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): February 23, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

DELAWARE	001-39717	20-2903526
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

680 East Colorado Blvd. Suite 180
Pasadena, California 91101
(Address of principal executive offices)

(631) 830-7092
(Registrant's telephone number, including area code)

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 (See General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act of 1933 (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(e) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock	LIXT	The Nasdaq Stock Market LLC
Warrant to Purchase Common Stock	LIXTW	The Nasdaq Stock Market LLC

Item 1.01 Entry into a Material Definitive Agreement.

On February 23, 2024, Lixte Biotechnology Holdings, Inc. (the "Company") entered into a Patent License Agreement (the "License Agreement") with the National Institute of Neurological Disorders and Stroke ("NINDS") and the National Cancer Institute ("NCI"), each an institute or center of the National Institute of Health ("NIH"). Pursuant to the License Agreement, the Company has licensed exclusively NIH's intellectual property rights claimed for a Cooperative Research and Development Agreement ("CRADA") subject invention co-developed with the Company, and the licensed field of use which focuses on promoting anti-cancer activity alone, or in combination with standard anti-cancer drugs. The scope of this clinical research extends to checkpoint inhibitors, immunotherapy, and radiation for the treatment of cancer. The License Agreement is effective, and shall extend, on a licensed product, licensed process, and country basis, until the expiration of the last-to-expire valid claim of the jointly owned licensed patent rights in each such country in the licensed territory, unless sooner terminated.

The License Agreement contemplates that the Company will seek to work with pharmaceutical companies and clinical trial sites (including comprehensive cancer centers) to initiate clinical trials within timeframes that will meet the benchmarks noted below. Data from the clinical trials will be the subject of various regulatory filings for marketing approval in applicable countries in the licensed territories. Subject to the receipt of marketing approval, the Company would be expected to commercialize the licensed products in markets where regulatory approval has been obtained.

The Company is obligated to pay the NIH a non-creditable, non-refundable license issue royalty of $50,000 and a first minimum annual royalty of $30,000, within sixty days from the effective date of the Agreement. The first minimum annual royalty may be prorated from the effective date of the License Agreement to the next subsequent January 1. Thereafter, the minimum annual royalty of $30,000 is due each January 1 and may be credited against any earned royalties due for sales made in that year.

The Company is obligated to pay the NIH, on a country-by-country basis, earned royalties of 2% on net sales of each royalty-bearing product and process, subject to reduction by 50% under certain circumstances relating to royalties paid by the Company to third parties, but not less than 1%. The Company's obligation to pay earned royalties under the License Agreement commences on the date of the first commercial sale of a royalty-bearing product or process and expires on the date on which the last valid claim of the licensed product or licensed process expires in such country.

The Company is obligated to pay the NIH benchmark royalties, on a one-time basis, within sixty days from the first achievement of each such benchmark. The License Agreement defines four such benchmarks, with deadlines of October 1, 2024, 2027, 2029 and 2031, respectively, each with a different specified benchmark payment amount payable within thirty days of achieving such benchmark. The October 31, 2024 benchmark is defined as the dosing of the first patient with a licensed product in a Phase 2 clinical study of such licensed product in the licensed fields of use. The total of all such benchmark payments is $1,225,000.

The Company is obligated to pay the NIH sublicensing royalties of 5% on sublicensing revenue received for granting each sublicense within sixty days of receipt of such sublicensing revenue.

The foregoing description of the License Agreement does not purport to be complete and is subject to and qualified in its entirety, by the full text of the License Agreement, a copy of which is filed hereto as Exhibit 10.1.

Item 8.01 Other Events.

On February 26, 2024, the Company issued a press release with respect to entering into the License Agreement with NINDS and NCI.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

We are filing as part of this Current Report on Form 8-K the exhibits listed on the accompanying Index to Exhibits, which information is incorporated herein by reference.

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.

Date: February 26, 2024

LIXTE BIOTECHNOLOGY HOLDINGS, INC.

By: */s/ BASTIAAN VAN DER BAAN*
Bastiaan van der Baan
President and Chief Executive Officer

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Exclusive Patent License with NINDS and NCI
99.1	Press Release announcing entering into the License Agreement with NINDS and NCI
104	Cover Page Interactive Data File (embedded within the Inline XBRL Document)

Exhibit 10.1

PUBLIC HEALTH SERVICE

PATENT LICENSE AGREEMENT – *EXCLUSIVE*

This **Agreement** is based on the model Patent License Exclusive Agreement adopted by the U.S. Public Health Service ("**PHS**") Technology Transfer Policy Board for use by components of the National Institutes of Health ("**NIH**"), the Centers for Disease Control and Prevention ("**CDC**"), and the Food and Drug Administration ("**FDA**"), which are agencies of the **PHS** within the Department of Health and Human Services ("**HHS**").

This Cover Page identifies the Parties to this **Agreement**:

The U.S. Department of Health and Human Services, as represented by the National Institute of Neurological Disorders and Stroke and National Cancer Institute each an Institute or Center (hereinafter referred to, individually or collectively, as the "**IC**" or collectively as the "**ICs**") of the
NIH

and

Lixte Biotechnology, Inc.,
hereinafter referred to as the "**Licensee**",
having offices at 680 E Colorado Blvd., Suite 180, Pasadena, CA 91101
created and operating under the laws of Delaware.
Tax ID No.: 20-2903526

For the **ICs'** internal use only:

License Number: L-080-2024-0

License Application Number: A-559-2022

Serial Number(s) of Licensed Patent(s) or Patent Application(s): The Jointly Owned Licensed Patent Rights are listed in Appendix A and are incorporated by reference herein.

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

CRADA No. 2013-167_NINDS2685 (C-124-2013) Materials CRADA entitled "Characterization of Proprietary Compounds from Lixte Biotechnology Holdings, Inc"

Additional Remarks: Intellectual property rights claimed in the **Jointly Owned Licensed Patent Rights** were developed under the above referenced CRADA

Public Benefit(s): Development of technologies that use Lixte's proprietary compounds in the LB-100 series, disclosed within Appendix A of CRADA No. 2013-167_NINDS2685 (C-124-2013) for the treatment of cancer

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 **IC** and the **Licensee** agree as follows:

1. BACKGROUND

1.1 In the course of conducting biomedical and behavioral research at the **NIH**, the **IC** investigators co-developed inventions with the **Licensee** that may have commercial applicability.

1.2 By assignment of rights from **IC** employees, **HHS**, on behalf of the **Government**, co-owns with the **Licensee**, intellectual property rights claimed in the **Jointly Owned Licensed Patent Rights**. **HHS** also owns any tangible embodiments of the inventions claimed therein actually reduced to practice by the **IC**.

1.3 The Secretary of **HHS** has delegated to the **IC** the authority to enter into this **Agreement** for the licensing of rights to these inventions.

1.4 The **IC** 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 The **Licensee** desires to acquire commercialization rights to 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 the **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. **Licensee's Affiliates** will have the benefit of all rights of **Licensee** under this **Agreement**. Accordingly, in this **Agreement** "**Licensee**" means "**Licensee** or its **Affiliates**" where necessary to give **Licensee's** Affiliates the benefit of the rights provided to **Licensee** in this **Agreement**; provided that, in any event **Licensee** will remain responsible for the acts and omissions of its **Affiliates.**

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

2.3 "**Combination Therapy**" means the use of a **Licensed Product(s)** or **Licensed Processes** that contain or use **LB-100** and additionally use, or are sold together or under a single label or for a single price with, a standard anti-cancer drug ("**Other Product")** such as a checkpoint inhibitor that falls within the **Jointly Owned Licensed Patent Rights**.

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

2.5 "**Commercially Reasonable Efforts**" means, with respect to the efforts to be expended by **Licensee** with respect to any objective, the reasonable, diligent, good faith efforts to accomplish such objective as **Licensee** would normally use to accomplish a similar objective under similar circumstances. It is understood and agreed that with respect to the research, development and sale of **Licensed Products** or **Licensed Process** by **Licensee**, such efforts shall be substantially equivalent to those efforts and resources commonly used by **Licensee** for products owned by it or to which it has rights, which product is at a similar stage in its development or product life cycle. **Commercially Reasonable Efforts** shall be determined on a market-by-market basis, and it is anticipated that the level of effort will be different for different markets, and will change over time, reflecting changes in the status of the **Licensed Products** or **Licensed Process** and the market(s) involved.

2.6 "**CRADA"** means a Cooperative Research and Development Agreement.

