UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington D.C. 20549

FORM 8-K/A
(Amendment No. 1)

CURRENT REPORT

PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): October 5, 2011

GENESIS BIOPHARMA, INC.
(Name of small business issuer specified in its charter)

Nevada	**000-53127**	**75-3254381**
(State or other jurisdiction of incorporation)	(Commission File No.)	(I.R.S. Employer Identification No.)

11500 Olympic Blvd., Suite 400
Los Angeles, CA 90064
(Address of principal executive offices)

Not Applicable.
(former name or former address, if changed since last report)

(866) 963-2220
(Registrant's telephone number)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

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

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

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

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

Explanatory Note

This Amendment No. 1 amends the Current Report on Form 8-K of Genesis Biopharma, Inc. filed with the Securities and Exchange Commission on October 11, 2011 (the "Report"). The Report included the Patent License Agreement (the "License Agreement") between the Company and the National Institutes of Health, an agency of the United States Public Health Service within the Department of Health and Human Services. Portions of the filed License Agreement were omitted based upon a request for confidential treatment filed with the Securities and Exchange Commission. The application for confidential treatment has been amended, and the enclosed License Agreement has been redacted to be consistent with the amended confidential treatment request. The information previously reported in the Report is incorporated by reference into this amendment.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits. The following exhibit is included as part of this report.

10.1 Patent License Agreement, effective October 5, 2011, by and between Genesis Biopharma, Inc. and the National Institutes of Health.†

† Certain portions of the Exhibit have been omitted based upon a request for confidential treatment filed by us with the Securities and Exchange Commission. The omitted portions of the Exhibit have been separately filed by us with the Securities and Exchange Commission.

SIGNATURES

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

GENESIS BIOPHARMA, INC.

Date: December 13, 2011

By: /s/ ANTHONY CATALDO
Anthony Cataldo, Chief Executive Officer

PUBLIC HEALTH SERVICE
PATENT LICENSE AGREEMENT – *NONEXCLUSIVE*

COVER PAGE

For PHS internal use only:

License Number:

License Application Number: A-196-2011

Serial Number(s) of Licensed Patent(s) or Patent Application(s):

1. United States Patent No. 5,399,346 issued March 21, 1995 [**HHS** Ref. No. E-189-1989/3-US-02]
2. United States Patent No. RE39788 issued August 21, 2007 [**HHS** Ref. No. E-189-1989/3-US-04]
3. United States Patent No. 5,830,755 issued November 3, 1998 [**HHS** Ref. No. E-093-1995/0-US-01]
4. Australian Patent No. 709122 issued December 2, 1999 [**HHS** Ref. No. E-093-1995/0-AU-03]
5. United States Patent No. 6,734,014 issued May 11, 2004 [**HHS** Ref. No. E-040-1996/0-US-07]
6. United States Patent No. 7,378,277 issued May 27, 2008 [**HHS** Ref. No. E-040-1996/0-US-08]
7. United States Patent No. 7,723,111 issued May 25, 2010 [**HHS** Ref. No. E-323-2000/0-US-01]
8. European Patent No. 1379670 issued August 6, 2008 [**HHS** Ref. No. E-323-2000/0-EP-03]
9. United States Patent Application No. 12/715,829 filed March 2, 2010 [**HHS** Ref. No. E-323-2000/0-US-09]
10. United States Patent Application No. 10/526,697 filed May 5, 2005 [**HHS** Ref. No. E-275-2002/1-US-02]
11. European Patent Application No. 3794636.5 filed April 4, 2005 [**HHS** Ref. No. E-275-2002/1-EP-03]
12. Canadian Patent Application No. 2,497,552 filed March 2, 2005 [**HHS** Ref. No. E-275-2002/1-CA-04]
13. Australian Patent Application No. 2003265948 filed September 5, 2003 [**HHS** Ref. No. E-275-2002/1-AU-05]
14. United States Patent Application No. 13/178,644 filed July 8, 2011 [**HHS** Ref. No. E-275-2002/1-US-06]
15. United States Patent No. 7,381,405 issued June 3, 2008 [**HHS** Ref. No. E-297-2002/0-US-02]
16. Canadian Patent Application No. 2,501,087 filed April 1, 2005 [**HHS** Ref. No. E-297-2002/0-CA-03]
17. Australian Patent No. 2002353822 issued February 23, 2009 [**HHS** Ref. No. E-297-2002/0-AU-04]
18. United States Patent No. 7,915,036 issued March 29, 2011 [**HHS** Ref. No. E-106-2004/0-US-02]
19. United States Patent Application No. 11/576,621 filed April 4, 2007 [**HHS** Ref. No. E-340-2004/2-US-02]
20. Canadian Patent Application No. 2,590,401 filed April 4, 2007 [**HHS** Ref. No. E-340-2004/2-CA-03]
21. Australian Patent No. 2005336093 issued June 9, 2011 [**HHS** Ref. No. E-340-2004/2-AU-04]
22. European Patent Application No. 05858553.0 filed April 5, 2007 [**HHS** Ref. No. E-340-2004/2-EP-05]
23. Australian Patent Application No. 2007248019 filed May 3, 2007 [**HHS** Ref. No. E-086-2006/0-AU-03]
24. Canadian Patent Application No. 2,651,174 filed November 3, 2008 [**HHS** Ref. No. E-086-2006/0-CA-04]
25. European Patent Application No. 07797329 filed May 3, 2007 [**HHS** Ref. No. E-086-2006/0-EP-05]
26. United States Patent Application No. 12/298,927 filed May 3, 2007 [**HHS** Ref. No. E-086-2006/0-US-06]

