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

FORM 8-K

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)

000-53127

(Commission File No.)

75-3254381 (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))

Nevada (State or other jurisdiction of incorporation)

ITEM 1.01 ENTRY INTO A MATERIAL DEFINITIVE AGREEMENT.

Effective October 5, 2011, Genesis Biopharma, Inc. (the "Company") entered into a Patent License Agreement (the "License Agreement") with the National Institutes of Health, an agency of the United States Public Health Service within the Department of Health and Human Services ("NIH"). Pursuant to the License Agreement, NIH granted to the Company a non-exclusive worldwide right and license to develop and manufacture certain proprietary autologous tumor infiltrating lymphocyte adoptive cell therapy products for the treatment of metastatic melanoma, ovarian cancer, breast cancer, and colorectal cancer. The intellectual property subject to the License Agreement is covered by 43 patents and patent applications, consisting of nine issued United States patents, 13 pending patent applications in the United States, and 21 foreign patents and patent applications as counterparts of U.S. patents/patent applications. The Company also has limited rights to sublicense the intellectual property subject to the License Agreement will expire on a product-by-product basis upon the expiration of the subject patent rights. These technologies were also the subject of the Cooperative Research and Development Agreement, effective August 5, 2011, that the Company entered into with the National Cancer Institute, as disclosed previously in the Company's Current Report on Form 8-K filed by the Company on August 11, 2011.

The Company has the right to terminate the License Agreement in any country on 60 days notice, and NIH may terminate the agreement if the Company is in material breach, and the breach is not cured within a specified cure period, upon certain bankruptcy and insolvency events, or if the Company fails to comply with or achieve certain benchmarks or development plans as set forth in the License Agreement.

In consideration for the rights granted pursuant to the License Agreement, the Company agreed to pay an estimated \$1,200,000 of upfront licensing fees and expense reimbursements within 60 days of the effectiveness of the License Agreement. In addition, the Company will have to pay royalties of six percent (6%) of net sales (subject to certain annual minimum royalty payments), a percentage of revenues from sublicensing arrangements, and lump sum benchmark royalty payments on the achievement of certain clinical and regulatory milestones for each of the various indications. The Company initially intends to focus on the development of licensed products in the metastatic melanoma field of use. If the Company achieves all benchmarks for metastatic melanoma, up to and including the product's first commercial sale in the United States, the total amount of such benchmark payments will be \$6,050,000. The benchmark payments for the other three indications, if all benchmarks are achieved, will be \$6,050,000 for ovarian cancer, \$12,100,000 for breast cancer, and \$12,100,000 for colorectal cancer. Accordingly, if the Company achieves all benchmarks for all four licensed indications, the aggregate amount of benchmark royalty payments that the Company will have to make to NIH will be \$36,300,000.

With the Company entering the License Agreement, the escrow provisions of the Company's previously reported July 27, 2011 \$5,000,000 seven (7%) percent senior convertible note and five (5) year warrant offering have been satisfied. Accordingly, the \$2,500,000 held in escrow pending the execution of the License Agreement has been released to the Company.

The foregoing description of the License Agreement does not purport to be complete and is qualified in its entirely by the form of the License Agreement.

Item 9.01. Financial Statements and Exhibits

- (d) <u>Exhibits</u>. The following exhibits are included as part of this report, and incorporated herein by reference in their entirety.
- 10.1 Patent License Agreement, effective October 5, 2011, by and between Genesis Biopharma, Inc. and the National Institutes of Health.⁺
- 99.1 Press release, issued October 11, 2011, regarding the Patent License Agreement entered into with 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: October 11, 2011

By: /s/ ANTHONY CATALDO

Anthony Cataldo, Chief Executive Officer

Text marked by *******Redacted******* has been omitted pursuant to a Request for Confidential Treatment and was filed separately with the Securities and Exchange Commission.