2.7 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

2.8 "**First Commercial Sale**" means (a) with respect to a **Licensed Product**, the first sale by or on behalf of the **Licensee, Affiliates** or **Sublicensees** of such **Licensed Product** to a **Third Party** (other than a **Sublicensee**) for end use of such **Licensed Product** in a regulatory jurisdiction after regulatory approval has been granted for such **Licensed Product** in such regulatory jurisdiction or
(b) with respect to a **Licensed Process**, the first practice of such **Licensed Process** by or on behalf of the **Licensee** or any of its **Affiliates** or its **Sublicensees** for a **Third Party** (other than a **Sublicensee**), in each case (a) and (b) in exchange for cash or some equivalent to which value can be assigned for the purpose of determining **Net Sales**.

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

2.10 "**Jointly Owned Licensed Patent Rights**" means:

(a) Patent applications (including provisional patent applications and PCT patent applications) or issued/granted 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, in each case to the extent they are co-assigned to **HHS**;

(b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in Paragraph 2.10(a) and are co-assigned to **HHS**:

(i) continuations-in-part of Paragraph 2.10(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 Paragraph 2.10(a); and

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

(c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in Paragraph 2.10(a): all counterpart foreign and U.S. patent applications and patents to Paragraphs 2.10(a) and 2.10(b), including those listed in Appendix A; and

(d) **Jointly Owned Licensed Patent Rights** shall *not* include Paragraphs 2.10(b) or 2.10(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in Paragraph 2.10(a).

2.11 "**LB-100**" means **Licensee's** or its **Affiliate's** proprietary drug products and product candidates that consist of the LB-100 series of pharmacologically active drugs that inhibit serine/threonine phosphatases.

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

2.13 "**Licensed Processes**" means processes that, in the course of being practiced in the **Licensed Territory**, would be within the scope of one or more **Valid Claims** in the **Licensed Territory.**

2.14 "**Licensed Products**" means tangible materials that, in the manufacture, use, sale or importation in the **Licensed Territory** would be within the scope of one or more **Valid Claims** in the **Licensed Territory.**

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

2.16 "**Net Sales**" means, with respect to any **Licensed Product** or **Licensed Process**, the total gross receipts by **Licensee** and its **Affiliates** and its **Sublicensees** for sales of such **Licensed Products** or practice of such **Licensed Processes** by or on behalf of the **Licensee** or any of its **Affiliates** or its **Sublicensees** to a **Third Party** (other than a **Sublicensee**) and from leasing, renting, or otherwise making **Licensed Products** available to a **Third Party** (other than a **Sublicensee**) without sale or other dispositions, whether invoiced or not, less the following:

(a) returns, refunds, credits and allowances to the extent actually granted and documented;

(b) packing costs, insurance costs, freight out and other transportation charges to the extent they are included in and separately itemized on the invoice;

(c) taxes, excise duties or other governmental charges imposed on the sales of such **Licensed Product** or practice of such **Licensed Process** to the extent included in and separately itemized on the invoice,

(d) wholesaler and cash and quantity discounts in amounts customary in the trade and other discounts, refunds or rebates to the extent actually granted;

(e) that portion of the annual fee on prescription drug manufacturers imposed by the Patient Protection and Affordable Care Act, Pub. L. No. 111-148 (as amended) to the extent (a) reasonably allocable to sales of such **Licensed Product** in accordance with **Licensee's**, its **Affiliates'** or **Sublicensees'** standard policies and procedures consistently applied across its products and (b) the selling party actually includes such fee as a deduction from gross revenue in its publicly filed financial reports; and

(f) rebates and chargeback payments granted to managed health care organizations, pharmacy benefit managers (or equivalents thereof), and other government agencies (to the extent not already reflected in the invoiced price).

No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the **Licensee**, or any of its **Affiliates** or its **Sublicensees**, and on its payroll, or for the cost of collections.

Notwithstanding the foregoing, sales or transfers of **Licensed Products** or practice of the **Licensed Processes** internally among **Licensee**, its **Affiliate(s)**, or their respective **Sublicensee(s)** shall not be included in the calculation of **Net Sales**, unless any such recipient is an end user of such **Licensed Product** or **Licensed Process**. The supply of **Licensed Products** as samples for charitable or promotional purposes, and/or the use of the **Licensed Process** or **Licensed Product** in non-clinical or clinical trials or any tests or other studies, or for compassionate use, indigent or other patient access or patient assistance programs, shall not be included in the computation of **Net Sales** as long as **Licensee** is not receiving revenue in excess of its costs from supplying such **Licensed Product** and/or use of **Licensed Process**. For the avoidance of doubt, all of the foregoing deductions shall be determined as actually incurred from the books and records of **Licensee**, its **Affiliates** or its **Sublicensees** maintained in accordance with GAAP standards.

If a **Licensed Product** or **Licensed Process** is sold as a part of a **Combination Therapy** in a given country of the **Licensed Territory**, the **Net Sales** of such **Licensed Product** or **Licensed Process** in such country for the purpose of calculating royalties owed under this **Agreement** for such **Combination Therapy**, shall be determined as follows: first, determine the actual **Net Sales** of such **Combination Therapy** (using the above provisions) and then (i) if both **LB-100** and the **Other Product(s)** in such **Combination Therapy** are sold separately in such country, the **Net Sales** shall be multiplied by the fraction A/(A+B), where A is the average gross selling price of **LB-100** in such country, when sold separately, and B is the sum of the gross selling price(s) in such country of each **Other Product** when sold separately. If the **Licensed Product** (or **Licensed Process,** as applicable) and the **Other Product**(s) that are not **Licensed Product** (or **Licensed Process,** as applicable) in such **Combination Therapy** are not sold separately in a given country of the **Licensed Territory,** then the Parties agree to negotiate in good faith regarding an appropriate allocation of **Net Sales**.

2.17 "**Other Product**" means a standard anti-cancer drug other than **LB-100**, such as a checkpoint inhibitor that falls within the **Jointly Owned Licensed Patent Rights**, that is sold as part of a therapy or product for use in combination with **LB-100**, under a single pricing scheme or under a single label.

2.18 "**Phase 2 Clinical Study**" means controlled human clinical studies conducted to evaluate the safety, and effectiveness of a product or drug for a particular indication or indications in patients with the disease or condition under study, and to determine the common short-time side effects and risks associated with the drug which, in the United States, satisfies the requirements of 21 C.F.R. § 312.21(b) and in any non-U.S. jurisdiction satisfies equivalent regulations, and shall include any clinical study that leads to a conditional regulatory approval, that may be followed by or run concurrently with a confirmatory **Phase 3 Clinical Study**.

2.19 "**Phase 3 Clinical Study**" means any expanded controlled or uncontrolled human clinical human trials pursuant to a randomized study with endpoints agreed upon by regulatory bodies for regulatory approval performed after or concurrent with **Phase 2 Clinical Study** evidence suggesting effectiveness of a drug has been obtained, and is intended to gather additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of a drug and to provide an adequate basis for regulatory approval and physician labeling which, in the United States, satisfies the requirements of 21 C.F.R. § 312 and in any non- U.S. jurisdiction satisfies equivalent regulations, and shall include a confirmatory study that is conducted following conditional regulatory approval.

2.20 "**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.

2.21 "**Research License**" means a nontransferable, nonexclusive license under the **IC's** ownership interest in the **Jointly Owned Licensed Patent Rights** to make and to use the **Licensed Products** or the **Licensed Processes** solely for purposes of internal research, internal clinical research studies, and not for purposes of commercial manufacture or distribution, sale or in lieu of purchase.

2.22 "**Sublicensee**" means a **Third Party** to whom **Licensee** (directly or via an **Affiliate)** has granted a permitted sublicense under any of the **Jointly Owned Licensed Patent Rights** licensed to **Licensee** hereunder, for permitting the manufacture, marketing, distribution, or sale of **Licensed Products** or **Licensed Processes.** For clarity, **Third Party** contract research organizations, distributors, wholesalers, contract manufacturing organizations, contract sales organizations and the like will not be **Sublicensees**, and agreements between **Licensee** and such entities will not be sublicenses under this **Agreement**.