27. United States Patent No. 7,820,174 issued October 26, 2010 [**HHS** Ref. No. E-106-2006/3-US-01]
28. United States Patent Application No. 12/870,941 filed August 30, 2010 [**HHS** Ref. No. E-106-2006/3-US-03]
29. Australian Patent Application No. 2009282886 filed August 20, 2009 [**HHS** Ref. No. E-106-2006/3-AU-04]
30. Canadian Patent Application No. 2,734,838 filed August 20, 2009 [**HHS** Ref. No. E-106-2006/3-CA-05]
31. European Patent Application No. 09791694.4 filed August 20, 2009 [**HHS** Ref. No. E-106-2006/3-EP-06]
32. Australian Patent Application No. 2008206442 filed January 11, 2008 [**HHS** Ref. No. E-059-2007/2-AU-02]
33. Canadian Patent Application No. 2,674,445 filed July 3, 2009 [**HHS** Ref. No. E-059-2007/2-CA-03]
34. European Patent Application No. 08727582.2 filed January 11, 2008 [**HHS** Ref. No. E-059-2007/2-EP-04]
35. United States Patent Application No. 12/522,321 filed July 7, 2009 [**HHS** Ref. No. E-059-2007/2-US-05]
36. PCT Patent Application No. PCT/US2010/021909 filed January 25, 2010 [**HHS** Ref. No. E-043-2009/0-PCT-02]
37. PCT Patent Application No. PCT/US2010/031988 filed April 22, 2010 [**HHS** Ref. No. E-170-2009/0-PCT-02]
38. PCT Patent Application No. PCT/US2010/048701 filed September 14, 2010 [**HHS** Ref. No. E-205-2009/0-PCT-02]
39. United States Patent Application No. 12/869,390 filed August 26, 2010 [**HHS** Ref. No. E-273-2009/0-US-02]
40. United States Provisional Patent Application No. 61/405,668 filed October 22, 2010 [**HHS** Ref. No. E-236-2010/0-US-01]
41. United States Provisional Patent Application No. 61/384,931 filed September 21, 2010 [**HHS** Ref. No. E-269-2010/0-US-01]
42. United States Provisional Patent Application No. 61/466,200 filed March 22, 2011 [**HHS** Ref. No. E-114-2011/0-US-01]
43. United States Provisional Patent Application No. 61/473,409 filed April 8, 2011 [**HHS** Ref. No. E-148-2011/0-US-01]

Licensee: Genesis Biopharma, Inc.

Cooperative Research and Development Agreement (CRADA) Number (if a subject invention):

Additional Remarks: **Licensee** executed a Cooperative Research and Development Agreement (CRADA) with the Surgery Branch at the National Cancer Institute (NCI) on August 5, 2011. The NIH Ref. No. for this CRADA is C-057-2011/0 and some of the intellectual property above is listed as background patent rights in this CRADA.

Public Benefit(s): The public will benefit from the development of **Licensed Products** by the **Licensee** that are granted **FDA** approval. There is a long felt need for better treatments for metastatic melanoma, breast, ovarian and colorectal cancers. The development of TIL-based therapies will provide patients with new cancer treatment options in the realm of personalized medicine to support public health.

This Patent License Agreement, hereinafter referred to as the "**Agreement**", consists of this Cover Page, an attached **Agreement**, a Signature Page, Appendix A (List of Patent(s) or Patent Application(s)), Appendix B (Fields of Use and Territory), Appendix C (Royalties), Appendix D ((Benchmarks and Performance), Appendix E (Commercial Development Plan), Appendix F (Example Royalty Report), and Appendix G (Royalty Payment Options). The Parties to this **Agreement** are:

1) The National Institutes of Health ("**NIH**") or the Food and Drug Administration ("**FDA**"), hereinafter singly or collectively referred to as "**PHS**", agencies of the United States Public Health Service within the Department of Health and Human Services ("**HHS**"); and

2) The person, corporation, or institution identified above and on the Signature Page, having offices at the address indicated on the Signature Page, hereinafter referred to as "**Licensee**."

PHS and **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research, **PHS** investigators made inventions that may have commercial applicability.

1.2 By assignment of rights from **PHS** employees and other inventors, **HHS**, on behalf of the **Government**, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. **HHS** also owns any tangible embodiments of these inventions actually reduced to practice by **PHS**.

1.3 The Secretary of **HHS** has delegated to **PHS** the authority to enter into this **Agreement** for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology Transfer Act of 1986, 15 U.S.C. §3710(a), and the regulations governing the licensing of Government-owned inventions, 37 C.F.R. Part 404.

1.4 **PHS** desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.

1.5 **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. DEFINITIONS

2.1 "**Affiliate(s)**" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with **Licensee**. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.

2.2 "**Benchmarks**" mean the performance milestones that are set forth in Appendix D.

2.3 "**Commercial Development Plan**" means the written commercialization plan attached as Appendix E.

2.4 "**First Commercial Sale**" means the initial transfer by or on behalf of **Licensee** or its sublicensees of **Licensed Products** or the initial practice of a **Licensed Process** by or on behalf of **Licensee** or its sublicensees in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

2.5 "**Government**" means the Government of the United States of America.

2.6 "**Licensed Fields of Use**" means the fields of use identified in Appendix B.

2.7 "**Licensed Patent Rights**" shall mean:

(a) Patent applications (including provisional patent applications and PCT patent applications) and patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all these patents;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.7(a):

(i) continuations-in-part of 2.7(a);

(ii) all divisions and continuations of these continuations-in-part;

(iii) all patents issuing from these continuations-in-part, divisions, and continuations;

(iv) priority patent application(s) of 2.7(a); and

(v) any reissues, reexaminations, and extensions of all these patents;

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.7(a): all counterpart foreign and U.S. patent applications and patents to 2.7(a) and 2.7(b), including those listed in Appendix A; and

(d) **Licensed Patent Rights** shall *not* include 2.7(b) or 2.7(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.7(a).

2.8 "**Licensed Processes**" means processes, which in the course of being practiced, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.9 "**Licensed Products**" means tangible materials, which in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the **Licensed Patent Rights** that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

2.10 "**Licensed Territory**" means the geographical area identified in Appendix B.

2.11 "**Net Sales**" means the total gross receipts for sales of **Licensed Products** or practice of **Licensed Processes** by or on behalf of **Licensee** or its sublicensees, and from leasing, renting, or otherwise making **Licensed Products** available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by **Licensee** or sublicensees, and on its payroll, or for the cost of collections.

2.12 "**Practical Application**" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or **Government** regulations available to the public on reasonable terms.

3. GRANT OF RIGHTS

3.1 **PHS** hereby grants and **Licensee** accepts, subject to the terms and conditions of this **Agreement**, a nonexclusive license under the **Licensed Patent Rights** in the **Licensed Territory** to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import or have imported any **Licensed Products** in the **Licensed Fields of Use** and to practice and have practiced any **Licensed Processes** in the **Licensed Fields of Use**.

