

**SAMPLE**  
**EXCLUSIVE LICENSE AGREEMENT FOR**  
**[ *TITLE* ]\***

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This exclusive license agreement (“AGREEMENT”) is effective on [*DATE*] (“Effective Date”), and is by and between THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, a California corporation, whose legal address is 1111 Franklin Street, 12th Floor, Oakland, California 94607-5200, acting through its Office of Technology Licensing, at the University of California, Berkeley, 2150 Shattuck Avenue, Suite 408, Berkeley, CA 94704-1362 (“REGENTS”) and [*LICENSEE name*], a [*State of incorporation*] corporation having a principal place of business at [*LICENSEE address*] (“LICENSEE”). The parties agree as follows:

**1. BACKGROUND**

- 1.1 REGENTS has an assignment of the [*Title*] invented by [*Inventors’ names*], employed by the University of California, Berkeley (the “INVENTION”), as described in REGENTS’ Case No. [*BK-XXXX-XXX*] and to the patents and patent applications under REGENTS’ PATENT RIGHTS as defined below, which are directed to the INVENTION.
- 1.2 LICENSEE has provided REGENTS with a commercialization plan for the INVENTION in order to evaluate its capabilities as a LICENSEE.
- 1.3 REGENTS and LICENSEE wish to have the INVENTION commercialized and marketed as soon as possible so that the resulting products may be available for public use and benefit.
- 1.4 LICENSEE wishes to acquire a license under REGENTS’ PATENT RIGHTS for the purpose of undertaking development and to manufacture, use, SELL, offer for SALE and import LICENSED PRODUCTS as defined below.
- 1.5 As part of its public mission to bring products to the marketplace, the REGENTS uses good faith efforts to enable underserved communities, which have limited access to adequate quantities of medical innovations arising from REGENTS’s laboratories, to have affordable access to these innovative products.
- 1.6 [*IF APPLICABLE*] *The development of the INVENTION was sponsored in part by various grants by U.S. Government agencies, and as a consequence, REGENTS elected to retain title to the INVENTION subject to the rights of the U.S. Government under 35 U.S.C. 200-212 and implementing regulations, including that REGENTS, in turn, has granted to the U.S. Government a non-exclusive, non-transferable irrevocable, paid-up license to practice or have practiced the INVENTION for or on behalf of the U.S. Government throughout the world. These U.S. Government grants*

\* The license agreement will not be limited to the provisions of this Sample License Agreement, and may include other provisions as appropriate on a case by case basis, such as provisions required for inventions arising from Howard Hughes Medical Institute appointees, and the like.

are \_\_\_\_\_ Contract No. \_\_\_\_\_ and \_\_\_\_\_ Contract No. \_\_\_\_\_.

- 1.7 **[IF APPLICABLE]** LICENSEE entered into a **[Agreement type]** agreement and extension thereof with REGENTS effective **[Date]**, terminating on **[Date]**, for the purpose of evaluating the INVENTION and granting LICENSEE an exclusive right to negotiate an option or exclusive license in REGENTS' PATENT RIGHTS to the INVENTION, which **[Agreement type]** agreement covers LICENSEE's commitment to reimburse REGENTS' patent costs during the period of good-faith negotiation for an exclusive license.

## 2. DEFINITIONS

- 2.1 "ACTIVE INGREDIENT" means an active ingredient as defined in 21 CFR 210.3(b)(7).
- 2.2 "AFFILIATE" means any entity which, directly or indirectly, CONTROLS LICENSEE, is CONTROLLED by LICENSEE, or is under common CONTROL with LICENSEE. "CONTROL" means (i) having the actual, present capacity to elect a majority of the directors, or the power to direct greater than fifty percent (50%) of the voting rights entitled to elect directors, of such entity; or (ii) in any country where the local law will not permit foreign equity participation of a majority, the ownership or control (directly or indirectly) of the maximum percentage of such outstanding stock or voting rights permitted by local law. For clarity, an entity will be deemed an AFFILIATE of LICENSEE solely for the term during which it satisfies the foregoing definition.
- 2.3 "CHANGE of CONTROL" means (i) a consolidation, acquisition or merger of the LICENSEE with or into any other corporation or other entity or person, or any other corporate reorganization, other than any such consolidation, acquisition, merger or reorganization in which the shares of capital stock of the LICENSEE immediately prior to such consolidation, acquisition, merger or reorganization continue to represent a majority of the voting power of the surviving entity immediately after such consolidation, acquisition, merger or reorganization; (ii) any transaction or series of related transactions to which the LICENSEE is a party in which in excess of 50% of the LICENSEE's voting power is transferred; or (iii) the sale or transfer of all or substantially all of the LICENSEE's assets, or the exclusive license of all or substantially all of the LICENSEE's intellectual property; provided that a CHANGE of CONTROL shall not include any transaction or series of transactions principally for bona fide equity financing purposes in which cash is received by the LICENSEE or any successor, indebtedness of the LICENSEE is cancelled or converted, or a combination thereof.
- 2.4 "COMBINATION PRODUCTS" means a combination of (a) a LICENSED PRODUCT and (b) OTHER COMPONENTS, where such combinations of (a) and (b) are co-formulated, co-packaged or SOLD under one pricing scheme (whether payment of such price is paid to the same or to more than one seller).

- 2.5 "HUMANITARIAN PURPOSES" means (a) the use of LICENSED PRODUCTS and LICENSED SERVICES for research and development purposes by any nonprofit organization or other third party, anywhere in the world that has the express purpose of developing the LICENSED PRODUCTS or LICENSED SERVICES for use solely for protection from, treatment of, or diagnosis of Neglected Diseases in a Low- or Middle-income country as that term is defined by the World Bank (hereinafter "LMI COUNTRY(IES)"); and (b) SALE of LICENSED PRODUCTS and LICENSED SERVICES in LMI COUNTRIES at or below the cost of manufacture and distribution.
- 2.6 "LICENSED COMPOUND" means any molecule or compound that constitutes a LICENSED PRODUCT *[or, if applicable, Know-How Product - To be defined]* that is included within a COMBINATION PRODUCT.
- 2.7 "LICENSED FIELD OF USE" means *[Field]*\_\_\_\_\_.
- 2.8 "LICENSED METHOD" means any process or method the use or practice of which, but for the license pursuant to this AGREEMENT, would infringe, or contribute to or induce the infringement of, any pending VALID CLAIM (were it to have issued) or issued VALID CLAIM under REGENTS' PATENT RIGHTS in that country in which the LICENSED METHOD is used or practiced.
- 2.9 "LICENSED PRODUCTS" means all kits, compositions of matter, articles of manufacture, materials, and products, the manufacture, use, SALE, offer for SALE, or import of which: a) would require the performance of the LICENSED METHOD; or b) but for the license granted pursuant to this AGREEMENT, would infringe, or contribute to or induce the infringement of, a pending VALID CLAIM (were it to have issued) or issued VALID CLAIM.
- 2.10 "LICENSED SERVICE" means a service provided using a LICENSED PRODUCT or LICENSED METHOD.
- 2.11 "LICENSED TERRITORY" means the United States of America, its territories and possessions, and any foreign countries where REGENTS' PATENT RIGHTS are licensed to LICENSEE under this AGREEMENT.
- 2.12 "NET SALES" means the total amount invoiced or otherwise charged (including fair market value of any non-cash consideration) by LICENSEE or a SUBLICENSEE on the SALE, lease, provision, transfer, or other disposition of a LICENSED PRODUCT or LICENSED SERVICE, after deduction of the following in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP") to the extent separately itemized in the applicable invoice, and not otherwise reimbursed, and allowed:
- (a) cash, trade or quantity discounts;
  - (b) sales, use, tariff, import/export duties or other excise taxes when included in gross sales, but not income taxes derived from such sales, and value added taxes, but only to the extent such value-added tax is not subject to a credit or deduction to a taxing authority;

- (c) discounts actually granted, rebates, refunds, chargebacks actually allowed or granted;
- (d) freight and other transportation or handling expenses or charges (actually incurred), including insurance; and
- (e) allowances or credits to customers because of rejections or returns.

If LICENSEE or a SUBLICENSEE makes any SALES to any third party in a transaction in a given country that is not an arms'-length transaction, or a LICENSED PRODUCT or LICENSED SERVICE is SOLD, transferred or otherwise provided to a third party without charge or at a discount, then NET SALES means the gross amount normally charged in arm's length transactions in such country less the allowable deductions set forth above.

In the case of transfers between any of LICENSEE, SUBLICENSEE, or their respective AFFILIATES, (i) a SALE to a SUBLICENSEE or AFFILIATE for end use (but not resale) by the SUBLICENSEE or AFFILIATE will be treated as a SALE at list price, and (ii) a SALE to a SUBLICENSEE or AFFILIATE for resale by the SUBLICENSEE or AFFILIATE will not be treated as a SALE; provided that NET SALES shall include the amounts invoiced by such AFFILIATE or SUBLICENSEE to a third party upon resale.

NET SALES shall not include SALES of any LICENSED PRODUCT used for regulatory approvals (e.g., clinical trials), compassionate uses, or other research and development, for which LICENSEE or a SUBLICENSEE does not receive consideration.

