foiapa

18-04075-E

From: Mark Edwards <medwards@biosciadvisors.com>
Sent: Saturday, April 21, 2018 3:30 AM
To: foiapa
Subject: FOIA Request

I would like to request access to Exhibit 10.9 to the Form F-1 filed by Merrion Pharmaceuticals, Ltd. on 3/30/2007. 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

May 17, 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. 18-04075-E

Dear Mr. Edwards:

This letter is in response to your request, dated April 21, 2018 and received in this office on April 23, 2018, for Exhibit 10.9 to the Form F-1, filed by Merrion Pharmaceuticals Ltd. on March 30, 2007.

The search for responsive records has resulted in the retrieval of 29 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 fultonc@sec.gov or 202-551-8186. 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,

Charlotte Fulton
FOIA Research Specialist

Enclosure

LICENSE AGREEMENT

This License Agreement (the "Agreement") is made and entered into as of January __, 2007, (the "Effective Date") by and between the Salk Institute for Biological Studies, a nonprofit public benefit corporation organized under the laws of the State of California ("Salk"), and Merrion Research I, Ltd., a corporation organized under the laws of Ireland ("Licensee").

WHEREAS, Salk is the owner of certain Patent Rights (as hereinafter defined);

WHEREAS, the development of the inventions contained in the Patent Rights was sponsored in part by the National Institutes of Health and, as a consequence, Salk is subject to obligations to the Federal Government as set forth in 35 U.S.C. §200 et seq.;

WHEREAS, Salk desires that the Patent Rights be developed and utilized to the fullest extent possible so that products resulting therefrom may be available for public use and benefit;

WHEREAS, Salk has determined that the best method for disseminating the Patent Rights is through the grant of an exclusive license to an entity willing to establish a program to develop therapeutic, diagnostic or research products in the Field of Use covered by such Patent Rights;

WHEREAS, Licensee represents that it has the intent and resources to develop and market products based upon the Patent Rights; and

WHEREAS, The parties executed an Option Agreement, effective January 23, 2006, and pursuant to the Option Agreement, Licensee wishes to obtain, and Salk is willing to grant, a license to the Patent Rights in the defined Field of Use, subject to the terms set forth below.

NOW, THEREFORE, in consideration of the above premises and the mutual covenants contained herein, the parties hereby agree as follows:

1 DEFINITIONS.

1.1 The term **"Affiliate"** shall mean any entity that controls, is controlled by or is under common control with Licensee, where "control" means (i) beneficial ownership of more than fifty percent (50%) of the outstanding shares or securities of the entity, or (ii) the ability otherwise to direct or cause the direction of the management and policies of such entity.

1.2 The term **"Commercial Sale"** shall mean any sale, lease, or other transaction that transfers to an independent third party in an arms-length transaction, for value, physical possession of and title to a Licensed Product, after which transfer the seller has no right or power to determine the purchaser's resale price. Transfer of possession and title to an Affiliate or Sublicensee shall not constitute a Commercial Sale unless the Affiliate or Sublicensee is an end user of the Licensed Product.

1.3 The term **"FDA"** shall mean the United States Food and Drug Administration.

1.4 The term "**Field of Use**" shall mean all therapeutic uses of the Patent Rights in humans and animals.

1.5 The term **"Licensed Product"** shall mean any product, the manufacture, use, importation, sale, or offer for sale of which, in the absence of this Agreement, would infringe the Patent Rights.

1.6 The term "**NDA**" shall mean a new drug application filed with the FDA pursuant to 21 U.S.C. Section 505 (b)(1) for marketing approval of a Licensed Product or any successor applications or procedures. Without limiting the foregoing, NDA includes Product License Applications (PLA) and Biologics License Applications (BLA).

1.7 The term **"NDA Approval"** shall mean receipt of such authorizations from the regulatory authorities in the U.S. (including marketing, labeling, packaging, pricing and reimbursement approvals) as are legally required before a Licensed Product may be commercialized or sold.

1.8 The term **"Net Sales"** shall mean the gross amounts received by Licensee, its Affiliates, and Sublicensees in the Commercial Sale of Licensed Product in the Territory, less the following amounts if separately stated on purchase orders, invoices, or other documents of sale:

(a) outbound shipping, storage, packing and insurance expenses, each as actually paid or allowed;

(b) amounts repaid or credited by reason of rejections, defects or returns, billing errors, recalls, or because of retroactive price reductions;

(c) sales and other excise taxes, use taxes, tariffs, export license fees and duties actually paid or allowed; and

(d) all trade, quantity, and cash discounts.

No deductions shall be made for commissions paid to individuals whether they are with independent sales agencies or regularly employed by Licensee, its Affiliates or Sublicensees and on its payroll, or for cost of collections. Net Sales shall occur on the date of receipt of revenue for a Licensed Product. If a Licensed Product is distributed at a discounted price that is substantially lower than the customary price charged by Licensee under similar circumstances, or distributed for non-cash consideration (whether or not at a discount), Net Sales shall be calculated based on the non-discounted price of the Licensed Product charged to an independent third party during the same reporting period or, in the absence of such sales, on the fair market value of the Licensed Product.

Net Sales shall include the fair market value of any non-cash consideration received by Licensee, its Affiliates or Sublicensees for the sale, lease, or transfer of Licensed Products. Licensed Product sold by Licensee to its Affiliates shall not be included in the calculation of Net Sales hereunder; provided that, any subsequent sale or revenue generating activity of such Affiliate shall be included in computing Net Sales. Further, Net Sales shall not include any consideration received by Licensee, its Affiliates or Sublicensees for the sale, use or other disposition of a Licensed Product as part of a clinical trial prior to the receipt of all regulatory approvals required to commence Commercial Sale of the Licensed Product.

If a Licensed Product is sold in combination with one or more other active products or components that is not a Licensed Product (a "**Combination Product**"), the portion of "Net Sales" attributable to the Licensed Product will be calculated by multiplying actual Net Sales for such Combination Product by the fraction A/(A+B) where A is the gross invoice price of the Licensed Product if sold separately, and B is the total gross invoice price of any other active components, or devices, in the combination if sold separately, in each case during the applicable reporting period or, if sales of both the Licensed Product and the other product(s) did not occur in such period, then in the most recent royalty reporting period in which sales of both occurred provided that the last such sale of the Licensed Product and the other product(s) is no more than six (6) months prior to the date the relevant calculation is to be made under

this paragraph. In the event that such gross invoice price cannot be determined for both the Licensed Product and all other products included in the Combination Product or the date on which the Licensed Product and such other products were both last sold was more than six (6) months before the date on which the relevant calculation is to be made, Net Sales for the purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Licensed Product by the fraction C/(C+D) where C is the standard fully absorbed cost of the Licensed Product and D is the sum of the standard fully absorbed costs of the other active elements or components included in the Combination Product, such costs being calculated in accordance with generally accepted accounting principles.