3.2 This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of **PHS** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. SUBLICENSING

4.1 Upon written approval, which shall include prior review of any sublicense agreement by **PHS** and which shall not be unreasonably withheld, **Licensee** may enter into sublicensing agreements under the **Licensed Patent Rights** prior to **FDA** approval or foreign equivalent for a **Licensed Product** within each **Licensed Field of Use** from Appendix B only when it concurrently licenses proprietary or in-licensed intellectual property rights. For the avoidance of doubt, **Licensee** does not have the right to solely sublicense the **Licensed Patent Rights** prior to **FDA** approval or foreign equivalent for a **Licensed Product** within each **Licensed Field of Use** from Appendix B. **Licensee** may also enter into sublicensing agreements under the **Licensed Patent Rights** following **FDA** approval or foreign equivalent for a **Licensed Product** within each **Licensed Field of Use** from Appendix B.

4.2 **Licensee** agrees that any sublicenses granted by it shall provide that the obligations to **PHS** of Paragraphs 5.1, 5.2, 8.1, 10.1, 10.2, 12.5, and 13.7-13.9 of this **Agreement** shall be binding upon the sublicensee as if it were a party to this **Agreement**. **Licensee** further agrees to attach copies of these Paragraphs to all sublicense agreements.

4.3 Any sublicenses granted by **Licensee** shall provide for the termination of the sublicense, or the conversion to a license directly between the sublicensees and **PHS**, at the option of the sublicensee, upon termination of this **Agreement** under Article 13. This conversion is subject to **PHS** approval and contingent upon acceptance by the sublicensee of the remaining provisions of this **Agreement**.

4.4 **Licensee** agrees to forward to **PHS** a complete copy of each fully executed sublicense agreement postmarked within thirty (30) days of the execution of the agreement. To the extent permitted by law, **PHS** agrees to maintain each sublicense agreement in confidence.

5. STATUTORY AND PHS REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1 Prior to the **First Commercial Sale**, **Licensee** agrees to provide **PHS** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **PHS** research use.

5.2 **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from **PHS**.

6. ROYALTIES AND REIMBURSEMENT

6.1 **Licensee** agrees to pay **PHS** a noncreditable, nonrefundable license issue royalty as set forth in Appendix C.

6.2 **Licensee** agrees to pay **PHS** a minimum annual royalty as set forth in Appendix C.

6.3 **Licensee** agrees to pay **PHS** earned royalties as set forth in Appendix C.

6.4 **Licensee** agrees to pay **PHS** benchmark royalties as set forth in Appendix C.

6.5 **Licensee** agrees to pay **PHS** sublicensing royalties as set forth in Appendix C.

6.6 A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:

(a) the application has been abandoned and not continued;

(b) the patent expires or irrevocably lapses; or

(c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.

6.7 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.

6.8 On sales of **Licensed Products** by **Licensee** to sublicensees or on sales made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.

6.9 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by **PHS** prior to the effective date of this **Agreement**, **Licensee** shall pay **PHS**, as an additional royalty, within sixty (60) days of **PHS'** submission of a statement and request for payment to **Licensee**, an amount equivalent to fifty percent (50%) of the unreimbursed patent expenses previously paid by **PHS**.

6.10 With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the **Licensed Patent Rights** and paid by **PHS** on or after the effective date of this **Agreement**, **PHS**, at its sole option, may require **Licensee**:

(a) to pay **PHS** on an annual basis, within sixty (60) days of **PHS**' submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s);

(b) to pay these unreimbursed expenses directly to the law firm employed by **PHS** to handle these functions. However, in this event, **PHS** and not **Licensee** shall be the client of the law firm; or

(c) under exceptional circumstances, **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide **PHS** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.

6.11 **PHS** agrees, upon written request, to provide **Licensee** with summaries of patent prosecution invoices for which **PHS** has requested payment from the **Licensee** under Paragraphs 6.9 and 6.10. **Licensee** agrees that all information provided by **PHS** related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.

6.12 **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Licensed Patent Rights** upon sixty (60) days written notice to **PHS** and owe no payment obligation under Paragraph 6.10 for patent-related expenses paid in that country after the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 **PHS** agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Licensed Patent Rights**.

7.2 **PHS** shall notify **Licensee** in writing upon receipt of all communications from global patent authorities relating the preparation, filing, prosecution, maintenance, allowance, rejection, claim restrictions or amendments for any and all patent applications or patents included in the **Licensed Patent Rights**. Such written notification by **PHS** to **Licensee** shall be done to allow **Licensee** the opportunity to decide whether **Licensee** desires to surrender rights pursuant to Section 6.11 herein.

8. RECORD KEEPING

8.1 **Licensee** agrees to keep accurate and correct records of **Licensed Products** made, used, sold, or imported and **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due **PHS**. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of **PHS**, by an accountant or other designated auditor selected by **PHS** for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to **PHS** information relating to the accuracy of reports and royalty payments made under this **Agreement**. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then **Licensee** shall reimburse **PHS** for the cost of the inspection at the time **Licensee** pays the unreported royalties, including any additional royalties as required by Paragraph 9.8. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date **PHS** provides **Licensee** notice of the payment due.

8.2 **Licensee** agrees to have an audit of sales and royalties conducted by an independent auditor at least every two (2) years if annual sales of the **Licensed Products** or **Licensed Processes** are over two (2) million dollars. The audit shall address, at a minimum, the amount of gross sales by or on behalf of **Licensee** during the audit period, terms of the license as to percentage or fixed royalty to be remitted to the **Government**, the amount of royalties owed to the **Government** under this **Agreement**, and whether the royalties owed have been paid to the **Government** and is reflected in the records of the **Licensee**. The audit shall also indicate the **PHS** license number, product, and the time period being audited. A report certified by the auditor shall be submitted promptly by the auditor directly to **PHS** on completion. **Licensee** shall pay for the entire cost of the audit.