- 2.13 "OTHER COMPONENTS" means any delivery system(s), device(s), companion diagnostics and/or one or more additional ACTIVE INGREDIENTS, none of which are LICENSED PRODUCTS, but which may each or collectively form the basis for a separate product, and: i) OTHER COMPONENT enhances the market value of the COMBINATION PRODUCT; and ii) the SALE, use or import of such OTHER COMPONENT by itself does not contribute to or induce the infringement of REGENTS' PATENT RIGHTS.
- 2.14 "REGENTS' PATENT RIGHTS" means REGENTS' rights in (a) the patent and patent applications expressly identified in Appendix C and their foreign counterparts; (b) any patent applications claiming priority to those identified in subpart (a) above such as divisionals, continuations and continuation-in-part applications (but with respect to continuations-in-part solely to the extent of those claims that are both entirely supported by the specification and entitled to the priority date of any patent application or patent identified in subpart (a) above); and (c) any patents issuing from any patent application identified in subparts (a)-(b), including reissues, reexaminations, and substitutions, as well as any applicable patent extensions or term adjustments.
- 2.15 "SALE" means, for LICENSED PRODUCTS and LICENSED SERVICES, the act of selling, leasing or otherwise transferring, providing, or furnishing such product or service, and for LICENSED METHOD the act of performing such method, for any

use or for any consideration. Correspondingly, "SELL" means to make or cause to be made a SALE, and "SOLD" means to have made or caused to be made a SALE.

- 2.16 "SUBLICENSE" means any transaction with a third party in which LICENSEE or SUBLICENSEE: (a) grants, transfers or agrees not to assert any of the rights licensed to LICENSEE hereunder, or (b) is under an obligation to grant or transfer such rights or to forebear from granting or transferring such rights, including by means of an option.
- 2.17 "SUBLICENSEE" means any third party, including AFFILIATES, granted a SUBLICENSE to all or any portion of REGENTS' PATENT RIGHTS.
- 2.18 "SUBLICENSE INCOME" means any consideration (including, without limitation, any licensing or optioning fees, or license maintenance fees, or milestone payments, and fair market value of any non-cash consideration) received by, or payable to, LICENSEE or SUBLICENSEE from any SUBLICENSEE, based in whole or in part on rights granted in a SUBLICENSE. SUBLICENSE INCOME excludes:
- (a) earned royalty payments but only to the extent such royalty payments are calculated using the same SALES that generated payment of an earned royalty to the REGENTS pursuant to Paragraph 6.1;
  - (b) payments for equity or debt securities of LICENSEE (except to the extent such payments exceed the fair market value of such securities upon date of receipt, in which case such premiums over fair market value shall be deemed to be "SUBLICENSE INCOME");
  - (c) payments for bona fide research or development to be applied directly to the future research and/or development of LICENSED PRODUCTS; and
  - (d) payments and reimbursement of Patent Costs previously paid to REGENTS by LICENSEE with respect to the filing, preparation, prosecution or maintenance of the REGENTS' PATENT RIGHTS.
- 2.19 "VALID CLAIM" means (a) any claim of a pending patent application included within the REGENTS' PATENT RIGHTS that has not been abandoned or has not been finally rejected without the possibility of appeal or refiling, or (b) any claim on an issued and unexpired patent included within the REGENTS' PATENT RIGHTS which has not been revoked or held unenforceable or invalid by a final judgment of a court or other governmental agency of competent jurisdiction from which no appeal can be or is taken, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise.

### 3. GRANT

- 3.1 **License Grant.** Subject to the limitations set forth in this AGREEMENT, including the license granted to the U.S. Government and the rights reserved in Paragraph 3.2 (Reservation of Rights), REGENTS hereby grants and LICENSEE hereby accepts an exclusive license under REGENTS' PATENT RIGHTS to make, use, offer for SALE, import, and SELL LICENSED PRODUCTS and LICENSED SERVICES, and to

practice LICENSED METHOD, in the LICENSED FIELD OF USE in the LICENSED TERRITORY.

- 3.2 **Reservation of Rights.** The REGENTS reserves on behalf of itself and any other educational or nonprofit institutions the right to make, use, and practice the INVENTION, the REGENTS' PATENT RIGHTS, and any technology created by the REGENTS relating to any of the foregoing for educational and research purposes, including publication and other communication of any research results.
- 3.3 **Humanitarian Purposes.**
- (a) REGENTS further reserves the right to license REGENTS' PATENT RIGHTS to any third parties solely for HUMANITARIAN PURPOSES. Such licenses for HUMANITARIAN PURPOSES will (i) expressly exclude the right of the third party licensee to export or SELL the LICENSED PRODUCTS from a LMI COUNTRY into a market outside of the LMI COUNTRY where LICENSEE has introduced or will introduce a LICENSED PRODUCT and where REGENTS' PATENT RIGHTS exist (such markets hereinafter the "LICENSEE MARKETS") and (ii) require the third party licensee to create and maintain distinctive trade dress and trademarks that clearly distinguish third party LICENSED PRODUCTS and LICENSED SERVICES from LICENSEE'S LICENSED PRODUCTS and LICENSED SERVICES, (iii) require such third party LICENSEE's sale of LICENSED PRODUCTS and LICENSED SERVICES in such LMI COUNTRIES be at or below cost. For avoidance of doubt, such third party licensee may be permitted to export LICENSED PRODUCTS from the LMI COUNTRY of origin to other LMI COUNTRIES and all other countries that are mutually agreed to by REGENTS and LICENSEE; and
- (b) Notwithstanding the foregoing, prior to issuance of any such license to REGENTS' PATENT RIGHTS to a third party, REGENTS will notify LICENSEE of its intention to grant such license so that LICENSEE may have the opportunity to fill the anticipated market need itself and/or to engage in discussions for a sublicense with such third party in accordance with the procedures set forth in Paragraph 4.8. In the event any LICENSED PRODUCT SOLD in any LMI COUNTRY by any such third party according to the provisions of Paragraph 3.3(a) is exported, re-SOLD or otherwise introduced in any LICENSEE MARKETS, LICENSEE will provide REGENTS with written notification thereof, and if such exportation, re-sale or introduction does not cease within ninety (90) days after the date of such notice, then an amount equal to the retail price of LICENSED PRODUCT so exported, re-SOLD or introduced to such LICENSEE Market will be credited to royalties due to REGENTS hereunder.
- 3.4 **Entity Status.** LICENSEE will have a continuing responsibility to keep REGENTS informed of the large/small entity status, as defined in 15 U.S.C. §632, of itself and its SUBLICENSEES.
- 3.5 **(IF APPLICABLE) U.S. Government Rights.** *The INVENTION was funded in part by the U.S. Government. In accordance with PL 96-517 as amended by PL 98-620, to the extent required by law or regulation, any products covered by patent*

*applications or patents claiming the INVENTION and SOLD in the United States will be substantially manufactured in the United States.*

3.6 **Permitted Subcontracting.** The license granted by REGENTS in Paragraph 3.1 includes the right to engage in Permitted Subcontracting, as defined herein. “Permitted Subcontracting” shall include the grant by LICENSEE or SUBLICENSEE of rights under this AGREEMENT to: (i) third parties contractually bound to LICENSEE or SUBLICENSEE for the sole purpose of marketing or promoting a LICENSED PRODUCT; (ii) third party contract research organizations contractually bound to LICENSEE or SUBLICENSEE with no other rights under REGENTS’ PATENT RIGHTS other than to perform research and development on behalf of LICENSEE or SUBLICENSEE; and (iii) third party contract manufacturing organizations contractually bound to LICENSEE or SUBLICENSEE with no other rights under REGENTS’ PATENT RIGHTS than to manufacture on behalf of LICENSEE or SUBLICENSEE. Such third parties listed in (i), (ii) and (iii) above are “Permitted Subcontractors” and any act or omission by a Permitted Subcontractor shall be deemed an act or omission of LICENSEE. For clarity, Permitted Subcontracting is not considered sublicensing of rights under this AGREEMENT. LICENSEE shall (and shall cause SUBLICENSEES, as the case may be) to incorporate terms and conditions into its agreement for Permitted Subcontracting that are sufficient to enable LICENSEE to comply with this AGREEMENT, and LICENSEE shall ensure that all such agreements do not conflict with the terms and conditions of this AGREEMENT. All such Permitted Subcontracting shall have subcontracts that provide for the automatic assignment to LICENSEE of any and all intellectual property generated by the Permitted Subcontractor, its employees, and consultants in the course of performing the subcontracted services to LICENSEE or SUBLICENSEE (other than with respect to intellectual property generated that relates to such Permitted Subcontractor’s platform or background intellectual property, ownership of which may remain with such subcontractor).