1.9 The term "**Patent Costs**" shall mean out-of-pocket expenses incurred by Salk for the Patent Rights in connection with the preparation, filing, prosecution, and maintenance of patent applications and patents included therein, including the reasonable fees and expenses of attorneys and patent agents, filing fees and maintenance fees, but excluding costs associated with any patent infringement actions.

1.10 The term **"Patent Rights"** shall mean the inventions claimed in the patents and patent applications described below:

(a) Patent applications listed in Exhibit A and patents issuing therefrom.

(b) Patents listed in Exhibit A.

(c) Divisional applications, provisional applications, and continuation applications that claim the benefit of priority to any of the patents described in (a) or (b) or patent applications described in (a) or (b) and patents issuing therefrom.

(d) Continuation-in-part applications only to the extent the claimed inventions are supported by the patents described in (a) or (b) or patent applications described in (a) or (b) and patents issuing therefrom.

(e) Reissue patents, extensions (including extensions under the United States Patent Term Restoration Act), renewals, substitutions and additions thereof, and reexamination patents related to patents described in (a), (b), (c) and (d).

(f) Any and all foreign counterparts of the patent applications and patents described in (a), (b), (c), (d) and (e).

1.11 The term "**Phase I Clinical Trial**" shall mean a human clinical trial in any country intended to obtain data regarding safety and pharmacokinetics of a Licensed Product that would satisfy the requirements of United States Code of Federal Regulations 21 CFR 312.21(a), or other comparable regulation imposed by the FDA.

1.12 The term "**Phase II Clinical Trial**" shall mean a human clinical trial in any country that is intended to initially evaluate the safety, dose range and efficacy of a Licensed Product for a particular indication or indications in human subjects with the disease or indication under study or that would otherwise satisfy the requirements of United States Code of Federal Regulations 21 CFR 312.21(b), or other comparable regulation imposed by the FDA, and that is not a Phase III Clinical Trial.

1.13 The term "**Phase III Clinical Trial**" shall mean a pivotal human clinical trial in any country the results of which could be used to establish statistical safety and efficacy of a Licensed Product as a basis for a NDA or that would otherwise satisfy the requirements of United States Code of Federal Regulations 21 CFR 312.21(c), or other comparable regulation imposed by the FDA.

1.14 The term **"Royalty Period**" shall mean that period beginning on the date of the first Commercial Sale of a Licensed Product by Licensee, its Affiliates, or Sublicensees, and ending on the expiration of the Patent Rights.

1.15 The term "**Sublicensee**" shall mean any non-Affiliate who sublicenses any of the rights granted Licensee under Section 2.

1.16 The term **"Sublicensing Revenue**" shall mean all upfront, license, and technology access fees, product milestone payments (whether research, preclinical or developmental), and other remuneration, however characterized (except for direct reimbursement of research or development expenditures actually incurred), received by Licensee under a sublicense or other agreement with a Third Party for the use of the Patent Rights or the transfer or use of Licensed Products by a Third Party. Any non-cash consideration received by Licensee from Sublicensees shall be valued at its fair market value as of the date of receipt. Sublicensing Revenue shall include any premiums paid on equity investment. The following payments received from Sublicensees shall not be considered Sublicensing Revenue: royalties paid for Net Sales of Licensed Products, sales of equity to Sublicensees for fair market value, reimbursement of patent costs, and money loaned to Licensee at or above the then-current prime rate. If Licensee grants a sublicense to Patent Rights together with the grant of other intellectual property owned or controlled by Licensee, Licensee shall act in good faith to allocate an appropriate portion of the aggregate consideration to the Patent Rights, and only such portion allocated to the Patent Rights shall be treated as Sublicensing Revenue.

1.17 The term **"Territory**" shall mean the United States.

1.18 The term "**Third Party**" shall mean persons or entities other than Licensee, Salk and their respective Affiliates.

2 GRANT OF RIGHTS.

2.1 Patent Rights. Salk hereby grants to Licensee subject to the terms and conditions hereof an exclusive license to the Patent Rights in the Field of Use, to develop, have developed, to make, have made, to use, have used, to import, have imported, to offer for sale, sell and have sold and otherwise commercialize any Licensed Product throughout the Territory.

2.2 Sublicenses.

(a) Licensee shall have the right to grant sublicenses of any of the rights, privileges and licenses granted hereunder consistent with this Agreement. Licensee agrees that any sublicenses granted by it shall be subject to the terms and conditions of this Agreement, which shall be binding upon the Sublicensee. Licensee is responsible for timely enforcement of sublicense agreements. Failure to enforce such sublicenses will be considered a material breach. Sublicensees shall not further grant sublicenses without Salk's prior written approval, such approval not to be unreasonably denied. No sublicense agreement shall contain any provision that would cause it to extend beyond the term of this Agreement. Licensee further agrees to deliver to Salk for informational purposes a true and correct copy of each sublicense granted by Licensee, and any modification or termination thereof, within thirty (30) days after execution, each modification, or termination. Failure to provide such copy will be considered a material breach of this Agreement. Upon termination of this Agreement for any reason, all sublicenses shall survive to the extent provided in the sublicense provided (i) the sublicense contains milestone payments and royalties greater than or equal to those included in this Agreement; (ii) the sublicensee is current on its obligations under the sublicense agreement and (iii) the sublicensee agrees to pay Salk Sublicensing Revenue due under Section 3.5, and a prorata share (based on the number of sublicensees) of the future annual maintenance fees due under Section 3.2 and Patent Costs due under Section 7.2b. Licensee agrees to assign all such sublicenses to Salk. All sublicenses not meeting the above criteria shall survive for a period of ninety (90) days after termination with Salk standing in the place of License. During this ninety (90) day period, Salk agrees to negotiate in good faith and execute an updated agreement with the affected sublicensees. If no new license is completed within the ninety (90) day period, the sublicense will terminate. All payments then or thereafter due to Licensee from each surviving sublicense shall become owed directly to Salk.

(b) If, after the first anniversary of the Effective Date, Salk identifies a third party that has a bona fide interest in developing and commercializing a Licensed Product, and if (i) Licensee is unable or unwilling to develop or commercialize that Licensed Product, and (ii) such Licensed Product would not compete with any Licensed Product then part of an active research, development or commercialization program of Licensee, its Affiliates, or Sublicensees, then Licensee will, at Salk's request, negotiate in good faith a sublicense on commercially reasonable terms with such third party for the development and commercialization of such Licensed Product.

2.3 Government Rights. Licensee acknowledges that the U.S. federal government retains a royalty-free, non-exclusive, non-transferable license to practice any government-funded invention in the Patent Rights, as set forth in 35 U.S.C. §§ 201-211 and the regulations promulgated thereunder, as amended, or any successor statutes or regulations.