9. REPORTS ON PROGRESS, BENCHMARKS, SALES, AND PAYMENTS

9.1 Prior to signing this **Agreement**, **Licensee** has provided **PHS** with the **Commercial Development Plan** in Appendix E, under which **Licensee** intends to bring the subject matter of the **Licensed Patent Rights** to the point of **Practical Application**. This **Commercial Development Plan** is hereby incorporated by reference into this **Agreement**. Based on this plan, performance **Benchmarks** are determined as specified in Appendix D.

9.2 **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for each of the **Licensed Fields of Use** within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacturing, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. **PHS** also encourages these reports to include information on any of **Licensee's** public service activities that relate to the **Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks**, **Licensee** shall explain the reasons for such differences. In any annual report, **Licensee** may propose amendments to the **Commercial Development Plan**, acceptance of which by **PHS** may not be denied unreasonably. **Licensee** agrees to provide any additional information reasonably required by **PHS** to evaluate **Licensee's** performance under this **Agreement**. **Licensee** may amend the **Benchmarks** at any time upon written approval by **PHS**. **PHS** shall not unreasonably withhold approval of any request of **Licensee** to extend the time periods of this schedule if the request is supported by a reasonable showing by **Licensee** of diligence in its performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** to the point of **Practical Application**.

9.3 **Licensee** shall report to **PHS** the dates for achieving **Benchmarks** specified in Appendix D and the **First Commercial Sale** in each country in the **Licensed Territory** within thirty (30) days of such occurrences.

9.4 **Licensee** shall submit to **PHS**, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the **Licensed Products** sold or **Licensed Processes** practiced by or on behalf of **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to **PHS** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.11 to determine **Net Sales** made under Article 6 to determine royalties due.

9.5 **Licensee** agrees to forward semi-annually to **PHS** a copy of these reports received by **Licensee** from its sublicensees during the preceding half-year period as shall be pertinent to a royalty accounting to **PHS** by **Licensee** for activities under the sublicense.

9.6 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due, and any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to **PHS** at its address for **Agreement** Notices indicated on the Signature Page.

9.7 **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay this tax and be responsible for all filings with appropriate agencies of foreign governments.

9.8 Additional royalties may be assessed by **PHS** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by **PHS** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent **PHS** from exercising any other rights it may have as a consequence of the lateness of any payment.

9.9 All plans and reports required by this Article 9 and marked "confidential" by **Licensee** shall, to the extent permitted by law, be treated by **PHS** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **PHS** under the Freedom of Information Act (FOIA), 5 U.S.C. §552 shall be subject to the predisclosure notification requirements of 45 C.F.R. §5.65(d).

10. PERFORMANCE

10.1 **Licensee** shall use its reasonable commercial efforts to bring the **Licensed Products** and **Licensed Processes** to **Practical Application**. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the **Commercial Development Plan** in Appendix E and performance of the **Benchmarks** in Appendix D. The efforts of a sublicensee shall be considered the efforts of **Licensee**.

10.2 Upon the **First Commercial Sale**, until the expiration or termination of this **Agreement**, **Licensee** shall use its reasonable commercial efforts to make **Licensed Products** and **Licensed Processes** reasonably accessible to the United States public.

10.3 **Licensee** agrees, after its **First Commercial Sale,** to make reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available to patient assistance programs.

10.4 **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.

10.5 **Licensee** agrees to supply, to the Mailing Address for **Agreement** Notices indicated on the Signature Page, the Office of Technology Transfer, **NIH** with inert samples of the **Licensed Products** or **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

11.1 **PHS** and **Licensee** agree to notify each other promptly of each infringement or possible infringement of the **Licensed Patent Rights**, as well as, any facts which may affect the validity, scope, or enforceability of the **Licensed Patent Rights** of which either Party becomes aware.

11.2 In the event that a declaratory judgment action alleging invalidity of any of the **Licensed Patent Rights** shall be brought against **PHS**, **PHS** agrees to notify **Licensee** that an action alleging invalidity has been brought. **PHS** does not represent that it shall commence legal action to defend against a declaratory action alleging invalidity. **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. Should the **Government** be made a party to any suit by motion or any other action of **Licensee**, **Licensee** shall reimburse the **Government** for any costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. Upon **Licensee's** payment of all costs incurred by the **Government** as a result of **Licensee's** joinder motion or other action, these actions by **Licensee** shall not be considered a default in the performance of any material obligation under this **Agreement**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 **PHS** offers no warranties other than those specified in Article 1.

12.2 **PHS** does not warrant the validity of the **Licensed Patent Rights** and makes no representations whatsoever with regard to the scope of the **Licensed Patent Rights**, or that the **Licensed Patent Rights** may be exploited without infringing other patents or other intellectual property rights of third parties.

12.3 **PHS** MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 **PHS** does not represent that it shall commence legal actions against third parties infringing the **Licensed Patent Rights**.

12.5 **Licensee** shall indemnify and hold **PHS**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:

(a) the use by or on behalf of **Licensee**, its sublicensees, its directors, employees, or third parties of any **Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or materials by **Licensee**, or other products or processes developed in connection with or arising out of the **Licensed Patent Rights**.

12.6 **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

13.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 14.15 are not fulfilled, and shall extend to the expiration of the last to expire of the **Licensed Patent Rights** unless sooner terminated as provided in this Article 13.

13.2 In the event that **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, **PHS** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the Federal Debt Collection Act.

13.3 In the event that **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, **Licensee** shall immediately notify **PHS** in writing. Furthermore, **PHS** shall have the right to terminate this **Agreement** immediately upon **Licensee's** receipt of written notice.

13.4 **Licensee** shall have a unilateral right to terminate this **Agreement** in any country or territory by giving **PHS** sixty (60) days written notice to that effect.

13.5 **PHS** shall specifically have the right to terminate or modify, at its option, this **Agreement**, if **PHS** determines that the **Licensee**:

(a) is not executing the **Commercial Development Plan** submitted with its request for a license and the **Licensee** cannot otherwise demonstrate to **PHS'** satisfaction that the **Licensee** has taken, or can be expected to take within a reasonable time, effective steps to achieve **Practical Application** of the **Licensed Products** or **Licensed Processes**;

(b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;

(c) has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by this **Agreement**;

(d) has committed a material breach of a covenant or agreement contained in this **Agreement**;

(e) is not keeping **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences;

(f) cannot reasonably satisfy unmet health and safety needs; or

(g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2, unless waived.

