof in its entirety and substituting therefor the following:

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"In further consideration of Protherics' past research and development, Altana shall pay to Protherics within thirty (30) days of the end of each calendar quarter royalties corresponding to five percent (5%) of the DigiFab™ Net Sales Revenue within the preceding calendar quarter; provided, however, that no such royalties shall be payable until such time as the product Digibind® Digoxin Immune Fab (Ovine) (currently manufactured by GlaxoSmithkline) is no longer marketed and sold in the Territory, whether by GlaxoSmithKline or any other Person or Persons other than Protherics. Such royalties shall be payable for the first three (3) years after Digibind® is no longer marketed and sold in the Territory."

4. Returns of Expired Product. To the extent that any End User returns expired DigiFab™ Product to Altana, Altana shall notify Protherics in writing of the quantity of such returned Product and request additional Product to replace the expired Product. If so requested, Protherics shall supply such additional quantities of Product as indicated in the notice. Altana shall reimburse Protherics the amount of $50 per vial of Product so replaced.

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5. Applicable Law. This Amendment and the rights of the parties hereto shall be governed by and construed and enforced in accordance with the laws of the State of Tennessee.

6. Severability. In case any one or more of the provisions contained in this Amendment or any application thereof shall be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained herein and any other application thereof shall not in any way be affected or impaired thereby.

7. Binding Effect. Except as herein otherwise provided to the contrary, the Agreement, as modified by this Amendment, shall be binding upon, and inure to the benefit of, the parties hereto and their respective heirs, executors, administrators, successors, transferees and assigns.

8. Section Captions. Section and other captions contained in this Amendment are for reference purposes only and are in no way intended to describe, interpret, define or limit the scope, extent or intent of this Amendment or any provision hereof.

9. Counterpart Execution. This Amendment may be executed in one (1) or more counterparts all of which together shall constitute one and the same Amendment.

[THE NEXT PAGE IS THE SIGNATURE PAGE]

IN WITNESS WHEREOF, this Amendment is executed effective as of the date first set forth above.

ALTANA, INC.:

By: _____

Title: PRESIDENT

PROTHERICS INC.:

By: _____

Title: President

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Ashurst Morris Crisp

Supply Agreement

Selborne Biological Services (Australia) Pty Limited

and

Protherics Australasia Pty Limited

21st October 2002

CONTENTS

THIS AGREEMENT is made on 21st October 2002

BETWEEN:-

(1) **SELBORNE BIOLOGICAL SERVICES (AUSTRALIA) PTY LIMITED** (ACN No. 054877975) whose registered office is at Mountford, Longford, Tasmania 7301, Australia (the **"Supplier"**); and

(2) **PROTHERICS AUSTRALASIA PTY LIMITED** (No. 062369724) whose registered office is at c/o PricewaterhouseCoopers, Level 14, 91 King William Street, Adelaide SA5000, Australia (the **"Customer"**).

RECITALS

(A) The Supplier carries on the business of producing and selling serum products, such as the Serum Products defined below.

(B) The Customer's Group, as defined below, carries on the business of selling Finished Products, as that term is also defined below, and the Customer wishes to purchase Serum Products from the Supplier in connection with that business.

(C) The Supplier is willing to supply Serum Products to the Customer on the terms set out in this agreement.

THE PARTIES AGREE AS FOLLOWS:-

1. **DEFINITIONS AND INTERPRETATION**

1.1 In this agreement the following words and expressions shall have the following meanings, unless the context otherwise requires:-

"Act" means A New Tax System (Goods and Services Tax) Act 1999 No. 55 of 1999;

"Affiliate" means any company, partnership or other entity which directly or indirectly controls, is controlled by or is under the common control of the Customer or the Supplier, as applicable;

"Bulk Immunogen" means the Customer's proprietary antigens prepared into lyophilised multiple dose format for use by the Supplier in the production of Serum Products;

"Business Day" means any day (excluding Saturdays) on which banks generally are open in Sydney for the transaction of normal banking business;

"Business Information" means all business, commercial, economic, financial, operational, technical, administrative, marketing, planning and staff information relating to a party or its interests;

"C of A" means Certificate of Analysis in the format set out in schedule 4 hereto;

"Change Control" means the Customer's system of evaluating, notifying and documenting planned changes from previously accepted practice and the impact thereof on the quality, safety and efficacy of Finished Products as regards the materials, components (including without limitation packaging, raw materials such as Serum Products and labeling), products, processes, computer systems, utilities or testing procedures used or involved in or relating to the production of Finished Products, whenever, howsoever and wherever in the course of such production they are relevant;

"Change Control Committee" means the committee established and appointed by the Customer from time to time, which is responsible for operating Change Control;

"Customer's Group" means the Customer, its subsidiaries, its holding company and the other subsidiaries of its holding company;

"Cycle" means each consecutive period of four weeks during the term of this agreement, the first such period to commence on the Effective Date;

"Effective Date" means 8 June 2001;

"Finished Products" means the Customer's proprietary antibody products;

"Goods and Services Tax" has the meaning ascribed to it in Chapter 6, section 195-1 of the Act;

"Husbandry Fee" means a fee of AU$0.61 per day; Confidential treatment requested

"Improvement" means all improvements, modifications and adaptations to any part of the process of producing the Serum Products, whether or not referred to in the Technical Agreement, which might reasonably be of commercial interest to either party in the design, manufacture or supply of the Serum Products and/or to the Customer in the design, manufacture or supply of the Finished Products and which may be made during the term of this agreement;

"Immunisation" means the procedure, conducted in accordance with this agreement, of inoculating with Immunogen Emulsion the sheep maintained by the Supplier pursuant to this agreement and used in the production of Serum Products, and **"Immunise"** shall be interpreted accordingly;

"Immunisation Fee" means a fee of AU$6.95 per Immunisation conducted in accordance with this agreement; Confidential treatment requested

"Immunogen Emulsion" means Bulk Immunogen solution for use in the Immunisation of sheep, prepared in accordance with the provisions of the Technical Agreement;

"Intellectual Property Rights" means any and all trade marks, rights in designs, get-up, trade, business or domain names, copyrights, future copyrights, patents, rights in databases (whether registered or not and any applications to register or rights to apply for registration

of any of the foregoing), rights in inventions, know how, trade secrets and other confidential information and all other intellectual property rights of a similar or corresponding nature which may now or in the future subsist in any part of the world;

"Priming Period" means the period of ten (10) Cycles following the Effective Date;

"Product Information" means all technical information and data relating to the Serum Products or their manufacture or to the Technical Agreement, including without limitation to and of the Customer's system for recording and tracing all procedures conducted in respect of sheep used in the production of Serum Products, known as "Tabpacs";

"Regulatory Inspection" means an inspection of the Supplier's premises, processes and/or equipment used in the production, storage or packaging of the Serum Products or in keeping or otherwise using or in relation to keeping or otherwise using such sheep as are used therein, by any appropriate regulatory authority including, but not limited to, the United States Food and Drug Administration (**"FDA"**) or by any officer in the performance of their duties pursuant to any legislation to which the Supplier is required to comply, in whole or in part, hereby, including without limitation, the Prevention of Cruelty to Animals Act 1985 (South Australia) and the Animal Welfare Act 1993 (Tasmania);

"Review Date" means the anniversary date of this agreement and each subsequent anniversary;

"Serum Products" means the products set out in schedule 1;

"Standard Operating Procedures" or **"SOPs"** means the Supplier's directions, as amended from time to time, for performing operations and procedures within the process of manufacturing Serum Products, including without limitation, those relating to cleaning, the use of protective clothing, environmental control and processing and sampling equipment operation;

"Taxable Supply" has the same meaning as in the Act;

"Technical Agreement" means the specification for the Serum Products and their manufacture by the Supplier, agreed between the parties on the same date as the date hereof, a copy of which is appended to this agreement as schedule 2;

"Test Bleed" means the test bleeding of sheep to be used in the production of Serum Products prior to the commencement thereof but otherwise in the same way as such bleeding would be conducted in the course of such production;

"Test Bleed Fee" means a fee of AU$5.97 per Test Bleed conducted in accordance with this agreement; 'Confidential treatment requested

"Value Added Tax" means Value Added Tax or any other tax of a similar nature that may be substituted for or levied in addition to it, in each case at the rate current from time to time; and

"Year" means a period of twelve (12) months from the date of this agreement and each consecutive period of twelve (12) months thereafter during the term of this agreement.

1.2 In this agreement unless otherwise specified, reference to:-

(a) a **"subsidiary"** or **"holding company"** is to be construed in accordance with section 9 of the Corporations Act 2001;

(b) a party means a party to this agreement and includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking;

(c) a person includes any person, individual, company, firm, corporation, government, state or agency of a state or any undertaking (whether or not having separate legal personality and irrespective of the jurisdiction in or under the law of which it was incorporated or exists);

(d) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;

(e) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(f) recitals, clauses, paragraphs or schedules are to recitals, clauses, and paragraphs of and schedules to this agreement. The schedules form part of the operative provisions of this agreement and references to this agreement shall, unless the context otherwise requires, include references to the recitals and the schedules;

(g) **"control"** is to be construed in accordance with section 50AA of the Corporations Act 2001 and **"controlling"** and **"controlled"** shall be construed accordingly.

1.3 The index to and headings in this agreement are for information only and are to be ignored in construing the same.

2. SUPPLY OF THE SERUM PRODUCTS AND BULK IMMUNOGEN

2.1 (a) Subject to clause 2.1(b) below and provided that the Customer complies with its obligations pursuant to clause 2.10(a) below, the Supplier shall supply and the Customer shall purchase such quantities of the Serum Products as the Customer may order from the Supplier from time to time in accordance with this agreement.

(b) The Supplier shall not be required to involve, at any given time, more than five thousand (5000) sheep in the production of Serum Products and shall not be required to supply the Customer with greater quantities of Serum Products than can be derived from such number of sheep, unless and until these limitations are amended pursuant to clause 2.1(c) below.

(c) The Supplier shall, as and when requested by the Customer, enter into good faith negotiations with the Customer to amend this clause 2.1 to:

(i) provide for an increase in the maximum number of sheep that the Supplier may be required to involve, at any given time, in the production of Serum Products; and

(ii) raise the limit imposed by clause 2.1(b) above on the maximum quantities of Serum Products which the Supplier may be required to provide to the Customer in accordance with this agreement.

2.2 The Customer shall notify the Supplier in writing of:-

(a) its estimated forecast for the Serum Products the Customer will require during the following twenty six (26) Cycles, on a rolling basis at the beginning of every fourth Cycle, the first such notification to be made by the Customer to the Supplier within ten (10) Business Days following the date of this agreement; and

(b) any revisions to those estimated forecast requirements as soon as reasonably practicable after such revisions are made.

2.3 (a) The Customer shall, on each occasion that it gives the Supplier notice of its estimated forecast requirements for Serum Products pursuant to clause 2.2(a) above, give the Supplier its order for those Serum Products with which it will require the Supplier to supply it during the subsequent thirteen (13) Cycles, the first such order to be made within ten (10) Business Days following the date of this agreement, provided that where any such order relates to any Cycle(s) in respect of which the Customer has already given its order to the Supplier, such order shall, to that extent, restate the order previously placed.

(b) Each such order shall specify:

(i) the exact type and quantity of the Serum Products required by the Customer; and

(ii) the date(s) on which, during the relevant period of thirteen (13) Cycles, such Serum Products shall be delivered to the Customer in accordance with this agreement.

(c) No order made pursuant to this clause 2.3 shall be for a larger quantity of Serum Products than the Customer's estimated forecast requirements in respect of the period to which such order relates.

2.4 Orders for the Serum Products shall be given by the Customer to the Supplier in writing or, if not, shall be confirmed in writing within ten (10) Business Days.

2.5 The Supplier shall be responsible for manufacturing adequate supplies of the Serum Products in accordance with this agreement to meet the Customer's estimated forecast requirements.

2.6 Notwithstanding the above, the Supplier shall be under no obligation to provide Serum Products to the Customer during the Priming Period.

2.7 The Supplier will notify the Customer in a timely manner of any material changes in the health status of the sheep flocks used to produce the Serum Products, or of any regulatory or legal changes affecting the management of such sheep flocks, or of any other aspect of the manufacturing process of the Serum Products that could have a material impact on the future supplies of or the quality of the raw materials required for manufacturing the Serum Products or, in each case, of the Serum Products themselves.

2.8 (a) The Supplier shall permit and provide all reasonable assistance to further the objectives of any Regulatory Inspections which any appropriate regulatory authority desires to undertake, including without limitation by answering all enquiries made in the course thereof and providing the relevant regulatory authority with access to relevant records.

(b) The Supplier shall notify the Customer of any pending Regulatory Inspection at the earliest opportunity and the Customer shall be granted the option of sending, at its own cost, a representative to be present at such Regulatory Inspection and shall receive copies of all reports produced therefrom, provided that the Customer shall ensure that such representative shall at all times comply with the Supplier's regulations and instructions relating to the safety and conduct of persons on its premises.

2.9 (a) If it becomes apparent that the Supplier will not be able to meet any order from the Customer for Serum Products, whether on the date(s) specified in that order or at all, the Supplier shall, as soon as practicable, notify the Customer and the Customer shall, without liability to the Supplier, be entitled to obtain Serum Products from any other person, in order that it acquires the quantities of Serum Products ordered from the Supplier. For the avoidance of doubt, if the Customer rejects any Serum Products pursuant to clause 8.1 below and the Supplier does not replace the same in accordance with clause 8.3, the Supplier shall, for the purposes of this clause, be deemed not to have met the order for Serum Products to which the same relates.

(b) If the Supplier subsequently notifies the Customer that it is able and willing to resume the supply of Serum Products in accordance with the Customer's orders, the Customer shall, without liability to the Supplier, remain entitled to fulfil its then existing contractual commitments to obtain Serum Products from any other supplier(s), prior to recommencing its orders for or acceptance of deliveries of Serum Products from the Supplier.

2.10 (a) The Customer shall supply, at no cost, the Supplier with such Bulk Immunogen as is sufficient, in the Customer's reasonable opinion, to enable the Supplier to produce, in accordance with this agreement, the Serum Products ordered by the Customer

pursuant hereto. The Customer shall ensure that during transport to the Supplier, such Bulk Immunogen is kept at temperatures between two (2) and eight (8) degrees Celsius and that each batch of Bulk Immunogen is accompanied by a completed C of A.

(b) The Customer shall supply Bulk Immunogen in accordance with this clause 2.10 on such dates as are notified to it in writing by the Supplier, provided that, in each case, the Supplier gives the Customer at least two (2) Cycles' notice of such dates, failing which, the Customer will satisfy such requests as soon as it is reasonably able.

(c) Supplies of Bulk Immunogen pursuant to this clause 2.10 shall be made at the Customer's expense, provided that if the Supplier requires the Customer to supply additional Bulk Immunogen, the Supplier shall pay for such additional supplies, payment to be made at the end of the month in which the Supplier receives the Customer's invoice therefor. For the avoidance of doubt, the Supplier shall pay for any Bulk Immunogen provided by the Customer additional to that which, in the Customer's reasonable opinion the Supplier would need to produce, in accordance with this agreement, the Serum Products ordered by the Customer, where Bulk Immunogen has been lost or otherwise cannot be used in the production of Serum Products through the Supplier's breach of this agreement or other default.

(d) The Supplier shall be responsible for obtaining any relevant Australian Quarantine and Inspection Service permits necessary to import Bulk Immunogen into Australia from the United Kingdom or elsewhere.

2.11 (a) The Supplier shall obtain and maintain throughout the term of this agreement all relevant or necessary licences under the Animal Welfare Act 1993 (Tasmania) to ensure its compliance therewith and shall otherwise comply in all respect with such legislation. The Supplier shall provide the Customer with copies of all such licences promptly upon obtaining the same.

(b) Throughout the term of this agreement, the Supplier shall, in the performance of its obligations hereunder, comply in all respects with the provisions of the:

(i) Animal Welfare Act 1993 (Tasmania);

(ii) Animal Health Act 1995 (Tasmania);

(iii) Animal Farming (Registration) Act 1994 (Tasmania) and all Regulations issued thereunder;

(iv) Environmental Management and Pollution Control Act 1994 (Tasmania), including without limitation in respect of its waste disposal and management procedures;

(v) Workplace Health and Safety Act 1995 (Tasmania); and

(vi) Export Control Act 1982 (Commonwealth).

(c) The Supplier shall obtain and maintain throughout the term of this agreement all applicable permits under the Environmental Management and Pollution Control Act 1994 (Tasmania) and shall provide the Customer with copies thereof upon obtaining the same.

3. CONDITIONS OF SALE

All sales of the Serum Products pursuant to this agreement shall, to the extent that they are applicable, be made on the Customer's standard terms and conditions of purchase which the Customer may issue from time to time and which are annexed to this agreement as schedule 3, save to the extent that:

(a) any provision of such terms and conditions is inconsistent with any provision of this agreement, in which case the latter shall prevail; or

(b) the Supplier and the Customer agree in writing to vary those terms and conditions of purchase.

