# PATENT LICENSE AGREEMENT

#### WITNESSETH

WHEREAS, certain inventions, generally characterized as [Technology Description], have been made in the course of research at Northeast Ohio Medical University conducted by [RESEARCH FACULTY] ("Inventor") and are covered by the Licensed Patents (as defined below);

WHEREAS, Licensor is the owner of the Licensed Patents and has the right to grant licenses thereunder.

WHEREAS, Licensor desires that the Licensed Patents be developed, commercialized and utilized to the fullest extent so that its benefits can be enjoyed by the general public;

WHEREAS, Licensee represented to Licensor that it has the necessary product development capabilities, manufacturing know-how, and marketing resources to introduce, manufacture and sell products based upon the Licensed Patents through its own channels of distribution;

WHEREAS, Licensee wishes to obtain from Licensor a license under certain rights for the commercial development, production, manufacture, use and sale of the Licensed Patents, and Licensor is willing to grant such a license upon the terms and conditions hereinafter set forth;

NOW THEREFORE, for and in consideration of the covenants, conditions and undertakings hereinafter set forth, the parties hereby agree as follows:

#### 1. Definitions

- **1.1 Affiliate** means any person or entity that controls, is controlled by, or is under common control with Licensee, directly or indirectly. For purposes of this definition, "control" and its various inflected forms means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such person or entity, whether through ownership of voting securities, by contract or otherwise.
- **1.2 Confidential Information** means all information that is of a confidential and proprietary nature to Licensor or Licensee, including, but not limited to, all unpatented and patentable technical information, development, discoveries, software, know-how, methods, techniques, data, processes, devices, models, documentation, information,

trade secrets, procedures, results and ideas and provided by one party to the other party under this Agreement. Confidential Information shall not include information that (a) can be demonstrated to have been in the public domain as of the Effective Date or comes into the public domain after the Effective Date through no fault of the receiving party; (b) can be demonstrated to have been known to the receiving party prior to execution of this Agreement and which was not acquired, directly or indirectly, from a third party under a continuing obligation of confidentiality or limited use to the disclosing party; (c) can be demonstrated to have been rightfully received by the receiving party after disclosure under this Agreement from a third party who did not acquire it, directly or indirectly, from the disclosing party under a continuing obligation of confidentiality; (d) can be demonstrated to have been independently developed by personnel of the receiving party who had no substantive knowledge of the disclosing party's information; or (e)is required to be disclosed pursuant to law or court order.

- **1.3 Export Laws** mean all applicable laws governing export of the Licensed Products including, but not limited to, the export Administration Regulations, the International Traffic in Arms Regulations and the various economic sanctions regulations administered by the U.S. Department of Treasury.
- **1.4** Field of Use means [To Be Defined].
- **1.5 Government** means the United States Government.
- 1.6 "Licensed Know-How" means any and all technical information, trade secrets, formulas, prototypes, specifications, directions, instructions, test protocols, procedures, results, studies, analyses, raw material sources, data, manufacturing data, formulation or production technology, conceptions, ideas, innovations, discoveries, inventions, methods, materials, machines, devices, formulae, processes, enhancements, modifications, technological developments, techniques, systems, tools, designs, drawings, plans, software, documentation, data, programs, and other knowledge, information, skills, and materials which are known, learned, invented, or developed or controlled by Licensor pertaining to the Licensed Products and/or useful in the manufacture, sale, or use of the Licensed Products and/ or Licensed Process and any modifications, variations, derivative works, and improvements of or relating to any of the foregoing.
- 1.7 Licensed Patents means Licensor's International Patent Application, Number [XYZ], ("Application") and (a) all divisionals, continuations and continuation-in-part (excluding new matter and claims containing new matter) applications that claim priority to any of the Applications; (b) any foreign application corresponding to any Application or application identified in (a); and (c) each patent that issues or reissues from any Application or application identified in (a) and (b).