13.6 In making the determination referenced in Paragraph 13.5, **PHS** shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, **PHS** shall give written notice to **Licensee** providing **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, **PHS'** concerns as to the items referenced in 13.5(a)-13.5(g). If **Licensee** fails to alleviate **PHS'** concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to **PHS'** satisfaction, **PHS** may terminate this **Agreement**.

13.7 **PHS** reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this **Agreement** if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by **Licensee**.

13.8 Within thirty (30) days of receipt of written notice of **PHS'** unilateral decision to modify or terminate this **Agreement**, **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **PHS** official. The decision of the designated **PHS** official shall be the final agency decision. **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.

13.9 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to **PHS** shall become immediately due and payable upon termination or expiration. If terminated under this Article 13, sublicensees may elect to convert their sublicenses to direct licenses with **PHS** pursuant to Paragraph 4.3. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to **PHS** or provide **PHS** with written certification of the destruction thereof. **Licensee** may not be granted additional **PHS** licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by **Licensee**.

14.2 This **Agreement** constitutes the entire agreement between the Parties relating to the subject matter of the **Licensed Patent Rights**, **Licensed Products** and **Licensed Processes**, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this **Agreement**.

14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.

14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.

14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

14.6 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the Signature Page, or to any other address as may be designated in writing by such other party. **Agreement** notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.

14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to **Licensee's Affiliate(s)** without the prior written consent of **PHS**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that **PHS** approves a proposed assignment, **Licensee** shall pay **PHS**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment

14.8 **Licensee** agrees in its use of any **PHS**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **PHS** and **HHS** regulations and guidelines. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with 21 C.F.R. Part 50 and 45 C.F.R. Part 46. **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying **PHS**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to **PHS** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.

14.9 **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological materials, and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. **PHS** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 **Licensee** agrees to mark the **Licensed Products** or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve **PHS** patent rights in those countries.

14.11 By entering into this **Agreement**, **PHS** does not directly or indirectly endorse any product or service provided, or to be provided, by **Licensee** whether directly or indirectly related to this **Agreement**. **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, **PHS**, any other **Government** organizational unit, or any **Government** employee. Additionally, **Licensee** shall not use the names of **NIH**, **PHS**, **FDA** or **HHS** or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of **PHS**.

14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **PHS** official, or designee, whose decision shall be considered the final agency decision. Thereafter, **Licensee** may exercise any administrative or judicial remedies that may be available.

14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Paragraphs 8.1, 9.7-9.9, 12.1-12.5, 13.8, 13.9, 14.12 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.

14.15 The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

PHS PATENT LICENSE AGREEMENT – *NONEXCLUSIVE*

SIGNATURE PAGE

For **PHS**:

/s/ RICHARD U. RODRIGUEZ — September 29, 2011
Richard U. Rodriguez — Date
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Mailing Address or E-mail Address for **Agreement** notices and reports:

Chief, Monitoring & Enforcement Branch
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

E-mail: LicenseNotices_Reports@mail.nih.gov

For **Licensee** (Upon, information and belief, the undersigned expressly certifies or affirms that the contents of any statements of **Licensee** made or referred to in this document are truthful and accurate.):

by:

/s/ ANTHONY J. CATALDO — October 5, 2011
Signature of Authorized Official — Date

Anthony J. Cataldo
Printed Name

Chairman and Chief Executive Officer
Title

I. Official and Mailing Address for **Agreement** notices:

Anthony J. Cataldo/Michael Handelman

Name

Chairman and Chief Executive Officer/Chief Financial Officer

Title

Mailing Address

A-196-2011

Genesis Biopharma, Inc.
10880 Wilshire Boulevard, Suite 950
Los Angeles, California 90024

Email Address: mhandelman@genesis-biopharma.com
Phone: 866-963-2220
Fax: 310-500-2151

AND

Martin Schroeder
Name

Executive Vice President and Managing Director
Title

Mailing Address

Emmes Group, Inc.
92 Natoma Street, Suite 200
San Francisco, California 94105

Email Address: martin_schroeder@emmesgroup.com
Phone: 415-495-7111
Fax: 415-495-3777

II. Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

Anthony J. Cataldo/Michael Handelman

Name

Chairman and Chief Executive Officer/Chief Financial Officer

Title

Mailing Address

Genesis Biopharma, Inc.
10880 Wilshire Boulevard, Suite 950
Los Angeles, California 90024

Email Address: mhandelman@genesis-biopharma.com
Phone: 866-963-2220
Fax: 310-500-2151

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) and/or imprisonment).

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APPENDIX A – PATENT(S) OR PATENT APPLICATION(S)

Patent(s) or Patent Application(s):