PUBLIC HEALTH SERVICE PATENT LICENSE AGREEMENT – NONEXCLUSIVE

COVER PAGE

For PHS internal use only:

License Number: ***Redacted***

License Application Number: ***Redacted***

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

- 1. United States Patent No. 5,399,346 issued March 21, 1995 [***Redacted***]
- 2. United States Patent No. RE39788 issued August 21, 2007 [***Redacted***]
- 3. United States Patent No. 5,830,755 issued November 3, 1998 [***Redacted***]
- 4. Australian Patent No. 709122 issued December 2, 1999 [***Redacted***]
- 5. United States Patent No. 6,734,014 issued May 11, 2004 [***Redacted***]
- 6. United States Patent No. 7,378,277 issued May 27, 2008 [***Redacted***]
- 7. United States Patent No. 7,723,111 issued May 25, 2010 [***Redacted***]
- 8. European Patent No. 1379670 issued August 6, 2008 [***Redacted***]
- 9. ***Redacted***
- 10. ***Redacted***
- 11. ***Redacted***
- 12. ***Redacted***
- 13. ***Redacted***
- 14. ***Redacted***
- 15. United States Patent No. 7,381,405 issued June 3, 2008 [***Redacted***]
- 16. ***Redacted***
- 17. ***Redacted***
- 18. United States Patent No. 7,915,036 issued March 29, 2011 [***Redacted***]
- 19. ***Redacted***
- 20. ***Redacted***
- 21. Australian Patent No. 2005336093 issued June 9, 2011 [***Redacted***]
- 22. ***Redacted***
- 23. ***Redacted***
- 24. ***Redacted***
- 25. ***Redacted***
- 26. ***Redacted***
- 27. United States Patent No. 7,820,174 issued October 26, 2010 ***Redacted***
- 28. ***Redacted***
- 29. ***Redacted***
- 30. ***Redacted***
- 31. ***Redacted***
- 32. ***Redacted***
- 33. ***Redacted***
- 34. ***Redacted***
- 35. ***Redacted***

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 1 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011] 36. ***Redacted***
37. ***Redacted***
38. ***Redacted***
39. ***Redacted***
40. ***Redacted***
41. ***Redacted***
42. ***Redacted***
43. ***Redacted***

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 ***Redacted***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."

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 2 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

1. <u>BACKGROUND</u>

- 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 <u>35 U.S.C. §§200-212</u>, the <u>Federal Technology Transfer Act of 1986</u>, <u>15 U.S.C. §3710(a)</u>, and the regulations governing the licensing of Government-owned inventions, <u>37 C.F.R. Part 404</u>.
- 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. <u>DEFINITIONS</u>

- 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:

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 3 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

- (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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 4 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011] 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. <u>GRANT OF RIGHTS</u>

- 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. <u>SUBLICENSING</u>

- 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 **Licensee Product** within each **Licensee Patent Rights** approval or foreign equivalent for a **Licensee Product** within each **Licensee 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 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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 5 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011] 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. <u>ROYALTIES AND REIMBURSEMENT</u>

- 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);

Redacted**CONFIDENTIAL** PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 6 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

- (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. <u>PATENT FILING, PROSECUTION, AND MAINTENANCE</u>

- 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. <u>RECORD KEEPING</u>

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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 7 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011] 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 Licensee 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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 8 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

- 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), <u>5 U.S.C. §552</u> shall be subject to the predisclosure notification requirements of <u>45 C.F.R. §5.65(d)</u>.

10. <u>PERFORMANCE</u>

- 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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 9 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

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 actions by Licensee shall not be considered a default in the performance of any material obligation under this Agreement.

12. <u>NEGATION OF WARRANTIES AND INDEMNIFICATION</u>

- 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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page 10 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

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 <u>Federal Debt Collection Act</u>.
- 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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—Nonexclusive_Sublicense

Page of 11 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

- 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 <u>35 U.S.C. §209(d)(3)</u> 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 <u>37 C.F.R. §404.11</u>, 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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 12 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

- 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 <u>21 C.F.R. Part 50</u> and <u>45 C.F.R. Part 46</u>. 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**.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 13 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

- 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 <u>37 C.F.R. Part 404</u> 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

RedactedCONFIDENTIAL
PHS Patent License Agreement—Nonexclusive_Sublicense
Page of 14 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

PHS PATENT LICENSE AGREEMENT - NONEXCLUSIVE

SIGNATURE PAGE

For PHS:

s// Richard U. Rodriguez

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

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 Signature of Authorized Official