- 1.8 Licensed Product means any product that if manufactured, used, sold, offered for sale, or imported would constitute, but for the license granted Licensee under this Agreement, direct infringement, induced infringement and/or contributory infringement of any pending or issued claim of the Licensed Patents.
- **1.9 Licensed Technology** means technology covered by any pending or issued claim of the licensed Patents and/or Technology.
- 1.10 Liquidation Event means a (i) merger, share ,exchange or other reorganization that results in a change of control (ii) the sale by one or more stockholders of a majority of the voting power of the Licensee ("Stock Sale"); or (iii) sale of all or substantially all of the assets of the Licensee (or that portion of its assets related to the subject matter of this Agreement) ("Asset Sale") in which for (i), (ii) and (iii) above, the stockholders of the Licensee prior to such transaction do not own a majority of the voting power of the acquiring, surviving or successor entity, as the case may be. Notwithstanding the foregoing, a Liquidation Event shall not include a bona fide financing transaction in which voting control of the Licensee transfers to one or more persons or entities who acquire shares of Licensee's capital stock from Licensee in exchange for either an investment in Licensee or the cancellation of indebtedness owed by Licensee, or a combination thereof.
- **1.11 Net Sales** means the gross amount of all sales or leases of Licensed Products by Licensee, Affiliates, or Sublicensees to any customer LESS properly documented:
  - (a) discounts and rebates customary to the trade that are actually granted;
  - (b) excise and sales taxes imposed on the License Products and actually paid;
  - (c) import, export and custom duties imposed on the License Products and actually paid; and
  - (d) freight, transit and insurance charges actually paid.
- Licensee means any entity to which an express sublicense has been granted by Licensee under the Licensed Patents. For clarity, a third party wholesaler or distributor who has no significant responsibility for marketing and promotion of the Licensed Product or Licensed Services within its distribution territory or field (i.e., the third party simply functions as a reseller), and who does not pay any consideration to Licensee or an Affiliate for such wholesale or distributor rights, shall not be deemed a Sublicensee; and the resale by such a wholesaler or distributor shall not be treated as royalty bearing Net Sales by a Sublicensee provided that a royalty is being paid by Licensee for the initial transfer to the wholesaler or distributor pursuant to Section 3.4. This definition does not limit Licensee's rights to grant or authorize sublicenses under the Agreement.

**1.13 Technology** means any information: (a) created prior to the Effective Date; (b) owned by Licensor; (c) not infringing any pending or issued claim in the Licensed Patents; and (d) necessary to practice inventions claimed in patents and/or patent applications included in the Licensed Patents.

# **1.14 Territory** is worldwide.

# 2. License Grant.

- **2.1 License Grant.** Licensor hereby grants to Licensee an exclusive commercial license under the Licensed Patents and Licensed Know-How to make, have made for it, use and sell Licensed Products in the Field of Use in the Territory during the Term of this Agreement, and the right to use Technology to make and have made for it the Licensed Products in the Field of Use in the Territory during the Term of this Agreement.
- **2.2 Sublicensing.** Licensee has the right to grant Sublicense Agreements under the Licensed Patents subject to the following:
  - (a) A Sublicense Agreement shall not exceed the scope and rights granted Licensee hereunder. Sublicensee must agree in writing to be bound by the applicable terms and conditions of the Agreement and shall indicate that Licensor is a third party beneficiary of the Sublicense Agreement. Any sublicense granted by Licensee to a Sublicensee shall prohibit the Sublicensee from further sublicensing.
  - (b) Licensee shall deliver to Licensor a true, complete, and correct copy of each Sublicense Agreement granted by Licensee, and any modification or termination thereof, within thirty (30) days following the applicable execution, modification, or termination of such Sublicense Agreement.
  - (c) Licensee shall collect and guarantee payment of all payments due, directly or indirectly, to Licensor from Sublicensees and summarize and deliver all reports and royalties due, directly or indirectly, to Licensor from Sublicensees.
  - (d) All rights and licenses of Sublicensees shall terminate upon termination of the Agreement See Section 8.6(a) below.
  - (e) Notwithstanding any sublicenses as permitted hereunder, Licensee shall remain primarily liable to Licensor for all of Licensee's duties and obligations contained in this Agreement, including without limitation the payment of running royalties due under Section 3.5 whether or not paid to Licensee by a Sublicensee. Any act or omission of a Sublicensee that would be a breach of this Agreement if performed by Licensee will be deemed to be a breach by Licensee of this Agreement.