4. TECHNICAL AGREEMENT

4.1 The Serum Products and their manufacture, storage and transport, and the manufacture, storage and transport of the materials from and with which they are produced, shall comply with the Technical Agreement in all respects and the Customer shall be entitled, in accordance with clause 8.1 below, to reject any Serum Products which do not so conform and to return such defective Serum Products to the Supplier or, at the Supplier's option, otherwise dispose of such defective Serum Products as the Supplier may direct and at the Supplier's expense.

4.2 The Customer shall provide such technical support and information to the Supplier as is reasonably requested to assist the Supplier to manufacture Serum Products in accordance with this agreement and shall be entitled to invoice the Supplier therefor in the event that the provision of such support or information causes the Customer expense in excess of AU$1,000 Confidential treatment requested

4.3 The parties shall meet from time to time to discuss possible amendments to the Technical Agreement.

4.4 Either party may propose an amendment to the Technical Agreement to take account of changes in relevant technology or any enactment or other change in relevant legislation or regulations and, where such amendment is proposed for such reason, the consent of the other party thereto shall not be unreasonably withheld or delayed.

4.5 All proposed amendments to the Technical Agreement made by the Supplier concerning the manufacturing of Serum Products or the testing thereof must be presented by the Supplier to the Customer in such a manner and format as to enable the Change Control Committee properly and fully to implement Change Control or in any other appropriate way to assess the impact, if any, of each such proposal on the quality, safety, efficacy and composition of

the Serum Products and Finished Products and no such proposed amendment shall be implemented until the Change Control Committee has, acting reasonably, so properly and fully implemented Change Control or otherwise assessed the impact of such proposed amendment, as is appropriate in the Customer's opinion.

4.6 Whilst the terms of the Technical Agreement are incorporated into this agreement, in the event of any conflict between the terms of the Technical Agreement and of this agreement, the terms of the Technical Agreement shall prevail.

5. PRODUCTION AND DELIVERY

5.1 The Supplier shall produce and maintain, in accordance with the Technical Agreement, sufficient stocks of Serum Products to meet the Customer's orders.

5.2 The Supplier shall use no antigens in the production of Serum Products other than Bulk Immunogen supplied by the Customer.

5.3 (a) Subject as provided in clause 5.4 below, the Supplier shall deliver the Serum Products ordered by the Customer either to an address within Australia or to an international airport in England or Wales, in each case on the date(s) specified in the relevant order(s) therefor, and shall notify the Customer at least two (2) Business Days in advance of each delivery and, where such delivery is to an airport in England and Wales, shall inform the Customer at the same time of the name of that airport and of the number of the flight on which the delivery will be made.

(b) Time for delivery shall be of the essence but the Supplier shall not be deemed to be in breach of this agreement for any failure to deliver on the specified date for such delivery, unless and until the Customer has given the Supplier ten (10) Business Days written notice requiring delivery, such notice not to be given until delivery is overdue.

5.4 (a) Until the Customer has been granted a licence by the FDA to manufacture Finished Products from Serum Products produced by the Supplier and to sell the same for human therapeutic use, the Customer shall store all Serum Products manufactured pursuant to this agreement at its facility and, for the avoidance of doubt, at temperatures between – 10 (negative ten) and – 26 (negative twenty six) degrees Celsius.

(b) Notwithstanding clause 5.4(a) above, the Supplier shall deliver to the Customer such quantities of Serum Products as are stored by the Supplier pursuant to clause 5.4(a) upon demand and in accordance with the provisions of this agreement relevant to the delivery of Serum Products, including without limitation those of clause 5.3.

(c) Upon receiving the licence referred to in clause 5.4(a) above, the Customer shall notify the Supplier that it has received the same, whereupon the parties shall agree a timetable for the delivery to the Customer of all Serum Products stored by the Supplier pursuant to clause 5.4(a), such deliveries in any event to be made in

accordance with the provisions of this agreement relevant to the delivery of Serum Products, including without limitation those of clause 5.3.

5.5 (a) The Supplier shall ensure that all Serum Products delivered to the Customer are packaged and handled in a manner appropriate to maintaining their condition and preventing its deterioration during transport, such measures to include, but not be limited to, the maintenance of temperature control and security of packaging.

(b) To the extent that it is applicable, the Supplier shall comply in all respects with the provisions of the Environment and Pollution Control Act 1994 (Tasmania) in delivering Serum Products to the Customer.

5.6 The Supplier shall procure from a reputable insurer comprehensive insurance against all risks in respect of each and every lot of Serum Products to be delivered to the Customer, including but not limited to goods in transit insurance and insurance of the Serum Products against fire and other risks while at the Supplier's premises. The Supplier shall not be required by this clause 5.6 to obtain insurance cover for each lot of Serum Products above the invoice value thereof.

5.7 The Supplier shall ensure that each lot of Serum Products to be delivered to the Customer is accompanied by documentation appropriate to comply with the formalities of any applicable regulatory authorities including, but not limited to, in the case of deliveries to the United Kingdom, the UK Ministry of Health and HM Customs & Excise and any shipping regulations, including commercial invoices, and with health/veterinary certificates and the applicable, completed C of A. Furthermore, the Supplier shall be responsible for obtaining any applicable licences or other consents for its export of Serum Products out of Australia when delivering the same to the United Kingdom.

5.8 Delivery of the Serum Products shall take place when they are received by the Customer or its agent at the address or airport to which they are delivered pursuant to clause 5.3 above.

6. SHEEP TO BE USED IN THE PRODUCTION OF SERUM PRODUCTS

6.1 The Supplier hereby acknowledges that the 1093 live sheep transferred by the Customer to the Supplier's facility at Mountford, Longford, Tasmania, on 8 June 2001 (the **"Original Sheep"**), are and shall remain the sole property of the Customer.

6.2 The Supplier shall acquire no sheep for use in the production of Serum Products additional to the Original Sheep (**"Additional Sheep"**), without the prior, written approval of the Customer.

6.3 (a) Subject to clause 6.2 above, the Supplier shall be responsible for determining whether, at any time, it will require any Additional Sheep in order to manufacture Serum Products ordered by the Customer and if so, how many Additional Sheep it will so require.

(b) The Supplier shall promptly notify the Customer upon determining that it will require any Additional Sheep in order to manufacture Serum Products ordered by the

Customer and, at the same time, shall inform the Customer of the number of Additional Sheep it considers that it will so require and by when it will require them.

(c) The Supplier shall promptly provide the Customer with such evidence as the Customer may request to verify any assessment by the Supplier that it will require Additional Sheep and of the number the Supplier considers it will so require.

6.4 In the event that the Customer notifies the Supplier in writing that it approves the acquisition of Additional Sheep by the Supplier, the Supplier shall purchase the same from sources and at prices approved in writing by the Customer, for and on behalf of the Customer and at the Customer's expense, and such Additional Sheep shall be and shall remain the sole property of the Customer. The Supplier shall arrange for the cost of all Additional Sheep acquired pursuant to this clause 6.4 to be invoiced directly to the Customer by the vendors thereof.

6.5 Notwithstanding that the same shall at all times be the Customer's property, the Supplier shall be responsible for the Original Sheep and any Additional Sheep, shall keep the same at its facility separately from any other livestock thereat and shall be responsible for the proper upkeep thereof in an appropriate manner and to appropriate standards prescribed by legislation for the use of the same in the production of Serum Products, (including, without limitation, by providing veterinary services therefor). For the purposes of this clause 6.5, applicable legislation with which the Supplier must comply includes but is not limited to those pieces of legislation referred to in clause 2.11.

6.6 (a) During the Priming Period, the Supplier shall charge the Customer, per Original Sheep:

(i) the Husbandry Fee;

(ii) the Immunisation Fee; and

(iii) the Test Bleed Fee;

such fees to be invoiced by the Supplier to the Customer at the end of the Cycle during which the same are incurred and to be payable in accordance with the terms of clause 7.

(c) In the event that any Additional Sheep are acquired on behalf of the Customer pursuant to clause 6.4 above, the Supplier shall charge the Customer, per Additional Sheep, during and in respect of the ten (10) Cycles following its acquisition:

(i) the Husbandry Fee;

(ii) the Immunisation Fee; and

(iii) the Test Bleed Fee;

such fees to be invoiced by the Supplier to the Customer at the end of the Cycle in which the same are incurred and to be payable in accordance with the terms of clause 7.

6.7 The Customer shall procure from a reputable insurance company insurance against the loss of the Original Sheep and any Additional Sheep used or to be used in the production of Serum Products and against the loss of their use in the production of Serum Products resulting therefrom or from their incapacity or unsuitability for use in the production of Serum Products for any other reason, and the Supplier shall provide the Customer with all information and other assistance as the Customer may reasonably require to assist it in procuring and maintaining such insurance.

6.8 (a) In the event that the Supplier, acting reasonably and on the basis of orders and forecasts for Serum Products received from the Customer pursuant to clauses 2.2 and 2.3 above, believes that it has more sheep available to use in the production of Serum Products than it requires to fulfil orders made pursuant to clause 2.3 above, the Supplier shall forthwith give notice to the Customer of the number of sheep it so considers to be surplus to its requirements and the date from when such sheep shall so become surplus to its requirements.

(b) On receipt of such notice, the Customer shall, in its discretion, be entitled to require the Supplier to, in which event the Supplier shall:

(i) maintain and Immunise all or some of such surplus sheep as the Customer specifies, without using the same in the manufacture of Serum Products but otherwise to the same standard as if they were so used, in respect of which the Customer shall pay the Husbandry Fee and the Immunisation Fee per sheep so maintained and Immunised without being used in the manufacture of Serum Products, until such time as it is again so used in such manufacture; or

(ii) maintain without Immunising all or some of such surplus sheep as the Customer specifies, without using the same in the manufacture of Serum Products but otherwise to the same standard as if they were so used, in respect of which the Customer shall pay the Husbandry Fee per sheep so maintained without being used in the manufacture of Serum Products, until such time as it is again so used in such manufacture;

provided that in neither case shall such sheep be used in the production of Serum Products until the Customer notifies the Supplier otherwise in writing.

(c) The Customer shall be entitled, at will, to require the Supplier to maintain and Immunise sheep in accordance clause 6.8(b)(i) above which were previously simply maintained in accordance with clause 6.8(b)(ii), and vice versa, provided that the sums payable by the Customer in respect of such sheep, as specified in such clauses, shall be substituted accordingly.

(d) In the event that and notwithstanding that the Customer does not, following receipt of a notice under clause 6.8(a) above, require the Supplier to maintain any or all such

surplus sheep or otherwise decides that the same should not be maintained, the Supplier may only destroy or otherwise dispose of the number of sheep stated in such notice or any of them after receiving prior written notice from the Customer authorising it to do as much. The Customer shall be responsible for all reasonable expenses related to such destruction or disposal.

(e) In the event that, within fifteen (15) Business Days of the Customer's receipt of a notice under clause 6.8(a) above, the Customer does not require the Supplier to maintain and/or Immunise such surplus sheep, or all of them, in accordance with clause 6.8(b) above, the Supplier shall maintain those sheep for which the Customer does not specify any such requirement in a good and proper manner but shall be under no obligation necessarily to maintain them as if the same were to be used in the production of Serum Products.

6.9 The Supplier shall be entitled to use the Original Sheep and any Additional Sheep in the production of Serum Products for the Customer in accordance with this agreement but for no other purpose without the express written consent of the Customer, which may be withheld for any reason.

7. PRICE AND PAYMENT

7.1 (a) Subject to clause 7.1(b) below, the Supplier shall at the time of each delivery of Serum Products issue a tax invoice in Australian Dollars to the Customer in respect of that delivery.

(b) Until the Customer has been granted a licence by the FDA to manufacture Finished Products from Serum Products produced by the Supplier and to sell the same for human therapeutic use, the Supplier shall, in respect of all Serum products stored by the Supplier pursuant to clause 5.4(a) and upon completion of their manufacture, invoice the Customer in Australian Dollars eighty (80%) percent of the price otherwise payable therefor. The Supplier shall invoice the remainder of the price payable for such Serum Products at the time of each delivery thereof to the Customer.

7.2 The price payable by the Customer for the Serum Products shall be as set out in schedule 1, and such price, the Husbandry Fee, the Immunisation Fee and the Test Bleed Fee shall remain fixed unless varied in accordance with this agreement, with no such variation, subject to clause 7.7 below, to be made other than on a Review Date.

7.3 (a) The parties shall meet either in person or by telephone at least fifty (50) Business Days in advance of each Review Date and shall negotiate in good faith to agree the percentage change, if any, over the preceding thirteen (13) Cycles in the cost to the Supplier of manufacturing and delivering the Serum Products in accordance with this agreement and in the event that they agree on that percentage, the price payable by the Customer for the Serum Products during the thirteen (13) Cycles following the next Review Date shall be increased or decreased, as applicable, by the same percentage. At the same time, the parties shall negotiate in good faith to agree the percentage changes, if any, over the preceding thirteen (13) Cycles in each of the

cost to the Supplier of maintaining sheep as if used in the production of Serum Products where the same are not so used, of Immunising sheep and of conducting Test Bleeds, and in the event that they agree on those percentages, the Husbandry Fee, the Immunisation Fee and the Test Bleed Fee during the thirteen (13) Cycles following the next Review Date shall respectively be increased or decreased, as applicable, by the same percentages.

(b) In the event that thirty (30) Business Days before such Review Date, the parties have not reached agreement in accordance with clause 7.3(a) above, they shall refer the matter for determination in accordance with clause 7.8, whereupon the price payable by the Customer for the Serum Products, the Husbandry Fee, the Immunisation Fee and the Test Bleed Fee during the thirteen (13) Cycles following the next Review Date shall respectively be increased or decreased, as applicable, by the same percentages as the percentage changes, if any, in the cost to the Supplier over the preceding thirteen (13) Cycles of manufacturing and delivering the Serum Products in accordance with this agreement, of maintaining sheep as if used in the production of Serum Products where the same are not so used, of Immunising sheep and of conducting Test Bleeds, each as determined pursuant to clause 7.8.

(c) Notwithstanding the above, if neither party requests a meeting pursuant to clause 7.3(a) within fifty (50) Business Days before the relevant Review Date, the price payable by the Customer for the Serum Products and the Husbandry Fee, the Immunisation Fee and the Test Bleed Fee during the thirteen (13) Cycles following such Review Date shall be the same as during the thirteen (13) Cycles preceding it, subject to any change to the price payable by the Customer for the Serum Products made pursuant to clause 7.7 below.

7.4 (a) Unless clearly indicated to the contrary, the prices set out in schedule 1, as amended, and all other amounts and consideration to be provided under or in connection with this agreement (**"Agreed Prices"**) are exclusive of any Goods and Services Tax and of any Value Added Tax or other United Kingdom taxes which is/are or may become payable as a consequence of importing Serum Products into the United Kingdom, but otherwise reflect the total prices payable by the Customer's Group for the Serum Products.

(b) Where an Agreed Price is exclusive of Goods and Services Tax, the Customer will pay to the Supplier such Agreed Price plus the amount of any Goods and Services Tax for which the Supplier becomes liable in respect of any Taxable Supply made by the Supplier in consideration for that Agreed Price.

(c) A member of the Customer's Group shall pay any Value Added Tax due at the point of import into the United Kingdom of Serum Products exported thereto by the Supplier.

7.5 The price of the Serum Products shall include all costs of packaging, carriage and insurance therefor.

7.6 The Customer shall pay the Supplier the amount stated on each invoice for Serum Products issued pursuant to clause 7.1 at the end of the month following the date on which such invoice or the relevant Serum Products themselves are received by the Customer, whichever is the later.

7.7 If at any time during the term of this agreement the Customer requests material changes to be made to the Technical Agreement which concern the manufacturing procedures used to manufacture Serum Products and which the Supplier can prove will increase the costs to the Supplier to manufacture Serum Products or which the Customer can prove will decrease such costs, the parties will negotiate in good faith to agree revised prices for the Serum Products to reflect such increased or decreased costs, such revised prices to take effect when the parties agree, provided that if the parties have not reached such agreement within a reasonable time, they shall refer the matter for determination in accordance with clause 7.8, whereupon any increase or decrease in such costs will be as determined pursuant to clause 7.8.

7.8 (a) In the event that clause 7.3(b) applies, or in the event that the Customer and the Supplier are unable to agree a change in the price for the Serum Products pursuant to clause 7.7, the parties shall refer the matter to a partner for the time being of any of the "big five" accountancy firms acceptable to both the Customer and the Supplier or failing him to such other person as the Customer and the Supplier may agree or in the absence of agreement such person as shall be appointed by the President for the time being of the Institute of Chartered Accounts in Australia upon the application of either party (the "**Expert**").

(b) The Expert shall act as an expert and not as an arbitrator, his decision shall (in the absence of manifest error) be final and binding on the parties and he shall use all reasonable endeavours to determine, within twenty (20) Business Days:

(i) in the case of a referral under clause 7.3(b), the percentage change, if any, over the preceding thirteen (13) Cycles in the cost to the Supplier of manufacturing and delivering Serum Products in accordance with this agreement, of maintaining sheep as if used in the production of Serum Products where the same are not so used, of Immunising sheep or of conducting Test Bleeds, as applicable; or

(ii) in the case of a referral under clause 7.7, a revised price for the Serum Products which reflects the change in the cost to the Supplier of manufacturing the same as a result of material changes to the Technical Agreement made at the Customer's request.