2.4 Retained Rights. Under the license granted herein, Salk reserves the right to use for research purposes including sponsored research and collaborations, as long as the other party to the sponsored research or collaboration does not obtain rights to the Patent Rights which have already been granted exclusively under this Agreement, and the right, upon written notice to Licensee, to allow other nonprofit or academic institutions to use for research purposes, any Patent Rights licensed hereunder, without Salk or such other institutions being obligated to pay Licensee royalties or other compensation. Such activity shall not constitute infringement for purposes hereof.

2.5 No Additional Rights.

(a) Nothing in this Agreement shall be construed to confer any rights upon Licensee by implication, estoppel, or otherwise as to any technology or patent rights of Salk or any other entity other than the Patent Rights, regardless of whether such technology or patent rights shall be dominant or subordinate to any Patent Rights.

(b) A license in any other field of use shall be the subject of a separate agreement and shall require Licensee's submission of evidence, satisfactory to Salk, demonstrating Licensee's willingness and ability to develop and commercialize in such other field of use.

2.6 Technology Transfer. Promptly upon request by Licensee, Salk shall take all such actions as may be reasonably requested to transfer to Licensee the ability to use and practice the Patent Rights in connection with the development, manufacture, marketing, sale and commercialization of Licensed Products. Without limiting the generality of the foregoing, Salk shall, upon request, provide

Licensee with copies of or access to any available data and analytical methods relating to the Patent Rights, and lists of suppliers of relevant materials.

3 PAYMENTS.

3.1 License Fee. As partial consideration for the rights granted to Licensee under this Agreement, and payable within fifteen (15) days of execution of this Agreement, Licensee shall pay to Salk the remaining Sixty-Five Thousand Dollars ($65,000) owed on a Seventy Five Thousand Dollars (US$75,000.00) nonrefundable license fee. Licensee represents that the execution and delivery of this Agreement and the payment of the license fee have been duly and validly authorized by all necessary corporate action by Licensee. An option fee of $10,000.00 was paid by Licensee on February 14, 2006, which is hereby credited against the license fee.

3.2 Annual Maintenance Fees. Licensee agrees to pay to Salk the sum of US$12,500.00 per year (the "Maintenance Fee"), within thirty (30) days of the initiation of a Phase II Clinical Trial and each anniversary thereafter, provided that a Phase I Clinical Trial is initiated by the first anniversary of the Effective Date. If a Phase I Clinical Trial is not initiated prior to the first anniversary of the Effective Date then the Maintenance Fee will be payable within thirty (30) days of the first anniversary of the Effective Date and each anniversary thereafter. The obligation to pay Maintenance Fees will terminate upon the filing of an NDA. The Maintenance Fee is non-refundable and not subject to proration.

3.3 Milestone Payments. Licensee shall provide Salk with written notice within thirty (30) days of each achievement by Licensee or its Affiliates of each of the milestone events set forth below. Within ten (10) days after delivering each such notice, Licensee shall pay to Salk the amounts set forth below:

Milestone	Amount
Initiation of Phase II Clinical Study with respect to the first Licensed Product (as demonstrated by dosing of the first subject)	$50,000.00
Initiation of Phase III Clinical Study with respect to the first Licensed Product (as demonstrated by dosing of the first subject)	$150,000.00

Submission and acceptance of an NDA to the FDA or foreign equivalent with respect to the first Licensed Product	$350,000.00
Approval of an NDA by the FDA or foreign equivalent with respect to first Licensed Product	$750,000.00
Filing of subsequent NDA with the FDA	$100,000.00
Approval of subsequent NDA by the FDA	$450,000.00

For the avoidance of doubt, for a particular Licensed Product, written notice and a payment is required the first time each milestone is achieved, but no additional written notice or payment is due to the extent that for the same Licensed Product a milestone is achieved again for the same indication. Any modifications of a Licensed Product are considered distinct Licensed Products, other than modifications which are limited to changes in the formulation of a Licensed Product. Also for the avoidance of doubt, a different indication must be a distinct and different disease state, and not a subset of the same disease or a label extension (e.g., secondary progressive multiple sclerosis is the same disease state, and therefore the same indication, as relapsing remitting multiple sclerosis).

Failure to make any milestone payment when due is considered a material breach of this Agreement and cause for termination under Section 9.2(b), subject to the cure period specified therein.

3.4 Royalty Payments.

(a) (a) Running Royalties. Licensee shall pay to Salk during the Royalty Period a royalty of three percent (3%) on Net Sales of Licensed Products sold by Licensee, its Affiliates or Sublicensees. Royalty payments shall be made in accordance with Section 8. Subject to Section 1.8, on sales of Licensed Products by Licensee to Sublicensees or on sales made in other than an arm's-length transaction, the value of the Net Sales attributed under this Article 3 to such a transaction shall be that which would have been received in an arm's-length transaction, based on sales of like quantity and quality products on or about the time of such transaction.

(b) Minimum Annual Royalties. Licensee shall pay to Salk a minimum royalty payment of One Hundred Thousand Dollars (US$100,000.00) annually during the Royalty Period, beginning on the one year anniversary date of the first Commercial Sale of a Licensed Product. This minimum annual royalty will be credited against the royalties due under Sections 3.4(a) for the immediately prior twelve month period for which the minimum royalty payment is to be made on a dollar-for-dollar basis up to the full One Hundred Thousand Dollar (US$100,000) paid for such twelve month period, and will be paid within thirty (30) days of each such anniversary. A minimum annual

royalty payment made in one twelve month period is not creditable against royalties accruing in a different twelve month period.

3.5 Other Payments. Licensee shall pay to Salk within thirty (30) days of Licensee's receipt, a share of Sublicensing Revenue, in an amount equal to twenty-five percent (25%) of Sublicensing Revenue if the sublicense is granted prior to initiation of a Phase II clinical trial (as demonstrated by dosing of the first patient), for a Licensed Product, and fifteen percent (15%) of Sublicensing Revenue for Licensed Products if the sublicense is granted anytime after the initiation of a Phase II clinical trial.

3.6 After the expiration of the Royalty Period, Licensee shall have no further obligation to pay royalties in connection with sales of Licensed Products and the licenses granted hereunder shall be fully paid-up.

4 OWNERSHIP OF INTELLECTUAL PROPERTY.

Licensee (for itself, its Affiliates and Sublicensees) acknowledges and agrees that Salk is and shall remain (as to Licensee) the owner of the Patent Rights, subject to the rights of the Federal Government as set forth in 35 U.S.C. §200 et seq., and that Licensee (including its Affiliates and Sublicensees) has no rights in or to the Patent Rights other than the rights specifically granted herein.

5 WARRANTIES AND DISCLAIMERS.

5.1 Warranty Disclaimer. Nothing in this Agreement is or shall be construed as:

(a) a warranty or representation by Salk as to the validity or scope of any Patent Rights;

(b) a warranty or representation that anything made, used, sold or otherwise disposed of under any license granted in this Agreement is or will be free from infringement of patents, copyrights and other rights of third parties;

(c) an obligation to bring or prosecute actions or suits against third parties for infringement, except to the extent and in the circumstances described in Section 7.3; or

(d) a grant by implication, estoppel, or otherwise of any licenses under patent applications or patents of Salk or other persons other than as provided in Section 2 hereof.