1. United States Patent No. 5,399,346 issued March 21, 1995 [**HHS** Ref. No. E-189-1989/3-US-02]
2. United States Patent No. RE39788 issued August 21, 2007 [**HHS** Ref. No. E-189-1989/3-US-04]
3. United States Patent No. 5,830,755 issued November 3, 1998 [**HHS** Ref. No. E-093-1995/0-US-01]
4. Australian Patent No. 709122 issued December 2, 1999 [**HHS** Ref. No. E-093-1995/0-AU-03]
5. United States Patent No. 6,734,014 issued May 11, 2004 [**HHS** Ref. No. E-040-1996/0-US-07]
6. United States Patent No. 7,378,277 issued May 27, 2008 [**HHS** Ref. No. E-040-1996/0-US-08]
7. United States Patent No. 7,723,111 issued May 25, 2010 [**HHS** Ref. No. E-323-2000/0-US-01]
8. European Patent No. 1379670 issued August 6, 2008 [**HHS** Ref. No. E-323-2000/0-EP-03]
9. United States Patent Application No. 12/715,829 filed March 2, 2010 [**HHS** Ref. No. E-323-2000/0-US-09]
10. United States Patent Application No. 10/526,697 filed May 5, 2005 [**HHS** Ref. No. E-275-2002/1-US-02]
11. European Patent Application No. 3794636.5 filed April 4, 2005 [**HHS** Ref. No. E-275-2002/1-EP-03]
12. Canadian Patent Application No. 2,497,552 filed March 2, 2005 [**HHS** Ref. No. E-275-2002/1-CA-04]
13. Australian Patent Application No. 2003265948 filed September 5, 2003 [**HHS** Ref. No. E-275-2002/1-AU-05]
14. United States Patent Application No. 13/178,644 filed July 8, 2011 [**HHS** Ref. No. E-275-2002/1-US-06]
15. United States Patent No. 7,381,405 issued June 3, 2008 [**HHS** Ref. No. E-297-2002/0-US-02]
16. Canadian Patent Application No. 2,501,087 filed April 1, 2005 [**HHS** Ref. No. E-297-2002/0-CA-03]
17. Australian Patent No. 2002353822 issued February 23, 2009 [**HHS** Ref. No. E-297-2002/0-AU-04]
18. United States Patent No. 7,915,036 issued March 29, 2011 [**HHS** Ref. No. E-106-2004/0-US-02]
19. United States Patent Application No. 11/576,621 filed April 4, 2007 [**HHS** Ref. No. E-340-2004/2-US-02]
20. Canadian Patent Application No. 2,590,401 filed April 4, 2007 [**HHS** Ref. No. E-340-2004/2-CA-03]
21. Australian Patent No. 2005336093 issued June 9, 2011 [**HHS** Ref. No. E-340-2004/2-AU-04]
22. European Patent Application No. 05858553.0 filed April 5, 2007 [**HHS** Ref. No. E-340-2004/2-EP-05]
23. Australian Patent Application No. 2007248019 filed May 3, 2007 [**HHS** Ref. No. E-086-2006/0-AU-03]
24. Canadian Patent Application No. 2,651,174 filed November 3, 2008 [**HHS** Ref. No. E-086-2006/0-CA-04]
25. European Patent Application No. 07797329 filed May 3, 2007 [**HHS** Ref. No. E-086-2006/0-EP-05]
26. United States Patent Application No. 12/298,927 filed May 3, 2007 [**HHS** Ref. No. E-086-2006/0-US-06]
27. United States Patent No. 7,820,174 issued October 26, 2010 [**HHS** Ref. No. E-106-2006/3-US-01]
28. United States Patent Application No. 12/870,941 filed August 30, 2010 [**HHS** Ref. No. E-106-2006/3-US-03]
29. Australian Patent Application No. 2009282886 filed August 20, 2009 [**HHS** Ref. No. E-106-2006/3-AU-04]
30. Canadian Patent Application No. 2,734,838 filed August 20, 2009 [**HHS** Ref. No. E-106-2006/3-CA-05]
31. European Patent Application No. 09791694.4 filed August 20, 2009 [**HHS** Ref. No. E-106-2006/3-EP-06]
32. Australian Patent Application No. 2008206442 filed January 11, 2008 [**HHS** Ref. No. E-059-2007/2-AU-02]
33. Canadian Patent Application No. 2,674,445 filed July 3, 2009 [**HHS** Ref. No. E-059-2007/2-CA-03]
34. European Patent Application No. 08727582.2 filed January 11, 2008 [**HHS** Ref. No. E-059-2007/2-EP-04]
35. United States Patent Application No. 12/522,321 filed July 7, 2009 [**HHS** Ref. No. E-059-2007/2-US-05]
36. PCT Patent Application No. PCT/US2010/021909 filed January 25, 2010 [**HHS** Ref. No. E-043-2009/0-PCT-02]
37. PCT Patent Application No. PCT/US2010/031988 filed April 22, 2010 [**HHS** Ref. No. E-170-2009/0-PCT-02]
38. PCT Patent Application No. PCT/US2010/048701 filed September 14, 2010 [**HHS** Ref. No. E-205-2009/0-PCT-02]
39. United States Patent Application No. 12/869,390 filed August 26, 2010 [**HHS** Ref. No. E-273-2009/0-US-02]
40. United States Provisional Patent Application No. 61/405,668 filed October 22, 2010 [**HHS** Ref. No. E-236-2010/0-US-01]
41. United States Provisional Patent Application No. 61/384,931 filed September 21, 2010 [**HHS** Ref. No. E-269-2010/0-US-01]
42. United States Provisional Patent Application No. 61/466,200 filed March 22, 2011 [**HHS** Ref. No. E-114-2011/0-US-01]
43. United States Provisional Patent Application No. 61/473,409 filed April 8, 2011 [**HHS** Ref. No. E-148-2011/0-US-01]

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. **Licensed Fields of Use:**

(a) The use of the **Licensed Patent Rights** to develop and manufacture autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma.

(b) The use of the **Licensed Patent Rights** to develop and manufacture autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of ovarian cancer.

(c) The use of the **Licensed Patent Rights** to develop and manufacture autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of breast cancer.

(d) The use of the **Licensed Patent Rights** to develop and manufacture autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of colorectal cancer.

Tumor infiltrating lymphocytes (TIL) are a subset of T lymphocytes (T cells) that migrate and are located within a tumor site. TIL isolated from these tumor sites exhibit natural anti-tumor activity without genetic modifications. For the avoidance of doubt, cell therapy products involving genetically modified tumor infiltrating lymphocytes are excluded from **Licensed Fields of Use** (a) – (d).

II. **Licensed Territory:**

(a) Worldwide

APPENDIX C – ROYALTIES

Royalties:

I. **Licensee** agrees to pay to **PHS** a noncreditable, nonrefundable license issue royalty in the amount of six hundred fifty thousand dollars ($650,000.00) within sixty (60) days from the effective date of this **Agreement.**

II. **Licensee** agrees to pay to **PHS** a nonrefundable minimum annual royalty in the amount of twenty thousand dollars ($20,000.00) as follows:

(a) The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and

(b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.

III. **Licensee** agrees to pay **PHS** earned royalties of six percent (6%) on **Net Sales** by or on behalf of **Licensee** or its sublicensees. **Licensee** shall be entitled to a credit of one-half percent (0.5%) against the earned royalty rate for each percent point in excess of four percent (4%) that **Licensee** must pay to an unaffiliated licensor for the manufacture and sale of **Licensed Product(s)** and **Licensed Process(es)**. Said credit, however, shall not reduce the earned royalty due to **PHS** for **Licensed Product(s)** and **Licensed Process(es)** below three percent (3%).