In making a determination pursuant to clause 7.8(b)(i) above, the Expert shall reduce his calculation of any percentage change over the preceding thirteen (13) Cycles in the cost to the Supplier of manufacturing and delivering Serum Products in accordance with this agreement, of maintaining sheep as if used in the production of Serum Products where the same are not so used, of Immunising sheep or of conducting Test Bleeds, as applicable, to discount any increases in the foregoing

which have already been reflected by increases, pursuant to clauses 7.7 or 7.8(b)(ii), in the price payable by the Customer for Serum Products.

(c) Each party shall co-operate fully with the Expert and shall bear the entire cost to it arising out of the discharge of its obligations pursuant to this clause and the expenses of all counsel and other advisers, witnesses and employees retained by it for the purposes of the determination, save that the costs and expenses of the Expert shall be borne by the parties in such proportions as he may direct or, in the absence of direction, equally.

(d) Subject to any rule of law or of any regulatory body or to any provision of any contract entered into prior to the date of this agreement to the contrary and to appropriate obligations of confidentiality, the Customer and the Supplier shall each give to the other and to the Expert such access to premises, papers, books, accounts, records, returns and other documents in their respective possession or control as may be required by the Expert to make his determination.

7.9 (a) Notwithstanding the contrary provisions of clauses 7.3 and 7.8, in the event that in respect of any period of thirteen (13) Cycles following a Review Date (the **"Following Year"**), the quantities of Serum Products ordered by the Customer pursuant to clause 2.3(a) are at least fifteen (15) per cent. higher than those ordered in respect of the thirteen (13) Cycles preceding such Review Date (the **"Previous Year"**), the price payable by the Customer for the Serum Products during the Following Year shall not be increased or decreased, as applicable, by a percentage equal to the percentage change, if any, in the cost to the Supplier of manufacturing and delivering the Serum Products in accordance with this agreement during the Previous Year, whether determined by agreement of the parties pursuant to clause 7.3 or by the Expert pursuant to clause 7.8(b), but shall be increased or decreased, as applicable, by a percentage equal to the projected percentage change, if any, in the cost to the Supplier of manufacturing and delivering the Serum Products in accordance with this agreement during the Following Year.

(b) In the event that clause 7.9(a) applies, the parties shall endeavour to agree the projected percentage change, if any, in the cost to the Supplier of manufacturing and delivering the Serum Products in accordance with this agreement during the Following Year at their meetings held pursuant to clause 7.3(a) and, in the event that they agree such percentage within thirty (30) Business Days before the relevant Review Date, the price payable by the Customer for the Serum Products shall be increased or decreased, as applicable, by the same percentage. In the event that the parties do not so agree such percentage within thirty (30) Business Days before the relevant Review Date, the matter shall be referred to the Expert who shall determine such percentage in accordance with clause 7.8.

8. DEFECTS

8.1 The Customer shall, within fifty (50) Business Days of the delivery of any shipment of Serum Products, notify the Supplier of any defect therein by reason of which the Customer alleges that such Serum Products do not comply with, or that their manufacture, storage or transport, or the manufacture, storage or transport of the materials from which they were

produced, has not complied with the requirements of this agreement, in which case the Customer shall be deemed to have rejected such shipment of Serum Products.

8.2 If the Customer fails to give such notice then, except in respect of any defect which is not apparent on reasonable inspection, the Customer shall be deemed to have accepted delivery of the Serum Products in such shipment, and the Supplier shall have no liability to the Customer in respect of late or missed delivery.

8.3 In the event that the Customer rejects any Serum Products pursuant to clause 8.1 above, the Supplier shall, within twenty (20) Business Days of being requested to do so, supply replacement Serum Products which accord with and whose manufacture, storage and transport, and the manufacture, storage and transport of the materials from which they were made accord with the requirements of this agreement, at no extra cost to the Customer.

9. INTELLECTUAL PROPERTY

9.1 All Intellectual Property Rights in the Serum Products and the Finished Product and in the process of producing Finished Products from Serum Products or otherwise, and in all Product Information furnished by or on behalf of the Customer to the Supplier and in any other subject matter supplied to the Supplier in relation to the production of the Serum Products shall belong to and be and remain vested exclusively in the Customer, and the Supplier shall, without charge, assign and transfer to the Customer, with full title guarantee, all Intellectual Property Rights in the foregoing and each part of each and every one of them, for the remainder of the term during which the said rights and any renewals or extensions thereof shall subsist, including the rights to sue for the past infringements of such Intellectual Property Rights and to retain any damages obtained as a result of such action.

9.2 The Supplier shall execute and do all such documents, deeds, matters, acts and things as the Customer may at any time require properly to vest the Intellectual Property Rights in the Serum Products and the Finished Products or any part of or any one or more of them in the Customer or, at the Customer's direction, any other member company of the Customer's Group, or otherwise to perfect the Customer's or such other member company of the Customer's Group's title thereto or to assist the Customer in enforcing its entitlement hereunder to sue for any past infringement thereof. The Customer shall pay the Supplier's reasonable expenses in performing its obligations under this clause 9.2 but, for the avoidance of doubt, the Customer shall make no additional charge for performing such obligations.

9.3 All the Intellectual Property Rights in the process of producing the Serum Products shall, from the outset, and as between the parties, be vested exclusively in the Supplier, save to the extent that they or the materials, technologies or techniques in which they subsist have been provided to the Supplier by or on behalf of the Customer or any other member company of the Customer's Group, in which case and to which extent they shall belong exclusively to the Customer or such other company, as applicable.

9.4 (a) The Customer shall provide and license the Supplier, for the term of this agreement, use of such Intellectual Property Rights in the Product Information owned by the Customer as shall be necessary for the Supplier to produce Serum Products in accordance with this agreement but for no other purpose and the Supplier shall keep

the same in the strictest confidence in accordance with the provisions of clause 16 hereto.

(b) Upon the termination of this agreement, the Supplier shall promptly return all materials provided by the Customer pursuant to this clause 9.4, along with all copies and notes thereof, whether of the whole of such materials or part only, in whatever form the same exist.

(c) Other than as expressly provided by this clause 9.4 or otherwise in writing, the Supplier has no entitlement to and shall make no use of any Intellectual Property Rights owned by or licensed to the Customer.

9.5 In performing its obligations pursuant to this agreement, the Supplier shall not knowingly infringe the Intellectual Property Rights of any third party and shall use its reasonable endeavours not to infringe any such Intellectual Property Rights.

10. IMPROVEMENTS AND INVENTIONS

10.1 If the Supplier makes or acquires an Improvement, it shall promptly and fully disclose and explain the same in confidence to the Customer to the extent that it is not prohibited by law, by any undertaking given to others or by considerations relating to the securing of a patent or other Intellectual Property Right protection.

10.2 The Supplier shall, at the Customer's request, grant a world-wide, non-exclusive, royalty free, irrevocable licence (including the right to grant sub-licences thereunder) to the Customer in respect of any Improvement it makes and discloses to the Customer under clause 10.1 above. The provisions of this clause 10.2 shall survive the termination of this agreement for whatever reason.

10.3 If any patent is obtained by the Supplier in respect of any Improvement, the Supplier shall, at the Customer's request, grant a non-exclusive, royalty free, irrevocable licence (including the right to grant sub-licences thereunder) to the Customer in all the countries in which patent protection is obtained, for the full term of such patent. The provisions of this clause 10.3 shall survive the termination of this agreement for whatever reason.

10.4 Any Improvement arising from work carried out jointly shall belong to the parties equally unless they shall otherwise agree. Each party:-

(a) shall have the irrevocable right to use such joint Improvement independently of the other;

(b) shall have, to the extent necessary for such use, a licence in respect of all jointly held Intellectual Property Rights relating thereto including the right to grant sub-licences thereunder; and

(c) hereby undertakes that, on request, it will confirm to any prospective licensee of the other the right of that other pursuant to this clause to grant such a licence.

10.5 (a) Where the Supplier has developed an Improvement it shall not publish the same or do anything that might prejudice the validity of any patent that might subsequently be granted on such Improvement until the Customer has had at least fifteen (15) Business Days from disclosure to it in writing of all information relating to such Improvement to consider whether patent or other protection should be applied for in respect thereof.

(b) The Supplier will, on request, notify the Customer whether it intends to seek any patent protection in respect of such Improvement and if it does not, it shall, on request, assign to the Customer or such other member company of the Customer's Group as the Customer may direct all rights therein and the obligation on the Supplier in clause 10.5(a) above shall continue for such time as may be reasonably required in order for the Customer or such other company, as applicable, to prepare and file an application for such patent protection.

10.6 The Supplier may, at any time in respect of an Improvement, elect not to pursue further an application for patent protection either jointly or on its own behalf or to maintain any such patent protection as it may have obtained but shall notify the Customer of any such election and shall offer the rights in such Improvement or patent to the Customer and shall, if so requested by the Customer, assign all rights it may have therein to the Customer, or such other member company of the Customer's Group as the Customer may direct, provided that the Supplier shall be entitled to a full, irrevocable, world-wide, perpetual, royalty free, non-exclusive licence under all relevant rights with the right to sub-license and assign the same.

10.7 Each party shall bare its own costs in respect of any patent applications it makes but the parties shall share equally the costs of filing and prosecuting, to the fullest extent possible, any future joint patent applications and of maintaining in all countries every patent granted pursuant to such applications.

10.8 (a) Each party shall inform the other of any infringement of any patent obtained in respect of any Improvement (for the purposes of this clause, a **"Patent"**) forthwith upon such infringement coming to its notice.

(b) In the event of such infringement and in the event that the party which owns a Patent chooses to pursue the infringer, the other party shall, at the first party's expense, provide all reasonable assistance to the first party, (including without limitation the use of its name in or being joined as a party to proceedings) in connection therewith.

(c) In the event of such infringement and in the event that the party which owns the relevant Patent chooses not to pursue the infringer, the other party may take all legitimate steps to halt the infringement and the first party shall, at the other party's expense, provide all reasonable assistance to the other party, (including without limitation the use of its name in or being joined as a party to proceedings) in connection with such steps.

(d) Except as expressly provided above, each party shall bear the costs of any proceedings taken in respect of such infringement.

11. QUALITY CONTROL AND COMPLIANCE WITH REGULATIONS

11.1 The Supplier shall at all times maintain, in a clean, safe and hygienic condition and in accordance with all appropriate statutes and regulations:-

(a) the premises at which it produces Serum Products;

(b) the equipment located in such premises which is used in connection with the production and packaging of Serum Products; and

(c) all packaging to be used in connection with Serum Products.

11.2 (a) In addition to the rights granted to the Customer by the Supplier by clause 2.8 above, the Supplier shall, on reasonable notice, permit the Customer's authorised representatives from time to time and during normal working hours to enter, assess and inspect the premises at which the Supplier produces Serum Products and its personnel involved in such production, in order to observe the Supplier's operations and methods, provided that the Customer shall ensure that such representatives shall at all times comply with the Supplier's regulations and instructions relating to the safety and conduct of persons on its premises.

(b) The Supplier shall provide all reasonable assistance to the Customer and its authorised representatives in conducting any assessment or inspection pursuant to this clause 11.2, including without limitation by answering all enquiries made in the course thereof and by providing access to relevant records.

11.3 The Supplier shall, on the fifteenth (15^{th}) day of each month, provide the Customer with a written report providing any information which might reasonably be of interest to the Customer relating to the following matters, such report to relate to the calendar month prior to that in which it is provided:

(a) the health status of the sheep involved in the production of Serum Products;

(b) the process of immunising and bleeding such sheep in the course of producing Serum Products;

(c) the yields of Serum Products obtained from such sheep; and

(d) any issues relating to quality control, non-compliance with Standard Operating Procedures, regulatory requirements, excursions or incidents involving such sheep or any aspect of the production of Serum Products.

11.4 The obligations of clause 11.3 above shall not apply insofar as the Supplier gives the Customer information which it would otherwise be required to do thereunder pursuant to other provisions of this agreement, including, for the avoidance of doubt, the Technical Agreement.

11.5 The Supplier shall dispose of any unused Bulk Immunogen and of any and all unneeded, unused or unusable Serum Products or the production stages thereof, of which it disposes for whatever reason, whether pursuant to this agreement or otherwise, at its own cost, appropriately, promptly and safely, in compliance with all applicable environmental and health and safety laws, regulations and legislation.

11.6 Without prejudice to the foregoing, the Supplier shall comply in all respects, including without limitation, in respect of workplace safety and the condition of the premises at which it produces the Serum Products, with the provisions of the Workplace Health and Safety Act 1995 (Tasmania).

11.7 The Customer shall have no liability to the Supplier for any claims brought by the Supplier's employees or agents pursuant to the Workers Rehabilitation and Compensation Act 1988 (Tasmania) or for breaches of the Workplace Health and Safety Act 1995 (Tasmania) in respect of the premises on which such employees or agents work.

11.8 The Customer shall have no liability to the Supplier for any payments to the Supplier's employees or agents, whether by remuneration, long service leave, or any other entitlements, or for any claims brought by the Supplier's employees or agents, whether pursuant to common law or any legislation.

12. WARRANTIES

12.1 The Supplier warrants to the Customer that it shall produce, handle, store and transport Serum Products and all materials and components used in their production with skill, competence, care and attention and in accordance with all appropriate legislation, regulations and other requirements of any appropriate regulatory authority which apply from time to time.

12.2 The Supplier warrants to the Customer that the Serum Products shall be of satisfactory quality and shall conform with the Technical Agreement and that the Supplier shall comply with the Technical Agreement and the requirements of all SOPs referred to therein in all respects.

12.3 The Supplier warrants to the Customer that the Serum Products are and shall continue to be, until title to them is transferred to the Customer (which shall occur when the Serum Products are delivered to the Customer or its agent pursuant to clause 5.8 above), its absolute property, free from any mortgage, charge, pledge, lien or third party right or interest of any kind, but for the avoidance of doubt, this clause 12.3 shall not operate to restrict the Supplier from offering its assets, other than Serum Products and the production stages thereof, as security for indebtedness which it incurs in the normal course of its business.

12.4 The Supplier warrants to the Customer that it shall keep all sheep used or to be used in the production of Serum Products at its facility separately from any other livestock thereat in an appropriate manner and to appropriate standards prescribed by legislation for the use of the same in such production including, without limitation, by providing veterinary services therefor.

12.5 The Supplier warrants to the Customer that it shall comply with all legislative or regulatory requirements imposed upon it by virtue of the performance of its obligations or the exercise of its rights pursuant to this agreement, including but not limited to the:

(i) Animal Welfare Act 1993 (Tasmania);

(ii) Animal Health Act 1995 (Tasmania);

(iii) Environmental Management and Pollution Control Act 1994 (Tasmania);

(iv) Environment Protection Act 1993 (Tasmania);

(v) Export Control Act 1982 (Commonwealth);

(vi) Workplace Health and Safety Act 1995 (Tasmania); and

(vii) Workers Rehabilitation and Compensation Act 1986 (Tasmania);

and, to the extent applicable, that it has given due consideration thereto and to any other appropriate legislation in preparing the SOPs, such that the SOPs, and the manufacture of Serum Products and the upkeep of the sheep used therein in accordance with such SOPs, comply and shall comply with such requirements.

12.6 The Supplier warrants that it shall comply with the Trade Practices Act 1974 (Commonwealth) in the provision of services to the Customer pursuant to this agreement.

12.7 Each party warrants to the other that it has obtained all corporate authorisations and all other applicable governmental, statutory, regulatory or other consents, licences, waivers or exemptions required to empower it to enter into and to perform its obligations under this agreement.

12.8 Each party warrants to the other that its entering into this agreement will not be a breach of any other agreement to which it is a party .

13. LIMITATION OF LIABILITY

13.1 The Supplier's liability to the Customer for:-

(a) death or injury resulting from its own negligence, or that of its employees, agents or subcontractors; and

(b) all loss or damage suffered by the Customer as a result of breach by the Supplier of statutorily implied terms in respect of the Serum Products relating to title, quiet possession and freedom from encumbrances;

shall not be limited.

13.2 Subject to clause 13.1 above, the Supplier's liability for any single breach of this agreement shall be limited to AU$15 million Confidential treatment requested

13.3 The Customer shall not be responsible in any way for ensuring or assisting the Supplier's compliance with such legislation as the Supplier is required to comply with hereby or otherwise, and shall have no liability to the Supplier for and in the event of the Supplier's failure so to comply with such legislation or any part thereof.

14. FORCE MAJEURE

14.1 "**Event of Force Majeure**" means, in relation to either party, an event or circumstance beyond the reasonable control of that party (the "**Claiming Party**") including, without limitation, strikes, lock-outs and other industrial disputes (in each case, whether or not relating to the Claiming Party's workforce).