#### 4. SUBLICENSES

4.1 REGENTS also grants to LICENSEE the right to SUBLICENSE to AFFILIATES and third parties the right to make, use, offer for SALE, import, and SELL LICENSED PRODUCTS and LICENSED SERVICES, and to practice LICENSED METHOD, provided that LICENSEE has exclusive rights under this AGREEMENT at the time of sublicensing. Every such SUBLICENSE will include:

- (a) a statement setting forth the date upon which LICENSEE's exclusive rights, privileges, and license hereunder will expire;
- (b) terms consistent with and be subject to, the terms in this AGREEMENT, including without limitation, all applicable obligations due to REGENTS and the provisions contained in:
  - (i) Paragraph 3.2 (Reservation of Rights); (ii) *(if applicable)* Paragraph 3.5 (*U.S. Government Rights*); (iii) Article 4 (Sublicenses); (iv) Paragraph 6.5 (Validity Challenge); (v) Article 9 (Books and Records); (vi) Article 15 (Marking); (vii) Article 16 (Use of Names and Trademarks); (viii) Article 17 (Limited

Warranties); (ix) Article 18 (Patent Infringement); (x) Article 19 (Indemnification); (xi) Article 20 (Compliance with Laws), (xii) Article 31 (Bankruptcy) etc., other than those rights and obligations specified in Paragraph 5.1 (License Issue Fee), Paragraph 6.2 (License Maintenance Fee) and Paragraph 6.3 (Minimum Annual Royalty) and, it being understood that, except as otherwise set forth in the AGREEMENT, LICENSEE is responsible to pay REGENTS a royalty as described in this AGREEMENT on SUBLICENSEE'S SALES of LICENSED PRODUCT or LICENSED SERVICE;

- (c) a provision requiring payment of royalties to LICENSEE in an amount sufficient to permit LICENSEE to meet its royalty obligations to REGENTS at the rates and basis set forth in this AGREEMENT; and
- (d) a prohibition on the grant of further SUBLICENSES.

4.2 LICENSEE will pay to REGENTS the following percentages of any SUBLICENSE INCOME:

(a) [Written percent] (XX%) of SUBLICENSE INCOME received with respect to a SUBLICENSE executed \_\_\_\_\_; and

(b) [Written percent] (XX%) of SUBLICENSE INCOME received with respect to a SUBLICENSE executed \_\_\_\_\_.

For the purposes of calculating the amount of SUBLICENSE INCOME due REGENTS, the amount of SUBLICENSE INCOME due REGENTS is based on when the SUBLICENSE is executed. SUBLICENSE INCOME received by LICENSEE, for achievement of any of the substantially the same milestone events by a SUBLICENSEE that is required to be paid to REGENTS, will be reduced by the amount of the milestone payment due and paid from LICENSEE to REGENTS in respect of the substantially the same milestone event.

4.3 LICENSEE will notify REGENTS of each SUBLICENSE granted hereunder and within 30 days after execution of each SUBLICENSE, will furnish to REGENTS a copy of each such SUBLICENSE and any amendments to the SUBLICENSE; provided, however, that LICENSEE has the right to redact any portion of the SUBLICENSE only as necessary to remove content that does not include obligations due to REGENTS.

4.4 AFFILIATES will have no licenses under REGENTS' PATENT RIGHTS except as granted by SUBLICENSE pursuant to this AGREEMENT.

4.5 For the purposes of this AGREEMENT, the operations of all SUBLICENSEES are deemed to be the operations of LICENSEE, for which LICENSEE is responsible.

4.6 LICENSEE will collect and guarantee payment of all monies and other consideration due REGENTS from SUBLICENSEES, and deliver all reports due REGENTS and received from SUBLICENSEES.

4.7 If the AGREEMENT terminates for any reason, REGENTS will provide to each SUBLICENSEE the right to enter into a license of the REGENTS' PATENT



RIGHTS in the applicable SUBLICENSE directly with REGENTS, under the same terms and conditions as the AGREEMENT (as reasonably applied to such REGENTS' PATENT RIGHTS); provided that (a) REGENTS and SUBLICENSEE will discuss in good faith any appropriate modifications to such terms and conditions and (b) REGENTS is not obligated to enter into a license agreement having a scope of REGENTS' PATENT RIGHTS, licensed field of use, territory, or other obligation on the part of REGENTS that would exceed those in the applicable SUBLICENSE.

REGENTS' obligation above will apply only if (i) REGENTS is legally, contractually, and per its policies permitted to enter into such license at the time; (ii) SUBLICENSEE provides written notice to both REGENTS and LICENSEE within 90 days after such termination of its desire for such discussions, and LICENSEE does not dispute the termination; (iii) SUBLICENSEE is not an AFFILIATE of LICENSEE; (iv) SUBLICENSEE is not currently involved in litigation as an adverse party to the REGENTS and (v) SUBLICENSEE is not in material breach of the SUBLICENSE in the two year period prior to the AGREEMENT termination. The SUBLICENSE shall not be terminated during the 90-day notice period and the negotiation period between REGENTS and SUBLICENSEE, unless SUBLICENSEE is in material breach of their SUBLICENSE.

4.8 (a) If REGENTS (to the extent of the actual knowledge of the licensing professional responsible for administration of this case) or a third party discovers and notifies that licensing professional that the INVENTION is useful for an application covered by the LICENSED FIELD OF USE, but for which LICENSED PRODUCTS have not been developed or are not currently under development by LICENSEE, then REGENTS, as represented by the Office of Technology Licensing, will give written notice to LICENSEE, except for: 1) information that is subject to restrictions of confidentiality with third parties, and 2) information which originates with REGENTS' personnel who do not assent to its disclosure to LICENSEE. LICENSEE will have ninety (90) days to give REGENTS written notice stating whether LICENSEE elects to develop LICENSED PRODUCTS for the application.

(b) If LICENSEE elects to develop and commercialize the proposed LICENSED PRODUCTS for the new application, LICENSEE will submit progress reports or royalty reports to REGENTS pursuant to Article 8 (Progress and Royalty Reports). If LICENSEE elects not to develop and commercialize the proposed LICENSED PRODUCTS for use in the new application, REGENTS may seek (a) third party(ies) to develop and commercialize the proposed LICENSED PRODUCTS for the new application. If REGENTS is successful in finding a third party, it will refer such third party to LICENSEE. If the third party requests a SUBLICENSE under this AGREEMENT, then LICENSEE will report the request to REGENTS within thirty (30) days from the date of such written request. If the request results in a SUBLICENSE, then LICENSEE will report it to REGENTS pursuant to Paragraph 4.3.

(c) If LICENSEE refuses to grant a SUBLICENSE to the third party, then within thirty (30) days after such refusal LICENSEE will submit to REGENTS a report specifying the license terms proposed by the third party and a written justification for LICENSEE's refusal to grant the proposed SUBLICENSE. If REGENTS, at its

sole discretion, determines that the terms of the SUBLICENSE proposed by the third party are reasonable under the totality of the circumstances, taking into account LICENSEE's LICENSED PRODUCTS in development, then REGENTS will have the right to grant to the third party a license to make, have made, use, SELL, offer for sale and import products for use in the LICENSED FIELD OF USE at substantially the same terms last proposed to LICENSEE by the third party providing royalty rates are at least equal to those paid by LICENSEE.

4.9 **Affordable Access Plan.** Within three (3) months of receiving FDA (or its foreign equivalent's) approval of a LICENSED PRODUCT, LICENSEE will provide the REGENTS with either (a) an Affordable Access Plan (defined below), or (b) a written explanation as to why such an Affordable Access Plan is not needed or infeasible. In the case of (b), LICENSEE agrees to discuss such reasoning with the REGENTS in good faith within one (1) month thereafter ("Initial Discussion") and, if following such Initial Discussion the REGENTS concludes an Affordable Access Plan is reasonable and desired, to provide an Affordable Access Plan to the REGENTS within three (3) months of such Initial Discussion. The "Affordable Access Plan" means LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in a) Low and Middle Income Countries as defined by the World Bank Group ("LMICs"), and b) vulnerable, underserved, and special needs populations in the U.S., as defined by the Department of Health and Human Services, such as through licensing or partnerships including with non-profit organizations. To the extent such Affordable Access Plan includes Proprietary Information, LICENSEE will also provide a non-confidential version or statement of such Plan that the REGENTS can make available to third parties:

- (a) A specified set of ("LMICs") in which the LICENSEE does not intend to commercialize the LICENSED PRODUCTS (the "Non-Commercialized Territory");
- (b) LICENSEE'S and/or its SUBLICENSEES' plans (including strategies and timelines) reasonably intended to support affordable access in LMICs and Non-Commercialized Territories, such as through licensing or partnerships including with non-profit organizations; and
- (c) LICENSEE'S and/or its SUBLICENSEE' plans (including strategies and timelines) reasonably intended to support affordable access for the vulnerable, underserved and special needs populations in the U.S.

Within thirty (30) days of the REGENTS' request (but no more often than once annually), LICENSEE agrees to confer with the REGENTS to review LICENSEE'S progress, and to consider in good faith any modifications suggested by the REGENTS, with respect to its Affordable Access Plan ("Progress Discussions"). For clarity, while the REGENTS may invite a designated entity to join either the Initial and/or Progress Discussions under this Paragraph 4.9, such discussions will at all times be made subject to the confidentiality obligations set forth in Article 25 (Confidentiality).

## 5. LICENSE ISSUE FEE

- 5.1 **License Issue Fee.** LICENSEE will pay to REGENTS a non-creditable, non-refundable license issue fee of [*Written amount*] (\$ *Number*) due upon signing of this AGREEMENT. This fee is non-refundable and not an advance against royalties or other payments due under this AGREEMENT.