- 2.3 Technology. If applicable, promptly following the Effective Date, Licensor shall bail to Licensee, the Technology to be used solely for the purposes of manufacturing Licensed Products for the term of this Agreement or earlier termination. Upon the earlier of (a) Licensee's cancellation of the bailment hereunder or (b) termination of this Agreement, all Technology shall be returned to Licensor in the same condition as when received, ordinary wear and tear excepted. Licensor at all times shall retain title to and have control over the use of the Technology. Licensee shall not have the right to sublicense nor transfer the Technology and hereby acknowledges the confidentiality of same.
- **2.4 Reservation of Rights.** Licensor reserves the right to use the Licensed Technology for educational, research, patient care and other educationally-related purposes; (b) publish or otherwise disseminate results of scientific studies relating to the Licensed Technology; and (c) grant rights to, and transfer embodiments of, the Licensed Technology to other academic institutions or non-profit research institutions for the purposes identified in (a) and (b) above.

# 3. Fees and Royalties.

- **3.1 Upfront Fee**. There is no up-front fee for this Agreement in consideration for the work done on behalf of the Licensed Product by Licensee.
- **3.2 Maintenance Fees.** Beginning in year three (3) and each year thereafter occurring prior to the date Minimum Royalty Payments are due, Licensee shall pay Licensor a nonrefundable maintenance fee in accordance with the schedule below.

Year	Date	Amount per year
3 – 5	TBD	\$10,000.00
5+	TBD	\$20,000.00

Licensee shall pay Licensor milestone fees as follows within ten (10) days after the applicable milestones are reached:

Milestone Events	Milestone Fees
TBD	\$TBD
TBD	\$TBD
TBD	\$TBD

- 3.3 Minimum Royalty. Commencing on the first day of the fifth year, Licensee shall pay Licensor Twenty-Five Thousand \$25,000 "Minimum Royalty Payment"). Licensor shall fully credit each Minimum Royalty Payment against any earned royalties paid by Licensee with respect to the quarter in which the Minimum Royalty Payment is paid.
- 3.4 Earned Royalty. Within thirty (30) days following each calendar quarter throughout the Term commencing on the calendar quarter during which the first sale of a Licensed Product occurs, Licensee shall pay Licensor an earned royalty of two percent (2%) of Net Sales of the Licensed Products approved by the FDA and three percent (3%) of all other products by or on behalf of Licensee. Licensee shall pay Licensor an earned royalty of one and a half percent (1.5%) of Net Sales of the Licensed Know-How, in the event the Licensed Products are not covered by Licensed Patents. Licensee shall pay Licensor on or before the quarterly payment deadline an additional amount equal to the difference between the Minimum Royalty Payment and the actual royalties paid to Licensor if the actual royalties paid to Licensor are less than the Minimum Royalty Payment.

# 3.5 Sublicensing Fee.

- (a) Licensee shall not Sublicense without the written consent of the Licensor. Said consent must be obtained from the Licensor's Vice President for Research and Sponsored Programs and the Chief Technology Transfer Officer.
- (b) Licensee shall pay to Licensor a royalty twenty percent (20%) of on total revenue, including, but not limited to any bonus payments, incentive payments, and equity consideration under any sublicense.
- 3.6 **Liquidation Event Payment.** As additional consideration for the licenses granted hereunder and as a condition precedent to executing an assignment of this Agreement pursuant to section 14. Licensee shall make a on-time cash payment to Licensor coincident with any Liquidation Event in the amount equal to 2.0% of the Licensee's fair market value at the time of the Liquidation Event.
- 3.7 Non-cash Consideration. Licensee shall not receive anything of value in lieu of cash payments in consideration for any agreements, including, but not limited to sublicense agreements, under this Agreement, without the express prior written consent of Licensor which may be withheld in Licensor's sole and absolute discretion. In the event non-cash consideration is permitted, such consideration shall be valued at its fair market value as of the date of receipt for purposes of calculating the payments due Licensor under this Agreement.

# 4. Payment.

**4.1** Quarterly Royalty Reports. Beginning with the first sale of a Licensed Product, Licensee

shall submit to Licensor a written report and an earned royalty payment within thirty [30] days after the end of each calendar quarter. Licensee shall submit this report even if it makes no sales of the Licensed Product during the reporting period. This report (in the form of Exhibit A) shall include:

- (a) Quantity of sales of Licensed Products segregated by product;
- (b) Gross Sales segregated by product;
- (c) Itemized deductions permitted by Section 1.7 segregated by product;
- (d) Net Sales segregated by product;
- (e) The applicable royalty rate;
- (f) Minimum Royalty Payments due under Section 3.3 above; and
- (g) Earned royalties due.