5.2 Representations and Warranties by Salk. Salk represents and warrants that as of the Effective Date: (a) it is the sole owner of the Patent Rights and has the right to grant rights to the Patent Rights as set forth in this Agreement; (b) it has not transferred any interest in the Patent Rights which may be inconsistent with the rights granted hereunder; (c) it has not received any notice or claim alleging that any of the Patent Rights are invalid or infringe on the rights of any third party; (d) it is not aware of any infringement of the Patent Rights by a third party; (e) it has prosecuted all patent applications within the Patent Rights in good faith and has no reason to believe that any patent or claim within the Patent Rights is invalid or would be held to be unenforceable by a court of competent jurisdiction; and (f) no litigation is pending and no claim has been made against Salk or, to the knowledge of Salk, is threatened, which may affect the rights of Licensee hereunder.

5.3 Mutual Representations and Warranties. Each party represents and warrants to the other that (i) it has the legal right and power to enter into this Agreement and to perform fully its obligations hereunder, (ii) this Agreement and the signatories hereto have been duly authorized, (iii) this Agreement is a valid and binding agreement of such party, enforceable in accordance with its terms, (iv) this Agreement does not violate the terms of any other contract to which such party is a party, and (v) in exercising its rights and fulfilling its obligations under this Agreement, it will fully comply with the requirements of any and all applicable laws, regulations, rules, and orders of any governmental body.

5.4 No Warranty. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION AND EXTENDS NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES AS TO TITLE, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

5.5 Disclaimer of Liability. Subject to Sections 6.2 and 6.3, in no event shall either party be liable to the other party for any incidental, special or consequential damages arising from or relating to the subject matter of this Agreement or its breach.

6 INDEMNIFICATION AND INSURANCE.

6.1 Indemnification by Licensee. Licensee agrees to indemnify, hold harmless and defend Salk, its trustees, officers, employees and agents, and the inventors (the "Salk Entities") of the patents

and patent applications included in the Patent Rights against any and all liability and/or damages with respect to any claims, suits, demands, judgments or causes of action asserted by third parties arising out of (a) the development, manufacture, storage, sale or other distribution, or any other use of Licensed Products or Patent Rights, or exercise of other rights granted hereunder, by Licensee, its Affiliates or Sublicensees, distributors, agents or representatives; (b) the use by end-users and other third parties of Licensed Products or Patent Rights; and/or (c) any representation, warranty or statement by Licensee or its Affiliates, Sublicensees, distributors, agents or representatives, concerning Salk, or the Patent Rights, except to the extent such liabilities and/or damages are the result of the Salk Entities' breach of this Agreement, gross negligence or willful misconduct. If a Salk Entity intends to claim indemnification under this Section, it shall promptly notify Licensee and Licensee shall assume the defense and shall control the defense or disposition of the claim, at Licensee's sole expense by counsel selected by Licensee. No settlement, consent judgment or other voluntary final disposition may be entered into that admits fault, wrongdoing or damages without the prior written consent of Salk, which consent shall not be unreasonably withheld or delayed. Salk shall cooperate fully with Licensee and its legal representatives in the investigation and defense of any matter giving rise to a claim for indemnification hereunder, at Licensee's expense.

6.2 Insurance.

(a) Subject to Section 6.2(c), Licensee shall maintain, during the Term (as defined below), comprehensive general liability insurance, including products liability insurance, with reputable and financially secure insurance carriers to cover the activities of Licensee, its Affiliates and Sublicensees. Such insurance shall include Salk as a named insured, shall require prior notice to Salk before cancellation, shall be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement and should be placed with carriers with ratings of at least A- as rated by A.M. Best. Such insurance shall have a minimum limit of one million dollars ($1,000,000.00) per specific occurrence and a minimum limit of one million dollars ($1,000,000.00) for aggregate liability insurance; provided, however, that when Licensee or its Affiliates or Sublicensees receives NDA Approval, such coverage shall be increased to a minimum limit of five million dollars ($5,000,000) per specific occurrence and a minimum limit of ten million dollars ($10,000,000) for aggregate liability insurance. The minimum amounts of insurance coverage required shall not be construed to create a limit of Licensee's liability with respect to its indemnification under this Agreement.

(b) Within ninety (90) days of the Effective Date of this Agreement, Licensee shall furnish a Certificate of Insurance evidencing primary coverage and additional insured requirements and provide Salk with copies of subsequent annual Certificates of Insurance. Licensee shall provide Salk

with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance. It is the intention of the parties hereto that Licensee shall, throughout the term of this Agreement, continuously and without interruption, maintain in force the required insurance coverages set forth in this Section. Failure of Licensee to comply with this requirement shall be considered a material breach of the Agreement.

(c) If Licensee or a Sublicensee elects to self-insure all or part of the limits described above (including deductibles or retentions that are in excess of $250,000 annual aggregate) such self-insurance program must be acceptable to Salk at its sole reasonable discretion.

(d) Licensee shall maintain commercial general liability insurance beyond the expiration or termination of this Agreement during: (i) any period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by Licensee, a Sublicensee, Affiliate or agent of Licensee; and (ii) thereafter for a period of three (3) years.

7 PROSECUTION AND MAINTENANCE OF PATENT RIGHTS.

7.1 Prosecution and Maintenance.

(a) Within thirty (30) days after the Effective Date, Salk shall disclose to Licensee copies of complete file histories of the Patent Rights and all other relevant documentation and information related thereto. Salk shall have full control over prosecution and maintenance of the patent applications and patents contained in the Patent Rights. Salk will keep Licensee advised of the status of patent prosecution by providing Licensee with copies of official communications about the patent applications and patents contained in the Patent Rights and provide Licensee with an opportunity to review and comment reasonably before the filing of such patent prosecution documents Notwithstanding Licensee's obligations of payment in Section 7.2 hereof, Salk shall select all outside counsel for prosecution of the Patent Rights and such counsel shall represent Salk in such prosecution. Upon Licensee's reasonable request, Salk shall apply for an extension of the term of any patent in the Patent Rights if appropriate under the US Drug Price Competition and Patent Term Restoration Act. Salk shall not abandon the prosecution of any patent application or the maintenance of any patent in the Patent Rights without first notifying Licensee in writing at least sixty (60) days prior to taking any action to abandon such Patent Rights, detailing the reason therefore, and providing Licensee with the opportunity to assume responsibility for the prosecution or maintenance of such patent(s).

(b) Licensee shall notify Salk as soon as reasonably possible of a change in its entity status under 37 C.F.R. section 1.27. Licensee's entity status may change due to a change in the number of its employees or if any rights under Patent Rights have been transferred to or released from an affiliate, collaborator or sublicensee.