## 6. ROYALTIES, LICENSE MAINTENANCE FEES, MINIMUM ANNUAL ROYALTIES

- 6.1 **Earned Royalty.** LICENSEE will pay to REGENTS earned royalties at the rate of [*Written percent*] (*Number*%) of the NET SALES of LICENSED PRODUCTS, LICENSED SERVICES, and LICENSED METHODS. Royalties will be payable on SALES covered by both pending patent applications and issued patents. Royalties accruing to REGENTS will be paid to REGENTS quarterly within sixty (60) days after the end of each calendar quarter.
- 6.2 **License Maintenance Fee.** LICENSEE will pay to REGENTS an annual license maintenance fee of [*Written amount*] U.S. Dollars (\$*Number*) on the one (1) year anniversary date of the Effective Date and on each anniversary of the Effective Date thereafter. Notwithstanding the foregoing, the license maintenance fee will not be due and payable on any anniversary of the Effective Date, if on such date the LICENSEE is selling LICENSED PRODUCTS or LICENSED METHODS, and LICENSEE pays an earned royalty to REGENTS.
- 6.3 **Minimum Annual Royalty.** Beginning in the calendar year after the first occurrence of SALES, and in each succeeding calendar year thereafter, LICENSEE will pay to REGENTS a minimum annual royalty of [*Written amount*] U.S. Dollars (\$ *Number*) for the life of this AGREEMENT. This minimum annual royalty will be paid to REGENTS by February 28 of each year and will be credited against the earned royalty due and owing for the calendar year in which the minimum payment is made.
- 6.4 **Milestone Payments.** [*TBD*].

LICENSEE shall make each such milestone payment to REGENTS irrespective of whether the associated milestone was reached by LICENSEE itself, by a SUBLICENSEE and/or by a third party acting on behalf of LICENSEE or SUBLICENSEE.

- 6.5 **Validity Challenge.** Should LICENSEE or a SUBLICENSEE, itself or through a third party, bring an action seeking to invalidate any REGENTS' PATENT RIGHTS and notwithstanding the earned royalty rates listed above:
- (a) LICENSEE or the SUBLICENSEE will pay royalties to REGENTS at the rate of two times Y percent (2xY%) of the NET SALES of all LICENSED PRODUCTS SOLD during the pendency of such action. Moreover, should

the outcome of such action determine that any claim of a patent challenged by LICENSEE is both valid and infringed by a LICENSED PRODUCT, LICENSEE or the SUBLICENSEE will pay royalties at the rate of three times Y percent (3xY%) of the NET SALES of all LICENSED PRODUCTS SOLD, when Y is the royalty rate in 6.1,

- (b) LICENSEE or the SUBLICENSEE will have no right to recoup any royalties paid before or during the period challenge,
- (c) any dispute regarding the validity of any REGENTS' PATENT RIGHTS will be litigated in the courts located in California, and the parties agree not to challenge personal jurisdiction in that forum, and;
- (d) LICENSEE or the SUBLICENSEE will provide written notice to REGENTS at least three months prior to bringing an action seeking to invalidate any REGENTS' PATENT RIGHTS. LICENSEE or the SUBLICENSEE will include with such written notice an identification of all prior art it believes invalidates any claim of REGENTS' PATENT RIGHTS.

6.6 **Payments.** All payments due REGENTS will be payable in United States dollars by check payable to "REGENTS of the University of California" or by wire transfer to REGENTS at the addresses shown in Article 23 (Notices). When LICENSED PRODUCTS or LICENSED SERVICES are SOLD for monies other than United States dollars, earned royalties will first be determined in the foreign currency of the country in which the SALE was made and then converted into equivalent United States dollars. The exchange rate will be that rate quoted in the *Wall Street Journal* on the last business day of the reporting period. REGENTS may provide invoices upon request or as a courtesy, but failure to receive an invoice from REGENTS does not relieve or otherwise change LICENSEE'S obligation to make accurate and complete payments at the time such payments are due.

- (a) **Taxes.** SUBLICENSE INCOME, earned royalties, and other consideration accrued in any country outside the United States may not be reduced by any taxes, fees or other charges imposed by the government of such country. LICENSEE will also be responsible for all bank transfer charges.
- (b) **Late Payments.** If monies owed to REGENTS under this AGREEMENT are not received by REGENTS when due, LICENSEE will pay to REGENTS interest charges at a rate of ten percent (10%) per annum. Such interest will be calculated from the date payment was due until actually received by REGENTS. Such accrual of interest will be in addition to, and not in lieu of, enforcement of any other rights of REGENTS related to such late payment. Acceptance of any late payment will not constitute a waiver under Article 24 (Waiver) of this AGREEMENT.
- (c) **Payments accrued prior to expiration.** If any patent or patent application, or any VALID CLAIM thereof, included within REGENTS' PATENT RIGHTS expires or is held invalid in a final decision by a court of competent jurisdiction and last resort and from which no appeal has been or can be taken, all obligations

to pay royalties based on such patent, patent application or VALID CLAIM, or any claims patentably indistinct therefrom will cease as of the date of such expiration or final decision. LICENSEE will not, however, be relieved from paying any royalties that accrued before such expiration or decision or that are based on another VALID CLAIM not expired or involved in such decision.

6.7 **Combination Products.** For COMBINATION PRODUCTS, NET SALES will be calculated as follows:

- (a) If the LICENSED PRODUCT and all OTHER COMPONENTS of the COMBINATION PRODUCT were SOLD separately during the same or immediately preceding calendar quarter, the proration factor will be determined by the formula  $[A / (A+B)]$ , where A is the weighted average invoice price of all LICENSED PRODUCT components during such period when SOLD separately from the OTHER COMPONENT(S), and B is the weighted average gross invoice price of the OTHER COMPONENTS during such period when SOLD separately from the LICENSED PRODUCT (as applicable);
- (b) If the LICENSED PRODUCT components containing only the LICENSED COMPOUND as its ACTIVE INGREDIENT are SOLD separately from the OTHER COMPONENTS, but the OTHER COMPONENTS in such COMBINATION PRODUCT are not SOLD separately, then the proration factor will be determined by the formula  $[A / C]$ , where A is the average gross sales price of all LICENSED PRODUCT components containing only the LICENSED COMPOUND as its ACTIVE INGREDIENT during such period when SOLD separately from the OTHER COMPONENTS, and C is the average gross sales price of the COMBINATION PRODUCT during such period;
- (c) If the LICENSED PRODUCT components containing only the LICENSED COMPOUND as its ACTIVE INGREDIENT are not SOLD separately from the OTHER COMPONENTS, but the OTHER COMPONENTS in such COMBINATION PRODUCT are SOLD separately, then the proration factor will be determined by the formula  $[(C- B) / C]$ , where B is the average gross sales price of the OTHER COMPONENTS included in such COMBINATION PRODUCT if SOLD separately from the OTHER COMPONENTS, and C is the average gross sales price of the COMBINATION PRODUCT during such period;  
or
- (d) If neither the LICENSED COMPOUND nor the OTHER COMPONENTS included in the COMBINATION PRODUCT were SOLD or provided separately during the relevant period, then the proration factor will be mutually agreed upon by the parties in good faith based on the relative value contributed by each component.
- (e) In the event that such separate SALES were not made or performed during the immediately preceding calendar year (“CY”), then the invoiced amounts for the COMBINATION PRODUCT for purposes of calculating NET SALES will be multiplied by the fraction  $C/(C + D)$ , where C is the average fully burdened cost of manufacture of the LICENSED PRODUCTS during the immediately preceding CY and D is the average fully burdened cost of manufacture of the additional items during the immediately preceding CY, in each case calculated in accordance with U.S. GAAP.

- (f) Notwithstanding anything in this AGREEMENT to the contrary, in no event shall the NET SALES for a COMBINATION PRODUCT be less than 50% of the NET SALES for the LICENSED PRODUCT.

## 7. DILIGENCE

7.1 **Development of Licensed Products and/or Licensed Services.** LICENSEE, upon execution of this AGREEMENT, will diligently proceed with the development, manufacture, and SALE of LICENSED PRODUCTS and/or LICENSED SERVICES, and will diligently market them in quantities sufficient to meet the market demand.

7.2 **Development Milestones.** In addition to its obligations under Paragraph 7.1, LICENSEE specifically commits to achieving (either itself or through the acts of a SUBLICENSEE) the following development milestones in its diligence activities under this AGREEMENT:

- (a)
- (b).

7.3 **Failure to Meet Development Milestones.**

(a) If LICENSEE is unable to meet any of its diligence obligations set forth in Paragraphs 7.1 and 7.2, then REGENTS will so notify LICENSEE of failure to perform. LICENSEE will have the right and option to extend the target date of any such due diligence obligation for a period of six (6) months upon the payment of [*Written amount*]-thousand dollars (\$ *Number*) within thirty (30) days of the date to be extended for each such extension option exercised by LICENSEE. LICENSEE may further extend the target date of any diligence obligation for an additional six (6) months upon payment of an additional [*Written amount*] thousand dollars (\$ *Number*). Additional extensions may be granted only by mutual written AGREEMENT of the parties to this AGREEMENT. These payments are in addition to the minimum royalty payments specified in Paragraph 6.3 (Minimum Annual Royalty). Should LICENSEE opt not to extend the obligation or fail to meet it by the extended target date, then REGENTS will have the right and option either to terminate this AGREEMENT or to reduce LICENSEE's exclusive license to a non-exclusive royalty-bearing license. This right, if exercised by REGENTS, supersedes the rights granted in Article 3 (Grant). The right to terminate this AGREEMENT or reduce LICENSEE's exclusive license granted hereunder to a non-exclusive license will be REGENTS' sole remedy for breach of Paragraph 7.1 or 7.2.