2.23 "**Sublicensing Revenue**" means any consideration actually received by the **Licensee** from a **Sublicensee** as consideration for the grant of rights to the **Jointly Owned Licensed Patent Rights**. **Sublicensing Revenue** includes, but is not limited to, upfront fees, license maintenance fees, and milestone payments, and other payments including in-kind payments with financial value such as stock options, in each case that are received by **Licensee** in consideration for any rights granted under **Jointly Owned Licensed Patent Rights** under a sublicense agreement, but excludes:

(a) earned royalties, profit share payments or other payments based on a percentage of **Net Sales** (where such royalties will be paid to **IC** per the terms of this **Agreement**);

(b) payments made by **Sublicensee** for the purchase of equity or debt of the **Licensee** to the extent not in excess of fair market value except payments for consideration of the sublicense of **Jointly Owned Licensed Patent Rights**;

(c) payments made after the effective date of this **Agreement**, and under the terms of research and development agreements, collaboration agreements or partnership agreements with a **Sublicensee** where the **Licensee** or an **Affiliate** is obligated to supply **Licensed Products** or perform research or development involving any of the **Jointly Owned Licensed Patent Rights**, that encompass the **Licensed Products** or **Licensed Processes**;

(d) payments for patent expenses; and

(e) payments for **Licensee's** performance of marketing or promotional activities, which reflect the fair market value of such activities. If **Licensee** receives any payments from a **Sublicensee** in consideration for the grant of a sublicense under the **Jointly Owned Licensed Patent Rights** and under other intellectual property licensed to such **Sublicensee**, **Licensee** shall fairly allocate such amounts among all licensed intellectual property, and only the portion allocated to the **Jointly Owned Licensed Patent Rights** will be included in **Sublicensing Revenue**.

2.24 "**Third Party**" means a person or entity other than (i) **Licensee** or any of its **Affiliates** and (ii) the **ICs**.

2.25 "**United States**" or "**U.S.**" means the United States of America.

2.26 "**Valid Claim"** means (a) a claim of an issued and unexpired patent within the **Jointly Owned Licensed Patent Rights**; or (b) a claim of a pending patent application within the **Jointly Owned Licensed Patent Rights** and, in each case which has not been (i) permanently revoked, disclaimed or admitted to be invalid or unenforceable through reissue, re-examination, disclaimer or otherwise, (ii) held unpatentable, invalid or unenforceable by a final decision of a court or governmental agency of competent jurisdiction, which decision can no longer be appealed or was not appealed within the time allowed, (iii) rendered unenforceable through disclaimer or otherwise, (iv) abandoned and not continued or (v) permanently lost through an interference or opposition proceeding without any right of appeal or review; provided, however, that if a claim of a pending patent application within the **Jointly Owned Licensed Patent Rights** shall not have issued within seven (7) years after its earliest priority date, such claim shall not constitute a Valid Claim for the purposes of this **Agreement** unless and until a patent issues with such claim (from and after which time the same would be deemed a Valid Claim).

3. GRANT OF RIGHTS

3.1 The **IC** hereby grants and the **Licensee** accepts, on behalf of itself and its **Affiliate(s)**, subject to the terms and conditions of this **Agreement**, an exclusive license under the **Jointly Owned Licensed Patent Rights** in the **Licensed Territory**, with the right to sublicense as set forth in Paragraph 4, under the **ICs'** interest in the **Jointly Owned Licensed Patent Rights** in the **Licensed Territory** (i) to make and have made, to use and have used, to sell and have sold, to offer to sell and have offered for sale, and to import and have imported any **Licensed Products** in the **Licensed Fields of Use** and (ii) to practice and have practiced any **Licensed Process(es)** 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 the **IC** 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 the **IC**, which shall not be unreasonably withheld, conditioned or delayed , the **Licensee** will be entitled to grant sublicenses to **Third Parties** under the **IC's** ownership interest in the **Jointly Owned Licensed Patent Rights**. Any such sublicense shall be on terms and conditions consistent with the terms of this **Agreement**.

4.2 The **Licensee** agrees that any sublicense(s) granted by it shall provide that the obligations to the **IC** of Paragraphs 5.1-5.4, 8.1, 10.1 (to the extent applicable to the scope of the said particular sublicense), 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**. The **Licensee** further agrees to attach copies of these Paragraphs to all of its sublicense agreements.

4.3 Any sublicense granted under the **IC's** ownership interest in the **Jointly Owned Licensed Patent Rights** by the **Licensee** shall provide for the termination of the sublicense or the conversion to a license directly between the **Sublicensee** and the **IC**, at the option of the **Sublicensee**, upon termination of this **Agreement** under Article 13. This conversion is subject to the **IC** approval (not to be unreasonably withheld, conditioned or delayed) and contingent upon acceptance by the **Sublicensee** of the remaining provisions of this **Agreement**.

4.4 The **Licensee** agrees to forward to the **IC** a complete copy of each fully executed sublicense agreement entered into by **Licensee** and its **Sublicensee**, postmarked within thirty (30) days of the execution of such agreement; provided that **Licensee** may redact any commercially sensitive information that does not materially affect the **IC's** ability to confirm (a) the identity of the **Sublicensee**, and (b) any royalties which are or may be owed to the **IC** under this **Agreement**, and (c) the **Licensee's** compliance with the requirements of Paragraphs 4.2 and 4.3 of this **Agreement**. To the extent permitted by law, the **IC** agrees to maintain each such sublicense agreement in confidence.

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

5.1

(a) the **IC** reserves on behalf of the **Government** an irrevocable, nonexclusive, nontransferable, royalty-free license for the practice of all Subject Inventions licensed under the **Jointly Owned Licensed Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory;

(b) Given that the **Jointly Owned Licensed Patent Rights** include Subject Inventions made under a **CRADA**, the **Licensee** grants to the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(A), a nonexclusive, nontransferable, irrevocable, paid-up license to practice the **Jointly Owned Licensed Patent Rights** or have the **Jointly Owned Licensed Patent Rights** practiced throughout the world by or on behalf of the **Government**. In the exercise of this license, the **Government** shall not publicly disclose trade secrets or commercial or financial information that is privileged or confidential within the meaning of 5 U.S.C. §552(b)(4) or which would be considered as such if it had been obtained from a non-Federal party;

(c) Prior to the **First Commercial Sale** of the first **Licensed Product** in the **Fields of Use** as described in Appendix B, the **Licensee** agrees to provide the **ICs** with reasonable quantities of the **Licensed Products** solely for **IC** internal, pre- clinical research use, as requested by the **IC** in writing. The **ICs** may not transfer or otherwise provide access to any such **Licensed Products** to any organization, entity, or governmental agency (other than the **ICs**) without the prior written consent of **Licensee**. The **ICs** acknowledge and agree that such **Licensed Products** are provided AS IS without any express or implied warranty of any kind, and that the **ICs** shall be solely responsible for any loss, damages or claims of any kind arising from the **ICs'** use of any **Licensed Products** provided by **Licensee** pursuant to this Paragraph 5.1.

5.2 **Licensee** agrees that **Licensed Products** used or sold in the **United States** that are covered by the **Jointly Owned Licensed Patent Rights** or products produced through use of the **Licensed Processes** that fall within the **Jointly Owned Licensed Patent Rights** shall be manufactured substantially in the **United States**, unless a written waiver is obtained in advance from the **IC**.

5.3 The **Licensee** acknowledges that the **IC** may enter into future **CRADAs** under the Federal Technology Transfer Act of 1986 that relate to the subject matter of this **Agreement**. The **Licensee** agrees not to unreasonably deny requests for a **Research License** from future collaborators with the **IC** when acquiring such **Research License** is necessary in order to make a **CRADA** project feasible. The **IC** shall notify **Licensee** of any such **CRADA** and **Licensee** may request an opportunity to join as a party to the proposed **CRADA**.

5.4

(a) in addition to the license of Paragraph 5.1(a), the **IC** reserves the right to grant **Research Licenses** directly or to require the **Licensee** to grant **Research Licenses** on reasonable terms. The purpose of these **Research Licenses** is to encourage basic research, whether conducted at an academic or corporate facility. In order to safeguard the **Jointly Owned Licensed Patent Rights**, however, the **IC** shall consult with the **Licensee** before granting to commercial entities a **Research License** or providing to them research samples of materials made through the **Licensed Processes**; and

(b) in exceptional circumstances, and in the event that the **Jointly Owned Licensed Patent Rights** are Subject Inventions made under a **CRADA**, the **Government**, pursuant to 15 U.S.C. §3710a(b)(1)(B), retains the right to require the **Licensee** to grant to a responsible applicant a nonexclusive, partially exclusive, or exclusive sublicense to use the **Jointly Owned Licensed Patent Rights** in the **Licensed Fields of Use** on terms that are reasonable under the circumstances, or if the **Licensee** fails to grant this license, the **Government** retains the right to grant the license itself. The exercise of these rights by the **Government** shall only be in exceptional circumstances and only if the **Government** determines:

(i) the action is necessary to meet health or safety needs that are not reasonably satisfied by or on behalf of the **Licensee**, or its **Affiliate** or **Sublicensee**;

(ii) the action is necessary to meet requirements for public use specified by Federal regulations, and these requirements are not reasonably satisfied by or on behalf of the **Licensee**, or its **Affiliate** or **Sublicensee**; or

(iii) the **Licensee** has failed to comply with an agreement containing provisions described in 15 U.S.C. §3710a(c)(4)(B); and

(c) the determination made by the **Government** under this Paragraph 5.4 is subject to administrative appeal and judicial review under 35 U.S.C. §203(b).