IV. **Licensee** agrees to pay **PHS Benchmark** royalties within sixty (60) days of achieving each **Benchmark**:

(a) Three hundred thousand dollars ($300,000.00) for completion of the first Phase 2 clinical study in each of **Licensed Field of Use** (a) and (b) from Appendix B.

(b) Six hundred thousand dollars ($600,000.00) for completion of the first Phase 2 clinical study in each of **Licensed Field of Use** (c) and (d) from Appendix B.

(c) Five hundred thousand dollars ($500,000.00) for completion of the first Phase 3 clinical study in each of **Licensed Field of Use** (a) and (b) from Appendix B.

(d) One million dollars ($1,000,000.00) for completion of the first Phase 3 clinical study in each of **Licensed Field of Use** (c) and (d) from Appendix B.

(e) Seven hundred fifty thousand dollars ($750,000.00) upon the first **FDA** approval or foreign equivalent for a **Licensed Product** or **Licensed Process** in each of **Licensed Field of Use** (a) and (b) from Appendix B.

(f) One million five hundred thousand dollars ($1,500,000.00) upon the first **FDA** approval or foreign equivalent for a **Licensed Product** or **Licensed Process** in each of **Licensed Field of Use** (c) and (d) from Appendix B.

(g) Three million dollars ($3,000,000.00) for the **First Commercial Sale** of a **Licensed Product** or **Licensed Process** in the United States for either of **Licensed Field of Use** (a) or (b) from Appendix B.

(h) Six million dollars ($6,000,000.00) for the **First Commercial Sale** of a **Licensed Product** or **Licensed Process** in the United States for either of **Licensed Field of Use** (c) or (d) from Appendix B.

(i) One million five hundred thousand dollars ($1,500,000.00) for the **First Commercial Sale** of a **Licensed Product** or **Licensed Process** in any foreign country for either of **Licensed Field of Use** (a) or (b) from Appendix B.

(j) Three million dollars ($3,000,000.00) for the **First Commercial Sale** of a **Licensed Product** or **Licensed Process** in any foreign country for either of **Licensed Field of Use** (c) or (d) from Appendix B.

V. **Licensee** agrees to pay **PHS**:

(a) additional sublicensing royalties of fifteen percent (15%) on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed prior to **FDA** approval or foreign equivalent for a **Licensed Product** or **Licensed Process** within each **Licensed Field of Use** from Appendix B; and

(b) additional sublicensing royalties of six percent (6%) on the fair market value of any consideration received for granting each sublicense within sixty (60) days of the execution of each sublicense if any such sublicense is executed following **FDA** approval or foreign equivalent for a **Licensed Product** or **Licensed Process** within each **Licensed Field of Use** from Appendix B.

APPENDIX D – BENCHMARKS AND PERFORMANCE

Licensee agrees to the following **Benchmarks** for its performance under this **Agreement** and, within thirty (30) days of achieving a **Benchmark**, shall notify **PHS** that the **Benchmark** has been achieved.

I.	Completion of the standard operation procedures (SOPs) for current Good Manufacturing Practices (cGMP) of autologous tumor infiltrating lymphocyte adoptive cell therapy products	within 18 months
II.	Completion of the first Phase 1/Phase 2 clinical trial for the treatment of metastatic Melanoma	within 36 months
III.	Completion of the first randomized Phase 3 clinical trial for the treatment of metastatic Melanoma	within 60 months
IV.	Regulatory Approval by the **FDA** (or foreign equivalent) of a **Licensed Product** or **Licensed Process** for the treatment of metastatic melanoma	within 72 months
V.	**First Commercial Sale** of a **Licensed Product** or **Licensed Process** for the treatment of metastatic melanoma	within 84 months
VI.	Completion of the first Phase 1/Phase 2 clinical trial for the treatment of ovarian cancer	within 36 months
VII.	Completion of the first randomized Phase 3 clinical trial for the treatment of ovarian Cancer	within 60 months
VIII.	Regulatory Approval by the **FDA** (or foreign equivalent) of a **Licensed Product** or **Licensed Process** for the treatment of ovarian cancer	within 72 months
IX.	**First Commercial Sale** of a **Licensed Product** or **Licensed Process** for the treatment of ovarian cancer	within 84 months
X.	Completion of the first Phase 1/Phase 2 clinical trial for the treatment of breast cancer	within 42 months
XI.	Completion of the first randomized Phase 3 clinical trial for the treatment of breast cancer	within 60 months
XII.	Regulatory Approval by the **FDA** (or foreign equivalent) of a **Licensed Product** or **Licensed Process** for the treatment of breast cancer	within 72 months
XIII.	**First Commercial Sale** of a **Licensed Product** or **icensed Process** for the treatment of breast cancer	within 84 months
XIV.	Completion of the first Phase 1/Phase 2 clinical trial for the treatment of colorectal cancer	within 48 months
XV.	Completion of the first randomized Phase 3 clinical trial for the treatment of colorectal Cancer	within 60 months

XVI. Regulatory Approval by the **FDA** (or foreign equivalent) of a **Licensed Product** or **Licensed Process** for the treatment of colorectal cancer

within 72 months

XVII. **First Commercial Sale** of a **Licensed Product** or **Licensed Process** for the treatment of colorectal cancer

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APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

DEVELOPMENT PLAN: Application of Tumor Infiltrating Lymphocytes (TILs) for the Treatment of Metastatic Melanoma.

****REDACTED****

Timeline and Costs

Licensee expects to submit its Biologics License Application to the U.S. Food and Drug Administration seeking market approval within 6 years from the date of execution of the subject license agreement:

A. Development of SOPs relating to cGMP manufacturing, tumor tissue harvest/chain-of-custody/ship logistics, QA/QC, cell isolation/expansion, ready-to-infuse product formulation, etc.: 18 months
B. Complete pilot Phase I/II clinical trial (30 patients; 3-5 sites):
18 months
C. Manufacturing scale-up & complete randomized Phase III clinical trial (200 patients; 5-7 sites):
36 months

Licensee estimates the overall administrative, product development, cGMP product manufacturing, QA/QC, clinical trials, and regulatory costs will approximate $100 million over the next 6 years:

A. Development of SOPs relating to cGMP manufacturing, chain-of-custody logistics, QA/QC, cell isolation and expansion, ready-to-infuse product formulation, etc.:
$10 million
B. Complete pilot Phase I/II clinical trial (30 patients; 3-5 sites):
$15 million
C. Manufacturing scale-up & complete randomized Phase III clinical trial (200 patients; 5-7 sites):
$50 million
D. Administrative, regulatory & other:
$25 million

****REDACTED****

1. DEVELOPMENT PLAN: Application of Tumor Infiltrating Lymphocytes (TILs) for the Treatment of Ovarian Epithelial Cancer.