7.2 Patent Costs.

(a) Upon execution of this Agreement, Licensee shall pay to Salk Three Thousand Four Hundred Thirty Eight dollars and Ten cents ($3,438.10) as reimbursement for Patent Costs incurred through the Effective Date with respect to the U.S. patents and patent applications within the Patent Rights.

(b) Licensee shall reimburse Salk for all Patent Costs incurred after the Effective Date. Salk will provide an invoice to Licensee for Patent Costs at least semiannually, and Licensee shall reimburse Salk for such Patent Costs within thirty (30) days after delivery of any such invoice. Pursuant to Section 8.5, late payments shall be subject to a charge of one and one-half percent (1.5%) per month compounded or the highest amount allowed by law, whichever is lower. The payment of such late charges shall not prevent Salk from exercising any other rights it may have as a consequence of the lateness of any payment. Failure to pay within thirty (30) days after receipt of invoice will be considered a material breach of this Agreement.

(c) Licensee may elect to surrender its Patent Rights in any country by providing to Salk written notice of such intent at least forty-five (45) days prior to such surrender. Such notice may be provided by mail, electronic mail or facsimile directly to Salk Patent Counsel. Such notice shall not relieve Licensee from responsibility to reimburse Salk for patent-related expenses incurred prior to the expiration of the forty-five (45) day notice period (or such longer period specified in Licensee's notice). In the event Licensee elects to surrender any Patent Rights, such patent application or patent shall be excluded from the definition of the Patent Rights and from the scope of the license granted under this Agreement, and all rights relating thereto shall revert to Salk and may be freely licensed by Salk.

7.3 Infringement of Patent Rights.

(a) In the event Licensee or Salk becomes aware of any actual or potential infringement of any Patent Rights, that party shall promptly notify the other, and shall provide the other party with any evidence available pertaining thereto, and the parties shall discuss the most appropriate action to take. Salk and Licensee will cooperate with each other to attempt to terminate such infringement without litigation. If attempts to abate such infringement are unsuccessful, Licensee shall

consult with Salk and shall consider the views of Salk regarding the advisability of any proposed action and its effect on the public interest. Licensee shall have the primary right, but not the obligation, to take whatever steps it considers necessary or appropriate, at its own expense, to protect or enforce the Patent Rights, by counsel of its choosing, including granting the infringer a sublicense of the Patent Rights. Salk shall cooperate with Licensee as reasonably requested, and Licensee shall reimburse Salk for any out of pocket expenses incurred in providing such assistance.

(b) No settlement, consent judgment or other voluntary final disposition of the action that adversely affects the rights or interests of Salk under this Agreement, including issues of validity of the Patent Rights, may be entered into without the prior written consent of Salk, which consent shall not be unreasonably withheld. To the extent Licensee's recoveries from such infringement action exceed Licensee's expenses, Licensee agrees to pay Salk an amount equal to ten percent (10%) of such excess recoveries.

(c) If required by law, Salk shall permit any action brought by Licensee under this Section to be brought in its name, including being joined as a party-plaintiff, provided that Licensee shall hold Salk harmless from, and indemnify Salk against, any costs, expenses, or liability that Salk incurs in connection with such action. To the extent recoveries from such action exceed Licensee's expenses, Licensee agrees to pay Salk an amount equal to ten percent (10%) of such excess recoveries.

(d) Salk may, on its own initiative, join such action at its own expense, it being understood that Licensee shall have the final decision-making authority with respect to any legal proceeding Licensee elects to pursue or defend. In the event recoveries exceed Salk and Licensee's expenses, Licensee agrees to pay Salk an amount equal to ten percent (10%) of such excess recoveries.

(e) In the event that Licensee elects not to institute or prosecute any suit to enjoin or recover damages from any infringer, then Licensee shall notify Salk in writing within sixty (60) days of determining that it shall neither enforce the Patent Rights nor engage in bona fide negotiations to abate the infringement or sublicense the infringer. Following such notification, then Salk alone may, in its sole discretion and at its expense, initiate and conduct an infringement action, and any settlement or award which may be obtained shall be solely Salk's.

7.4 Defense against Third Party Infringement Claims. In the event any Licensed Product becomes the subject of a claim for patent or other proprietary right infringement anywhere in the world by virtue of the incorporation of the Patents Rights, the parties shall promptly give notice to the other and meet to consider the claim and the appropriate course of action. Licensee shall have the right and

responsibility to conduct the defense, by counsel of its own choice and at its own expense, of any such suit brought against Licensee and/or Salk. In no event shall Licensee enter into any settlement, consent judgment or other voluntary final disposition of the suit which makes any admission regarding (i) wrongdoing on the part of Salk, or (ii) the invalidity, unenforceability or absence of infringement of Patent Rights, without the prior written consent of Salk, which consent shall not be unreasonably withheld. The parties shall cooperate with each other in connection with any such claim, suit or proceeding and shall keep each other reasonably informed of all material developments in connection with any such claim, suit or proceeding.

7.5 Marking. Licensee agrees to mark and to require any Affiliate or Sublicensee to mark any Licensed Products (or their containers or labels) made, sold, or otherwise distributed by it or them with any notice of patent rights necessary under applicable law to enable the Patent Rights to be enforced to their full extent in any country where Licensed Products are made, used, sold, or offered for sale.

8 REPORTING, VERIFICATION AND PAYMENT.

8.1 Books and Records. Licensee agrees to keep proper records of scientific research and books of account in accordance with generally accepted accounting practices. Such records and books shall include all information necessary for the accurate determination of royalty payments, Sublicensing Revenue, diligence obligation and milestone achievement. Licensee agrees to deliver to Salk, within forty-five (45) days after the end of each calendar quarter (March 31st, June 30th, September 30th and December 31st) during the Royalty Period, a report showing the information on which payments herein provided are calculated, including a breakdown of income from sales of each Licensed Product and to accompany each such report with the payment shown to be due thereby. All amounts accrued for the benefit of Salk shall be deemed held in trust for the benefit of Salk until payment of such amounts is made pursuant to this Agreement. Progress Reports showing records of scientific research are to be provided in accordance with Section 12.3. All reports required hereunder shall be deemed Licensee Confidential Information pursuant to Article 10.

8.2 Audit. On reasonable written notice (at least ten (10) days)) and no more than once per year, Salk, at its own expense, shall have the right to have an independent certified public accountant inspect and audit the books and records of Licensee and Affiliates during usual business hours for the sole purpose of, and only to the extent necessary for, determining the correctness of royalty payments, Sublicensing Revenue, and milestone achievement under this Agreement. Such examination with respect to any calendar quarter, shall not take place later than three (3) years following the end of such calendar

quarter. Such certified public accountant shall execute a written non-disclosure agreement reasonably acceptable to Licensee. The expense of any such audit shall be borne by Salk; provided, however, that, if the audit discloses an error in excess of five percent (5%) in favor of Licensee, then Licensee shall pay, in addition to the amount of any underpayment, the cost to Salk of the audit.