(b) To exercise either the right to terminate this AGREEMENT or to reduce the license to a non-exclusive license for lack of diligence under Paragraph 7.1 or 7.2, REGENTS will give LICENSEE written notice of the deficiency. LICENSEE thereafter has sixty (60) days to cure the deficiency. If REGENTS has not received satisfactory tangible evidence that the deficiency has been cured by the end of the sixty (60) - day period, then REGENTS may, at its option, either terminate the AGREEMENT or reduce LICENSEE's exclusive license to a non-exclusive license by giving written notice to LICENSEE. These notices will be subject to Article 23 (Notices).

## 8. PROGRESS AND ROYALTY REPORTS

- 8.1 **Progress Reports.** For the period beginning [*Date*], LICENSEE will submit to REGENTS a semi-annual progress report covering LICENSEE's activities related to the development and testing of all LICENSED PRODUCTS, LICENSED SERVICES and LICENSED METHODS and the obtaining of necessary governmental approvals, if any, for marketing in the United States. These progress reports will be made for all development activities until the first SALE occurs in the United States. Each progress report will be a sufficiently detailed summary of activities of LICENSEE and any SUBLICENSEES so that REGENTS may evaluate and determine LICENSEE's progress in development of LICENSED PRODUCTS, LICENSED SERVICES, and LICENSED METHODS, and in meeting its diligence obligations under Article 7 (Diligence), and will include (but not be limited to) the following: summary of work completed and in progress; current schedule of anticipated events and milestones, including diligence milestones under Paragraph 7.2; anticipated market introduction dates for the LICENSED TERRITORIES; status of implementation of the Affordable Access Plan and SUBLICENSEE's activities during the reporting period. LICENSEE also will report to REGENTS in its immediately subsequent progress and royalty reports, the date of first SALE.
- 8.2 **Royalty Reports.** After the first SALE anywhere in the world, LICENSEE will make quarterly royalty reports to REGENTS within sixty (60) days after the quarters ending March 31, June 30, September 30, and December 31, of each year. If no SALES have occurred during the report period, a statement to this effect is required in the royalty report for that period. Each such royalty report will be substantially similar to APPENDIX A and include at least the following:
- (a) The number of LICENSED PRODUCTS manufactured and the number SOLD;
  - (b) Gross revenue from SALE of LICENSED PRODUCTS, LICENSED SERVICES and LICENSED METHODS;
  - (c) NET SALES pursuant to Paragraph 2.12;
  - (d) Total royalties due REGENTS; and
  - (e) Names and addresses of any new SUBLICENSEES along with a summary of the material terms of each new SUBLICENSE entered into during the reporting quarter.

## 9. BOOKS AND RECORDS

- 9.1 **Accounting.** LICENSEE will keep, and will require its AFFILIATES and SUBLICENSEES to keep, accurate books and records showing all payments due REGENTS and all LICENSED PRODUCTS manufactured, used, offered for SALE, imported, SOLD, and/or otherwise exploited under the terms of this AGREEMENT. Books and records may encompass data maintained on LICENSEE's accounting and enterprise resource planning systems including, but not limited to production and manufacturing data, general ledger data, and data showing territory of sale, customer name and location, invoice number and date, ship date, part number and/or

description, quantity SOLD, gross SALES, deductions taken, and NET SALES. Books and records will be preserved for at least seven (7) years after the date of the payment to which they pertain.

9.2 **Auditing.** Books and records kept in accordance with Paragraph 9.1 will be open to inspection by representatives or agents of REGENTS at reasonable times to determine the completeness and accuracy of those payments and to assess the LICENSEE's compliance with terms of this AGREEMENT. As necessary and reasonable, LICENSEE will make its personnel available to interpret documents, understand accounting methodologies employed, and to run reports from LICENSEE's accounting and enterprise resource planning systems to permit REGENTS agents and representatives to verify the completeness and accuracy of LICENSEE's payments due REGENTS. The agents or representatives of REGENTS may retain one copy of books and records supporting their findings until the matters identified during the course of the inspection are resolved. Notwithstanding any other provision of this AGREEMENT or any confidentiality agreement between LICENSEE and agents or representatives of REGENTS, such agents and representatives are permitted to disclose their findings regarding the completeness and accuracy of LICENSEE's payments to REGENTS as well as the evidentiary basis therefore. REGENTS right to conduct an inspection will be preserved for one year following the later of the termination or expiration of this AGREEMENT or the LICENSEE's final report setting forth royalties due in connection with LICENSED PRODUCTS manufactured or in inventory at the expiration or termination of the AGREEMENT. The fees and expenses of representatives of REGENTS performing such an inspection will be borne by REGENTS. If, however, the payments made to REGENTS under this AGREEMENT by the LICENSEE are found after REGENTS initiate their inspection to be less than ninety-five percent (95%) of the total payments due to REGENTS under this AGREEMENT for any year, LICENSEE will bear the cost of the inspection. Should an overpayment by LICENSEE be discovered after REGENTS initiate their inspection, LICENSEE will be entitled to a credit equal to such excess payment, minus the expenses of such inspection, against the payment obligations next accruing under the AGREEMENT, provided such payments are due and payable.

9.3 **LICENSEE Audit.** LICENSEE will conduct an independent audit of SALEs and royalties at least every two (2) years if annual SALEs of LICENSED PRODUCT are over Five Million (\$5,000,000) US Dollars. The audit will address, at a minimum, the amount of gross SALEs by or on behalf of LICENSEE during the audit period, the amount of funds owed to REGENTS under this AGREEMENT, and whether the amount owed has been paid to REGENTS and is reflected in the records of LICENSEE. LICENSEE will submit the auditor's report promptly to REGENTS upon completion. LICENSEE will pay for the entire cost of the audit.

## 10. LIFE OF THE AGREEMENT

10.1 **Term.** Unless otherwise terminated by the operation of law or by acts of the parties in accordance with the terms of this AGREEMENT, this AGREEMENT will be in



force from the Effective Date and will remain in effect for the life of the last-to-expire patent or last-to-be-abandoned patent application licensed under this AGREEMENT, whichever is later. Any termination of this AGREEMENT will not relieve LICENSEE of its obligation to pay any monies due or owing at the time of such termination and will not relieve any obligations, of either party to the other party, established prior to termination or expiration.

10.2 **Survival.** Any termination or expiration of this AGREEMENT will not affect the rights and obligations set forth in the following articles:

Article 2	Definitions
Article 4	Sublicenses
Article 5	License Issue Fee
Paragraph 6.6	Payments
Article 9	Books and Records
Article 10	Life of the Agreement
Article 13	Disposition of Licensed Products Upon Termination
Article 16	Use of Names and Trademarks
Article 17	Limited Warranties
Article 19	Indemnification
Article 23	Notices
Article 25	Confidentiality
Article 28	Applicable Law; Venue; Attorney's Fees

## 11. TERMINATION BY REGENTS

11.1 If LICENSEE should violate or fail to perform any term of this AGREEMENT, then REGENTS may give written notice of such default ("NOTICE OF DEFAULT") to LICENSEE. If LICENSEE should fail to repair such default within sixty (60) days of the effective date of such notice, REGENTS will have the right to terminate this AGREEMENT and the licenses herein by a second written notice ("Notice of Termination") to LICENSEE. If a Notice of Termination is sent to LICENSEE, this AGREEMENT will automatically terminate on the effective date of such notice. Such termination will not relieve LICENSEE of its obligation to pay any royalty or license fees owing at the time of such termination and will not impair any accrued rights of REGENTS. These notices will be subject to Article 23 (Notices).

## 12. TERMINATION BY LICENSEE

12.1 LICENSEE will have the right at any time to terminate this AGREEMENT in whole or as to any portion of REGENTS' PATENT RIGHTS by giving notice in writing to REGENTS. Such notice of termination will be subject to Article 23 (Notices) and termination of this AGREEMENT will be effective ninety (90) days after the effective date of such notice.

- 12.2 Any termination pursuant to Paragraph 12.1 will not relieve LICENSEE of any obligation or liability accrued prior to such termination or rescind anything done by LICENSEE or any payments made to REGENTS prior to the time such termination becomes effective, and such termination will not affect in any manner any rights of REGENTS arising under this AGREEMENT prior to such termination.

### **13. DISPOSITION OF LICENSED PRODUCTS UPON TERMINATION**

- 13.1 Upon termination of this AGREEMENT, for a period of one hundred twenty (120) days after the date of termination LICENSEE may complete and SELL any partially made LICENSED PRODUCTS and continue to render any previously commenced LICENSED SERVICES, and continue the practice of LICENSED METHOD only to the extent necessary to do so; provided, however, that all such SALES will be subject to the terms of this AGREEMENT including, but not limited to, the payment of royalties at the rate and at the time provided herein and the rendering of reports thereon.