All reports due under this Agreement shall be sent to Licensor's Vice President for Research and Sponsored Programs and a copy to the Chief Technology Transfer Officer at the address first listed above.

- **4.2 Records.** Licensee shall keep, and shall require its Affiliates and Sublicensees to keep, accurate and correct books of account, records of all Licensed Products manufactured, used, and sold, sublicense fees received under this Agreement and any and all other records that may be necessary for the purpose of showing the amounts payable to Licensor hereunder for at least six (6) years from the end of the calendar year of the record documents. Said records shall be kept at Licensee's principle place of business.
- 4.3 Audit. Licensee shall keep, and shall require Sublicensees to keep, true and accurate records containing data reasonably required for the computation and verification of payments due under this Agreement. Licensee shall, and it shall require all Sublicensees and those making Licensed Products, to: (a) open such records for inspection upon reasonable notice during business hours, and no more than once per year, by either Licensor's auditor(s) or an independent certified accountant selected by Licensor, for the purpose of verifying the amount of payments due; and (b) retain such records for six (6) years from date of origination.

The terms of this Article shall survive any termination of this Agreement. Licensor is responsible for all expenses of such inspection, except that if any inspection reveals an underpayment greater than five percent (5%) of royalties due Licensor, then Licensee shall pay all expenses of that inspection and the amount of the underpayment and interest to Licensor within thirty (30) days of written notice thereof. Licensee shall also reimburse Licensor for reasonable expenses required to collect the amount underpaid.

- **4.4 Payment.** All payments to Licensor shall be made in U.S. dollars by check payable to Licensor through its Accounting Offices at the address first listed above or to another address designated in writing in advance by Licensor.
- 4.5 Late Payments. Amounts past due under this Agreement shall accrue a late charge from the due date until paid at an annual rate equal to ten percent (10%), but not in excess of the maximum legal rate.
- 5. <u>Performance Milestones</u>. Licensee agrees to use commercially reasonable and diligent efforts to develop, manufacture and sell Licensed Product(s) and develop markets for Licensed Product(s) in order to make them readily available to the general public as soon as possible. Licensee shall complete the milestones set forth in <u>Exhibit B</u> attached hereto on or before the deadlines set therein. Licensor shall have sole discretion to determine if Licensee has satisfied a milestone.
- 6. Reporting. Beginning on the Effective Date and ending on the date of the first commercial sale of a Licensed Product, Licensee shall provide to Licensor within thirty (30) days following each calendar quarter, a report detailing Licensee's progress for the preceding calendar quarter to bring the Licensed Products to market including: (a) efforts to obtain necessary government approvals; (b) summary of work completed; (c) summary of work in progress; (d) summary of progress on milestones; (e) scheduled plan for next quarter; (f) marketing plans for introduction of Licensed Products (if applicable); and (g) summary of resources, including resources (dollar value) spent during reporting period and resources (dollar value) available as of report date. All reports required hereunder shall be sent to Licensor at the address designated in Section 4.1 above.
- **Board of Directors**. At all times during the Term, a representative of Licensor, at Licensor's election, shall be permitted to observe on Licensee's Board of Directors and shall have all of the rights and responsibilities prescribed to such duty in Licensee's Code of Regulations. Such representative shall be prohibited from participating in any decisions for Licensee that would create a conflict of interest between such representative's capacity for Licensor and that for Licensee.

# 8. <u>Term and Termination</u>.

- **8.1 Term.** Unless terminated earlier as provided for herein, the "Term" of this Agreement will commence on the Effective Date and continue until the latest date of expiration of an issued Licensed Patent or twenty (20) years, whichever occurs later.
- 8.2 Termination by Licensee. Licensee may terminate this Agreement without cause at any given time by giving Licensor written notice at least thirty (30) days in advance of the effective date of termination identified by Licensee, and all Licensee's rights associated with this Agreement shall cease as of that effective date of termination without further

action by either party.