6. ROYALTIES AND REIMBURSEMENT

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

6.2 The **Licensee** agrees to pay the **IC** a nonrefundable minimum annual royalty as set forth in Appendix C.

6.3 The **Licensee** agrees to pay the **IC** earned royalties as set forth in Appendix C.

6.4 The **Licensee** agrees to pay the **IC** benchmark royalties as set forth in Appendix C.

6.5 The **Licensee** agrees to pay the **IC** 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 **Jointly Owned Licensed Patent Rights** for the purpose of computing earned royalty payments, when there is no longer any **Valid Claim** existing in such patent or patent application in the **Licensed Territory**. For the avoidance of doubt, if a patent application within the **Jointly Owned Licensed Patent Rights** is pending for more than seven (7) years from its earliest priority date subsequently issues as a patent in the **Licensed Territory**, the **Licensee** shall pay any earned royalties only from and including the date that the patent application issues as a patent.

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

6.8 On sales of the **Licensed Products** or **Licensed Process** by the **Licensee** to **Affiliates** or **Sublicensees**, or on sales made in other than an arm's-length transaction, and in each case provided that such sales are not excluded from **Net Sales** as set forth in its definition, the value of the **Net Sales** attributed under this Article 6 to such a transaction shall be that which would have been received in an arm's-length transaction in the same country, based on sales of like quantity and quality products in the same country on or about the time of such transaction.

6.9 The **Licensee** may elect to surrender its rights in any country of the **Licensed Territory** under any of the **Jointly Owned Licensed Patent Rights** upon thirty (30) days' written notice to the **IC** and, in the case that either Paragraph 7.3 or Paragraph 7.4 take effect, **Licensee** shall owe no payment obligation for patent-related expenses paid in that country after ninety (90) days of the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 The **Licensee** or its **Affiliate** agrees to take responsibility for the preparation, filing, prosecution, and maintenance (including any interferences, reissue proceedings, reexaminations, inter partes review, patent term extensions, applications for supplementary protection certificates and oppositions) of any and all patent applications or patents included in the **Jointly Owned Licensed Patent Rights** and shall, on an ongoing basis, promptly furnish copies of all relevant patent-related documents to the **IC**. The **Licensee** or its **Affiliate** shall select registered patent attorneys or patent agents to provide these services on behalf of the **Licensee**. The **IC** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **Licensee** or its **Affiliate** and its attorneys or agents shall inform the **IC** in connection with the preparation, filing, prosecution and maintenance of patent applications and patents included within the **Jointly Owned Licensed Patent Rights**.

7.2 Each party shall promptly inform the other as to all matters that come to its attention that may affect the preparation, filing, prosecution, or maintenance of the **Jointly Owned Licensed Patent Rights** and permit each other to provide comments and suggestions with respect to the preparation, filing, prosecution, and maintenance of the **Jointly Owned Licensed Patent Rights**, which comments and suggestions shall be considered in good faith by the other party.

7.3 Upon any determination by the **Licensee** not to proceed or continue with the preparation, filing, prosecution, or maintenance (or combination thereof) of any patent application or patent included in the **Jointly Owned Licensed Patent Rights**, the **Licensee** shall provide the **IC** with written notice of such determination at least sixty(60) days prior to the deadline for taking any action for such patent application or patent or the date on which the abandonment of any such patent or application would become effective, whichever is earlier, and the **IC** shall have the right but not the obligation to assume the responsibility for the preparation, filing, prosecution, and maintenance of any such patent application or patent included in the **Jointly Owned Licensed Patent Rights**. If the **IC** elects to assume responsibility for the preparation, filing, prosecution and maintenance of such patent application or patent, then the **IC** shall promptly notify **Licensee** of **IC's** election in writing and shall, on an ongoing basis, promptly furnish copies of all relevant documents in connection with such patent application or patent to the **Licensee**. In this event, the **IC** shall select registered patent attorneys or patent agents to provide services in connection with such patent application or patent on behalf of the **IC** and the **Licensee.** The **Licensee** shall provide appropriate powers of attorney and other documents necessary to undertake this action to the patent attorneys or patent agents providing these services. The **IC** and its attorneys or agents shall consult with the **Licensee** in all aspects of the preparation, filing, prosecution and maintenance of such patent application or patent included within the **Jointly Owned Licensed Patent Rights** and shall provide the **Licensee** sufficient opportunity to comment on any document that the **IC** intends to file or to cause to be filed with the relevant intellectual property or patent office.

7.4 At any time, the **Licensee** may provide the **IC** with written notice that the **Licensee** wishes the **IC** to assume control of the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Jointly Owned Licensed Patent Rights**, and such assumption of control shall be at the **IC's** sole discretion. If the **IC** assumes these responsibilities, the Licensee agrees to cooperate fully with the **IC**, its attorneys, and agents in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the **Jointly Owned Licensed Patent Rights** and to provide the **IC** with complete copies of any and all documents or other materials that the **IC** deems necessary to undertake such responsibilities. The **Licensee** shall be responsible for all costs associated with transferring patent prosecution responsibilities to an attorney or agent of the **IC**'s choice.

8. RECORD KEEPING

8.1 The **Licensee** agrees to keep accurate and correct records of the **Licensed Products** made, used, sold, or imported and the **Licensed Processes** practiced under this **Agreement** appropriate to determine the amount of royalties due the **IC**. 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 the **IC**, by an accountant or other designated auditor selected by the **IC** and reasonably acceptable to the **Licensee** for the sole purpose of verifying reports and royalty payments hereunder. The **IC** may conduct such audits no more than once per calendar year, and may inspect records from a particular reporting period only once. The accountant or auditor shall sign the **Licensee's** standard confidentiality agreement prior to the inspection and shall only disclose to the **IC** 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 the **Licensee** shall reimburse the **IC** for the cost of the inspection at the time the **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 the **IC** provides to the **Licensee** notice of the payment due. If any inspection shows an overpayment by the **Licensee** for any period, then the **Licensee** shall be permitted to credit the amount of such overpayment against any future amounts owed by the **Licensee** under this **Agreement**.

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

9.1 Prior to signing this **Agreement**, the **Licensee** has provided the **IC** with the **Commercial Development Plan** in Appendix E, under which the **Licensee** (or its **Affiliate** or **Sublicensee**) intends to develop the **Jointly Owned 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 The **Licensee** shall provide written annual reports on its product development progress or efforts to commercialize under the **Commercial Development Plan** for 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, status of manufacturing, sublicensing, marketing, importing, and sales during the preceding calendar year, as well as plans for the present calendar year. The **IC** also encourages these reports to include information on any of the **Licensee's** public service activities that relate to the **Jointly Owned Licensed Patent Rights**. If reported progress differs from that projected in the **Commercial Development Plan** and **Benchmarks** in a material way, the **Licensee** shall explain the reasons for such differences. The **Licensee** agrees to provide any additional information reasonably required by the **IC** to evaluate the **Licensee's** performance under this **Agreement**. The **Licensee** may amend the **Commercial Development Plan** and the **Benchmarks**, at any time upon written approval by the **IC**. The **IC** shall not unreasonably withhold, condition, or delay approval of any request of the **Licensee** to amend the **Commercial Development Plan** and/or **Benchmarks** and to extend the time periods of the **Benchmarks** if the request is supported by a reasonable showing by the **Licensee** of diligence in its (or its **Affiliate's** or **Sublicensee's**) performance under the **Commercial Development Plan** and toward bringing the **Licensed Products** or **Licensed Processes** to the point of **Practical Application**, as defined in 37 C.F.R. §404.3(d). The **Licensee** shall amend the **Commercial Development Plan** and **Benchmarks** at the request of **IC** in case if something is missing and/or **Licensee** is developing a **Licensed Product** or **Licensed Process** that was not specifically addressed in the **Commercial Development Plan** originally submitted and if **Licensee** is not developing a **Licensed Product** or **Licensed Process** as originally described in the **Commercial Development Plan**.