### **14. PATENT PROSECUTION AND MAINTENANCE**

- 14.1 REGENTS will diligently prosecute and maintain the United States and foreign patent applications and patents under REGENTS' PATENT RIGHTS, subject to LICENSEE'S reimbursement REGENTS' out of pocket costs under Paragraph 14.3 below, and all patent applications and patents under REGENTS' PATENT RIGHTS will be held in the name of REGENTS. REGENTS will have sole responsibility for retaining and instructing patent counsel, but continued use of such counsel at any point in the patent prosecution process subsequent to initial filing of a U.S. patent application covering the INVENTION will be subject to the approval of LICENSEE. If LICENSEE rejects three of REGENTS' choice of prosecution counsel, then REGENTS may select new prosecution counsel without LICENSEE's consent. REGENTS will promptly provide LICENSEE with copies of all relevant documentation so that LICENSEE may be currently informed and apprised of the continuing prosecution and LICENSEE agrees to keep this documentation confidential in accordance with Article 25 (Confidentiality). LICENSEE may comment upon such documentation, provided, however, that if LICENSEE has not commented upon such documentation in reasonable time for REGENTS to sufficiently consider LICENSEE's comments prior to the deadline for filing a response with the relevant government patent office, REGENTS will be free to respond appropriately without consideration of LICENSEE's comments. LICENSEE and LICENSEE's patent counsel will have the right to consult with patent counsel chosen by REGENTS.
- 14.2 REGENTS will use reasonable efforts to prepare or amend any patent application to include claims reasonably requested by LICENSEE to protect the LICENSED PRODUCTS contemplated to be SOLD or to be practiced under this AGREEMENT.
- 14.3 Subject to Paragraph 14.4, LICENSEE will bear all out-of-pocket costs incurred by the REGENTS for preparing, filing, prosecuting, protecting and maintaining all

United States and foreign patent applications, and patents under REGENTS' PATENT RIGHTS ("Patent Costs"). LICENSEE must reimburse to REGENTS Patent Costs incurred prior to the term of this AGREEMENT ("Past Patent Costs") within thirty (30) days of LICENSEE's receipt of an invoice from REGENTS. With respect to Patent Costs incurred during the term of this AGREEMENT ("Ongoing Patent Costs"), LICENSEE is required to pay in advance REGENTS' patent counsel's estimated costs for undertaking Patent Actions that occur during the term of this AGREEMENT before REGENTS authorizes its patent counsel to proceed ("Advanced Payment"). The absence of this Advanced Payment will be deemed to be an election by LICENSEE not to secure the patent rights associated with the specific phase of patent prosecution in such territory, and such patent application(s) and patent(s) will not be part of the REGENTS' PATENT RIGHTS and therefore not be subject to this AGREEMENT, and LICENSEE will have no further rights or license to them. At REGENTS' sole discretion, rather than requiring an Advanced Payment, REGENTS may: (1) bill LICENSEE for Ongoing Patent Costs after such amounts are incurred, in which case payment will be due to REGENTS within thirty (30) days of LICENSEE's receipt of an invoice from REGENTS, or (2) have Ongoing Patent Costs directly billed to LICENSEE by REGENTS' patent counsel. If REGENTS reduces the exclusive licenses granted herein to non-exclusive licenses pursuant to this AGREEMENT and REGENTS grants additional license(s), the costs of preparing, filing, prosecuting and maintaining such patent applications and patents will be divided equally among the licensed parties from the effective date of each subsequently granted license agreement.

- 14.4 LICENSEE's obligation to underwrite and to pay all domestic and foreign patent filing, prosecution, and maintenance costs will continue for so long as this AGREEMENT remains in effect, provided, however, that LICENSEE may terminate its obligations with respect to any given patent application or patent in any or all designated countries upon ninety (90) days written notice to REGENTS. REGENTS will use its best efforts to curtail patent costs when such a notice is received from LICENSEE. REGENTS may continue prosecution and/or maintenance of such applications or patents at its sole discretion and expense; provided, however, that LICENSEE will have no further right or licenses thereunder.

## 15. MARKING

- 15.1 Prior to the issuance of patents under REGENTS' PATENT RIGHTS, LICENSEE agrees to mark, and have SUBLICENSEE'S mark, LICENSED PRODUCT(S) (or their containers or labels) made, SOLD, licensed or otherwise disposed of by it in the United States under the license granted in this AGREEMENT with the words "Patent Pending," and following the issuance in the United States of one or more patents under REGENTS' PATENT RIGHTS, with the numbers of REGENTS' PATENT RIGHTS. All LICENSED PRODUCTS shipped to, manufactured, or SOLD in other countries will be marked in such manner as to conform with the patent laws and practice of such countries.

## **16. USE OF NAMES AND TRADEMARKS**

16.1 Nothing contained in this AGREEMENT will be construed as conferring any right to use in advertising, publicity or other promotional activities any name, trademark, trade name, or other designation of either party hereto by the other (including any contraction, abbreviation, or simulation of any of the foregoing), except that REGENTS may publicly identify LICENSEE's name and contact information as an entity whom REGENTS has an agreement with that involves the commercialization of technology developed at REGENTS. Unless required by law or consented to in writing by REGENTS, the use by LICENSEE of the name "REGENTS of the University of California" or the name of any University of California campus in advertising, publicity or other promotional activities is expressly prohibited.

## **17. LIMITED WARRANTIES**

17.1 This license and the associated INVENTION are provided WITHOUT WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER WARRANTY, EXPRESSED OR IMPLIED. REGENTS MAKES NO REPRESENTATION OR WARRANTY THAT THE INVENTION, REGENTS' PATENT RIGHTS, LICENSED PRODUCTS, LICENSED SERVICES OR LICENSED METHOD WILL NOT INFRINGE ANY PATENT OR OTHER PROPRIETARY RIGHT.

17.2 REGENTS WILL NOT BE LIABLE FOR ANY LOST PROFITS, COSTS OF PROCURING SUBSTITUTE GOODS OR SERVICES, LOST BUSINESS, ENHANCED DAMAGES FOR INTELLECTUAL PROPERTY INFRINGEMENT, OR FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE, OR OTHER SPECIAL DAMAGES SUFFERED BY LICENSEE, SUBLICENSEES, PERMITTED SUBCONTRACTORS, JOINT VENTURES, OR AFFILIATES ARISING OUT OF OR RELATED TO THIS AGREEMENT FOR ALL CAUSES OF ACTION OF ANY KIND (INCLUDING TORT, CONTRACT, NEGLIGENCE, STRICT LIABILITY, AND BREACH OF WARRANTY) EVEN IF REGENTS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. REGENTS WILL NOT BE LIABLE FOR ANY DIRECT DAMAGES SUFFERED BY LICENSEE, SUBLICENSEES, JOINT VENTURES OR AFFILIATES ARISING OUT OF OR RELATED TO PATENT RIGHTS TO THE EXTENT ASSIGNED OR LICENSED BY REGENTS' INVENTORS TO THIRD PARTIES.

17.3 Nothing in this AGREEMENT is or will be construed as:

- (a) A warranty or representation by REGENTS as to the validity, enforceability or scope of any REGENTS' PATENT RIGHTS; or
- (b) A warranty or representation that anything made, used, or SOLD under any license granted in this AGREEMENT is or will be free from infringement of patents of third parties; or
- (c) An obligation to bring or prosecute actions or suits against third parties for patent infringement, except as provided in Article 18 (Patent Infringement); or

- (d) Conferring by implication, estoppel, or otherwise any license or rights under any patents of REGENTS other than REGENTS' PATENT RIGHTS as defined herein; or
- (e) An obligation to furnish any know-how not provided in the patents and patent applications under REGENTS' PATENT RIGHTS.

## 18. PATENT INFRINGEMENT

- 18.1 If either party learns of infringement of potential commercial significance of any of the REGENTS' PATENT RIGHTS, it will provide the other with: (i) written notice of such infringement and (ii) any evidence of such infringement available to it (the "Infringement Notice"). Neither party will put an alleged infringer on notice of the existence of any of the REGENTS' PATENT RIGHTS without first obtaining consent of the other. Both the REGENTS and the LICENSEE will use their diligent efforts to terminate such infringement without litigation.
- 18.2 If the matter described in the Infringement Notice is not resolved within ninety (90) days of receipt of the Infringement Notice, then the LICENSEE may institute suit for patent infringement. The LICENSEE may not join the REGENTS as a party in such suit without the REGENTS' prior written consent. If the REGENTS joins such suit at the LICENSEE's request or is involuntarily joined, the LICENSEE will pay all out-of-pocket costs incurred by the REGENTS arising out of such suit.
- 18.3 If, within a hundred and twenty (120) days of receipt of the Infringement Notice, the matter described in the Infringement Notice has not been resolved and the LICENSEE has not filed suit against the infringer, then the REGENTS may institute suit for patent infringement against the infringer. If the REGENTS institutes such suit, then the LICENSEE may not join such suit without the REGENTS' consent and may not thereafter commence suit against the infringer for the acts of infringement that are the subject of the REGENTS' suit or any judgment rendered in that suit.
- 18.4 Notwithstanding anything to the contrary in this AGREEMENT, in the event that either party receives written notice of infringement under the Drug Price Competition and Patent Term Restoration Act of 1984 (and/or foreign counterparts of this Law) ("The Act"), then the party in receipt of such notice under the Act will promptly provide the Infringement Notice to the other party. If under the Act the LICENSEE will lose the right to pursue legal remedies for infringement by not filing suit, the notification period and the time period to file suit under Paragraph 18.2 will be accelerated to within forty-five (45) days from receipt of the Infringement Notice to either party.
- 18.5 Any recovery or settlement received in connection with any suit will first be shared by the REGENTS and the LICENSEE equally to cover any litigation costs each incurred and will next be paid to the REGENTS or the LICENSEE to cover any litigation costs it incurred in excess of the litigation costs of the other. In any suit initiated by the LICENSEE, any recovery in excess of litigation costs will be shared between LICENSEE and the REGENTS as follows: (a) for any recovery other than amounts paid for willful infringement: (i) the REGENTS will receive fifteen percent

(15%) of the recovery if the REGENTS did not incur any litigation costs or all of the REGENTS' litigation costs were reimbursed by LICENSEE, (ii) the REGENTS will receive thirty percent (30%) of the recovery if the REGENTS incurred any litigation costs in connection with the litigation that were not reimbursed by LICENSEE; and (b) for any recovery for willful infringement, the REGENTS will receive fifty percent (50%) of the recovery. In any suit initiated by the REGENTS, any recovery in excess of litigation costs will belong to the REGENTS. The REGENTS and the LICENSEE agree to be bound by all determinations of patent infringement, validity and enforceability (but no other issue) resolved by any adjudicated judgment in a suit brought in compliance with this Article 18 (Patent Infringement).