8.3 Foreign Payments. Royalties based on Net Sales in any foreign country shall be payable to Salk in the United States in United States Dollars. Dollar amounts shall be calculated using the foreign exchange rate, as published by the eastern edition of The Wall Street Journal, in effect for such foreign currency on the last business day of the applicable calendar quarter for which a report is required. Where royalties are due for Net Sales in a country where, for reasons of currency, tax or other regulations, transfer of foreign currency out of such country is prohibited, Licensee has the right to place Salk's royalties in a bank account in such country in the name of and under the sole control of Salk; provided, however, that the bank selected be reasonably acceptable to Salk and that Licensee inform Salk of the location, account number, amount and currency of money deposited therein. After Salk has been so notified, those monies shall be considered as royalties duly paid to Salk and will be completely controlled by Salk.

8.4 Taxes. Licensee shall be responsible for any and all taxes that may be levied by a proper taxing authority on royalties or other payments accruing to Salk under this Agreement. Such taxes may not be deducted from royalties or other payments to be paid to Salk hereunder. Licensee acknowledges that Salk, as a not-for-profit corporation, does not qualify under U.S. tax laws for a tax credit on any taxes paid by Licensee.

8.5 Late Payments. Late payments shall be subject to a charge of one and one-half percent (1.5%) per month compounded, or the maximum amount allowed by applicable law, whichever is lower. The payment of such late charges shall not prevent Salk from exercising any other rights it may have as a consequence of the lateness of any payment.

9 TERM AND TERMINATION.

9.1 Term. Unless earlier terminated under this Section 9, this Agreement shall begin on the Effective Date and expire on the date of expiration or abandonment of the last to expire or be abandoned of any patent included in the Patent Rights.

9.2 Termination.

(a) Termination by Licensee. Licensee may initiate termination of this Agreement by giving written notice to Salk. Sixty (60) days after such notice and upon Licensee fulfilling the below obligations, the License will be deemed terminated.

(ii) Licensee shall pay all amounts due to Salk under this Agreement through the termination date; and

(iii) Licensee shall submit a report of the type described in Section 8.1; and

(iv) Licensee shall return any materials, samples, documents, and information, which embody or disclose Patent Rights provided to Licensee by Salk in connection with this Agreement

(b) Termination By Salk. Salk has the right to terminate this Agreement as follows:

(i) If Licensee does not make a payment due hereunder and fails to cure such non-payment (including the payment of interest in accordance with Section 8.5) within thirty (30) days after the date of notice in writing of Licensee's failure to meet a payment obligation;

(ii) If Licensee defaults in its indemnification and insurance obligations under Section 6 and fails to cure such default within thirty (30) days after the date of notice in writing;

(iii) If, at any time, Licensee does not meet the diligence requirements pursuant to Section 12, and fails to cure such default within thirty (30) days after the date of notice in writing;

(iv) If Licensee knowingly attempts to use, sublicense, transfer or assign its rights or obligations under this Agreement in any manner contrary to the terms of this Agreement or in derogation of Salk's proprietary rights.

(v) If Licensee fails to provide reports (progress reports, royalty reports) or copies of sublicense agreements and fails to cure such deficits within thirty (30) days after the date of notice in writing of such deficit by Salk;

(vi) If an examination by an independent accountant pursuant to Section 8.2 shows an underreporting or underpayment by Licensee in excess of twenty percent (20%) for any

twelve (12) month period, and Licensee fails to cure such underreporting or underpayment within thirty (30) days after the date of notice in writing;

(vii) If Licensee is convicted of a felony relating to the manufacture, use or sale of Licensed Products or Biological Materials; or

(viii) Except as provided in subparagraphs (i) - (vii) above, if Licensee defaults in the performance of any obligations under this Agreement and the default has not been remedied within sixty (60) days after the date of notice in writing of such default by Salk. The failure of Salk to exercise its rights of termination shall not be deemed to be a waiver of any right Salk might have, nor shall such failure preclude Salk from exercising or enforcing said right upon any subsequent failure by Licensee.

(c) Termination for Breach. Either Party shall have the right to terminate this Agreement if the other party materially breaches or defaults in the performance of any obligations under this Agreement (in such capacity, the "Breaching Party") and the default has not (i) been remedied within sixty (60) days after receipt of notice in writing specifying such breach or default, or (ii) if such breach is not susceptible to cure within sixty (60) days of the receipt of written notice of the breach, the Breaching Party is diligently pursuing a cure and both parties have mutually agreed on a time for cure in excess of sixty (60) days. The failure of a party to exercise its rights of termination shall not be deemed to be a waiver of any right that party might have, nor shall such failure preclude Salk from exercising or enforcing said right upon any subsequent failure by Licensee.

(c) Termination for Insolvency. Except to the extent prohibited by law, either party may, at its option and without notice, terminate this Agreement, effective immediately, if the other party: (i) admits in writing its inability to pay its debts generally as they become due; (ii) is adjudicated by a court of competent jurisdiction as being insolvent; (iii) has a decree entered against it by a court of competent jurisdiction appointing a receiver, liquidator, trustee, or assignee in insolvency covering all or substantially all of such party's property (which appointment is not vacated within sixty (60) days of the entry of the order of appointment) or providing for the liquidation of such party's property or business affairs; (iv) makes an assignment for the benefit of creditors; or (v) shall have a petition in bankruptcy filed for or against it (which is not dismissed within sixty (60) days of the petition).

9.3 Consequences of Expiration or Termination.

(a) In the event of expiration of this Agreement or termination of the Agreement for any reason whatsoever:

(i) Licensee shall not thereby be discharged from any liability or obligation to Salk that became due or payable prior to the effective date of such expiration or termination.

(ii) The rights and obligations of the parties under Sections 5, 6, 7, 8.2, 9.3, 10, 11, and 14 shall survive any expiration or termination of this Agreement.

(iii) Licensee shall promptly return all documents, information, and other materials received from Salk which embody or disclose Patent Rights.

(iv) All sublicenses shall survive to the extent provided in Section 2.2. All payments then or thereafter due to Licensee from each surviving sublicense shall become owed directly to Salk; provided that, Salk shall remit to Licensee the amount by which any such payments exceed the corresponding amount that would have been payable by Licensee to Salk hereunder.

(b) In the event of termination of the Agreement:

(i) If Licensee, its Affiliates or its Sublicensees then possess Licensed Product, have started the manufacture thereof or have accepted orders therefor, Licensee, its Affiliates or its Sublicensees shall have the right, for up to one hundred eighty (180) days following the date of termination, to sell their inventories thereof, complete the manufacture thereof and market such fully manufactured Licensed Product, in order to fulfill such accepted orders, subject to the obligation of Licensee to pay Salk the royalty payments therefor as provided in Section 3 of this Agreement;

(ii) Subject to Section 9.3(b)(i), Licensee shall discontinue and shall cause its Affiliates to discontinue, the manufacture, use, marketing, offering for sale and sale of Licensed Products.