14.2 The Claiming Party shall not be deemed to be in breach of this agreement or otherwise liable to the other party (the "**Non-Claiming Party**") for any delay in performance or any non-performance of any obligations under this agreement (and the time for performance shall be extended accordingly) to the extent that the delay or non-performance is due to an Event of Force Majeure, provided that:-

(a) the Claiming Party could not have avoided the effect of the Event of Force Majeure by taking precautions which, having regard to all matters known to it before the occurrence of the Event of Force Majeure and all relevant factors, it ought reasonably to have taken but did not take; and

(b) the Claiming Party has used reasonable endeavours to mitigate the effect of the Event of Force Majeure and to carry out its obligations under this agreement in any other way that is reasonably practicable.

14.3 The Claiming Party shall promptly notify the Non-Claiming Party of the nature and extent of the circumstances giving rise to the Event of Force Majeure.

14.4 If the Event of Force Majeure in question prevails for a continuous period in excess of three (3) months after the date on which it began, the Non-Claiming Party may give notice to the Claiming Party terminating this agreement. The notice to terminate must specify the termination date, which must not be less than thirty (30) clear days after the date on which the notice to terminate is given. Once the notice to terminate has been validly given, this agreement will terminate on the termination date set out in the notice. Neither party shall have any liability to the other in respect of termination of this agreement due to an Event of Force Majeure, but rights and liabilities which have accrued prior to termination shall subsist, including without limitation those under clause 16.

15. DURATION AND TERMINATION

15.1 (a) This agreement shall come into effect on the Effective Date and shall continue in force for a period of five (5) years (the "**Initial Term**"), unless terminated earlier pursuant to this clause 15. Confidential treatment requested

(b) Following the expiry of the Initial Term, and provided that neither party has given the other notice of termination, such notice to be given at least eighteen (18) months prior to the end of the Initial Term, this agreement shall remain in force until terminated by either party giving to the other party not less than eighteen (18) months' written notice.

15.2 A party (the "**Initiating Party**") may terminate this agreement with immediate effect by written notice to the other party (the "**Breaching Party**") on or at any time after the occurrence of any of the following events:

(a) the Breaching Party being in continuing or material breach of an obligation under this agreement and, if the breach is capable of remedy, failing to remedy the breach within thirty (30) Business Days starting on the day after receipt of written notice from the Initiating Party giving full details of the breach and requiring the Breaching Party to remedy the breach;

(b) the Breaching Party passing a resolution for its winding-up or a court of competent jurisdiction making an order for the Breaching Party's winding-up or dissolution;

(c) the making of an administration order in relation to the Breaching Party or the appointment of a receiver over, or an encumbrancer taking possession of or selling an asset of the Breaching Party; and

(d) the Breaching Party making an arrangement or composition with its creditors generally or making an application to a court of competent jurisdiction for protection from its creditors generally.

15.3 For the purpose of clause 15.2(a):

(a) a breach will be considered capable of remedy if time is not of the essence in performance of the obligation in question and if the Breaching Party can comply with the obligation within the thirty (30) Business Day period referred to in such clause; and

(b) without limitation, a breach by either party of any legislative or regulatory requirement with which it is required to comply hereunder shall constitute a material breach of an obligation under this agreement.

15.4 Notwithstanding the above, the Customer may terminate this agreement forthwith and without liability to the Supplier in the event that:

(a) the Customer receives notification that the FDA will not grant its approval to sale of Finished Products for human therapy if manufactured from Serum Products produced for the Customer by the Supplier;

(b) the Customer does not receive such approval within a reasonable time following the Effective Date;

(c) such approval, if granted, is withdrawn; or

(d) the Customer determines in its reasonable discretion not to request such approval on the basis that it does not reasonably consider that the FDA will grant the same.

15.5 Following the termination of this agreement for whatever reason, the parties shall negotiate in good faith the removal of the Original Sheep and any Additional Sheep from the Supplier's premises but until the same are so removed, the Supplier shall maintain them at the Customer's expense in such manner as immediately prior to such termination or as the Customer otherwise directs.

15.6 Upon the termination of this agreement, for whatever reason, the Supplier shall promptly execute all such documents, deeds, matters, acts and things as the Customer may require properly to vest in the Customer or, at the Customer's direction, any other member of the Customer's Group, such Intellectual Property Rights to which the Customer is entitled pursuant to this agreement and which have not, prior to such termination, been so executed. The Customer shall pay the Supplier's reasonable expenses in performing its obligations under this clause 15.6 but, for the avoidance of doubt, the Customer shall make no charge for performing such obligations.

16. CONFIDENTIALITY

16.1 Each party shall, during the full term of this agreement and thereafter, keep secret and confidential the contents of this agreement, the Technical Agreement and all Business Information and Product Information disclosed to it by or on behalf of the other party or otherwise belonging to the other party (and shall procure that its agents and/or employees are similarly bound) and shall not disclose the same to any person, save to the extent necessary to perform its obligations under this agreement in accordance with its terms and save as expressly authorised in writing to be disclosed by the other party.

16.2 The obligation of confidentiality contained in clause 16.1 shall not apply or (as the case may be) shall cease to apply to Business Information or Product Information which:-

(a) at the time of its disclosure by the disclosing party is already in the public domain or which subsequently enters the public domain other than by breach of the terms of this agreement by the receiving party;

(b) is already known to the receiving party (as evidenced by written records) at the time of its disclosure by the disclosing party and was not otherwise acquired by the receiving party from the disclosing party under any obligations of confidence;

(c) is at any time after the date of this agreement acquired by the receiving party from a third party having the right to disclose the same to the receiving party without breach of obligation owed by that third party to the disclosing party; or

(d) is required to be disclosed by applicable law or order of a court of competent jurisdiction or government department or agency or by the rules and standards of the

London Stock Exchange plc or the Listing Rules of the UK Listing Authority or the rules and requirements of any other regulatory body, including without limitation, the Australian Securities and Investments Commission, provided that prior to such disclosure the receiving party shall advise the disclosing party of the proposed form of the disclosure.

16.3 Notwithstanding the foregoing provisions of this clause 16, the Customer and any of its sub-licensees pursuant to this agreement shall be entitled to disclose Business Information or Product Information of the Supplier to:

(i) actual or potential customers for Finished Products, insofar as such disclosure is reasonably necessary to promote the sale or use of Finished Products; and

(ii) any other member company of the Customer's Group.

16.4 Each party shall procure that all its employees, contractors, consultants, advisers and sub-licensees pursuant to this agreement (if any) who have access to any information of the other to which the obligations of clause 16.1 apply shall be made aware of and subject to these obligations and shall further procure that so far as is reasonably practicable, all such employees, contractors and sub-licensees shall enter into written undertakings in favour of the other party to this end.

16.5 Any disclosures made by a party under this agreement to the other party which are specific or a combination of features shall not be deemed to fall within the above exceptions merely because any specific disclosure is covered by a general disclosure or because individual features are within or subsequently enter the public domain or the other party's possession and the above exceptions shall only apply in the case of disclosure of a combination of features if the combination and its principle of operation is within or subsequently enters the public domain or the other party's possession following acquisition by that other party from a third party entitled to make such disclosure without breach of any obligation of confidence.

17. COSTS

Save as expressly otherwise provided in this agreement each of the parties shall bear its own legal, accountancy and other costs, charges and expenses connected with the negotiation, preparation and implementation of this agreement and any other agreement incidental to or referred to in this agreement.

18. VARIATIONS

18.1 This agreement may be varied only by a document signed by each of the Supplier and the Customer, except that:

(a) the Customer may amend at will its standard terms and conditions of purchase annexed hereto as schedule 3; and

(b) in the event that the Customer reasonably requests amendments to be made to the Technical Agreement, such amendments shall take effect upon the Customer giving notice thereof to the Supplier.

18.2 In the event that the Customer amends its standard terms and conditions of purchase annexed hereto as schedule 3, it shall promptly notify the Supplier of such amendments.

19. WAIVER

19.1 A waiver of any term, provision or condition of, or consent granted under this agreement shall be effective only if given in writing and signed by the waiving or consenting party and then only in the instance and for the purpose for which it is given.

19.2 No failure or delay on the part of any party in exercising any right, power or privilege under this agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or privilege preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

19.3 No breach of any provision of this agreement shall be waived or discharged except with the express written consent of the parties.

19.4 The rights and remedies herein provided are cumulative with and not exclusive of any rights or remedies provided by law.

20. INVALIDITY

If any provision of this agreement is or becomes (whether or not pursuant to any judgment or otherwise) invalid, illegal or unenforceable in any respect under the law of any jurisdiction:-

(a) the validity, legality and enforceability under the law of that jurisdiction of any other provision; and

(b) the validity, legality and enforceability under the law of any other jurisdiction of that or any other provision,

shall not be affected or impaired in any way thereby.

21. NOTICES

21.1 Any notice, demand or other communication given or made under or in connection with the matters contemplated by this agreement shall be in writing and shall be delivered by hand or sent by prepaid post (airmail if sent abroad) or sent by facsimile transmission and immediately confirmed by hand delivery or registered post:-

In the case of the Supplier to:
Address: Mountford, Longford, Tasmania 7301, Australia
Fax: +61 (0)3 6391 2723
Attention: The General Manager

In the case of the Customer to:

Address: Protherics Australasia Pty Ltd, RSD Turretfield Research Centre, Rosedale, South Australia 5350

Fax: + 61 (0)8 8524 9113

Attention: Operations ~~Manager~~ DIRECTOR JC N.C.P.

and a notice given in accordance with this clause shall be deemed received:-

(a) if delivered by hand, upon the date of delivery;

(b) if sent by pre-paid post, seven (7) Business Days after the date of posting;

(c) if sent by fax, on the day the transmission is sent (but only if the sender has a confirmation report specifying a facsimile number of the recipient, the number of pages and date of transmission),

provided that if, in accordance with the above provision, any such notice, demand or other communication would otherwise be deemed to be given or made after 5.00 p.m., such notice, demand or other communication shall be deemed to be given or made at 9.00 a.m. on the next Business Day.

21.2 A party may notify the other party to this agreement of a change to its name, relevant addressee, address or fax number for the purposes of clause 21.1 provided that such notification shall only be effective on:-

(a) the date specified in the notification as the date on which the change is to take place; or

(b) if no date is specified or the date specified is less than five (5) Business Days after the date on which notice is given, the date falling five (5) Business Days after notice of any such change has been given.

22. NO PARTNERSHIP

22.1 Nothing in this agreement and no action taken by the parties pursuant to this agreement shall constitute, or be deemed to constitute, the parties a partnership, association, joint venture or other co-operative entity.

22.2 At no time shall either of the parties have the authority to hold itself out as the agent of the other or as being empowered to bind the other in any way whether contractually or otherwise.

23. ASSIGNMENT AND SUB-CONTRACTING

23.1 Subject to clause 23.2, this agreement is personal to the parties to it and accordingly, neither party may, without the prior written consent of the other, assign the benefit of all or any its obligations under this agreement, nor any benefit arising under or out of this agreement.

23.2 The Customer shall be entitled without the prior written consent of the Supplier to assign, transfer or in any manner make over the benefit and/or burden of this agreement to an Affiliate or member company of the Customer's Group or to any joint venture company where it is the beneficial owner of at least fifty (50) per cent. of the issued share capital thereof or to any company with which it may merge or to any company to which it may transfer its assets and undertaking provided that such Affiliate or other company undertakes and agrees in writing to assume, observe and perform the rights and powers and/or duties and obligations of the Customer under this agreement.

23.3 This agreement shall be binding upon the successors and assignees of the parties hereto and the name of a party appearing herein shall be deemed to include the name of its successors and assignees, provided always that nothing shall permit any assignment by either party except as expressly provided herein.

23.4 The Supplier may sub-contract any of its obligations under this agreement, provided that:

(a) it has used all due diligence in selecting the third party to which it sub-contracts such obligations, by evaluating the competency of such third party to undertake the same;

(b) it advises the Customer in advance of its intention to sub-contract such obligations to a third party and at such time identifies such third party to the Customer and informs the Customer of the terms of such proposed sub-contracting arrangement; and

(c) the Customer consents in writing to such sub-contracting to such party on such terms, which consent may be withheld for any reason.

23.5 Notwithstanding any sub-contracting of its obligations to a third party, the Supplier shall remain fully responsible for the performance of its obligations under and fully liable for any breach of this agreement.

23.6 In the event that the Supplier sub-contracts any of its obligations under this agreement to a third party, the Supplier shall conduct audits of such third party's performance on at least an annual basis and promptly report the results of such audits to the Customer.

24. GOVERNING LAW AND JURISDICTION

24.1 This agreement (and any dispute, controversy, proceedings or claims of whatever nature arising out of or in any way relating to this agreement or its formation) shall be governed by and construed in accordance with the laws of South Australia.

24.2 Each of the parties to this agreement irrevocably agrees that the courts of South Australia shall have non-exclusive jurisdiction to hear and decide any suit, action or proceedings, and/or to settle any disputes, which may arise out of or in connection with this agreement and, for these purposes, each party irrevocably submits to the non-exclusive jurisdiction of the courts of South Australia.

24.3 Neither party not commence any court or arbitration proceedings in relation to any dispute arising out of the subject matter of this agreement unless (except where such party seeks urgent interlocutory relief) it:

(a) gives written notice to the other party specifying the nature of the dispute; and

(b) then endeavours to resolve the dispute with the other party expeditiously using formal dispute resolution techniques such as mediation, expert evaluation or determination or similar techniques agreed by them.

24.4 If the parties do not agree within seven (7) days of service of the notice referred to in clause 24.3(a) (or such further period as they may agree in writing) as to:

(a) the dispute resolution techniques and procedures to be adopted;

(b) the timetable for all steps in those procedures; and

(c) the selection and compensation of the independent person required for such technique;

the parties shall mediate the dispute in accordance with Practice Direction No. 12 of the Supreme Court of South Australia (Guidelines for Conduct of Mediation) and execute an agreement to mediate in a form approved by the Law Society of South Australia. The President of the Law Society of South Australia or the President's nominee will select the mediator and determine the mediator's remuneration.

25. EXCLUSION OF THIRD PARTY RIGHTS

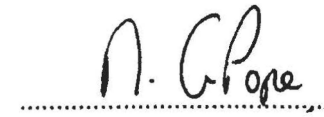
This agreement is not for the benefit of any person who is not a party signatory hereto or specifically named as a beneficiary herein.

26. ENTIRE AGREEMENT

Other than in the case of any claim or proceeding based upon fraud (including without limitation fraudulent concealment), this agreement, incorporating the Technical Agreement, constitutes the entire and only agreement and understanding of the parties and supersedes all prior oral or written agreements, undertakings, representations or arrangements between them relating to the subject matter of this agreement. Neither party shall be entitled to rely on any agreement, understanding, representation or arrangement which is not expressly contained in this agreement.

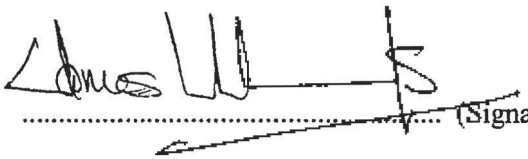
IN WITNESS whereof this agreement has been executed on the date first above written.

Signed by
for and on behalf of **SELBORNE BIOLOGICAL SERVICES (AUSTRALIA) PTY LIMITED**



..... (Signature)

Signed by
for and on behalf of **PROTHERICS AUSTRALASIA PTY LIMITED**



..... (Signature)

Ashurst Morris Crisp

Confidential treatment requested 4.12

Manufacturing Agreement

Protherics UK Limited

and

Chesapeake Biological Laboratories Inc.

19 March 2003

MAL/DTB/PRO05.00021

CONTENTS

THIS AGREEMENT is made on 19 March 2003

BETWEEN:-

(1) **PROTHERICS UK LIMITED** (No. 3464264) whose registered office is at Blaenwaun, Ffostrasol, Llandysul, Ceredigion SA44 5JT, UK (**"Protherics"**); and

(2) **CHESAPEAKE BIOLOGICAL LABORATORIES INC.** (No. D01116516) whose registered office is at Camden Industrial Park, 1111 S. Paca Street, Baltimore, M.D. 21230-2591, USA (**"Chesapeake"**).

RECITALS

(A) Protherics carries on the business of selling Finished Products produced from Bulk Products, in each case as defined below.

(B) Chesapeake carries on the business of freeze-drying and packaging pharmaceutical products such as Bulk Products.

(C) Protherics wishes to engage Chesapeake to Manufacture (as defined below) Finished Products and Chesapeake is willing to undertake such work, on the terms and conditions set out in this agreement.