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

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 15 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011] October 5, 2011

Date

Genesis Biopharma	a, Inc.	
10880 Wilshire Bo	ulevard, Suite 950	
Los Angeles, Califo	ornia 90024	
Email Address:	mhandelman@genesis-biopharma.com	
Phone:	866-963-2220	
Fax:	310-500-2151	
AND		
Martin Schroeder		
Name		
Executive Vice Pre	sident and Managing Director	
Title		
Mailing Address		
Emmes Group, Inc.		
92 Natoma Street, S	Suite 200	
San Francisco, Cali	ifornia 94105	
Email Address:	martin_schroeder@emmesgroup.com	
Phone:	415-495-7111	
Fax:	415-495-3777	
II. Official and Mailin	g Address for Financial notices (Licensee's contact pers	on for royalty payments)
	/Michael Handelman	_
Name		
Chairman and Chie Title	f Executive Officer/Chief Financial Officer	
Mailing Address		

Redacted**CONFIDENTIAL** PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 16 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

Genesis Biopharma, Inc	c	
10880 Wilshire Boulev	ard, Suite 950	
Los Angeles, California	a 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 <u>31 U.S.C. §§3801-3812</u> (civil liability) and <u>18 U.S.C. §1001</u> (criminal liability including fine(s) and/or imprisonment).

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 17 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

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 [***Redacted***]
- 2. United States Patent No. RE39788 issued August 21, 2007 [***Redacted***]
- 3. United States Patent No. 5,830,755 issued November 3, 1998 [***Redacted***]
- 4. Australian Patent No. 709122 issued December 2, 1999 [***Redacted***]
- 5. United States Patent No. 6,734,014 issued May 11, 2004 [***Redacted***]
- 6. United States Patent No. 7,378,277 issued May 27, 2008 [***Redacted***]
- 7. United States Patent No. 7,723,111 issued May 25, 2010 [***Redacted***]
- 8. European Patent No. 1379670 issued August 6, 2008 [***Redacted***]
- ***Redacted***
 Redacted
- 11. ***Redacted***
- 12. ***Redacted***
- 13. ***Redacted***
- 14. ***Redacted***
- 15. United States Patent No. 7,381,405 issued June 3, 2008 [***Redacted***]
- 16. ***Redacted***
- 17. ***Redacted***
- 18. United States Patent No. 7,915,036 issued March 29, 2011 [***Redacted***]
- 19. ***Redacted***
- 20. ***Redacted***
- 21. Australian Patent No. 2005336093 issued June 9, 2011 [***Redacted***]
- 22. ***Redacted***
- 23. ***Redacted***
- 24. ***Redacted***
- 25. ***Redacted***
- 26. ***Redacted***
- 27. United States Patent No. 7,820,174 issued October 26, 2010 ***Redacted***
- 28. ***Redacted***
- 29. ***Redacted***
- 30. ***Redacted***
- 31. ***Redacted***
- 32. ***Redacted***
- 33. ***Redacted***
- 34. ***Redacted***
- 35. ***Redacted***
- 36. ***Redacted***
- 37. ***Redacted***
- 38. ***Redacted***
- 39. ***Redacted***
- 40. ***Redacted***
- 41. ***Redacted***
- 42. ***Redacted***
- 43. ***Redacted***

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 18 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

I. Licensed Fields of Use:

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

RedactedCONFIDENTIAL PHS Patent License Agreement—Nonexclusive_Sublicense

Page of 19 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

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.

Redacted**CONFIDENTIAL** PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 20 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

- (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.