(iii) Licensee shall provide a final report of the type described in Section 8.1, including any allowable post-termination sales.

10 CONFIDENTIAL INFORMATION.

(a) The term "**Confidential Information**" means all confidential scientific, technical, financial, or business information furnished by a party (the "**Disclosing Party**") to the other party (the "**Receiving Party**") in connection with this Agreement, including, without limitation, information contained in patent applications and Licensee's business and financial information. Confidential Information that is disclosed in writing shall be marked with the legend "CONFIDENTIAL" or similar legend. 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 thirty (30) days of the date of disclosure. Such notice shall summarize the Confidential Information disclosed to the Receiving Party and reference the time and place of disclosure.

(b) The Receiving Party shall and shall cause its employees engaged in the performance of this Agreement to (i) maintain all Confidential Information in strict confidence, (ii) use Confidential Information only for the purposes of this Agreement, and (iii) not disclose Confidential Information to a third party, except that the Receiving Party may disclose or permit the disclosure of any Confidential Information to its directors, officers, employees, and agents who are obligated to maintain the confidential nature of such Confidential Information and who need to know such Confidential Information to perform tasks under this Agreement.

(c) The obligations with respect to Confidential Information shall not apply to Confidential Information to the extent that a party can demonstrate by competent written evidence: (i) was in the public domain at the time of disclosure hereunder, (ii) later became part of the public domain after the time of its disclosure hereunder through no act or omission of the Receiving Party, its employees agents, successors, or assigns, (iii) was lawfully disclosed to the Receiving Party at any time by a third party having the right to disclose it, (iv) was already known by the Receiving Party at the time of disclosure or is independently developed or discovered by the Receiving Party without resort to such Confidential Information, (v) is required to be disclosed by Receiving Party to a governmental agency pursuant to such agency's rule and regulations in order to secure regulatory approval for a Licensed Product, provided that Licensee shall first give notice to Salk of such disclosure and shall have made a reasonable effort to maintain the confidentiality of such information, or (vi) is required to be disclosed to comply with applicable laws or regulations, or with a court or administrative order, provided that the Disclosing Party receives, to the extent practicable, prior written notice of such required disclosure and that the Receiving Party takes all reasonable and lawful actions to obtain confidential treatment for such disclosure and to minimize the extent of such disclosure. Nothing contained herein shall prevent Licensee or its Affiliates from disclosing information to actual and prospective investors, Sublicensees,

funding sources, merger partners and professional advisers in connection with any such transaction so long as such disclosures are governed by these or substantially similar confidentiality provisions.

11 CHOICE OF LAW; DISPUTE RESOLUTION.

11.1 Governing Law. This Agreement is made in accordance with and shall be governed and construed in accordance with the laws of the State of New York, without regard to conflicts of laws rules.

11.2 Dispute Resolution. If a dispute arises between the parties relating to the interpretation or performance of this Agreement or the grounds for the termination thereof, the parties agree to hold a meeting, attended by individuals with decision-making authority regarding the dispute, to attempt in good faith to negotiate a resolution of the dispute prior to pursuing other available remedies. If the dispute remains unresolved forty-five (45) days after the first meeting for the purpose of dispute resolution, then each party shall have the right to pursue alternate dispute resolution or other remedies legally available to resolve the dispute. In the case of such alternate dispute resolution or other legal remedies, the prevailing party will be entitled to receive from the other party its reasonable attorneys' fees and costs. If both parties receive judgment in any dollar amount, the court will determine the prevailing party, taking into consideration the merits of the claims asserted by each party, the amount of the judgment received by each party and the relative equities between the parties.

12 COMMERCIALIZATION.

12.1 Commercial Development Obligation. In order to maintain in force the license granted hereunder, Licensee shall use reasonable efforts and diligence to develop Licensed Products, as promptly as is reasonably and commercially feasible, and thereafter to produce and sell reasonable quantities of Licensed Products. Mere sublicensing is not considered reasonable commercial efforts. The parties hereto acknowledge and agree that achievement of the milestones described in Section 12.2 shall be evidence of compliance by Licensee with its commercial development obligations hereunder for the time periods specified in 12.2. In the event Salk, at any time, has a reasonable basis to believe that Licensee is not using reasonable efforts and diligence as required hereunder, including failure to achieve the milestones described in Section 12.2, Salk shall provide Licensee with a notice that specifies the basis for such belief. Upon such notice, Licensee has sixty (60) days to respond in writing with proof of diligence and/or a plan for cure to Salk's satisfaction or Salk has the right to terminate the Agreement.

12.2 Diligence Milestones. Prior to signing this Agreement, Licensee shall have provided to Salk the Commercial Development Plan attached hereto as Exhibit B, under which Licensee intends to bring the subject matter of the Patent Rights to the point of commercial use. This Commercial Development Plan is hereby incorporated by reference into this Agreement.

Licensee's failure to perform its obligations under Exhibit B will be considered a material breach of this Agreement. Salk shall provide Licensee with a notice that specifies the basis for such belief. Upon such notice, Licensee has thirty (30) days to respond in writing with proof of diligence and/or a plan for cure to Salk's satisfaction or Salk has the right to terminate the Agreement.

12.3 Progress Reports. Beginning on the first anniversary of the Effective Date and terminating on the date of first Commercial Sale of a Licensed Product, Licensee shall provide to Salk on or before February 15 of each year a written report of its progress with respect to the scientific research and discovery, development, and commercialization of Licensed Products. Such report shall include (i) identification of the Licensee, Affiliate or Sublicensee officers and employees having primary responsibility for developing such products, and (ii) the current status of and timetable for developing such products including if applicable, plans for preclinical studies and estimated dates for initiation and completion of clinical trials, manufacturing, sublicensing, marketing and sales during the most recent twelve (12) month period and plans for the forthcoming year. If actual progress differs from that anticipated in the Commercial Development Plan required under Section 12.2, Licensee shall provide to Salk a written explanation of the reasons for the difference and a modified Commercial Development Plan. The modified Commercial Development Plan shall require Salk's approval if it contains modified performance milestones unless such modifications are the result of changes required by the FDA in the scope or extent of testing required for Licensed Products prior to first Commercial Sale.