18.6 Any agreement made by the LICENSEE for purposes of settling litigation or other dispute will comply with the requirements of Article 4 (Sublicenses) of this AGREEMENT.

**19. INDEMNIFICATION**

19.1 **Indemnification.** LICENSEE will, and will require its SUBLICENSEES and Permitted Subcontractors to, indemnify, hold harmless, and defend REGENTS and its officers, employees, and agents; sponsor(s) of the research that led to the INVENTION; and the inventors of any patents and patent applications under REGENTS' PATENT RIGHTS and their employers against any and all claims, suits, losses, damages, costs, fees, and expenses resulting from or arising out of exercise of this AGREEMENT or any SUBLICENSE. This indemnification will include, but not be limited to, any product liability.

19.2 **Insurance.** LICENSEE, at its sole cost and expense, will insure its activities in connection with any work performed hereunder and will obtain, keep in force, and maintain the following insurance:

(a) Prior to first use in humans and prior to SALE of a LICENSED PRODUCT or LICENSED SERVICE, Commercial Form General Liability Insurance (contractual liability included) with limits as follows:

Each Occurrence.....\$2,000,000  
 Products/Completed Operations Aggregate.....\$5,000,000  
 Personal and Advertising Injury.....\$2,000,000  
 General Aggregate.....\$5,000,000

(b) At a first use in humans or at a first SALE of a LICENSED PRODUCT or LICENSED SERVICE, Commercial Form General Liability Insurance (contractual liability included) with limits as follows:

Each Occurrence .....\$5,000,000  
 Products/Completed Operations Aggregate....\$10,000,000  
 Personal and Advertising Injury ..... \$5,000,000  
 General Aggregate .....\$10,000,000

If the above insurance is written on a claims-made form, it will continue for three (3) years following termination or expiration of this AGREEMENT. The insurance must have a retroactive date of placement prior to or coinciding with the Effective Date of this AGREEMENT; and

- (c) Worker's Compensation as legally required in the jurisdiction in which LICENSEE is doing business.

19.3 **Certificates.** The coverage and limits referred to in Subparagraphs 19.2(a) through 19.2(c) above will not in any way limit the liability of LICENSEE under this Article. Upon the execution of this AGREEMENT, LICENSEE will furnish REGENTS with certificates of insurance evidencing compliance with all requirements. Such certificates will:

- (a) provide for thirty (30) days' (ten (10) days for non-payment of premium) advance written notice to REGENTS of any cancellation of insurance coverages and LICENSEE will promptly notify REGENTS of any material modification of the insurance coverages;
- (b) indicate that REGENTS has been endorsed as an additional insured under the coverage described above in Paragraph 19.2; and
- (c) include a provision that the coverage will be primary and will not participate with, nor will be excess over, any valid and collectable insurance or program of self-insurance maintained by REGENTS.

19.4 **Notifications.** REGENTS will promptly notify LICENSEE in writing of any claim or suit brought against REGENTS for which REGENTS intends to invoke the provisions of this Article 19. LICENSEE will keep REGENTS informed of its defense of any claims pursuant to this Article 19.

## 20. COMPLIANCE WITH LAWS

20.1 LICENSEE will, and will ensure that its SUBLICENSEE and Permitted Subcontractors, comply with all applicable international, national, state, regional, and local laws and regulations in performing its obligations hereunder and in its use, manufacture, SALE or import of the LICENSED PRODUCTS, LICENSED SERVICES, or practice of the LICENSED METHOD. LICENSEE understands that REGENTS is subject to United States laws and regulations (including the Arms Export Control Act, as amended, and the Export Administration Act of 1979), controlling the export of technical data, computer software, laboratory prototypes and other commodities, and REGENTS' obligations under this AGREEMENT are contingent on compliance with such laws and regulations. The transfer of certain technical data and commodities may require a license from the cognizant agency of the United States Government and/or written assurances by LICENSEE that LICENSEE will not export such technical data and/or commodities to certain foreign countries without prior approval of such agency. REGENTS neither represents that a license will not be required nor that, if required, it will be issued.

## 21. GOVERNMENT APPROVAL OR REGISTRATION

21.1 If this AGREEMENT or any associated transaction is required by the law of any nation to be either approved or registered with any governmental agency, LICENSEE will assume all legal obligations to do so. LICENSEE will notify REGENTS if it becomes aware that this AGREEMENT is subject to a United States or foreign government reporting or approval requirement. LICENSEE will make all necessary filings and pay all costs including fees, penalties, and all other out-of-pocket costs associated with such reporting or approval process.

## 22. ASSIGNMENT/CHANGE of CONTROL

22.1 This AGREEMENT is binding upon, and will inure to the benefit of, REGENTS, its successors and assigns. LICENSEE may assign or transfer this AGREEMENT only with the prior written consent of REGENTS. The prior written consent of REGENTS will not be required if the assignment or transfer of this AGREEMENT is in conjunction with a bona fide arms' length transaction involving a CHANGE of CONTROL, so long as LICENSEE is in good standing with its obligations under this AGREEMENT and REGENT is legally, contractually, and, per its policies, able to enter into an agreement with such assignee. In any assignment or transfer of this AGREEMENT or CHANGE of CONTROL, the conditions (a)-(c) below must be timely met:

- (a) provide REGENTS written notice identifying the proposed acquirer's or successor entity's name and contact information prior to any such assignment or transfer;
- (b) provide REGENTS with a written agreement signed by the proposed acquirer or successor entity agreeing to be bound by all of the provisions of this AGREEMENT, as well as assume all responsibilities and liabilities that arose under this AGREEMENT prior to the effective date of the proposed assignment, as if such acquirer or successor entity were the original LICENSEE within thirty (30) days after any such assignment or transfer; and
- (c) pay to REGENTS an assignment/change of control fee of [*Written amount*] (*\$Number*) ("ASSIGNMENT/CHANGE of CONTROL FEE") within thirty (30) days after any such assignment or transfer.

22.2 For avoidance of doubt, the requirements (a) – (c) above are triggered when the LICENSEE is acquired but remains a subsidiary such that no assignment occurs. Any attempted assignment or transfer by LICENSEE other than in accordance with this Article will be null and void.

## 23. NOTICES

23.1 All notices under this AGREEMENT will be deemed to have been fully given and effective when done in writing and delivered in person, or mailed by registered or certified U.S. mail, or deposited with a carrier service requiring signature by recipient, and addressed as follows:



For the LICENSEE: **See APPENDIX B**

For the REGENTS: **Office of Technology Licensing  
2150 Shattuck Avenue, Suite 408  
Berkeley, CA 94704-1362  
Attn.: Director (UC Case No.: **BK-XXXX-XXX**)**

Either party may change its address upon written notice to the other party.

Remittance address for royalty and fee payments, as well as legal reimbursements associated with this license AGREEMENT are to be sent to **(Please reference the UC Berkeley Invoice Number, UC Berkeley Case Number or UC Berkeley AGREEMENT Control Number with your payment):**

**University of California  
Innovation Transfer and Entrepreneurship  
Attn: ITE Accounting Services  
1111 Franklin Street, 5th Floor  
Oakland, CA 94607**

All Advanced Payments due under this AGREEMENT must be sent via wire transfer as follows. In order to ensure that funds are properly credited to your account, **please reference the UC Berkeley Agreement Control Number on all wire transfers.**

**Wire:**

**Bank of America  
100 West 33rd Street,  
New York, New York, 10001  
Account: OTT Depository Account No. 1233717062  
Beneficiary Name: Regents of the University of California  
Domestic Wire ABA: 026009593 (within U.S. only)  
Foreign Wire Swift: BOFAUS3N**

**ACH:**

**Bank of America CA4-704-05-41  
2000 Clayton Rd.,  
Concord, CA 94520  
Account: OTT Depository Account No. 1233717062  
Beneficiary Name: Regents of the University of California  
ACH/EFT Routing No.: 121000358**

- 23.2 **LICENSEE Contact Information:** LICENSEE must provide to the REGENTS the completed LICENSEE contact information form attached hereto as APPENDIX B concurrent to execution of this AGREEMENT and incorporated herein by this reference, showing the contacts responsible for (i) Patent Prosecution, (ii) Progress Reports, (iii) Royalty Reports, and (iv) Invoices.