THE PARTIES AGREE AS FOLLOWS:-

1. **DEFINITIONS AND INTERPRETATION**

1.1 In this agreement the following words and expressions shall have the following meanings, unless the context otherwise requires:-

"Affiliate" means, in respect of each party, any company, partnership or other entity which directly or indirectly controls, is controlled by or is under the common control with such party;

"Batch" means a batch of Finished Products;

"Batch Production and Control Record" means comprehensive histories, produced by Chesapeake, of the Manufacture of each Batch;

"Business Day" means any day (excluding Saturdays and Sundays) on which banks generally are open in the City of London for the transaction of normal banking business;

"Business Information" means all business, commercial, economic, financial, operational, administrative, marketing, planning and staff information relating to a party or its interests;

"Buffer" means the solution supplied by Protherics to be used for wetting filters used in Manufacture;

"Bulk Products" means Protherics' bulk formulated proprietary antibody products from which Finished Products are Manufactured, supplied by Protherics to Chesapeake pursuant to this agreement;

"cGMP" means the Code of Federal Regulations, Part 21, Sections 210 and 211 and such other Sections thereof as are designated by the title "Good Manufacturing Practices" and promulgated under the United States Federal Food, Drug and Cosmetic Act, as are in effect from time to time;

"Change Control" means Protherics' system of evaluating, notifying and documenting planned changes from previously accepted practice and the impact thereof on the quality, safety and efficacy of Finished Products as regards the materials, components (including without limitation packaging, labeling and Materials), products, processes, computer systems, utilities or testing procedures, used or involved in or relating to the Manufacture, storage or delivery of Finished Products, whenever, howsoever and wherever in the course thereof they are relevant;

"Change Control Committee" means the committee established and appointed by Protherics from time to time, which is responsible for operating Change Control;

"Effective Date" means the date of this agreement;

"EMEA" means the European Medicines Evaluation Agency;

"Expert" means a person to whom reference is made pursuant to clause 13.2 and who is appointed as specified therein;

"Expert Determination" means the determination of a dispute or difference between the parties by an Expert, in accordance with clause 13;

"Facility" means Chesapeake's facility for the sterile filtration, filling and freeze-drying of pharmaceutical products at Camden Industrial Park, 1111 S. Paca Street, Baltimore, M.D. 21230-2591, USA;

"FDA" means the United States Food and Drug Administration;

"FDA Approval" means the receipt by Protherics of confirmation from the FDA that the FDA approves Chesapeake to Manufacture Finished Products on the licence concerning Finished Products granted to Protherics by the FDA;

"Final Release" means final approval for sale of Finished Products given by the relevant Regulatory Authority or Regulatory Authorities and/or by Protherics, and in the event that such approval is given by Protherics and one or more Regulatory Authorities, the last such approval so given;

"Finished Products" means the products specified in schedule 1;

"Intellectual Property Rights" means any and all trade marks, rights in designs, get-up, business names, copyrights, future copyrights and patents (whether registered or not and any

applications to register or rights to apply for registration of any of the foregoing), rights in inventions, know-how, trade secrets and other confidential information and all other intellectual property rights of a similar or corresponding nature, which may now or in the future subsist in any part of the world;

"Materials" means all materials, components and reagents, other than Bulk Products and Buffer, used by Chesapeake in the Manufacture of Finished Products;

"Manufacture" means the manufacture of Finished Products from Bulk Products through their sterile filtration, filling and freeze-drying and the testing, packing and labelling thereof, and **"Manufactured"** and **"Manufacturing"** shall be construed accordingly;

"MCA" means the United Kingdom Medicines Control Agency;

"Pack of Finished Products" means a pack containing the number of Vials of Finished Products set out in the Specification, which such Vials shall be packed in accordance with the Technical Agreement;

"Product Information" means all technical information and data relating to the Bulk Products, Finished Products and Specification, and the contents of the Technical Agreement;

"Quality Control Certificate of Release" means a certificate of release in the form attached to this agreement as schedule 5;

"Qualified Person" has the same meaning as in European Directive 75/319/EEC;

"Regulatory Authority" means the FDA, the MCA and EMEA;

"Regulatory Inspections" means an inspection by any Regulatory Authority of the Facility or of Chesapeake's processes and/or equipment used in Manufacture or in the storage of Finished Products, or any part or component thereof;

"Rejects" means Vials rejected by Chesapeake or Protherics for containing Finished Products not conforming to the Specification and/or not Manufactured, stored, handled or transported in accordance with this agreement and the Technical Agreement;

"Renewal Date" means the second anniversary of the Effective Date;

"Specification" means the specification for the Finished Products appended to this agreement as schedule 2;

"Target" means, in respect of any Batch, the number of Vials comprising such Batch as would be produced by utilising all Bulk Products supplied by Protherics for use in the Manufacture of the Finished Products comprising such Batch and were such quantity of such Bulk Products as Protherics specifies pursuant to clause 3.3 to be included therein in the course of such Manufacture, less the number of Vials within such Batch as are used by Chesapeake in conducting sterility tests in accordance with the Technical Agreement, as specified in schedule 8;

"Technical Agreement" means the agreed specification for Manufacture of the same date as the date hereof, a copy of which is appended to this agreement as schedule 3;

"Technology Transfer Period" means the period of six (6) months following the Effective Date;

"Value Added Tax" means Value Added Tax or any other tax of a similar nature that may be substituted for or levied in addition to it, in each case at the rate current from time to time;

"Vial" means the type of vial to be used in packing Finished Products as part of Manufacture, as provided by the Technical Agreement, containing the appropriate quantity of the relevant Finished Product;

"Water for Injection" means water complying with the United States Environmental Protection Agency National Primary Drinking Water Regulations or comparable regulations of the European Union, purified by distillation and by reverse osmosis and containing no added substances; and

"Yield" means, in respect of any Batch, the number of Vials of Finished Products Manufactured in accordance with this agreement net of Rejects and which are potentially available for sale by Protherics in the course of its business.

1.2 In this agreement unless otherwise specified, reference to:-

(a) a **"subsidiary"** or **"holding company"** is to be construed in accordance with section 736 of the Companies Act 1985;

(b) a party means a party to this agreement and includes its permitted assignees and/or the respective successors in title to substantially the whole of its undertaking;

(c) a person includes any person, individual, company, firm, corporation, government, state or agency of a state or any undertaking (whether or not having separate legal personality and irrespective of the jurisdiction in or under the law of which it was incorporated or exists);

(d) a statute or statutory instrument or any of their provisions is to be construed as a reference to that statute or statutory instrument or such provision as the same may have been or may from time to time hereafter be amended or re-enacted;

(e) words denoting the singular shall include the plural and vice versa and words denoting any gender shall include all genders;

(f) recitals, clauses or schedules are to recitals and clauses of and schedules to this agreement. The schedules form part of the operative provisions of this agreement and references to this agreement shall, unless the context otherwise requires, include references to the recitals and the schedules;

(g) **"control"** is to be construed in accordance with section 416 of the Income and Corporation Taxes Act 1988 and **"controlling"** and **"controlled"** shall be construed accordingly.

1.3 The index to and headings in this agreement are for information only and are to be ignored in construing the same.

2. PRODUCTION OF FINISHED PRODUCTS BY CHESAPEAKE

2.1 Chesapeake shall Manufacture and store Finished Products at the Facility in accordance with the terms of this agreement, the Technical Agreement and cGMP, and shall ensure that such Finished Products comply with the Specification in all respects.

2.2 Protherics shall notify Chesapeake in writing of:

(a) its estimated forecast of the number of Vials of each of the Finished Products which it will require to be Manufactured each month during the subsequent twelve (12) months of the term of this agreement, such forecasts to be given on a rolling basis every month, the first to be given within ten (10) Business Days following FDA Approval; and

(b) any revisions to the estimated forecast requirements that Protherics has already given to Chesapeake pursuant to clause 2.2(a) above as soon as reasonably practicable after such revisions are made.

2.3 (a) Chesapeake shall notify Protherics of all proposed and scheduled shutdowns or other suspensions of the operation of the Facility or of any part or parts thereof or of any machinery therein, the effect of which will or may be that for the duration of the same Chesapeake will be unable to Manufacture, at the relevant time, the Finished Products which Protherics has notified Chesapeake in accordance with clause 2.2 above that Protherics estimates it will require to be Manufactured in any particular month (**"Proposed and Scheduled Shutdowns"**).

(b) Chesapeake shall notify Protherics of all Proposed and Scheduled Shutdowns (including of the dates thereof) as soon as reasonably practicable after the same are first proposed or scheduled to occur, as applicable, and shall in any event confirm details thereof to Protherics in writing every six (6) months of the term of this agreement, the first such confirmation to be so given no later than ten (10) Business Days after the Effective Date.

2.4 (a) Protherics shall, on each occasion that it gives Chesapeake notice of its estimated forecast requirements for Finished Products pursuant to clause 2.2(a) above, give Chesapeake its binding order in writing for the quantities of each of the Finished Products which it will require Chesapeake to Manufacture in a single month after that in which such binding order is given.

(b) Each binding order given by Protherics pursuant to clause 2.4(a) above shall specify the week of the month to which such binding order relates in which Protherics would like Chesapeake to Manufacture the Finished Products ordered thereby.

(c) Protherics shall ensure that it gives Chesapeake each binding order pursuant to clause 2.4(a) above at least sixty five (65) Business Days prior to the commencement of the month to which such binding order relates.

(d) Protherics shall give no binding order pursuant to clause 2.4(a) above for Finished Products which it knows Chesapeake will not be able to Manufacture when specified in such binding order because of any Proposed and Scheduled Shutdowns of which Protherics has been notified pursuant to clause 2.3.

2.5 (a) As soon as reasonably practicable following receipt of any binding order pursuant to clause 2.4(a) above, Chesapeake shall determine when it will Manufacture the Finished Products to which such binding order relates, which Manufacture shall, subject to clause 2.5(b) below, take place during the week specified by Protherics pursuant to clause 2.4(b) above (the **"Allocated Manufacturing Date"**).

(b) Notwithstanding clause 2.5(a) above, provided that Chesapeake has Protherics' prior written consent so to do, Chesapeake may schedule an Allocated Manufacturing Date other than in the week specified by Protherics pursuant to clause 2.4(b) above in the binding order for the Finished Products to be Manufactured on such Allocated Manufacturing Date.

(c) Chesapeake shall notify Protherics in writing of each Allocated Manufacturing Date no later than two (2) Business Days after receipt of the binding order to which it relates or the day forty (40) Business Days prior to such Allocated Manufacturing Date, whichever is the later to occur.

2.6 Chesapeake shall use all reasonable endeavours to avoid scheduling any shutdowns or other suspensions of the operation of the Facility or of any part or parts thereof or of any machinery therein, the effect of which will or may be that Chesapeake will be unable to Manufacture any Finished Products on the relevant Allocated Manufacturing Date and supply the same to Protherics in accordance with this agreement in the month specified in the relevant binding order therefor given pursuant to clause 2.4(a) above, provided that this clause shall not prevent Chesapeake scheduling any such shutdowns which are necessary in the event of any emergency or other similar occurrence.

2.7 (a) Subject to clause 2.7(b) below, Chesapeake shall Manufacture and supply such quantities of Finished Products as Protherics may order pursuant to clause 2.4(a) above in accordance with the binding orders given pursuant to that clause, including without limitation by:

(i) Manufacturing the same on the relevant Allocated Manufacturing Date therefor determined in accordance with clause 2.5 above; and

(ii) supplying such Finished Products to Protherics in accordance with this agreement in the month specified in the relevant binding order therefor;

provided that Protherics supplies Chesapeake with sufficient quantities of Bulk Products and Buffer for Chesapeake so to do.

(b) Notwithstanding the foregoing, Chesapeake may:

(i) Manufacture Finished Products up to ten (10) Business Days after the relevant Allocated Manufacturing Date therefor; or

(ii) with Protherics' prior written consent, Manufacture Finished Products up to ten (10) Business Days before the relevant Allocated Manufacturing Date therefor;

without breaching clause 2.7(a) above.

2.8 (a) Protherics may request the postponement of the scheduled Manufacture of any Finished Products which it has, in accordance with this agreement, ordered to be Manufactured (a **"Scheduled Fill"**) to a date after the Allocated Manufacturing Date therefor, by giving written notice to Chesapeake.

(b) If Protherics requests the postponement of any Scheduled Fill by twenty (20) Business Days or less, Chesapeake shall use its best endeavours to Manufacture the Finished Products relevant thereto on the date to which Protherics requests such Manufacture to be postponed, failing which, Chesapeake will Manufacture such Finished Products as soon as it can thereafter.

(c) If Protherics requests the postponement of any Scheduled Fill by more than twenty (20) Business Days, including without limitation pursuant to clause 2.11(a) below, Chesapeake shall use all reasonable endeavours to Manufacture the Finished Products relevant thereto on the date to which Protherics requests such Manufacture to be postponed, failing which, Chesapeake will Manufacture such Finished Products as soon as reasonably practicable thereafter.

(d) In the event that Protherics requests the postponement of any Scheduled Fill pursuant to clause 2.8(a) above, Protherics may revoke the postponement thereof, in which event Chesapeake shall use all reasonable endeavours to Manufacture the Finished Products applicable thereto on the Allocated Manufacturing Date for such Finished Products or as soon as reasonably practicable thereafter.

(e) Without prejudice to clauses 2.8(d) above and 2.9(e) below, in the event that Protherics requests the postponement of any Scheduled Fill, Chesapeake shall use all reasonable endeavours to arrange to manufacture alternative products for any of its other clients on the Allocated Manufacturing Date therefor.

2.9 (a) Subject to clauses 2.9(b), (c), (d) and (e) below, Protherics shall be liable to pay Chesapeake a postponement fee in respect of each Scheduled Fill which it requests pursuant to clause 2.8(a) above be postponed by more than twenty (20) Business Days, such fee to be as provided in schedule 6.

(b) In the event that Protherics requests the postponement of any Scheduled Fill, and following the revocation of such postponement pursuant to clause 2.8(d) above, the same takes place on the Allocated Manufacturing Date therefor, Protherics shall be

deemed not to have postponed such Scheduled Fill and shall not be liable to pay any postponement fee pursuant to clause 2.9(a) in respect thereof.

(c) In the event that Protherics requests the postponement of any Scheduled Fill and Chesapeake manufactures any product for any other client of Chesapeake on any Allocated Manufacturing Date for such Scheduled Fill, in accordance with clause 2.8(e) above, Protherics shall not be liable to pay any postponement fee pursuant to clause 2.9(a) above in respect thereof.

(d) In the event that Protherics requests the postponement of a Scheduled Fill before having been notified pursuant to clause 2.5(c) above of the Allocated Manufacturing Date for the Finished Products relevant thereto, Protherics shall not be liable to pay Chesapeake a postponement fee pursuant to clause 2.9(a) above in respect of the same.

(e) In the event that Protherics requests the postponement of any Scheduled Fill pursuant to clause 2.8(a) above, Protherics may, at the time of so requesting the postponement of such Scheduled Fill, notify Chesapeake that it would like Chesapeake to Manufacture other Finished Products (whether or not already ordered by Protherics to be Manufactured at some future date) in place of those relevant to such Scheduled Fill, in which event Chesapeake shall, notwithstanding that the Manufacture of the same may not have been ordered in accordance with clause 2.4(a) above, Manufacture such other Finished Products in place of those relevant to such Scheduled Fill on the Allocated Manufacturing Date for those relevant to such Scheduled Fill (provided that Protherics supplies sufficient quantities of Bulk Products and Buffer for Chesapeake so to do), in which event Protherics shall not be liable to pay any postponement fee pursuant to clause 2.9(a) above in respect of the postponement of the Manufacture of the same.

2.10 (a) Notwithstanding the foregoing but subject to clause 2.10(b) below, if Protherics postpones more than three (3) Scheduled Fills in any twelve (12) months period, Protherics shall be liable to pay Chesapeake a postponement fee in respect of each Scheduled Fill which Protherics postpones thereafter, such fee to be as provided in schedule 6, provided that Protherics shall not be required to pay more than one (1) such postponement fee in respect of any given postponement of any Scheduled Fill.

(b) In the event that clause 2.10(a) above applies, the provisions thereof shall remain in force until a period of twelve (12) months has passed during which Protherics postpones no more than three (3) Scheduled Fills.

(c) The provisions of clause 2.10(a) above may apply more than once during the term of this agreement.

2.11 (a) Subject to 2.11(b) below, in the event that Protherics postpones more than three (3) Scheduled Fills in any twelve (12) months period, Protherics shall give Chesapeake at least forty (40) Business Days' notice of the date on which it would like the Finished Products relevant to any further Scheduled Fills which it postpones to be Manufactured.

(b) In the event that clause 2.11(a) above applies, the provisions thereof shall remain in force until a period of twelve (12) months has passed during which Protherics postpones no more than three (3) Scheduled Fills.

(c) The provisions of clause 2.11(a) above may apply more than once during the term of this agreement.

(d) In the event that clause 2.11(a) applies such that a Scheduled Fill which Protherics had requested be postponed by twenty (20) Business Days or less is postponed by more than twenty (20) Business Days, such postponement shall be deemed to be for less than twenty (20) Business Days for the purposes of clauses 2.8(b) and (c) above.

2.12 Chesapeake shall invoice Protherics for any sums due pursuant to clause 2.9(a) above no sooner than forty (40) Business Days following the same becoming due and all such invoices shall be payable in accordance with clause 9.4 below.

2.13 Chesapeake shall, as specified therein, report to Protherics the results of all tests which it conducts pursuant to the Technical Agreement.