- **8.3 Termination by Licensor.** Licensor may terminate this Agreement if Licensee:
  - (a) is delinquent more than 60 calendar days in any report or payment due under this Agreement;
  - (b) is not using commercially reasonable and diligent efforts to commercialize Licensed Products;
  - (c) fails to meet a milestone set forth in Exhibit B;
  - (d) is in breach of any provision of this Agreement; or
  - (e) provides any false report.
- **8.4 Cure Period.** Termination under Section 8.3 will take effect automatically and without further action by either party sixty (60) calendar days after written notice by Licensor unless Licensee cures the identified default on or before the final day of such thirty (30) day period.
- **8.5 Bankruptcy.** This Agreement shall automatically terminate without further action by either party if Licensee files for bankruptcy, has a bankruptcy action against it, becomes insolvent, enters into a composition with creditors or has a receiver appointed for it.
- **8.6 Effect of Termination.** If the Agreement is terminated for any reason:
  - (a) All rights and licenses of Sublicensees shall terminate upon termination of the Agreement; provided however, if the Sublicense Agreement is for all of the Fields Worldwide, and the Sublicensee is in good standing and agrees in writing to assume all of the obligations of Licensee and provides Licensor with written notice thereof within 30 days after termination of the Agreement, then such Sublicense Agreement shall survive; and
  - (b) Licensee shall cease making, having made, distributing, having distributed, using, selling, offering to sell, leasing, loaning and importing any Licensed Products by the effective date of termination; and
  - (c) Licensee shall tender payment of all accrued royalties and other payments due to Licensor as of the effective date of termination; and
  - (d) Nothing in this Agreement will be construed to release either party from any obligation that matured prior to the effective date of termination.
- **8.7 Surviving Provisions**. The following Sections shall survive the termination of this Agreement:

- (a) Section 9 (Confidentiality)
- (b) Section 10.3 (Infringement of the Licensed Patents)
- (c) Section 11.4 (Government Rights)
- (d) Section 12 (Warranties and Disclaimers)
- (e) Section 13 (Risk)
- (f) Section 15 (Use of Name)
- (g) Section 16 (Notices)
- (h) Section 17 (General Provisions)

The following Paragraphs and Articles shall survive termination with respect to any activities and payment obligations accruing prior to termination or expiration of the Agreement:

- (i) Section 3 (Fees and Royalties)
- (j) Section 4 (Payment)
- (k) Section 9.1(a) (Patent Costs)
- 9. Confidentiality. Licensor and Licensee each agree that all Confidential Information disclosed in tangible form, and marked "confidential" and forwarded to one by the other, or if disclosed orally, is designated as confidential at the time of disclosure: (i) is to be held in strict confidence by the receiving party, (ii) is to be used by and under authority of the receiving party only as authorized in the Agreement, and (iii) shall not be disclosed by the receiving party, its agents or employees without the prior written consent of the disclosing party. Licensee has the right to use and disclose Confidential Information of Licensor reasonably in connection with the exercise of its rights under the Agreement, including without limitation disclosing to Affiliates, Sublicensees, potential investors, acquirers, and others on a need to know basis, if such Confidential Information is provided under conditions which reasonably protect the confidentiality thereof. Each party's obligation of confidence hereunder includes, without limitation, using at least the same degree of care with the disclosing party's Confidential Information as it uses to protect its own Confidential Information, but always at least a reasonable degree of care.

#### 10. Patent Matters.

#### **10.1** Patent Costs and Prosecution.

(a) Licensee shall reimburse Licensor for all expenses Licensor has incurred relating

to the preparation, filing, prosecution and maintenance of the Licensed Patents prior to the date of this Agreement in accordance with the following schedule:

En	d of Year	Date	%
1	20XX	December 31, 20XX	33%
2	20XY	December 31, 20XY	33%
3	20XZ	December 31, 20XZ	34%

Thereafter, Licensee shall reimburse Licensor for all expenses as Licensor incurs those expenses relating to the preparation, filing, prosecution and maintenance of the Licensed Patents for so long as, and in such countries as, the Agreement remains in effect. All payments due pursuant to this Section 9.1(a) shall be made within thirty (30) days of Licensor's delivery of an invoice for such charges and are subject to Sections 4.4 and 4.5 above.

- (b) Licensor will diligently prosecute applications included in the Licensed Patents using outside counsel of its choice. Licensor will provide Licensee with copies of all relevant documentation relating to such prosecution and Licensee shall keep this documentation confidential. Outside counsel shall take instructions only from Licensor.
- (c) All patent applications and patents will be in the name of Licensor (and any coowner, if applicable) and owned by Licensor (and such co-owner, if any).
- (d) If Licensee terminates its rights with respect to certain Licensed Patents or patent application(s) (i) Licensor shall be free, at its discretion, to either abandon such applications or patents or to continue such preparation, prosecution, and/or maintenance activities; (ii) Licensor may license such Licensed Patents to any third party upon such terms and conditions as Licensor deems appropriate; and (iii) Licensee shall have no further rights thereto.
- **10.2 Marking.** Licensee shall mark all Licensed Products made, used or sold under the terms of this Agreement, or their containers, in accordance with all applicable patent marking laws as same may be amended from time to time.
- 10.3 Infringement of the Licensed Patents.