## 24. WAIVER

- 24.1 The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this AGREEMENT will not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party. None of the terms and conditions of this AGREEMENT can be waived except by the written consent of the party waiving compliance.

## 25. CONFIDENTIALITY

- 25.1 LICENSEE and the REGENTS will hold the other party's proprietary business information ("Proprietary Information") in confidence, using at least the same degree of care as the receiving party uses to protect its own proprietary information of a similar nature. Proprietary Information will be protected from the date of disclosure until five (5) years after the termination or expiration of this AGREEMENT. ***INCLUDE THIS IF THERE IS AN EXECUTED A SECRECY AGREEMENT:*** *[This confidentiality obligation will apply to the information defined as "Data" under the Secrecy Agreement and such Data will be treated as Proprietary Information hereunder.]*
- 25.2 LICENSEE and the REGENTS may disclose Proprietary Information to their employees, agents, provided that such parties are bound by a like duty of confidentiality as set forth in this Article 25 (Confidentiality). In addition, if a third party inquires whether a license to REGENTS' PATENT RIGHTS is available, the REGENTS may disclose to the third party the existence of this AGREEMENT and the extent of the grant in Paragraph 3.1 (License Grant) and related definitions, but will not disclose the name of the LICENSEE unless that information is already public.
- 25.3 All written Proprietary Information will be marked confidential or proprietary. If the Proprietary Information is orally disclosed, then it will be reduced to writing, marked as confidential by the disclosing party and delivered to the receiving party within thirty (30) days after the oral disclosure.
- 25.4 Nothing contained herein will in any way restrict the right of the LICENSEE or the REGENTS to use or disclose any Proprietary Information that the recipient can demonstrate by written records:
- (a) was previously known to it prior to its disclosure by the disclosing party;
  - (b) is public knowledge other than through acts or omissions of recipient;
  - (c) was lawfully obtained without restrictions on the recipient from sources independent of the disclosing party; or
  - (d) was independently developed by recipient.
- 25.5 Nothing in this AGREEMENT will restrict either party from producing Proprietary Information that is required to be disclosed: (i) in litigation or by a governmental entity or agency, or (ii) by law (including the California Public Records Act or similar applicable law), provided that the recipient uses reasonable efforts to give the party that disclosed the Proprietary Information sufficient notice to allow it a reasonable

opportunity to object. To the extent feasible, the party with the obligation to disclose under subparagraph (i) in the previous sentence will make reasonable efforts to make such disclosure subject to confidentiality obligations at least as protective as the terms set forth in this Paragraph.

25.6 Upon termination or expiration of this AGREEMENT, the LICENSEE and the REGENTS upon request will destroy or return any of the disclosing party's Proprietary Information in its possession within fifteen (15) days following the termination of this AGREEMENT and provide written confirmation of such to the other party. Each party may, however, retain one copy of such Proprietary Information for archival purposes in non-working files.

## **26. FORCE MAJEURE**

26.1 Except for LICENSEE's obligation to make any payments to REGENTS hereunder, the parties to this AGREEMENT are excused from any performance required hereunder if such performance is rendered impossible or unfeasible due to any catastrophes or other major events beyond their reasonable control, including, without limitation, war, riot, and insurrection; laws, proclamations, edicts, ordinances, or regulations; strikes, lockouts, or other serious labor disputes; and floods, fires, explosions, pandemics, or other natural disasters. When such events have abated, the parties' respective obligations hereunder will resume.

## **27. SEVERABILITY**

27.1 The provisions of this AGREEMENT are severable, and in the event that any provision of this AGREEMENT will be determined to be invalid or unenforceable under any controlling body of law, such invalidity or enforceability will not in any way affect the validity or enforceability of the remaining provisions hereof.

## **28. APPLICABLE LAW; VENUE; ATTORNEYS' FEES**

28.1 THIS AGREEMENT WILL BE CONSTRUED, INTERPRETED, AND APPLIED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA, excluding any choice of law rules that would direct the application of the laws of another jurisdiction, but the scope and validity of any patent or patent application under REGENTS' PATENT RIGHTS will be determined by the applicable law of the country of such patent or patent application. Any legal action brought by the parties relating to this AGREEMENT will be conducted in San Francisco, California. The prevailing party in any legal action under this AGREEMENT will be entitled to recover its reasonable attorneys' fees in addition to its costs and necessary disbursements.

## **29. SCOPE OF AGREEMENT**

29.1 This AGREEMENT (*except for the Agreements(s) dated \_\_\_\_\_*), *which will continue to the extent it is not inconsistent with this AGREEMENT*) incorporates the entire AGREEMENT between the parties with respect to the subject matter hereof, and this AGREEMENT may be altered or modified only by written amendment duly executed by the parties hereto.

**30. ELECTRONIC COPY**

30.1 The parties to this document agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The parties further waive any right to challenge the admissibility or authenticity of this document in a court of law based solely on the absence of an original signature.

**31. BANKRUPTCY**

31.1 In the event of a bankruptcy or insolvency, assignment of this AGREEMENT is only permitted to a party that can provide adequate assurance of future performance, including diligent development and SALES of LICENSED PRODUCT.

**IN WITNESS WHEREOF, the parties hereto have executed this AGREEMENT in duplicate originals by their duly authorized officers or representatives.**

REGENTS OF THE  
UNIVERSITY OF CALIFORNIA

[*LICENSEE NAME*]

By \_\_\_\_\_

By \_\_\_\_\_

Title \_\_\_\_\_

Title \_\_\_\_\_

Date \_\_\_\_\_

Date \_\_\_\_\_

APPENDIX A

UNIVERSITY OF CALIFORNIA AT BERKELEY  
OFFICE OF TECHNOLOGY LICENSING

1111 FRANKLIN STREET, 11TH FLOOR  
OAKLAND, CA 94607-5200

DATE

Company Name  
Address

Reference: Agreement between The Regents of the University of California and  
Company Name  
UC Control No. [Case No.] [Licensing Officer], Effective Date  
Agreement Reference Paragraph:

ROYALTY REPORT REQUEST FOR  
THE PERIOD [DATES: From - To]

REPORT AND PAYMENT DUE DATE:

Product NAME

Royalty:

Calculated Royalty This Period:

\$ \_\_\_\_\_

New Products

\_\_\_\_\_

\$ \_\_\_\_\_

Total Royalties this Period:

\$ \_\_\_\_\_

Minimum Royalty Credit Available \$

Show Minimum Royalty Credit To Apply

-\$ \_\_\_\_\_

Show Any Credit To Apply (other than Minimum Royalty)

-\$ \_\_\_\_\_

Total Royalty Amount Due:

\$ \_\_\_\_\_

Have you removed or added products this period? If applicable, provide the commercial name and approval date of any FDA-approved product utilizing the invention that became commercially available during this period.

Product \_\_\_\_\_ Removed \_\_\_\_/\_\_\_\_/\_\_\_\_ Added \_\_\_\_/\_\_\_\_/\_\_\_\_

Commercial Name \_\_\_\_\_ FDA-Approved \_\_\_\_/\_\_\_\_/\_\_\_\_

Submitted By: \_\_\_\_\_

Date: \_\_\_\_\_ Title \_\_\_\_\_

PLEASE RETURN THIS COMPLETED FORM WITH A CHECK PAYABLE TO 'THE REGENTS OF THE UNIVERSITY OF CALIFORNIA [Agreement #]' AT THE ABOVE ADDRESS.

If you have questions please call (510) 587-6019, or send an e-mail to valerie.redmond@ucop.edu. Thank you for your prompt attention.

**APPENDIX B**  
Licensee Contact Information

<b>LICENSEE NAME:</b>		<b>UC CONTROL NO.:</b>
<b>PATENT PROSECUTION CONTACT</b>		
NAME:		TELEPHONE:
TITLE:		EMAIL:
ADDRESS:		
CITY, STATE, ZIP:		
COUNTRY:		
<b>PROGRESS REPORT CONTACT</b>		
NAME:		TELEPHONE:
TITLE:		EMAIL:
ADDRESS:		
CITY, STATE, ZIP:		
COUNTRY:		
<b>ROYALTY REPORT CONTACT</b>		
NAME:		TELEPHONE:
TITLE:		EMAIL:
ADDRESS:		
CITY, STATE, ZIP:		
COUNTRY:		
<b>INVOICE CONTACT</b>		
NAME:		TELEPHONE:
TITLE:		EMAIL:
ADDRESS:		
CITY, STATE, ZIP:		
COUNTRY:		

## APPENDIX C

### REGENTS' PATENT RIGHTS

1) UC Berkeley Case No. [Number] (“[INVENTION NAME]”)

U.S. Provisional Patent Application No. [Number] entitled, “[INVENTION NAME]”, filed [FILING DATE] (UC Berkeley Case No. [UC Berkeley CASE No.]).

U.S. Patent Application No. [Number] entitled, “[INVENTION NAME]”, filed [FILING DATE] (UC Berkeley Case No. [UC Berkeley CASE No.]).

U.S. Patent No. [Number] entitled, “[INVENTION NAME]”, filed [FILING DATE] (UC Berkeley Case No. [UC Berkeley CASE No.]).

for reference only