2.14 Chesapeake shall obtain and maintain at its own expense and risk, all equipment, plant, apparatus and appliances necessary to enable it to store the Bulk Products, Buffer and all Materials and to Manufacture and store Finished Products in accordance with cGMP, the Technical Agreement and this agreement.

2.15 Chesapeake shall provide and maintain clean and safe storage for all Bulk Products, Buffer and Materials in accordance with cGMP and the Technical Agreement.

2.16 Chesapeake shall obtain all Materials and other components used in the Manufacture of Finished Products (except for Bulk Products and Buffer) and only from sources approved in advance by Protherics.

2.17 Within twenty five (25) Business Days of completing the Manufacture of each Batch, Chesapeake shall send Protherics a Batch Production and Control Record in respect thereof.

3. SUPPLY OF BULK PRODUCTS BY PROTHERICS

3.1 Chesapeake shall accept such quantities of Bulk Products and Buffer as Protherics delivers to the Facility from time to time.

3.2 Chesapeake shall use all Bulk Products received from Protherics to Manufacture Finished Products in accordance with this agreement and shall be responsible for ensuring that it is able to do so, subject to Protherics providing Chesapeake with sufficient Buffer for that purpose.

3.3 Protherics shall ensure that each delivery of Bulk Products is accompanied by a Quality Control Certificate of Release, which shall specify the quantity of such Bulk Products as are to be incorporated within each Vial in the course of Manufacturing the Finished Products contained therein and as are Manufactured from such Bulk Products.

3.4 Chesapeake shall store all Bulk Products obtained from Protherics in accordance with clause 3 of the Technical Agreement and, upon receipt of each delivery thereof, shall conduct those inspections specified in clause 2.5 of the Technical Agreement and shall promptly inform Protherics of any non-conformance which it discovers thereby.

3.5 (a) Title and risk in the Bulk Products shall remain with Protherics at all times.

(b) Notwithstanding the above, but without prejudice to Protherics' other rights and remedies hereunder, Chesapeake shall reimburse Protherics for the cost of all Bulk Products lost or destroyed while in Chesapeake's custody or under its control, subject to a limit of US$100,000 per Batch in respect of the Manufacture of which the same were or would have been utilised, and all payments due under this clause shall be made by Chesapeake to Protherics by credit note, direct reimbursement or at the reasonable discretion of Protherics.

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3.6 Protherics shall provide Chesapeake with reasonable information concerning the Finished Products to assist Chesapeake in understanding and discharging its obligations under this agreement and with details of any relevant requirements of any Regulatory Authority.

4. DELIVERY OF FINISHED PRODUCTS

4.1 (a) Within ten (10) Business Days after freeze-drying each Batch as part of the process of Manufacturing the same, Chesapeake shall make available such number of properly filled, labelled and packaged Vials as Protherics requests containing Finished Products from such Batch and no other (**"Advanced Samples"**) for Protherics' designated carrier to take delivery of the same at the Facility.

(b) Chesapeake shall notify Protherics of the date on which such Advanced Samples will be ready for Protherics' designated carrier to take delivery of the same, such notice to be given at least three (3) Business Days before the end of the ten (10) Business Days period specified in clause 4.1(a) above.

(c) No less than one (1) Business Day prior to the day on which Protherics' designated carrier will take delivery of such Advanced Samples, Protherics shall inform Chesapeake of such carrier's identity and of such carrier's estimated time of arrival at the Facility, which shall be during Chesapeake's normal business hours.

4.2 (a) Without prejudice to clause 4.1 above, Chesapeake shall make available the properly filled, labelled and packaged Finished Products ordered by Protherics in accordance with clause 2, less such as were comprised within already delivered Advanced Samples, for Protherics' designated carrier to take delivery of the same at the Facility.

(b) Protherics shall arrange for its designated carrier to take delivery of such Finished Products within ten (10) Business Days following Final Release thereof and shall notify Chesapeake of the date on which such carrier will so take delivery of the same, such notice to be given at least three (3) Business Days before the end of such ten (10) Business Days period.

(c) No less than one (1) Business Day prior to the day on which Protherics' designated carrier will take delivery of such Finished Products, Protherics shall inform Chesapeake of such carrier's identity and of such carrier's estimated time of arrival at the Facility, which shall be during Chesapeake's normal business hours.

4.3 Chesapeake shall permit Protherics' designated carrier to take delivery of Finished Products pursuant to clauses 4.1 and 4.2 on the dates and times specified pursuant thereto or such other reasonable dates and times as such carrier may otherwise attend the Facility for such purpose within Chesapeake's normal business hours and shall give such carrier all reasonable assistance in so taking delivery of the same.

4.4 Subject to any contrary provisions herein, all deliveries of Finished Products pursuant to clauses 4.1 or 4.2 above shall be FCA (Incoterms 2000) at the Facility, such that Chesapeake shall, without limitation, be responsible at its expense for loading the same at the Facility onto the relevant means of carriage therefor.

4.5 Title in the Finished Products shall vest in and remain at all times with Protherics whereas risk therein shall remain with Chesapeake until delivery, whereupon it shall pass to Protherics.

4.6 Protherics may appoint more than one carrier to take delivery of Finished Products in accordance with clauses 4.1 and 4.2, including of Finished Products within any given Batch, but shall in any event comply with the obligations in clauses 4.1(c) and 4.2(c) with respect to each such carrier.

4.7 Until such time as they are delivered to Protherics pursuant to clauses 4.1 or 4.2 above, Chesapeake shall store all Finished Products and for the avoidance of doubt and in accordance with clause 2.1 above, shall ensure that such storage complies with the requirements of the Technical Agreement.

5. PACKAGING OF FINISHED PRODUCTS

5.1 Protherics shall provide Chesapeake with details of Protherics' trade mark livery, together with any associated original artwork and relevant wording that Protherics requires be used on the packaging of and/or on the Finished Products or on the product–inserts to be packaged therewith, which livery, artwork and wording Chesapeake shall use on such packaging as directed by Protherics.

5.2 Subject to clause 5.3 below, Protherics shall give Chesapeake sixty five (65) Business Days' notice of any change in the trade mark livery, artwork or wording to be used on the packaging of and/or on the Finished Products or on the product-inserts to be packaged therewith, before Chesapeake shall be required to start using the same in accordance with clause 5.1 above.

5.3 If any Regulatory Authority requires a change to the packaging and/or labelling used on Finished Products, Protherics shall inform Chesapeake in writing within two (2) Business Days of being notified of such requirement and shall provide Chesapeake with full details of the changes to be made, in which event Chesapeake shall make such changes to the packaging of and/or labelling used on the Finished Products or on the product-inserts to be packaged therewith according to the time schedule dictated by such Regulatory Authority.

5.4 Protherics hereby grants Chesapeake a non-exclusive licence of those trade marks, details of which it provides Chesapeake pursuant to clauses 5.1 or 5.2 above, and its associated get-up, for the term of this agreement, only for the purpose of using the same on the packaging of and/or on the Finished Products, in accordance with Protherics' instructions, such licence neither to be assigned nor sub-licensed other than with Chesapeake's obligations pursuant to this agreement as provided for herein.

5.5 All use of Protherics' trade marks by Chesapeake shall at all times be for the benefit of Protherics and any goodwill accrued to Chesapeake by its use of such trade marks shall accrue to and be held in trust by Chesapeake for Protherics, which goodwill Chesapeake agrees to assign to Protherics at its request at any time, whether during or after the subsistence of this agreement, and this clause 5.5 shall survive the termination of this Agreement for whatever reason.

5.6 Notwithstanding the other provisions of this clause 5, Chesapeake shall provide Protherics with proofs of all packaging, labels and all product-inserts to be used on or for or to be packaged with the Finished Products, and shall use none of these without Protherics' prior approval. In the event that Protherics requests any changes to be made to such packaging or product-inserts, Chesapeake shall promptly effect such changes and re-submit the same to Protherics for approval.

5.7 (a) Protherics shall provide Chesapeake with details of the validated packaging plan for all Finished Products within ten (10) Business Days following FDA Approval and, subject to clause 5.7(b) below, Chesapeake shall ensure that all Finished Products delivered pursuant to this agreement shall be packaged for delivery as specified therein.

(b) Protherics may provide Chesapeake with amendments to the validated packaging plan provided pursuant to clause 5.7(a) above, including without limitation amendments thereto which are specific to any particular Finished Product or in respect of Finished Products to be transported to any particular destination or destinations, in which event Chesapeake shall ensure that all Finished Products delivered pursuant to this agreement shall be packaged for delivery as specified in such amended packaging plans.

(c) For the avoidance of doubt, Protherics may provide Chesapeake with amendments to the validated packaging plans provided pursuant to clause 5.7(a) above as and when Protherics determines and on any number of occasions.

6. VARIATIONS TO THE SPECIFICATION AND TECHNICAL AGREEMENT

6.1 (a) Protherics may at any time propose a variation to the Specification or to the Technical Agreement by written notice to Chesapeake and Chesapeake's agreement to any such variation shall not be unreasonably withheld or delayed, provided that Protherics shall not propose a variation to the Specification or to the Technical Agreement during the Technology Transfer Period.

(b) If Chesapeake does not consent within twenty (20) Business Days to a variation to the Specification or Technical Agreement proposed by Protherics, Protherics shall be entitled to give written notice to terminate this agreement forthwith and without further

liability, unless Chesapeake acted reasonably in not giving such consent within such time period.

(c) For the avoidance of doubt, Chesapeake shall not be considered to have unreasonably withheld its consent to a variation to the Specification or Technical Agreement proposed by Protherics if such consent was withheld because implementing the proposed variation would have caused Chesapeake to incur expense which it would not otherwise have incurred, which expense Protherics was not willing to bear.

(d) Chesapeake shall implement all agreed variations to the Specification or Technical Agreement proposed by Protherics as quickly as reasonably practicable following Chesapeake consenting to the same in accordance herewith.

6.2 (a) Chesapeake may, at any time, in order to comply with applicable law, propose a variation to the Specification or the Technical Agreement, in which event the parties shall negotiate in good faith to agree the proposed variation and the time scale in which to implement it in order to comply with such law.

(b) Notwithstanding clause 6.2(a) above, all amendments to the Technical Agreement or the Specification proposed by Chesapeake must be presented by Chesapeake to Protherics in such a manner and format as to enable the Change Control Committee properly and fully to implement Change Control or in any other appropriate way to assess the impact, if any, of each such proposal on the quality, safety, efficacy and composition of the Finished Products, and no such proposed amendment shall be implemented until the Change Control Committee has, acting reasonably, so properly and fully implemented Change Control or otherwise assessed the impact of such proposed amendment, as is appropriate in Protherics' opinion.

7. INSPECTIONS AND RESPONSIBILITIES OF THE PARTIES

7.1 (a) If asked by any Regulatory Authority to provide it with any information relating to the Finished Products, the Manufacture or the work performed for Protherics by Chesapeake, Chesapeake shall notify Protherics as soon as practicable of such request and shall provide the information so requested in the time scale stated by such Regulatory Authority, provided that Protherics has first reviewed and has approved the same.

(b) If asked by Protherics to provide it with any documents, information or other data relating to the Finished Products, the Manufacture or the work performed for it by Chesapeake, Chesapeake shall provide Protherics with the same without delay.

7.2 Subject to clause 7.5 below, Chesapeake shall, on reasonable notice, permit Protherics' authorised representatives from time to time during normal working hours to enter and inspect the Facility and any other premises where Bulk Products, Finished Products, Materials or Buffer are processed in the course of or in relation to the Manufacture and/or where the same are stored (together and individually, the **"Premises"**), in order to:

(a) inspect the Premises and all equipment therein used in or in connection with the Manufacture;

(b) inspect and take away samples of Finished Products, Bulk Products, Buffer and Materials;

(c) observe and inspect operations, methods and records relating to the Manufacture and Chesapeake's storage or handling of Finished Products, Bulk Products, Materials and Buffer, including without limitation manufacturing and quality control records;

(d) audit the Manufacture for compliance with Regulatory Authority requirements;

(e) review Chesapeake's facility master file, any correspondence, reports or other documents from Chesapeake to any Regulatory Authority or from any Regulatory Authority to Chesapeake, relating to the Finished Products, Materials or the Manufacture or, in so far as the same relate to the Finished Products or the Manufacture, to the Premises; and

(f) approve any variances which occur during the Manufacture or the storage or handling of Finished Products, Bulk Products, Materials and Buffer, including without limitation approval of the text of labels or other packaging used or to be used therewith;

and Chesapeake shall provide Protherics with reasonable assistance in so doing.

7.3 (a) Should Protherics reasonably believe that Chesapeake is failing or is at material risk of failing to Manufacture or store Finished Products as required by this agreement, Protherics will report such concerns to Chesapeake, in which event, Protherics shall, in addition to its rights under clause 7.2 above but subject to clauses 7.3(c) and 7.5 below, be entitled to send a representative to attend the Premises to monitor and report back to Protherics on Chesapeake's Manufacturing and storage of Finished Products and its storage and handling of Bulk Products, Buffer and Materials, and to assist Chesapeake therewith.

(b) Chesapeake shall provide all reasonable assistance to any representative of Protherics attending the Premises pursuant to this clause 7.3, who shall be entitled to return to and to remain there until Protherics is reasonably satisfied that Chesapeake's Manufacturing and its storage of Finished Products and its storage and handling of Bulk Products, Buffer and Materials, complies with the requirements of this agreement.

(c) No representative of Protherics attending the Premises pursuant to this clause 7.3 may instruct Chesapeake to take any steps or otherwise interfere with Chesapeake's performance of its obligations under this agreement.

(d) No representative of Protherics attending the Premises pursuant to this clause 7.3 shall be entitled to any permanent office facilities or secretarial support from Chesapeake by virtue hereof, but Chesapeake shall provide him with a reasonable location within the Premises at which he will be reasonably able to undertake such of his work as is of an office-like nature, including by allowing him access to a mains electricity power point

from which he shall be entitled to draw electricity for the purposes of his work and by giving him reasonable access to telephones.

(e) Notwithstanding the other provisions of this clause 7.3, no representative of Protherics attending the Premises pursuant hereto shall be entitled to enter such parts of the Premises as are designated areas of restricted access within the same, including without limitation clean rooms, but shall be entitled to observe the interiors of such areas of restricted access from outside thereof, including by closed circuit television, where in operation.

7.4 (a) Chesapeake shall permit any Regulatory Authority wishing to conduct a Regulatory Inspection to do so whenever it chooses or otherwise agrees with Chesapeake.

(b) Chesapeake shall notify Protherics of any pending Regulatory Inspection at the earliest opportunity and, subject to clause 7.5 below, Protherics shall be entitled to send a representative to be present at such Regulatory Inspection and shall receive copies of all reports produced therefrom.

(c) Chesapeake shall provide all reasonable assistance to further the objectives of any Regulatory Inspections, including without limitation by answering all enquiries made in the course thereof and providing the relevant Regulatory Authority with access to all relevant records.

7.5 Protherics shall ensure that any representative which it sends to and/or who otherwise attends the Premises pursuant to this clause 7 shall at all times comply with Chesapeake's regulations and instructions relating to the safety and conduct of persons thereat and such representative shall be so sent to and/or otherwise attend the Premises at Protherics' cost.

7.6 (a) Insofar as is necessary for it to undertake the Manufacture and to perform its obligations hereunder, in particular with regard to the intention to use the Finished Products in human clinical therapy, Chesapeake shall maintain its Annual Registration of Drug Establishment (form FDA 2656e) and its Annual Registration of Device Establishment (form FDA 2891a) granted by the FDA in good order and up to date and shall promptly provide copies of the same and of all related documents to Protherics upon request.

(b) Chesapeake shall file and maintain a facility master file as required by the FDA and shall maintain Finished Products complaint files pursuant to applicable United States Federal regulations, in each case as provided by Chesapeake's then current written standard operating procedures.

(c) Chesapeake shall maintain one or more facility master files at the FDA and shall provide Protherics with any requisite letters authorising the FDA to access the same in connection with any Regulatory Inspection.

7.7 Chesapeake shall promptly notify Protherics of all communications which it receives from any Regulatory Authority, which relate to or may impact upon or affect the Manufacture or the Finished Products, and shall provide Protherics with copies of the same. In particular, Chesapeake shall promptly notify Protherics of any correspondence which it receives from any

Regulatory Authority in respect of any audit of the Manufacture or of its procedures, methods or facilities, or which may in any way affect its ability to Manufacture Finished Products in accordance with this agreement, including without limitation any warnings received from any Regulatory Authority concerning any of the foregoing, and shall provide Protherics with details of the same and shall co-operate with Protherics in all reasonable respects as regards its response thereto and its handling of any issues raised thereby.

7.8 (a) Protherics shall have sole responsibility at its own cost

(i) for obtaining such approvals or permits as may be applicable in respect of the distribution, export and sale of the Finished Products to customers and for complying with such other regulatory requirements as are applicable in respect of the same and of the Manufacture, other than those expressly stated hereunder to be the responsibility of Chesapeake;

(ii) for submitting claim files and applicable reports to any applicable Regulatory Authority; and

(iii) for obtaining such approvals or permits as may be applicable to import Bulk Products into the United States, including without limitation such as are necessary from the United States Department of Agriculture and, if requested, shall make copies of such licences and consents available to Chesapeake.