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****REDACTED****

Budget:

Year 1:
R&D (Personnel and reagents): $250,000

Year 2:
R&D (Personnel and reagents): $250,000
GMP product development (aAPC master cell banks, finalize and validate SOPs): $100,000
IRB and IND filing costs (personnel and regulatory office fees at host institutions): $100,000

Year 3:
R&D (Personnel and reagents): $150,000
IRB and IND filing costs (personnel and regulatory office fees at host institutions): $100,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $500,000

Year 4:
R&D (Personnel and reagents for clinical trial immunocorrelative studies): $150,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $2,000,000

Year 5:
R&D (Personnel and reagents for clinical trial immunocorrelative studies): $150,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $2,000,000

TOTAL: $5,750,000

Plan for Development of TIL Adoptive Cell Therapy Program for Metastatic Breast Cancer.

****REDACTED****

Budget:

Year 1:
R&D (Personnel and reagents): $250,000

Year 2:
R&D (Personnel and reagents): $250,000
GMP product development (aAPC master cell banks, finalize and validate SOPs): $100,000
IRB and IND filing costs (personnel and regulatory office fees at host institutions): $100,000

Year 3:
R&D (Personnel and reagents): $150,000
IRB and IND filing costs (personnel and regulatory office fees at host institutions): $100,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $500,000

Year 4:
R&D (Personnel and reagents for clinical trial immunocorrelative studies): $150,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $2,000,000

Year 5:
R&D (Personnel and reagents for clinical trial immunocorrelative studies): $150,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $2,000,000

TOTAL: $5,750,000

2. Plan for Development of TIL Adoptive Cell Therapy Program for Metastatic Colorectal Cancer.

****REDACTED****

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Budget:

Year 1:
R&D (Personnel and reagents): $500,000

Year 2:
R&D (Personnel and reagents): $500,000
GMP product development (aAPC master cell banks, finalize and validate SOPs): $100,000
IRB and IND filing costs (personnel and regulatory office fees at host institutions): $100,000

Year 3:
R&D (Personnel and reagents): $150,000
IRB and IND filing costs (personnel and regulatory office fees at host institutions): $100,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $500,000

Year 4:
R&D (Personnel and reagents for clinical trial immunocorrelative studies): $150,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $2,000,000

Year 5:
R&D (Personnel and reagents for clinical trial immunocorrelative studies): $150,000
Clinical trial costs (personnel, GMP TIL production, related clinical trial costs): $2,000,000

TOTAL: $6,250,000

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APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- OTT license reference number (L-XXX-200X/0)
- Reporting period
- Catalog number and units sold of each Licensed Product (domestic and foreign)
- Gross Sales per catalog number per country
- Total Gross Sales
- Itemized deductions from Gross Sales
- Total Net Sales
- Earned Royalty Rate and associated calculations
- Gross Earned Royalty
- Adjustments for Minimum Annual Royalty (MAR) and other creditable payments made
- Net Earned Royalty due

Example

Catalog Number	Product Name	Country	Units Sold	Gross Sales (US$)
1	A	US	250	62,500
1	A	UK	32	16,500
1	A	France	25	15,625
2	B	US	0	0
3	C	US	57	57,125
4	D	US	12	1,500

Total Gross Sales	153,250
Less Deductions:	
Freight	3,000
Returns	7,000
Total Net Sales	143,250
Royalty Rate	8%
Royalty Due	11,460
Less Creditable Payments	10,000
Net Royalty Due	**1,460**

APPENDIX G – ROYALTY PAYMENT OPTIONS

The OTT License Number MUST appear on payments, reports and correspondence.

Automated Clearing House (ACH) for payments through U.S. banks only

The NIH encourages our licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: **https://www.pay.gov.** Locate the "NIH Agency Form" through the Pay.gov "Agency List".

Electronic Funds Wire Transfers

The following account information is provided for wire payments. In order to process payment via Electronic Funds Wire Transfer sender MUST supply the following information within the transmission:

Drawn on a **U.S. bank account** via FEDWIRE should be sent directly to the following account:

Beneficiary Account:	Federal Reserve Bank of New York or TREAS NYC
Bank:	Federal Reserve Bank of New York
ABA#	021030004
Account Number:	75080031
Bank Address:	33 Liberty Street, New York, NY 10045
Payment Details:	License Number (L-XXX-XXXX) Name of Licensee

Drawn on a **foreign bank account** should be sent directly to the following account. Payment must be sent in **U.S. Dollars (USD)** using the following instructions:

Beneficiary Account:	Federal Reserve Bank of New York/ITS or FRBNY/ITS
Bank:	Citibank N.A. (New York)
SWIFT Code:	CITIUS33
Account Number:	36838868
Bank Address:	388 Greenwich Street, New York, NY 10013
Payment Details (Line 70):	NIH 75080031 License Number (L-XXX-XXXX) Name of Licensee
Detail of Charges (line 71a):	Charge Our

Checks

All checks should be made payable to “NIH Patent Licensing”

Checks drawn on a **U.S. bank account** and sent by US Postal Service should be sent directly to the following address:

National Institutes of Health (NIH)
P.O. Box 979071
St. Louis, MO 63197-9000

Checks drawn on a U.S. bank account and sent by **overnight or courier** should be sent to the following address:

US Bank
Government Lockbox SL-MO-C2GL
1005 Convention Plaza
St. Louis, MO 63101
Phone: 314-418-4087

Checks drawn on a **foreign bank account** should be sent directly to the following address:

National Institutes of Health (NIH)
Office of Technology Transfer
Royalties Administration Unit
6011 Executive Boulevard
Suite 325, MSC 7660
Rockville, Maryland 20852

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