12.4 U.S. Manufacture. To the extent necessary to comply with US Government regulations for the licensing of federally funded inventions, Licensee, its Affiliates and any sublicensee(s) will commit, to the extent required by law, that Licensed Products sold in the US will be manufactured substantially in the US. Notwithstanding the foregoing, if during the term of the License Agreement, Licensee, its Affiliates and/or its sublicensees can provide compelling evidence to Salk that such manufacture in the US would impose an extraordinary burden on Licensee, its Affiliates or any sublicensee, Salk shall at that time agree to seek a waiver from the US Government with respect to the requirement that Licensed Products for sale in the US be manufactured substantially in the US. Licensee understands that Salk cannot guarantee that such waiver can be obtained. Licensee shall bear all costs associated with seeking such waiver.

12.5 Foreign Registration. Licensee agrees to register this Agreement with any foreign governmental agency that requires such registration, and Licensee shall pay all costs and legal fees in connection therewith. In addition, Licensee shall assure that all foreign laws affecting Licensee's performance under this Agreement or the sale of Licensed Products are fully satisfied.

13 ADDRESSES.

Except as otherwise provided, payments to be made hereunder to Salk shall be made by wiring the required amount to Salk's bank in accordance with Salk's instructions or by mailing or sending by commercial courier checks for the required amount to Salk's address. Except as otherwise provided, notices and reports provided for herein shall effectively be given by mailing the same by certified or registered mail or by delivery by commercial courier, in each case properly addressed to the other party with charges prepaid. For the purposes of making payments and giving notices, the addresses of the parties hereto are as follows:

If to Salk: The Salk Institute for Biological Studies
10010 North Torrey Pines Road
La Jolla, CA 92037
Attn: Licensing Administrator, Office of Technology Management

If to Licensee: Merrion Research II, Ltd.
3rd Floor Biotechnology Building
Trinity College, Dublin 2 Dublin IRELAND
Attn: Dr. Thomas Leonard, Director

or to such subsequent addresses as either party may furnish the other by giving notice thereof as provided in this Section 13.

14 MISCELLANEOUS.

14.1 Assignment.

(a) Licensee may assign this Agreement as part of:

(i) Sale, merger or other transfer of Licensee's entire business; or

(ii) Sale or other transfer of that part of Licensee's business to which the license granted hereby relates; or

(iii) A transaction other than described in (i) or (ii), following payment to Salk of a fee of One Hundred Thousand Dollars ($100,000).

(b) Salk shall release Licensee of liability hereunder upon receipt of writing from successor or assignee expressly agreeing to be bound by all the terms and provisions of this Agreement.

(c) Licensee shall notify Salk within ten (10) days of any assignment of this Agreement by Licensee and provide the new contact information of assignee.

(d) Upon assignment of this Agreement to a successor or assignee as provided under 14.1(a), the term "Licensee" as used herein shall mean such successor assignee.

(e) Salk may not assign or otherwise transfer this Agreement without the consent of Licensee.

14.2 Headings. The headings used in this Agreement are for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

14.3 Amendment. No amendment or modification hereof shall be valid or binding upon the parties unless made in writing and signed by both parties.

14.4 Bankruptcy. Licensee agrees to provide notice to Salk of its intention to file a voluntary petition in bankruptcy or, where known to Licensee, of another party's intention to file an involuntary petition in bankruptcy for Licensee, said notice to be received by Salk at least one hundred and twenty (120) days prior to filing such voluntary petition. Salk may terminate this Agreement upon receipt of such notice at its sole discretion. Unless otherwise provided by law, Licensee's failure to provide such notice to Salk will be deemed a material, pre-petition, incurable breach of this Agreement and the Agreement will terminate automatically on the date of filing such voluntary or involuntary petition in bankruptcy. Notwithstanding the above, Licensee agrees to provide notice to Salk upon filing a voluntary petition in bankruptcy.

14.5 Force Majeure. Any delays in performance by any party under this Agreement (other than the payment of monies due) shall not be considered a breach of this Agreement if and to the extent

caused by occurrences beyond the reasonable control of the party affected, including but not limited to: acts of god, embargoes, governmental restrictions, strikes or other concerted acts of workers, fire, flood, explosion, riots, wars, civil disorder, rebellion or sabotage. The party suffering such occurrence shall immediately notify the other party and any time for performance hereunder shall be extended by the actual time of delay caused by the occurrence.

14.6 Independent Contractors. In making and performing this Agreement, Salk and Licensee act and shall act at all times as independent contractors and nothing contained in this Agreement shall be construed or implied to create an agency, partnership or employer and employee relationship between Salk and Licensee. At no time shall one party make commitments or incur any charges or expenses for or in the name of the other party except as specifically provided herein.

14.7 Use of Salk's Name. Except as otherwise provided herein or required by law, Licensee will not originate any publication, news release or other public announcement, written or oral, whether in the public press or otherwise, relating to this Agreement or to the performance hereunder, without the prior written approval of Salk, which approval will not be unreasonably withheld. Such planned publication, news release or other public announcement shall be provided five (5) days in advance for approval by Salk. Notwithstanding the foregoing, Salk agrees that Licensee may make known in promotional and technical literature that the Patent Rights were developed at Salk by Dr. Jean E.F. Rivier and other scientists in his/her laboratory and that products are offered under license from Salk; provided, however, that such use shall not state or imply that Salk has any relationship with Licensee other than as licensor.

14.8 Publication. Licensee agrees that Salk (including its employees) shall have a right to publish in accordance with its general policies, and that this Agreement shall not restrict, in any fashion, Salk's right to publish, subject to Section 10 of this Agreement.

14.9 Severability. If any term, condition or provision of this Agreement is held to be unenforceable by a court having proper jurisdiction for any reason, it shall, if possible, be interpreted rather than voided, in order to achieve the intent of the parties to this Agreement to the extent possible. In any event, all other terms, conditions and provisions of this Agreement shall be deemed valid and enforceable to the full extent of the law.

14.10 Waiver. None of the terms, covenants, and conditions of this Agreement can be waived except by the written consent of the party waiving compliance. Waiver of one term, covenant or condition, shall not be construed as waiver of any other term, covenant or condition.

14.11 Entire Agreement. This Agreement and Exhibits attached hereto contain the entire agreement and understanding between the parties with respect to the subject matter hereof, and merges all prior discussions, representations and negotiations with respect to the subject matter of this Agreement.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement by their duly authorized officers or representatives.

SALK INSTITUTE FOR BIOLOGICAL STUDIES

By: _____

Anne-Marie Mueller.

Title: Director, Office of Technology Management

MERRION RESEARCH I, LTD.

By: _____

Dr. Thomas Leonard

Title: Director, Merrion Research

EXHIBIT A

PATENT RIGHTS

U.S. Patent No. 5,506, 207, issued April 9, 1996, entitled, "GnRH Antagonists XIII"

EXHIBIT B

Licensee Commercial Development Plan

Principal activities	**Quarter Initiated**
Clinical trials supplies manufacturing for Phase I	Q3/07
Phase I clinical trials	Q4/07
Phase II clinical trials	Q4/08
CTM for Phase III	Q2/09
Phase III Clinical Trials (2 studies)	Q4/09
NDA submission	Q1/12