(b) Chesapeake will provide Protherics with copies of all documents required by Protherics to support Protherics' applications for regulatory approvals or permits and with such other reasonable assistance as is required by Protherics to comply with other requirements referred to in clause 7.8(a).

(c) In the event that in complying with its obligations pursuant to clause 7.8(b) above, Chesapeake undertakes work of any of the types specified in schedule 7, Chesapeake may charge Protherics for undertaking such work, at the rates specified in schedule 7, provided that:

(i) Chesapeake shall use all reasonable endeavours to minimise such number of hours;

(ii) before any such work is undertaken, Chesapeake shall issue Protherics with a quote for the cost to Protherics pursuant to this clause therefor and shall not commence any such work until Protherics both approves such quote and authorises such work in writing; and

(iii) notwithstanding the foregoing, without Protherics' prior approval, Chesapeake shall not charge Protherics any more for such work than it has quoted pursuant to clause 7.8(c)(ii) above.

(d) Chesapeake shall invoice Protherics for sums due pursuant to clause 7.8(c) following the completion of the work to which such sums relate and such invoices shall be payable in accordance with clause 9.4.

Protherics shall without undue delay following a request for the same from Chesapeake, provide Chesapeake with such documents, information or data as Chesapeake may reasonably require to fulfil its obligations hereunder or as Protherics is expressly required by this agreement to provide to Chesapeake.

7.10 Protherics will notify Chesapeake without undue delay of any consumer or other complaints concerning the Finished Products which it receives and which might reasonably be attributed to any default on the part of Chesapeake.

8. YIELD

8.1 Chesapeake shall use all reasonable endeavours to minimise waste of Bulk Products in Manufacture and shall, in any event, ensure that the Yield of each Batch is limited to between 92 per cent. and 100 per cent. of the Target.

8.2 (a) Should the Yield of any Batch be less than the lower limit or greater than the upper limit specified in clause 8.1 above (a **"Non-Conforming Yield"**), Chesapeake shall promptly notify as much to Protherics and, should Protherics elect in its discretion to reject the same pursuant to clause 10.1 below, Chesapeake shall promptly reimburse Protherics in accordance with clause 10.3 below.

(b) Should any Batch have a Non-Conforming Yield such that its Yield is less than the lower limit specified in clause 8.1 above, and should Protherics elect in its discretion not to reject the same pursuant to clause 10.1 below, Chesapeake shall, without prejudice to Protherics' other rights and remedies hereunder, reimburse Protherics for the difference between the cost of the Bulk Products used in the Manufacture of such Batch and the cost of the theoretical quantity of Bulk Products which would have been used in the Manufacture of the number of Vials within such Batch had the Finished Products within such Vials have been Manufactured from such theoretical quantity of Bulk Products and should the Yield thereof have been 100% of the Target, subject to a limit of US$100,000 in respect of each such Batch.

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(c) Payments due under this clause shall be made by Chesapeake to Protherics by credit note, direct reimbursement or at the reasonable discretion of Protherics.

8.3 (a) In the event that a Batch has a Non-Conforming Yield, Chesapeake shall promptly upon becoming aware of as much conduct an investigation to determine the cause thereof, with which investigation Protherics shall co-operate in all reasonable respects and in which it shall be entitled to participate and to which it shall be entitled to have full access, and Chesapeake shall, within five (5) Business Days following the production of the relevant Batch, notify Protherics of the occurrence of the same and of the Yield of such Batch.

(b) Chesapeake shall submit to Protherics a written report of the findings of the investigations conducted pursuant to clause 8.3(a) above within twenty (20) Business Days following the date of Manufacture of the Batch to which they relate.

8.4 If Chesapeake experiences two (2) Non-Conforming Yields in any rolling twelve (12) month period, Protherics shall, in addition to its rights set out above, have the right to terminate this

agreement without further liability by providing sixty (60) Business Days' written notice to Chesapeake.

8.5 (a) Notwithstanding the above, but subject to clause 8.5(b) below, the provisions of clauses 8.1, 8.2 and 8.4 above shall not take effect until the date one (1) year after the Effective Date, although Chesapeake shall use all reasonable endeavours to minimise any waste of Bulk Products in the Manufacture of the Finished Products Manufactured prior thereto.

(b) The application of clause 8.3 above shall not be affected by clause 8.5(a), and clauses 8.1 and 8.2(a) above shall apply to this agreement from and including the Effective Date solely in so far as is necessary to give effect to the said clause 8.3.

(c) For the avoidance of doubt, clause 8.5(a) above shall not effect Protherics' rights pursuant to clause 10.1 below.

8.6 In the event that the average Yield of the Batches Manufactured by Chesapeake in the year following the Effective Date, irrespective of which Finished Products comprise the same, is less than the lower limit or greater than the upper limit specified in clause 8.1 above, Chesapeake may request that the parties meet to discuss revising such limits, in which event the parties shall so meet as soon as reasonably practicable, provided that:

(a) Chesapeake can demonstrate that such average Yield was less than such lower limit or greater than such upper limit, as applicable, as a consequence of:

(i) an inherent property of the Finished Products; or

(ii) an incompatibility of the Finished Products or the Manufacture with Chesapeake's Manufacturing process or the machinery or other equipment used by Chesapeake in Manufacture; and

was not due to the fault of Chesapeake; and

(b) Chesapeake makes such request between the first anniversary of the Effective Date and the date falling thirty (30) Business Days thereafter.

8.7 In the event that the parties meet pursuant to clause 8.6 above to discuss revising the permissible upper or lower limits of the Yield specified in clause 8.1 above and do not reach agreement on whether to revise the same or what such revised limits should be within thirty (30) Business Days (or such other time period as the parties agree) of first so meeting, either party may terminate this agreement forthwith by notice to the other, provided that such notice is given within five (5) Business Days of the end of such thirty (30) Business Days period (or such other time period as the parties may have agreed in accordance herewith).

8.8 In the event that, pursuant to clause 8.6 above, the parties discuss revising the upper or lower limits of the Yield specified in clause 8.1 above, the provisions of clause 8.5 above shall additionally apply until the end of the thirty (30) Business Days period referred to in clause 8.7 above, provided that:

(a) Chesapeake has requested that the parties enter into such discussions after the first anniversary of the Effective Date but no later than thirty (30) Business Days after such anniversary; and

(b) such discussions do not end prior to the end of the thirty (30) Business Days period referred to in clause 8.7 above.

9. PRICE AND PAYMENT

9.1 Chesapeake shall invoice Protherics in United States dollars in respect of its Manufacture and storage of Finished Products pursuant to this agreement, each such invoice to be issued upon and relate to:

(a) a delivery to Protherics of Finished Products comprised within an Advanced Sample; or

(b) a delivery of Finished Products not comprised within an Advanced Sample.

9.2 The sums for which Chesapeake may invoice Protherics pursuant to clause 9.1 above shall be as set out in schedule 4, the figures therein to remain fixed unless varied in accordance with clauses 9.5 or 9.6.

9.3 The sums for which Chesapeake may invoice Protherics pursuant to clause 9.1 above shall include all costs of insurance and all applicable taxes, excluding any United Kingdom Value Added Tax which may be payable in respect of the importation of Finished Products into the United Kingdom, which shall, if payable, be borne by Protherics.

9.4 Protherics shall pay Chesapeake the amount stated on each invoice issued to it pursuant hereto at the end of the calendar month following the date of such invoice and payment shall be made into a bank account designated by Chesapeake, details of which have been notified to Protherics from time to time.

9.5 (a) The parties shall commence discussions:

(i) one hundred (100) Business Days prior to the Renewal Date; and

(ii) one hundred (100) Business Days prior to every third anniversary of the Renewal Date thereafter;

concerning whether to increase or decrease the figures specified in schedule 4 and by how much, which discussions the parties shall conduct in good faith, provided that neither party shall be required by this clause to continue such discussions as begin before the Renewal Date beyond the Renewal Date, or such discussions as begin before any anniversary of the Renewal Date beyond such anniversary.

(c) In the event that the parties agree any increase or decrease in such figures, such increase or decrease shall take effect from the Renewal Date or the relevant anniversary thereof, as applicable.

(d) In the event that during any such discussions, the parties fail to agree whether, and by how much, to increase or decrease such figures, either party may terminate this agreement upon not less than one (1) year's notice to the other, provided that such notice is given within thirty (30) Business Days following the end of the relevant discussions further to which the parties so failed to reach agreement.

(e) In the event that either party gives notice pursuant to clause 9.5(d) above to terminate this agreement, the figures specified in schedule 4 shall be increased by the lesser of:

(i) such amount as Chesapeake may have requested by which they be increased in the course of the discussions pursuant to clause 9.5(a) above next preceding such notice; and

(ii) five (5%) percent;

and such figures, as increased in accordance with this clause 9.5(e), shall apply for the remainder of the term of this agreement.

9.6 If at any time during the term of this agreement the parties agree pursuant to clause 6 to make changes to the Technical Agreement and/or the Specification and accordingly to alter the amount payable by Protherics for Finished Products, such alterations to such amounts payable shall take effect when the parties agree.

10. DEFECTS

10.1 Protherics shall be entitled to reject any Finished Products which it determines do not conform with the Specification and to return them to Chesapeake or otherwise dispose of them as Chesapeake may direct, in either case, at Chesapeake's expense. Protherics shall act reasonably in determining whether any Finished Products are defective, which determination shall be conclusive.

10.2 Protherics shall upon becoming aware of the same notify Chesapeake of any defect in any Finished Products which occurs during transit to the designated recipient and by reason of which Protherics alleges that they do not conform with the Specification and because of which it has rejected the same.

10.3 In the event that Protherics rejects any Finished Products, Chesapeake shall, without prejudice to Protherics' other rights and remedies hereunder, reimburse Protherics for the cost of the Bulk Products used in the Manufacture of such rejected Finished Products, subject to a limit of US$100,000 per Batch in respect of the Manufacture of which the same were utilised. Payments due under this clause shall be made by Chesapeake to Protherics by credit note, direct reimbursement or at the reasonable discretion of Protherics.

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10.4 If any Finished Products are rejected by Protherics, Protherics shall not be required to pay any amount otherwise payable to Chesapeake in respect thereof.

11. WARRANTIES

11.1 Chesapeake warrants that:

(a) it shall Manufacture, store and deliver Finished Products with skill, competence, care and attention and in accordance with the terms of this agreement, the Technical Agreement and all appropriate legislation, and the rules and other requirements of any appropriate Regulatory Authority which apply from time to time, including without limitation cGMP.

(b) it shall at all times maintain in a clean, safe and hygienic condition and in accordance with all appropriate statutes and regulations:-

(i) the Premises;

(ii) the plant and machinery located in the Premises which are used in connection with the Manufacture and storage of Finished Products; and

(iii) all packaging used or to be used for Finished Products.

(c) the labels used by Chesapeake on the Finished Products will conform with Protherics' requirements or those of any applicable Regulatory Authority notified to Chesapeake pursuant to clause 5 above and that the same shall not be used without Protherics' prior approval;

(d) all Finished Products shall be of satisfactory quality and shall, at the time of delivery to the designated recipient, conform with the Specification.

(e) all Finished Products will, during their normal shelf life, continue to conform to the warranties in this clause 11.1 provided always that they are correctly transported, stored and handled;

(f) no Finished Products shall be misbranded or adulterated;

(g) all Bulk Products, Buffer and Materials shall be stored in accordance with the requirements for storage specified in the Technical Agreement.

11.2 Protherics warrants that:

(a) it is authorised to provide all instructions, specifications and other information which it may give to Chesapeake in connection with the Manufacture of Finished Products and that in complying therewith, Chesapeake shall not infringe the rights of any third party.

(b) subject to any default on the part of Chesapeake, if Manufactured in accordance with the Specification, the Technical Agreement and Protherics' other instructions, if any, the Manufacture by Chesapeake of Finished Products will not infringe any patent or other similar Intellectual Property Right anywhere in the world belonging to any third party.

11.3 Chesapeake shall indemnify and hold harmless Protherics from and against:-

(a) all actions, demands, losses, costs (including reasonable legal fees), claims, damage or liability, which Protherics may suffer or incur from any third party claims that arise from (i) a breach of any of Chesapeake's agreements or warranties contained herein, (ii) Chesapeake's negligence or other wrongful conduct or (iii) the Finished Products, their Manufacture, storage, distribution, sale or use being in violation of any third party Intellectual Property Right (other than a claim covered under clause 11.4 below); and

(b) all actions, demands, losses, costs (including reasonable legal fees), claims, damage or liability (excluding consequential loss) which Protherics may suffer or incur arising out of the Finished Products not complying with the Specification (other than as a result of any defect in the Bulk Products or any information supplied by or on behalf of Protherics).

It is a condition of the foregoing indemnity that Protherics shall forward to Chesapeake a copy of any claims, actions and demands, as soon as reasonably practicable and shall not admit any liability nor make any payment, settlement or compromise in respect thereof without the written consent of Chesapeake and that Chesapeake shall, if it so chooses and by prior written notice to Protherics, in the name of Protherics, control the conduct of the defence, settlement, compromise, counterclaim and all third party action in respect of such claims, actions and demands, provided that Chesapeake shall keep Protherics regularly informed as to the conduct thereof.

11.4 Protherics hereby undertakes to indemnify and hold harmless Chesapeake:

(a) from and against:-

(i) all actions, demands, losses, costs (including reasonable legal fees), claims, damage and liability which Chesapeake may suffer or incur from any third party claim arising from Protherics' breach of any of its agreements or warranties contained herein or from Protherics' negligence or other wrongful conduct; or

(ii) as a result of a defect or error contained in any incorrect or defective information or instructions provided in writing by Protherics.

It is a condition of the foregoing indemnity that Chesapeake shall forward to Protherics a copy of all such claims, actions and demands as soon as reasonably practicable and shall not admit any liability nor make any payment, settlement or compromise in respect thereof without the written consent of Protherics and that Protherics shall, if it so chooses and by prior written notice to Chesapeake, in the name of Chesapeake, control the conduct of the defence, settlement, compromise, counterclaim and all third party action in respect of such claims, actions and demands, provided that Protherics shall keep Chesapeake regularly informed as to the conduct thereof.

12. LIMITATION OF LIABILITY

12.1 Nothing in this agreement shall limit Chesapeake's liability in respect of any claim:

(a) for death or personal injury caused by its negligence;

(b) under Part 1 of the Consumer Protection Act 1987;

(c) in respect of any liability which arises under any safety regulation made under Section 10 of the Consumer Protection Act 1987 and which such regulation does not allow to be excluded; or

(d) any other liability which may not be limited or excluded at law.

12.2 Neither party shall be liable to the other for any indirect or consequential loss or for any loss of profits or loss of goodwill which it may suffer even if such loss is reasonably foreseeable or if it had been advised of the possibility of incurring the same.

12.3 In the event that Chesapeake reimburses Protherics any sum pursuant to clauses 3.5(b), 8.2(b) or 10.3 above, and in the event that, but for the limitation of US$100,000 on such reimbursement provided by such clause, such reimbursement would have exceeded, in respect of any Batch, US$100,000 (notwithstanding that as a consequence of such limitation, such reimbursement did not exceed US$100,000), the parties shall meet in good faith to discuss amending such limitation retroactively such that, in the event that the parties agree on such an amendment, Chesapeake will reimburse Protherics a sum greater than US$100,000, provided that the loss in respect of which such reimbursement is made arises as a consequence of any:

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(a) cross contamination of any Bulk Product or Finished Product;

(b) failure of any freeze-drier during the drying cycle of the Manufacture of any Batch;

(c) non-sterility of any part of the Facility which is required by this agreement (including without limitation the Technical Agreement) or by any Regulatory Authority to be sterile;

(d) withholding or withdrawal by the FDA of its approval of any programme the subject of clause 10 of the Technical Agreement, or Chesapeake's failure properly to implement or adhere to any such programme or otherwise to comply with any of the requirements of such clause; or

(e) failure properly to segregate Vials from different Batches.

13. EXPERT DETERMINATION

13.1 In the event of a dispute or difference arising out of or relating to the Technical Agreement, the Specification or any technical issue, either party may notify the other in writing of the dispute or difference (the **"Dispute Notice"**) together with reasonable details of such dispute or difference, whereupon the parties shall endeavour to resolve all matters in dispute as soon as practicable.

13.2 In the event of the parties' failing to resolve such matters within twenty (20) Business Days of service of the Dispute Notice, either party may refer the dispute or difference for determination to an Expert, who shall be appointed by agreement of the parties or, in default

of agreement on such appointment within thirty (30) Business Days of the service of the Dispute Notice, on the application of either party, to an independent testing organisation chosen by Protherics, provided the same is acceptable to Chesapeake, such acceptance not to be unreasonably withheld or delayed.

13.3 In making such determination the Expert shall act as an expert and not as an arbitrator and his decision shall (in the absence of manifest error (and the Expert shall give reasons for his determination)) be final and binding on the parties.