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

9.4 After the **First Commercial Sale** of the first **Licensed Product** or **Licensed Process**, in any country in the **Licensed Territory**, the **Licensee** shall submit to the **IC**, 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 the **Licensee** in each country within the **Licensed Territory**, the **Net Sales**, and the amount of royalty accordingly due. With each royalty report, the **Licensee** shall submit payment of earned royalties due. If no earned royalties are due to the **IC** for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the **Licensee** and shall include a detailed listing of all deductions made under Paragraph 2.16 to determine **Net Sales** made under Article 6 to determine royalties due. The royalty report shall also identify the site of manufacture for the **Licensed Product(s)** sold in the United States.

9.5 The **Licensee** agrees to forward semi-annually to the **IC** a copy of these reports received by the **Licensee** from its **Sublicensees** during the preceding half-year period as shall be pertinent to a royalty accounting to the **IC** by the **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. Any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the **Licensee**. The royalty report required by Paragraph 9.4 shall be mailed to the **IC** at its address for **Agreement** Notices indicated on the Signature Page or electronically mailed to the email address indicated on the Signature Page.

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

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

9.9 All written plans, reports and other proprietary information required under this **Agreement**, that is provided to **IC** by the **Licensee** pursuant to this Article 9 should be marked "confidential" by **Licensee**, and all such written plans, reports and other proprietary information shall, to the extent permitted by law, be treated by the **IC** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records, written plans, reports and other proprietary information by the **IC** 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 The **Licensee** shall use **Commercially Reasonable Efforts** to (a) bring the **Licensed Products** and, if applicable, the **Licensed Processes** to **Practical Application**, pursuant to the **Commercial Development Plan** in Appendix E, and (b) achieve the **Benchmarks** in Appendix D. The efforts of any **Affiliate** or **Sublicensee** shall be considered the efforts of the **Licensee**.

10.2 Upon the **First Commercial Sale** in the **United States**, until the expiration or termination of this **Agreement**, the **Licensee** shall use **Commercially Reasonable Efforts** to make the **Licensed Products** and **Licensed Processes** reasonably accessible to the **United States** public. The efforts of any **Affiliate** or **Sublicensee** shall be considered the efforts of the **Licensee**.

10.3 The **Licensee** agrees, after its **First Commercial Sale** in each jurisdiction in which approval to sell and market a **Licensed Product** has been granted**,** to make commercially reasonable quantities of **Licensed Products** or materials produced through the use of **Licensed Processes** available to patient assistance programs as appropriate and applicable.

10.4 The **Licensee** agrees, after its **First Commercial Sale** in each jurisdiction of the **Licensed Territory** in which approval to market and sell a **Licensed Product** has been granted**,** and as part of its marketing and product promotion of such **Licensed Product**, to develop, as appropriate, educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing such **Licensed Products** and/or medical aspects of the prophylactic and therapeutic uses of such **Licensed Product.**

10.5 Within ninety (90) days after the **First Commercial Sale**, the **Licensee** agrees to supply, upon the **IC's** written request, 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 the **Licensed Processes** or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

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

11.2 Pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29, the **Licensee** or its **Affiliate** or **Sublicensee** shall have the right (but not the obligation) to:

(a) bring suit in its own name, at its own expense, and on its own behalf for infringement of presumably **Valid Claims** in the **Jointly Owned Licensed Patent Rights**;

(b) in any suit, enjoin infringement and collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; or

(c) settle any claim or suit for infringement of the **Jointly Owned Licensed Patent Rights** provided, however, that the **IC** and appropriate Government authorities shall have the first rights to take such actions; and

(d) If the **Licensee** or its **Affiliate** or **Sublicensee** desires to initiate a suit for patent infringement, the **Licensee** or its **Affiliate** or **Sublicensee** shall notify the **IC** in writing of such desire. If the **IC** does not notify the **Licensee** of its intent to pursue legal action within ninety (90) days of **Licensee's** (or its **Affiliate's** or **Sublicensee's**) notice to the **IC**, then the **Licensee** shall be free to initiate suit. For expedited proceedings that, by law, require a plaintiff to pursue legal action within ninety (90) days of a triggering event, such as the period prescribed by 35 U.S.C. § 271(e)(5), **Licensee** shall notify the **IC** immediately upon receipt of any information that may give rise to a triggering event. If the **IC** does not inform the **Licensee** of its intent to pursue legal action within (10) business days of the triggering event, the **Licensee** shall be free to initiate suit. The **IC** shall have a continuing right to intervene in the suit, at its own expense. The **Licensee** or its **Affiliates** or **Sublicensees** shall not compel the **Government** either to initiate or to join in any suit for patent infringement. The **Licensee** may request the **Government** to initiate or join in any suit if necessary to avoid dismissal of the suit, and the **Government** shall not unreasonably withhold, condition or delay its agreement to such. Should the **Government** be made a party to any such suit brought by the **Licensee** or its **Affiliate** or **Sublicensee**, the **Licensee** shall reimburse the **Government** for any reasonable costs, expenses, or fees which the **Government** incurs as a result of the motion or other action. In all such cases, the **Licensee** or its **Affiliate** or **Sublicensee** agrees to keep the **IC** reasonably apprised of the status and progress of any such litigation. The **Licensee** shall notify the **IC**, before the **Licensee** commences an infringement action in accordance with the foregoing, and give careful consideration to the views of the **IC** provided to **Licensee** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.3 In the event that a declaratory judgment action alleging invalidity, unenforceability or non-infringement of any of the **Jointly Owned Licensed Patent Rights** shall be brought against the **Licensee** or its **Affiliate** or **Sublicensee** raised by way of counterclaim or affirmative defense in an infringement suit brought by the **Licensee** or its **Affiliate** or **Sublicensee** under Paragraph 11.2, pursuant to this **Agreement** and the provisions of 35 U.S.C. Chapter 29 or other statutes, or in the event of any other legal action involving the defense of the validity and/or enforceability of any **Jointly Owned Licensed Patent Rights**, including actions brought through any inter partes review, post-grant review, and any other post-grant proceedings, including reexamination, reissue, supplemental examination, opposition, revocation and other similar proceedings, the **Licensee** or its **Affiliate** or **Sublicensee** shall have the right (but not the obligation) to:

(a) defend the suit or action in its own name, at its own expense, and on its own behalf for presumably **Valid Claims** in the **Jointly Owned Licensed Patent Rights**;

(b) in any suit or action, ultimately to enjoin infringement and to collect for its use, damages, profits, and awards of whatever nature recoverable for the infringement; and

(c) settle any claim or suit for declaratory judgment or other action involving the **Jointly Owned Licensed Patent Rights** provided, however, that the **IC** and appropriate **Government** authorities shall have the continuing right to intervene in the suit at its own expense; and

(d) if the **IC** does not notify the **Licensee** of its intent to respond to such legal action within a reasonable time, not to exceed ninety (90) days from when such action is brought, the **Licensee** shall be free to do so. The **Licensee** shall take no action to compel the **Government** either to initiate or to join in any declaratory judgment action. The **Licensee** may request the **Government** to initiate or to join any suit if necessary to avoid dismissal of the suit, and the **Government** shall not unreasonably withhold, condition or delay its agreement to such. Should the **Government** be made a party to any such suit by motion or any other action of the **Licensee**, the **Licensee** shall reimburse the **Government** for any reasonable costs, expenses, or fees, which the **Government** incurs as a result of the motion or other action. If the **Licensee** elects not to defend against the declaratory judgment action, the **IC**, at its option, may do so at its own expense. In all cases, the **Licensee** agrees to keep the **IC** reasonably apprised of the status and progress of any litigation. Before the **Licensee** commences an infringement action, the **Licensee** shall notify the **IC** and give careful consideration to the views of the **IC,** and to any potential effects of the litigation on the public health in deciding whether to bring suit.

11.4 Except as otherwise provided in Paragraphs 11.2(c) or 11.3(d), in any action brought under Paragraphs 11.2 or 11.3, the expenses, including costs, fees, attorney fees, and disbursements, shall be paid by the **Licensee** (or its **Affiliate** or **Sublicensee**) if the **Licensee** elects to commence or defend such action. The value of any recovery made by the **Licensee** through court judgment or settlement shall be treated as **Net Sales** and subject to earned royalties after reimbursing for such expenses paid by **Licensee** or **Government**.