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 21 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

APPENDIX D – BENCHMARKS AND PERFORMANCE

REDACTED

Redacted**CONFIDENTIAL** PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 22 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

****REDACTED****

Redacted**CONFIDENTIAL** PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 23 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

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	А	UK	32	16,500
1	А	France	25	15,625
2	В	US	0	0
3	С	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

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 24 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

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:

****REDACTED****

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:

*****REDACTED*****

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 25 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]

<u>Checks</u>

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

RedactedCONFIDENTIAL

PHS Patent License Agreement—*Nonexclusive_Sublicense* Page of 26 of 26 [FINAL] [Genesis Biopharma, Inc.] [September 29, 2011]



INVESTOR CONTACT: LHA Anne Marie Fields Senior Vice President <u>afields@lhai.com</u> (212) 838-3777

GENESIS BIOPHARMA SIGNS WORLDWIDE LICENSE AGREEMENT WITH THE NIH FOR ADOPTIVE CELL THERAPY TO TREAT A VARIETY OF CANCERS

Lead Indication To Treat Stage IV Metastatic Melanoma

LOS ANGELES (October 11, 2011) – Genesis Biopharma, Inc. (OTCBB: GNBP), a biotechnology company developing targeted cancer immunotherapies, today announced it has entered into a Patent License Agreement (the "License Agreement") with the National Institutes of Health, an agency of the United States Public Health Service within the Department of Health and Human Services ("NIH"). Pursuant to the License Agreement, NIH granted to the Company a non-exclusive worldwide license to 43 patents and patent applications, consisting of 9 issued United States patents, 13 United States patent applications, and 21 foreign corresponding patents and patent applications relating to adoptive cell therapy using autologous tumor infiltrating lymphocytes (TILs) for the treatment of certain cancers. The Company also has rights to sublicense the intellectual property subject to the terms and conditions set forth in the License Agreement. The License Agreement will expire on a product-by-product basis upon the expiration of the subject patent rights.

These technologies were also the subject of the Cooperative Research and Development Agreement, effective August 5, 2011, as disclosed previously in the Company's Current Report on Form 8-K filed on August 11, 2011.

In consideration for the the License Agreement, the Company agreed to pay approximately \$1.2 million in upfront licensing fees and expense reimbursements within 60 days of the effectiveness of the License Agreement, royalties based on a percentage of net sales (subject to certain annual minimum royalty payments), and a percentage of revenues from any sublicensing arrangements. In addition, the Company will make additional payments on the achievement of certain clinical and regulatory milestones for each of the various indications.

"We are very pleased to finalize this License Agreement as it will now allow us to move forward with the clinical development for Contego[™], our ready-toinfuse adoptive cell therapy using TILs, to treat Stage IV metastatic melanoma. We already have a process development and scale-up agreement for the manufacture of Contego with Lonza, one of the world's leading suppliers to the pharmaceutical, healthcare and life science industries," stated Anthony J. Cataldo, Chairman and Chief Executive Officer of Genesis Biopharma.

"Adoptive cell therapy using autologous TILs is presently being administered as a physician-sponsored investigational therapy to Stage IV metastatic melanoma patients at the National Cancer Institute (NCI), MD Anderson Cancer Center and H. Lee Moffitt Cancer Center & Research Institute. The medical oncology community is very aware of this innovative work using adoptive cell therapy and autologous tumor infiltrating lymphocytes for the treatment of Stage IV metastatic melanoma," added Mr. Cataldo.

About Genesis Biopharma, Inc.

Genesis Biopharma, Inc. is engaged in the development and commercialization of autologous cell therapies for the treatment of various cancers. The Company's lead product candidate, Cōntego[™], is a ready-to-infuse autologous cell therapy utilizing tumor infiltrating lymphocytes for the treatment of patients with Stage IV metastatic melanoma. Cōntego[™] is based on a currently available physician-sponsored investigational therapy at the National Cancer Institute, MD Anderson Cancer Center and the H. Lee Moffitt Cancer & Research Institute for the treatment of Stage IV metastatic melanoma.

For more information about the company, visit www.genesis-biopharma.com.

Forward-Looking Statements

The foregoing announcement contains forward-looking statements that can be identified by such terminology as "expects", "hopes", "potential", "suggests", "bodes", "may", "should", "could", or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause the actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. In particular, management's expectations regarding future research, development and/or commercial results could be affected by, among other things, uncertainties relating to clinical trials and product development; availability of future financing; unexpected regulatory delays or government regulation generally; the company's ability to obtain or maintain patent and other proprietary intellectual property protection; and competition in general. Forward-looking statements speak only as of the date they are made. The company does not undertake to update forward-looking statements to reflect circumstances or events that occur after the date the forward-looking statements are made.

#