13.4 Each party shall bear the costs and expenses of all counsel and other advisers, witnesses and employees retained by it and the costs and expenses of the Expert shall be borne by the parties in the proportions he may direct or, in the absence of direction, equally.

13.5 Subject to any rule of law or of any regulatory body or any provision of any contract or arrangement entered into prior to the date of this agreement to the contrary, the parties shall afford as soon as reasonably practicable upon request to the other and their respective agents and to the Expert, all facilities and access to their respective premises, personal papers, books, accounts, records, returns and other documents as may be in their respective possession or under their respective control as may be required by the Expert to make his determination.

13.6 For the avoidance of doubt, this clause 13 shall not operate to lessen Protherics' rights under clause 10 above.

14. FORCE MAJEURE

14.1 **"Event of Force Majeure"** means, in relation to either party, an event or circumstance beyond the reasonable control of that party (the **"Claiming Party"**) including, without limitation, strikes, lock-outs and other industrial disputes (in each case, whether or not relating to the Claiming Party's workforce).

14.2 The Claiming Party shall not be deemed to be in breach of this agreement or otherwise liable to the other party (the **"Non-Claiming Party"**) for any delay in performance or any non-performance of any obligations under this agreement (and the time for performance shall be extended accordingly) to the extent that the delay or non-performance is due to an Event of Force Majeure provided that:-

(a) the Claiming Party could not have avoided the effect of the Event of Force Majeure by taking precautions which, having regard to all matters known to it before the occurrence of the Event of Force Majeure and all relevant factors, it ought reasonably to have taken but did not take; and

(b) the Claiming Party has used reasonable endeavours to mitigate the effect of the Event of Force Majeure and to carry out its obligations under this agreement in any other way that is reasonably practicable.

14.3 The Claiming Party shall promptly notify the Non-Claiming Party of the nature and extent of the circumstances giving rise to the Event of Force Majeure.

14.4 If the Event of Force Majeure in question prevails for a continuous period in excess of six (6) months after the date on which it began, the Non-Claiming Party may give notice to the Claiming Party terminating this agreement. The notice to terminate must specify the termination date, which must not be less than twenty five (25) Business Days clear days after the date on which the notice to terminate is given. Once the notice to terminate has been validly given, this agreement will terminate on the termination date set out in the notice. Neither party shall have any liability to the other in respect of termination of this agreement due to an Event of Force Majeure, but rights and liabilities which have accrued prior to termination shall subsist including without limitation those under clause 16.

15. DURATION AND TERMINATION

15.1 (a) This agreement shall come into effect on the date hereof and shall continue in force for a period of five (5) years (the **"Initial Term"**), unless terminated earlier pursuant to this clause 15 or clauses 6.1(b), 8.4, 8.7, 9.5(d) or 14.4.

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(b) Following the expiry of the Initial Term, and provided that neither party has given the other notice of termination, such notice to be given, if given by Protherics, at least twelve (12) months prior to the end of the Initial Term and if given by Chesapeake, at least twenty four (24) months prior to the end of the Initial Term, this agreement shall remain in force until terminated by either party giving to the other not less than the respective aforementioned periods of written notice unless otherwise terminated pursuant to this clause 15 or clauses 6.1(b), 8.4, 8.7, 9.5(d) or 14.4.

15.2 This agreement shall terminate in the event that Protherics ceases the business of selling Finished Products, provided however that in such circumstances Protherics shall give Chesapeake six (6) months' notice of its intention to cease such business.

15.3 A party (the **"Initiating Party"**) may terminate this agreement with immediate effect by written notice to the other party (the **"Breaching Party"**). on or at any time after the occurrence of any of the following events:

(a) the Breaching Party being in breach of a material obligation under this agreement and, if the breach is capable of remedy, failing to remedy the breach within twenty five (25) Business Days starting on the day after receipt of written notice from the Initiating Party giving full details of the breach and requiring the Breaching Party to remedy the breach;

(b) the Breaching Party passing a resolution for its winding-up or a court of competent jurisdiction making an order for the Breaching Party's winding-up or dissolution;

(c) the making of an administration order in relation to the Breaching Party or the appointment of a receiver over, or an encumbrancer taking possession of or selling, an asset of the Breaching Party;

(d) the Breaching Party making an arrangement or composition with its creditors generally or making an application to a court of competent jurisdiction for protection from its creditors generally; and

(e) a change of control of the Breaching Party;

or the equivalent of any of the events specified in clauses 15.3(c) to (d) in any relevant jurisdiction.

15.4 For the purpose of clause 15.3(a) above, a breach will be considered capable of remedy if time is not of the essence in performance of the obligation in question and if the Breaching Party can comply with the obligation within the twenty five (25) Business Days period referred to in clause 15.3(a).

15.5 Notwithstanding the above, Protherics may terminate this agreement forthwith and without liability to Chesapeake in the event that:

(a) Protherics receives notification that the FDA will not grant its approval to Chesapeake Manufacturing Finished Products on the licence granted to Protherics by the FDA concerning Finished Products;

(b) Protherics does not receive such approval within a reasonable time following the Effective Date;

(c) such approval, if granted, is withdrawn; or

(d) Protherics determines in its reasonable discretion not to request such approval on the basis that it does not reasonably consider that the FDA will grant the same.

15.6 In the event of the termination of this agreement, other than pursuant to clause 14.4 above, Chesapeake shall, notwithstanding such termination, Manufacture, store and deliver all Finished Products and provide Protherics with all documentation and information in respect thereof, the Manufacture of which Finished Products Protherics has ordered in accordance herewith prior to such termination, in accordance with the terms and subject to the conditions of this agreement including without limitation the relevant provisions of clauses 2, 4, 5 and 8 above, and, notwithstanding such termination, the provisions of clause 3 above shall apply to all Bulk Products supplied by Protherics to Chesapeake, which are relevant to such Manufacture.

15.7 Notwithstanding the termination of this agreement for whatever reason, clauses 1, 2.13, 7.1 - 7.2, 7.4, 7.5, 7.7 - 7.9, 10 –14 and 17 – 27, and, in accordance with clause 16.5, clause 16, shall remain in full force and effect.

16. CONFIDENTIALITY

16.1 As used in this agreement, the term **"Confidential Information"** means any technical or business information furnished by one party (the **"Disclosing Party"**) to the other party (the **"Receiving Party"**) in connection with this agreement or the parties' obligations hereunder, having the nature of confidentiality. Such Confidential Information may include, without limitation, trade secrets, know-how, inventions, technical data or specifications, testing methods, Business Information, Product Information, financial information, research and development activities, regulatory data, product and marketing plans, customer and supplier information and such information as may be provided by either party to the other pursuant to

the provisions of clause 7. Confidential Information that is disclosed orally or visually shall be documented in a written notice prepared by the Disclosing Party and delivered to the Receiving Party within twenty five (25) Business Days of disclosure; such notice shall summarise the Confidential Information disclosed to the Receiving Party and reference the time and place of disclosure.

16.2 The Receiving Party agrees that it shall:-

(a) maintain all Confidential Information in strict confidence, except that the Receiving Party may disclose or permit the disclosure of any Confidential Information to its directors, officers, employees, consultants and advisors, who are obligated to maintain the confidential nature of such Confidential Information, for the purposes set forth in this agreement;

(b) use all Confidential Information solely for the purposes set forth in this agreement or as otherwise authorised by this agreement;

(c) allow its directors, officers, employees, consultants and advisors to reproduce the Confidential Information only to the extent necessary to effect the purposes set forth in this agreement or as otherwise authorised by this agreement, with all such reproductions being considered Confidential Information.

16.3 The obligation set out in clause 16.2 above shall not apply to the extent that the Receiving Party can demonstrate that the relevant Confidential Information:-

(a) was in the public domain prior to the time of its disclosure under this agreement;

(b) entered the public domain after the time of its disclosure under this agreement through means other than an unauthorised disclosure resulting from an act or omission of the Receiving Party;

(c) was subsequently disclosed to the Receiving Party without any obligation of confidence by a third party provided that such third party was acting lawfully and not in breach of any duty of confidence;

(d) is required to be disclosed to comply with applicable laws or regulations, or with a court or administrative order, provided that the Disclosing Party takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and, if possible, to minimise the extent of such disclosure.

16.4 Following the termination of this agreement, the Receiving Party shall return to the Disclosing Party all originals, copies and summaries of documents, materials and other manifestations of Confidential Information, whether tangible or stored on computer, in the possession or control of the Receiving Party save that either party may retain one copy of any such Confidential Information if required to do so under any regulatory or legal requirement.

16.5 The obligations set forth in this clause shall survive for a period of 10 years following termination of this agreement.

17. INTELLECTUAL PROPERTY

17.1 Except as expressly set out in clause 5.4 above, nothing in this agreement shall affect or grant any right to any Intellectual Property Rights owned by the parties prior to the commencement of this agreement. In particular, Protherics shall remain solely entitled to all Intellectual Property Rights in the Bulk Products and the Finished Products, which entitlement shall not be affected in any way by this agreement and Chesapeake's right to use Protherics' trade marks shall be solely as specified in clause 5.4 above.

17.2 All Intellectual Property Rights which may arise in any documents, drawings, items, designs, processes, software or any other thing (collectively known as **"Improvement IP Rights"**) developed by Chesapeake or any of its employees or agents in performance of this agreement shall vest in Chesapeake.

17.3 Chesapeake shall consider favourably any request made by Protherics (or an Affiliate of Protherics) to licence the Improvement IP Rights or any of them to a third party contract manufacturer to be engaged by Protherics or an Affiliate of Protherics, and shall not unreasonably withhold or delay its consent to such a licence being granted on reasonable commercial terms.

17.4 Protherics shall be responsible, at its expense, for obtaining on behalf of Chesapeake all necessary consents in respect of the use of any third party Intellectual Property Rights in information provided by Protherics necessary for the performance of Chesapeake's obligations under this agreement through utilising such information.

18. COSTS

Save as expressly otherwise provided in this agreement each of the parties shall bear its own legal, accountancy and other costs, charges and expenses connected with the negotiation, preparation and implementation of this agreement and any other agreement incidental to or referred to in this agreement.

19. VARIATIONS

This agreement may be varied only by a document signed by each of the parties.

20. WAIVER

20.1 A waiver of any term, provision or condition of, or consent granted under, this agreement shall be effective only if given in writing and signed by the waiving or consenting party and then only in the instance and for the purpose for which it is given.

20.2 No failure or delay on the part of either party in exercising any right, power or privilege under this agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or privilege preclude any other or further exercise thereof or the exercise of any other right, power or privilege.

20.3 No breach of any provision of this agreement shall be waived or discharged except with the express written consent of the parties.

20.4 The rights and remedies herein provided are cumulative with and not exclusive of any rights or remedies provided by law.

21. INVALIDITY

If any provision of this agreement is or becomes (whether or not pursuant to any judgment or otherwise) invalid, illegal or unenforceable in any respect under the law of any jurisdiction:-

(a) the validity, legality and enforceability under the law of that jurisdiction of any other provision; and

(b) the validity, legality and enforceability under the law of any other jurisdiction of that or any other provision,

shall not be affected or impaired in any way thereby.

22. NOTICES

22.1 Any notice, demand or other communication given or made under or in connection with the matters contemplated by this agreement shall be in writing and shall be delivered personally or sent by fax or prepaid first class post (air mail if posted to or from a place outside the United Kingdom):-

In the case of Protherics to:
Blaenwaun,
Ffostrasol,
Llandysul,
Ceredigion SA44 5JT,
UK
Fax: +44 (0)1239 858 800
Attention: Company Secretary

In the case of Chesapeake to:
Camden Industrial Park,
1111 S. Paca Street,
Baltimore,
M.D. 21230-2591,
USA
Fax: +1 410 843 4414
Attention: The President

and shall be deemed to have been duly given or made as follows:-

(a) if personally delivered, upon delivery at the address of the relevant party;

(b) if sent by first class post, two Business Days after the date of posting;

(c) if sent by air mail, five (5) Business Days after the date of posting; and

(d) if sent by fax, when despatched;

provided that if, in accordance with the above provision, any such notice, demand or other communication would otherwise be deemed to be given or made after 5.00 p.m. in the recipient's time zone such notice, demand or other communication shall be deemed to be given or made at the start of working hours on the next Business Day.

22.2 A party may notify the other party to this agreement of a change to its name, relevant addressee, address or fax number for the purposes of clause 22.1 provided that such notification shall only be effective on:-

(a) the date specified in the notification as the date on which the change is to take place; or

(b) if no date is specified or the date specified is less than five (5) Business Days after the date on which notice is given, the date falling five (5) Business Days after notice of any such change has been given.

23. NO PARTNERSHIP

23.1 Nothing in this agreement and no action taken by the parties pursuant to this agreement shall constitute, or be deemed to constitute, the parties a partnership, association, joint venture or other co-operative entity.

23.2 At no time shall either of the parties have the authority to hold itself out as the agent of the other or as being empowered to bind the other in any way whether contractually or otherwise.

24. ASSIGNMENT AND SUB-CONTRACTING

24.1 Neither party may, without the prior written consent of the other, assign the benefit of all or any of the other party's obligations under this agreement, nor any benefit arising under or out of this agreement.

24.2 Chesapeake may sub-contract any of its obligations under this agreement, provided that:

(a) it has used all due diligence in selecting the third party to which it sub-contracts such obligations, by evaluating the competency of such third party to undertake the same;

(b) it advises Protherics in advance of its intention to sub-contract such obligations to a third party and at such time identifies such third party to Protherics and informs Protherics of the terms of such proposed sub-contracting arrangement; and

(c) Protherics consents in writing to such sub-contracting to such party on such terms, which consent may be withheld for any reason.

24.3 Notwithstanding any sub-contracting of its obligations to a third party, Chesapeake shall remain fully responsible for the performance of its obligations under this agreement and fully liable for any breach thereof.

In the event that Chesapeake sub-contracts any of its obligations under this agreement to a third party, Chesapeake shall conduct audits of such third party's performance on at least an annual basis and promptly report the results of such audits to Protherics, and, in the event that such audits reveal any non- or mal-performance by such third party of such sub-contracted obligations, Chesapeake shall immediately terminate such sub-contracting arrangement.

24.5 Protherics shall be entitled, at will and upon reasonable notice, to undertake cGMP audits of any third party to which Chesapeake sub-contracts any or all of its obligations under this agreement and Chesapeake shall ensure that such third party consents and submits to such entitlement.

25. GOVERNING LAW AND JURISDICTION

25.1 This agreement (and any dispute, controversy, proceedings or claims of whatever nature arising out of or in any way relating to this agreement or its formation) shall be governed by and construed in accordance with English law.

25.2 Each of the parties to this agreement irrevocably agrees that the courts of England and Wales shall have exclusive jurisdiction to hear and decide any suit, action or proceedings, and/or to settle any disputes, which may arise out of or in connection with this agreement and, for these purposes, each party irrevocably submits to the jurisdiction of the courts of England and Wales.

26. EXCLUSION OF THIRD PARTY RIGHTS

The Contracts (Rights of Third Parties) Act 1999 shall not apply to this agreement and no rights or benefits expressly or impliedly conferred by it shall be enforceable under that Act against the parties to it by any other person.

27. ENTIRE AGREEMENT

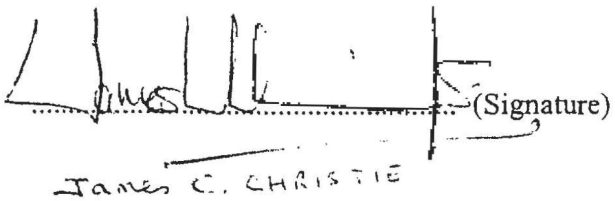
27.1 Subject to clause 27.3, this agreement constitutes the entire and only agreement between the parties relating to the subject matter hereof and neither party has been induced to enter into this agreement in reliance upon, nor has either party been given, any warranty, representation, statement, assurance, covenant, agreement, undertaking, indemnity or commitment of any nature whatsoever other than as are expressly set out herein and, to the extent that any of them has been, it unconditionally and irrevocably waives any claims, rights or remedies which it might otherwise have had in relation thereto.

27.2 Subject to clause 27.3, neither party has any right to rescind or terminate this agreement either for breach of contract or for negligent or innocent misrepresentation or otherwise.

27.3 The provisions of this clause 27 shall not exclude any liability which either party would otherwise have to the other party or any right which either of them may have in respect of any statements made fraudulently by either of them prior to the execution of this agreement or any rights which either of them may have in respect of fraudulent concealment by the other.

IN WITNESS whereof this agreement has been executed on the date first above written.

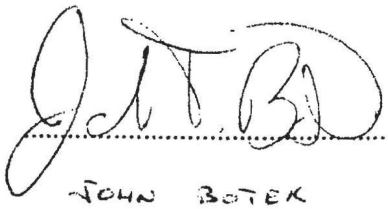
ıed by
duly authorised representative of **PROTHERICS UK LIMITED**



.....(Signature)

JAMES C. CHRISTIE

Signed by
a duly authorised representative of **CHESAPEAKE BIOLOGICAL LABORATORIES INC.**



..... (Signature)

JOHN BOTEK