11.5 The **IC** shall cooperate fully with the **Licensee** or its **Affiliate** or **Sublicensee** in connection with any action under Paragraphs 11.2 or 11.3. The **IC** agrees promptly to provide access to all necessary documents and personnel, e.g., co-inventors, and to render reasonable assistance in response to a request by the **Licensee** or its **Affiliate** or **Sublicensee**.

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

12.1 The **IC** represents that the IC has the authority, by delegation from the Secretary of HHS, to enter into this **Agreement**. The **IC** offers no other warranties other than those specified in Article 1

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

12.3 THE PARTIES MAKE NO WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE **JOINTLY OWNED LICENSED PATENT RIGHTS** OR TANGIBLE MATERIALS RELATED THERETO.

12.4 Neither the **Licensee** nor the **IC** represents that it shall commence legal actions against third parties infringing the **Jointly Owned Licensed Patent Rights**.

12.5 The **Licensee** shall indemnify and hold the **IC**, 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 to the extent arising out of any suit or proceeding brought by a **Third Party** for:

(a) the use by or on behalf of the **Licensee**, its **Affiliates**, its **Sublicensees**, or their respective directors or employees, or **Third Parties** acting on their behalf, of any **Jointly Owned Licensed Patent Rights**; or

(b) the design, manufacture, distribution, or use of any **Licensed Products**, **Licensed Processes** or other materials, products, or processes developed by or on behalf of **Licensee** and its **Affiliate**s and its **Sublicensees** in connection with or arising out of the **Jointly Owned Licensed Patent Rights**;

except, in each case of (a) or (b), to the extent arising out of either **IC's** breach of this **Agreement** or the negligence or willful misconduct of either **IC** or any of the **ICs'** employees, students, fellows, agents, or consultants.

12.6 The **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 14.16 are not fulfilled, and shall extend, on a **Licensed Product**-by-**Licensed Product**, **Licensed Process**-by-**Licensed Process** and country-by-country basis, until the expiration of the last-to- expire **Valid Claim** of the **Jointly Owned Licensed Patent Rights** in such country in the **Licensed Territory** unless sooner terminated as provided in this Article 13.

13.2 In the event that the **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, the **IC** 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 the **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, the **Licensee** shall immediately notify the **IC** in writing.

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

13.5 The **IC** shall specifically have the right to terminate or modify this **Agreement**, if the **IC** determines that the **Licensee** (and its **Affiliates and Sublicensees**):

(a) is not executing the **Commercial Development Plan** submitted with its request for a license, and the **Licensee** cannot otherwise demonstrate to the **IC's** reasonable satisfaction that the **Licensee** (and/or its **Affiliate and/**or its **Sublicensee**) has taken, effective steps to achieve the **Practical Application** of the **Licensed Products** or the **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 the **Licensed Products** or **Licensed Processes** reasonably available to the public after commercial use commences;

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

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

(h) has been found by a court of competent jurisdiction to have violated the Federal antitrust laws in connection with its performance under this **Agreement.**

13.6 In making the determination referenced in Paragraph 13.5, the **IC** 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 the **Licensee** under Paragraph 9.2. Prior to invoking termination or modification of this **Agreement** under Paragraph 13.5, the **IC** shall give written notice to the **Licensee** providing the **Licensee** specific notice of, and a ninety (90) day opportunity to respond to, the **IC's** concerns as to the items referenced in 13.5(a)-13.5(h). If the **Licensee** fails to reasonably alleviate the **IC's** concerns as to the items referenced in 13.5(a)-13.5(h) or fails to develop a corrective action plan and initiate such corrective action plan to the **IC's** reasonable satisfaction, the **IC** may terminate this **Agreement**.

13.7 Subject to Paragraph 13.9 below, the **IC** 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 the **Licensee**.

13.8 Within thirty (30) days after receipt of written notice of the **IC's** unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated **IC** official or its designee. The decision of the designated **IC** official or its designee shall be the final agency decision. The **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 the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), that are due to the **IC** 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 the **IC** pursuant to Paragraph 4.3. The **Licensee** may not be granted additional **IC** 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 any party 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 that party or excuse a similar subsequent failure to perform any of these terms or conditions by the other party.

14.2 This **Agreement** constitutes the entire agreement between the parties relating to the subject matter of the **Jointly Owned Licensed Patent Rights**, the **Licensed Products** and the **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 in writing either by email notice, prepaid, first class, registered or certified mail, or by an express/overnight delivery service provided by a commercial carrier, each properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the 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. The 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 Without the prior written consent of the **IC**, 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 the **Licensee's Affiliate(s)** or to a successor in interest by way of merger, consolidation, or sale of all or substantially all of **Licensee's** assets to which this **Agreement** relates. 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; provided that, for clarity, **Licensee** may perform its obligations under this **Agreement** through its **Affiliates**, **Sublicensees** or authorized subcontractors, but **Licensee** shall remain directly responsible for all of its obligations hereunder. In the event that the **IC** approves a proposed assignment to a non-**Affiliate Third Party**, the **Licensee** shall pay the **IC**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for such assignment within sixty (60) days of the said assignment. If the **IC** questions the amount of the additional royalty paid by **Licensee**, the **IC** may, at its own expense, use the services of an independent auditor to assess the fair market value of the consideration received for assignment of this **Agreement.** For avoidance of doubt, an assignment under this Paragraph 14.7 is not a sublicense.

14.8 The **Licensee** agrees in its use of any **IC**-supplied materials (if any) to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use such materials (if any) 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. The **Licensee** agrees not to use such materials (if any) for research involving human subjects or clinical trials outside of the United States without notifying the **IC**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **IC** of research using such materials (if any) 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 The **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 the **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. The **IC** neither represents that a license is or is not required or that, if required, it shall be issued.

14.10 The **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 the **Licensed Products** manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the **IC's** patent rights in those countries.

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

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 Paragraph 13.8. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **IC** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **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 CFR Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.

14.14 Any formal recordation of this **Agreement** required by the laws of any **Licensed Territory** as a prerequisite to enforceability of the **Agreement** in the courts of any foreign jurisdiction or for other reasons shall be carried out by the **Licensee** at its expense, and appropriately verified proof of recordation shall be promptly furnished to the **IC**.

14.15 Paragraphs 4.3, 8.1, 9.5-9.9, 12.1-12.5, 13.8, 13.9, 14.1, 14.3, 14.5, 14.6, 14.10, 14.11, 14.12 and 14.15 of this **Agreement** shall survive termination of this **Agreement**.

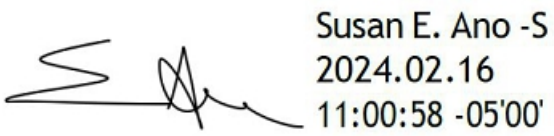
14.16 The terms and conditions of this **Agreement** shall, at the **IC's** sole option, be considered by the **IC** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is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

SIGNATURES BEGIN ON NEXT PAGE

NIH PATENT LICENSE AGREEMENT – *EXCLUSIVE*

SIGNATURE PAGE

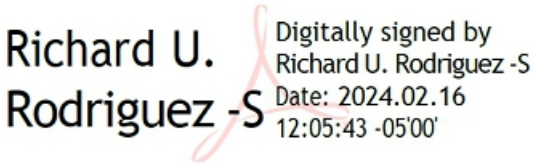
For the **National Institute of Neurological Disorders and Stroke**:



Susan Ano, PhD
Technology Development Coordinator
Technology Transfer Office
The National Institute of Neurological Disorders and Stroke National Institutes of Health

Date

For the **National Cancer Institute**:



Richard U. Rodriguez, MBA
Associate Director
Technology Transfer Center
The National Cancer Institute
National Institutes of Health

Date

Address for **Agreement** notices and reports:

E-mail: LicenseNotices_Reports@mail.nih.gov (preferred)

Mail: License Compliance and Administration
Monitoring & Enforcement
Office of Technology Transfer
National Institutes of Health
6701 Rockledge Drive, Suite 700, MS 7788
Bethesda, Maryland 20892 U.S.A.

(For courier deliveries please check https://www.ott.nih.gov/licensing/license-noticesreports)

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

by:

Bastiaan van der Baan
Signature of Authorized Official

Feb 23, 2024
Date

Bastiaan van der Baan
Printed Name

CEO
Title

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

Bastiaan van der Baan
Name

CEO
Title

Mailing Address

680 E Colorado Blvd
Suite 180
91101 Pasadena CA

Email Address: bvanderbaan@lixte.com

Phone: 631 830 7092

Fax:

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

Bastiaan van der Baan
Name

CEO
Title

Mailing Address:

680 E Colorado Blvd
Suite 180
91101 Pasadena CA

Email Address: bvanderbaan@lixte.com

Phone: 631 830 7092

Fax:

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) or imprisonment).