- (a) If either Licensor or Licensee becomes aware of any infringement or potential infringement of Licensed Patents, each party shall promptly notify the other of such in writing.
- (b) Licensee shall enforce the Licensed Patents against any infringement by a third party. Licensee shall be responsible for payment of all fees and expenses associated with such enforcement incurred by Licensee and incurred by Licensor in providing cooperation or joining as a party as provided in Section 10.3(e). Licensee shall pay Licensor a percentage equivalent to the Sublicense Fee rate set forth in Section 3.5 above on any monetary recovery, including any punitive damages, in excess of Licensee's documented, third-party expenses in enforcing the Licensed Patents and amounts reimbursed to Licensor under this Section 10.3. Licensee shall not settle, enter into voluntary disposition of, or compromise any such suit in a manner that imposes any obligations or restrictions on Licensor or grants any rights to the Licensed Patents without Licensor's prior written permission.
- (c) If Licensee does not file suit within six (6) months after a written request by Licensor to initiate an infringement action, then Licensor shall have the right, at its sole discretion, to bring suit to enforce any Licensed Patents against the infringing activities, with Licensor retaining all recoveries from such enforcement. If Licensor pursues such infringement action, Licensor may, as part of the resolution of such efforts, grant non-exclusive license rights to the alleged infringer notwithstanding Licensee's exclusive license rights. In addition, Licensor, in its sole discretion, shall have the right at any time to intervene at Licensor's own expense and join Licensee in any claim or suit for infringement of the Licensed Patents. In the event Licensor elects to join in such claim or suit, any consideration received in connection with any such claim or suit shall be shared between Licensor and Licensee in proportion with their share of the litigation expenses in such infringement action.
- (d) In any infringement suit or dispute, the parties agree to cooperate fully with each other. At the request of the party bringing suit, the other party will permit reasonable access after reasonable advance notice to all relevant personnel, records, papers, information, samples, specimens, etc., during regular business hours, as is necessary for the infringement suit or dispute and/or to comply with lawful process of a court of competent jurisdiction.
- (e) If it is necessary to name Licensor as a party in such action for infringement, then Licensee must first obtain Licensor's prior written permission, which permission shall not be unreasonably withheld, provided that Licensor shall

have reasonable prior input on choice of counsel on any matter where such counsel represents Licensor, and Licensee and such counsel agree to follow all required procedures of the Ohio Attorney General regarding retention of outside counsel for state entities.

#### 10.4 Challenging the Licensed Patents.

- (a) In the event that Licensee or its Sublicensee(s), during the Term of this Agreement, contest the validity or unenforceability of any Licensed Patents or whether there is infringement of the Licensed Patents (collectively, "Patent Challenge"), Licensee agrees, and shall require its Sublicensees to agree, to pay to Licensor all royalties due under the Agreement during the period of the Patent Challenge. Such amounts shall be paid directly to Licensor as specified in Section 4.4 and not into any escrow or other account.
- (b) In the event that a Patent Challenge brought by Licensee is successful, Licensee shall have no right to recoup any royalties paid prior to the conclusion of the Patent Challenge. The parties agree that a Patent Challenge is concluded when a court of competent jurisdiction enters final judgment or when a national patent office enters a final determination (in the U.S., a determination that is appealable to the Board of Patent Appeals and Interferences).
- (c) In the event of a Patent Challenge brought by Licensee, Licensee shall pay the reasonable attorney fees and costs of Licensor in such action if the challenged Licensed Patent(s) is/are not found invalid, unenforceable or by a United States District Court or national patent office including the U.S.P.T.O. or another competent jurisdiction.
- (d) Licensor reserves the right to terminate this Agreement immediately if Licensee or its Affiliate or Sublicensee initiates any proceeding or action to challenge the validity, enforceability, or scope of one or more of the Patent Rights, or assist a third party in pursuing such a proceeding or action.