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

Patent(s) or Patent Application(s) entitled "OXABICYCLOHEPTANES FOR MODULATION OF IMMUNE RESPONSE" (E-130-2022)

I. U.S. Provisional Application No. 62/465,001, filed February 28, 2017

II. U.S. Provisional Application No. 62/545,373, filed August 14, 2017

III. International Application No. PCT/US2017/065270, filed December 8, 2017

IV. Australian Patent No. 2017370731, granted September 15, 2022

V. Brazilian Application No. 11201911627-3, filed December 8, 2017

VI. Canadian Application No. 3046515, filed December 8, 2017

VII. Chinese Patent No. ZL 201780084881.1, granted May 23, 2023

VIII. Chinese Application No. 202310498623.5, filed May 5, 2023

IX. European Patent No. 3551629, granted November 15, 2023

X. European Application No. 23202240.0, filed October 6, 2023

XI. Hong Kong Application No. 62020005213.7, filed December 8, 2017

XII. India Application No. 201917023002, filed December 8, 2017

XIII. Israeli Patent No. 267134, granted July 2, 2022

XIV. Israeli Patent No. 290857, granted February 2, 2023

XV. Japanese Patent No. 7246309, granted March 16, 2023

XVI. Japanese Application No. 2023-003205, filed January 12, 2023

XVII. South Korean Application No. 10-2019-7019763, filed December 8, 2017

XVIII. Mexican Patent No. 396386, granted October 12, 2022

XIX. New Zealand Application No. 754522, filed December 8, 2017

XX. U.S. Application No. 16/467,721, filed June 7, 2019

APPENDIX B – LICENSED FIELDS OF USE AND TERRITORY

Licensed Fields of Use:

Promoting anti-cancer activity alone or in combination with standard anti-cancer drugs, including checkpoint inhibitors, and/or immunotherapy and/or radiation for treatment or prevention that falls within the **Jointly Owned Licensed Patent Rights**.

Licensed Territory:

(a) Worldwide

APPENDIX C – ROYALTIES

Royalties:

I. The **Licensee** agrees to pay to the **IC** a noncreditable, nonrefundable license issue royalty in the amount of fifty thousand dollars ($50,000.00) within sixty (60) days from the effective date of this **Agreement.**

II. The **Licensee** agrees to pay to the **IC** a nonrefundable minimum annual royalty in the amount of Thirty thousand dollars ($30,000.00) 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.

(a) On a country-by-country basis, **Licensed Product**-by-**Licensed Product** and **Licensed Process**-by-**Licensed Process** basis, the **Licensee** agrees to pay the **IC** earned royalties of two percent (2%) on **Net Sales** during the period commencing on the **First Commercial Sale** of such **Licensed Product** in such country and expiring on the expiration of the last-to-expire **Jointly Owned Licensed Patent Rights** in such country that covers such **Licensed Product** and **Licensed Process** in such country. Such royalties shall be payable in accordance with Paragraph 9.4.

(b) **Licensee** (or its **Affiliate** or **Sublicensee**) shall be entitled to a credit against earned royalties due to the **IC** under this **Agreement** with respect to any **Licensed Product** in an amount equal to up to fifty percent (50%) of the aggregate royalties, paid by **Licensee** (or its **Affiliate** or **Sublicensee**) to a **Third Party** under any patents that are deemed necessary by **Licensee** (or its **Affiliate** or **Sublicensee**) to make and have made, use and have used, to sell and have sold, to offer to sell, and to import any **Licensed Products**, provided, however, that with respect to each **Licensed Product** the reduction in royalties due to the **IC** under this **Agreement** shall not be reduced to an effective earned royalty rate that is less than one percent (1.%). Upon request, **Licensee** shall furnish documentation to **IC** evidencing its payments and payment obligations to **Third Parties** under this Paragraph, including the identity of those patents or other intellectual property rights for which such payments are paid to a **Third Party**.

IV. The **Licensee** agrees to pay the following **IC Benchmark** royalties for the first **Licensed Product or Licensed Process** within sixty (60) days of the first achievement of each such **Benchmark** by **Licensee** or **Affiliate** or **Sublicensee.** For clarity, the **Benchmark** royalties shall be payable one (1) time only, upon achievement by the first **Licensed Product or Licensed Process** in the **Licensed Field of Use**, regardless of the number of **Licensed Products** or **Licensed Process** that achieve such **Benchmarks.**

(a) One hundred thousand Dollars ($100,000.00) upon dosing of the first patient with the first **Licensed Product** or **Licensed Process** in the first **Phase 2 Clinical Study** or foreign equivalent of such **Licensed Product** in the **Licensed Fields of Use**.

(b) Two hundred thousand Dollars ($200,000.00) upon dosing of the first patient with the first **Licensed Product** or **Licensed Process** in the first **Phase 3 Clinical Study** or foreign equivalent of such **Licensed Product** or **Licensed Process** in the **Licensed Fields of Use**.

(c) Three hundred thousand Dollars ($300,000.00) upon acceptance for review of the first New Drug Application ("**NDA**") filed with the **FDA** for the first **Licensed Product** or **Licensed Process** in the **Licensed Fields of Use**.

V. Six hundred twenty-five thousand Dollars ($625,000.00) upon the **First Commercial Sale** of the first **Licensed Product** or **Licensed Process** in the **United States**. The **Licensee** agrees to pay the **IC** sublicensing royalties of five percent (5%) on **Sublicensing Revenue** received for granting each sublicense to a **Sublicensee** within sixty (60) days of its receipt of such **Sublicensing Revenue**. To avoid double counting of payments to the **IC** hereunder, **Licensee** shall have the right to credit specific **Benchmark** royalties paid under Section IV for achievement of the same specific **Benchmark** activity by the **Sublicensee** on behalf of the **Licensee**, and shall not be subject to the **Sublicensing Revenue** under this Section V.

APPENDIX D – BENCHMARKS AND PERFORMANCE

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

Benchmark	Deadline

Dosing of the first patient with a **Licensed Product** in a **Phase 2 Clinical Study** of such **Licensed Product** in the **Licensed Fields of Use**	October 1, 2024
Dosing of the first patient with a **Licensed Product** in a **Phase 3 Clinical Study** of such **Licensed Product** in the **Licensed Fields of Use**	October 1, 2027
Acceptance for review of the first **NDA** filed with the **FDA** for a **Licensed Product** in the **Licensed Fields of Use**	October 1, 2029
First Commercial Sale of a **Licensed Product** or **Licensed Process** in the **United States**	October 1, 2031

APPENDIX E – COMMERCIAL DEVELOPMENT PLAN

Licensee and/or its **Affiliate** intends to strategically collaborate with one or more large pharmaceutical companies that have the in-house expertise and resources to expedite the clinical trials needed for regulatory approval of **Licensed Products**. **Licensee** believes that successful clinical trials showing efficacy in multiple cancer types will significantly increase the attractiveness of **Licensed Products** to large pharmaceutical companies and likelihood of rapid and successful development of LB-100 as a widely useful potentiator of cancer immunotherapy. Based on the outcome of human clinical trials and subsequent approval of **Licensed Products** by appropriate regulatory authorities in applicable countries or jurisdictions in the **Licensed Territory**, **Licensee** (or its **Affiliate** and/or **Sublicensees**) will finalize marketing and sales strategies in those countries or jurisdictions. **Licensee's** and its **Affiliate's** plan is for one or more large pharmaceutical companies having established regional marketing capabilities to market the **Licensed Products** in the applicable countries of the **Licensed Territory**.

- **Licensee** recently signed an agreement with GlaxoSmithKline (GSK) and MD Anderson Cancer Center to conduct a phase 1b clinical trial with **Licensee's** LB-100 and GSK's immunotherapy Dostarlimab in ovarian clear cell carcinoma. Details about the trial can be found on www.clinicaltrials.gov (NCT06065462). **Licensee** is in advanced discussions with the Netherlands Cancer Institute and Roche to conduct a clinical trial testing Roche's checkpoint inhibitor drug Atezolizumab and **Licensee's** drug LB- 100 combination in metastatic colon cancer (NCT06012734). Currently **Licensee** and/or its **Affiliate** is conducting a phase 1b clinical trial in Small Cell Lung Cancer with two large comprehensive cancer centers in the United States, designed to show the safety of the combination of **Licensee's** LB-100 and standard of care immunotherapy (NCT04560972). **Licensee** anticipates that the clinical studies for metastatic colorectal cancer and for ovarian clear cell carcinoma will commence in 2023 and that one or more Phase 2 Clinical Studies will commence in 2024.

- **Licensee** and/or its **Affiliate** will seek to work with pharmaceutical companies and clinical trial sites (including comprehensive cancer centers) to initiate clinical trials within timeframes that will meet the **Benchmarks**. To this end, **Licensee** and/or its **Affiliate** has established a clinical supply of LB-100 approved in both the United States and in an EU country.

- Data from the clinical trials will be the subject of various regulatory filings for marketing approval in applicable countries in the **Licensed Territory**.

- Once marketing approval is received, **Licensee** (or its **Affiliate** and/or **Sublicensee**) will commercialize the **Licensed Products** in markets where regulatory approval is obtained.

APPENDIX F – EXAMPLE ROYALTY REPORT

Required royalty report information includes:

- 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

New Payment Options Effective March 2018

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

Credit and Debit Card Payments: Credit and debit card payments can be submitted for amounts up to $24,999. Submit your payment through the U.S. Treasury web site located at: **https://www.pay.gov/public/form/start/28680443.**

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

The **IC** encourages its 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/public/form/start/28680443. Please note that the IC "only" accepts ACH payments through this U.S. Treasury web site.

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:

Please provide the following instructions to your Financial Institution for the remittance of Fedwire payments to the NIH ROYALTY FUND.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3400}	Receiver ABA routing number*	**021030004**
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	**CTR** (*or CTP*)
{4200}	Beneficiary Identifier (account number)	*(enter 12 digit gateway account #)* **875080031006**
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS / NIH (75080031)**
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY NAME**
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER**
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* ***INVOICE NUMBER***
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the payment)*

Notes:
*The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.

Agency Contacts: Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

Drawn on a **foreign bank account** via FEDWIRE:

The following instructions pertain to the Fedwire Network. Deposits made in US Dollars (USD).

Should your remitter utilize a correspondent US domestic bank in transferring electronic funds, the following Fedwire instructions are applicable.

Fedwire Field Tag	Fedwire Field Name	Required Information
{1510}	Type/Subtype	**1000**
{2000}	Amount	*(enter payment amount)*
{3100}	Sender Bank ABA routing number	*(enter the US correspondent bank's ABA routing number)*
{3400}	Receiver ABA routing number*	**021030004**
{3400}	Receiver ABA short name	**TREAS NYC**
{3600}	Business Function Code	**CTR** (*or CTP*)
{4200}	Beneficiary Identifier (account number)**	*(enter 12 digit gateway account #)* **875080031006**
{4200}	Beneficiary Name	*(enter agency name associated with the Beneficiary Identifier)* **DHHS / NIH (75080031)**
{5000}	Originator	*(enter the name of the originator of the payment)* **COMPANY'S NAME**
{6000}	Originator to Beneficiary Information – Line 1	*(enter information to identify the purpose of the payment)* **ROYALTY**
{6000}	Originator to Beneficiary Information – Line 2	*(enter information to identify the purpose of the payment)* **LICENSE NUMBER**
{6000}	Originator to Beneficiary Information – Line 3	*(enter information to identify the purpose of the payment)* ***INVOICE NUMBER***
{6000}	Originator to Beneficiary Information – Line 4	*(enter information to identify the purpose of the payment)*

Notes:
*The financial institution address for Treasury's routing number is 33 Liberty Street, New York, NY 10045.
Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – **SWIFT CODE: FRNYUS33

Agency Contacts:

Office of Technology Transfer (OTT) (301) 496-7057 OTT-Royalties@mail.nih.gov

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
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
3180 Rider Trail S.
Earth City, MO 63045
Phone: (800) 495-4981

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

National Institutes of Health
Office of Technology Transfer
License Compliance and Administration
Royalty Administration
6701 Rockledge Drive, Suite 700, MS 7788
Bethesda, Maryland 20892 U.S.A.

Exhibit 99.1

LIXTE Biotechnology Enters into Exclusive Immune Oncology Patent License Agreement with NINDS and NCI

Agreement Focuses on Combining LIXTE's LB-100 with Various Innovative Cancer Immunotherapies

PASADENA, CA, February 26, 2024 — LIXTE Biotechnology Holdings, Inc. (Nasdaq: LIXT and LIXTW) ("LIXTE" or the "Company") today announced the signing of an exclusive patent license agreement with the National Institute of Neurological Disorders and Stroke (NINDS) and National Cancer Institute (NCI), each a component of the National Institute of Health (NIH).

Under the terms of the license agreement, LIXTE has licensed exclusively NIH's intellectual property rights claimed for a Cooperative Research and Development Agreement (CRADA) subject invention co-developed with Lixte, and the licensed field of use, which focuses on promoting anti-cancer activity alone, or in combination with standard anti-cancer drugs. The scope of this clinical research extends to checkpoint inhibitors, immunotherapy, and radiation for the treatment of cancer.

"This strategic collaboration marks a significant milestone in advancing LIXTE's mission to advance cancer therapy by developing its first-in-class lead clinical PP2A inhibitor, LB-100, as a potentiator of cancer immunotherapy," said Bas van der Baan, Chief Executive Officer of LIXTE. "We are excited to embark on this journey as it opens up new avenues for advancing our commitment to developing effective and targeted anti-cancer therapies. The agreement reinforces our dedication to pioneering research and delivering innovative solutions to patients battling cancer," he added.

The collaboration harnesses the synergies of LIXTE's innovative compound, LB-100, and NINDS's and NCI's cutting-edge research capabilities. The licensed patent rights provide LIXTE with a unique opportunity to explore and develop novel combination therapies that can potentially transform the landscape of cancer treatment.

LIXTE recently announced the entry of the first patient into a Phase 1b/2 clinical trial to assess whether adding LIXTE's LB-100 to GSK's programmed death receptor-1 (PD-1)-blocking monoclonal antibody, dostarlimab-gxly, has the ability to enhance the effectiveness of immunotherapy in the treatment of ovarian clear cell carcinoma (OCCC). Another Phase 1b clinical trial in small cell lung cancer combining LB-100 with Roche's atezolizumab and chemotherapy is also actively recruiting. The Company intends to develop additional clinical trials with LB-100 to enhance the efficacy of chemotherapy and immunotherapy.

About LIXTE Biotechnology Holdings, Inc.

LIXTE Biotechnology Holdings, Inc. is a clinical-stage pharmaceutical company focused on new targets for cancer drug development and developing and commercializing cancer therapies. LIXTE has demonstrated that its first-in-class lead clinical PP2A inhibitor, LB-100, is well-tolerated in cancer patients at doses associated with anti-cancer activity. Based on extensive published preclinical data (see www.lixte.com), LB-100 has the potential to significantly improve outcomes for patients undergoing various chemotherapies or immunotherapies. LIXTE's new approach has no known competitors and is covered by a comprehensive patent portfolio. Proof-of-concept clinical trials are in progress.

Forward-Looking Statement Disclaimer

This announcement contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934. For example, statements regarding the Company's financial position, business strategy and other plans and objectives for future operations, and assumptions and predictions about future activities, including the continuing development of proprietary compounds, the planning, funding, coordination and potential results of clinical trials, the patent and legal costs to protect and maintain the Company's intellectual property worldwide, and the Company's ability to obtain and maintain compliance with Nasdaq's continued listing requirements, are all forward-looking statements. These statements are generally accompanied by words such as "intend," anticipate," "believe," "estimate," "potential(ly)," "continue," "forecast," "predict," "plan," "may," "will," "could," "would," "should," "expect" or the negative of such terms or other comparable terminology.

The Company believes that the assumptions and expectations reflected in such forward-looking statements are reasonable, based on information available to it on the date hereof, but the Company cannot provide assurances that these assumptions and expectations will prove to have been correct or that the Company will take any action that the Company may presently be planning. However, these forward-looking statements are inherently subject to known and unknown risks and uncertainties. Actual results or experience may differ materially from those expected or anticipated in the forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, regulatory policies, available cash resources, research results, competition from other similar businesses, and market and general economic factors.

Readers are urged to read the risk factors set forth in the Company's filings with the United States Securities and Exchange Commission at https://www.sec.gov. The Company disclaims any intention or obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

For more information about LIXTE, Contact: info@lixte.com
General Phone: (631) 830-7092; Investor Phone: (888) 289-5533

or

PondelWilkinson Inc. Investor Relations
pwinvestor@pondel.com
Roger Pondel: (310) 279-5965; Laurie Berman: (310) 279-5962