# 11. Government Laws and Regulations.

- **11.1 Government Approvals.** Licensee, at Licensee's expense, shall obtain all necessary government approvals for the development, production, distribution, sale and use of any Licensed Product.
- **11.2 Government Registration**. 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 shall assume all legal obligations to do so and shall do so at Licensee's expense.

- 11.3 Export Control. Licensee shall observe all Export Laws. Licensee warrants and covenants that it will not, directly or indirectly, export nor re-export the Licensed Products (including any associated products, items, articles, computer software, media, services, technical data and other information) in violation of applicable U.S laws and regulations, including the Export Laws. Licensee shall include a provision that is substantially similar to this Section 11.3 in its agreements with its Sublicensees, third party wholesalers and distributors, and physicians, hospitals or other healthcare providers who purchase a Licensed Product.
- developed under a funding agreement with the Government and, if so, the Government may have certain rights relative thereto. This Agreement is made subject to the Government's rights under any such agreement and under any applicable Government law or regulation, including, but not limited to, 35 U.S.C. 200-212. To the extent that there is a conflict between any such agreement, such applicable law or regulation and this Agreement, the terms of such Government agreement and applicable law or regulation shall prevail. Licensee agrees that, to the extent required by U.S. laws and regulations, Licensed Products used or sold in the U.S. will be manufactured substantially in the U.S. unless a written waiver is obtained in advance from the U.S. Government.

#### 12. Warranties and Disclaimers.

- **12.1 Licensor Representations and Warranties.** Except for the rights, if any, of the Government as set forth in Section 11.4, Licensor represents and warrants to Licensee that to the best of the knowledge of Licensor, Licensor has the lawful right to grant the license set forth in this Agreement.
- LICENSOR'S DISCLAIMER OF WARRANTIES. EXCEPT AS SPECIFICALLY SET FORTH ABOVE, LICENSEE UNDERSTANDS AND AGREES THAT LICENSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, AS TO THE LICENSED PRODUCTS, OR AS TO THE OPERABILITY OR FITNESS FOR ANY USE OR PARTICULAR PURPOSE, MERCHANTABILITY, SAFETY, EFFICACY, APPROVABILITY BY REGULATORY AUTHORITIES, TIME AND COST OF DEVELOPMENT, PATENTABILITY, NONINFRINGEMENT, AND/OR BREADTH OF PATENT RIGHTS. LICENSOR MAKES NO REPRESENTATION AS TO WHETHER ANY CLAIM OR PATENT WITHIN PATENT RIGHTS IS VALID, OR AS TO WHETHER THERE ARE ANY PATENTS NOW HELD, OR WHICH WILL BE HELD, BY OTHERS OR BY LICENSOR THAT MIGHT BE REQUIRED FOR USE OF PATENT RIGHTS IN FIELD OF USE. NOTHING IN THE AGREEMENT WILL BE CONSTRUED AS CONFERRING BY IMPLICATION, ESTOPPEL OR OTHERWISE ANY LICENSE OR RIGHTS TO ANY PATENTS OR TECHNOLOGY OF LICENSOR OTHER THAN THE PATENT RIGHTS,

WHETHER SUCH PATENTS ARE DOMINANT OR SUBORDINATE TO THE PATENT RIGHTS, OR THE TECHNOLOGY RIGHTS SPECIFICALLY DESCRIBED HEREIN.

Licensee's Representations and Warranties. Licensee represents and warrants that it has full corporate power and authority to enter into this Agreement, this Agreement constitutes the binding legal obligation of the Licensee, and execution and performance of this Agreement by Licensee will not violate or conflict with any other agreement to which Licensee is a party or by which it is bound or with any law, rule or regulation applicable to Licensee. Licensee further represents and warrants that it is a duly organized, validly existing entity, and is in good standing under the laws of its jurisdiction of organization, in Ohio, and any other jurisdiction where required by law.

#### 13. Risk.

#### 13.1 Indemnification.

Licensee agrees to indemnify, defend (with counsel selected by Licensor) and (a) hold harmless Licensor, Inventor, The REDIzone®, and their respective trustees, officers, directors, managers, employees, students and agents ("Indemnitees") against any and all liabilities, claims, suits, causes of action, judgments, liens, losses, damages, costs, fees, penalties, fines and expenses (including, without limitation, reasonable attorneys' fees and other expenses of litigation) ("Liabilities") resulting from claims or demands brought by third parties against an Indemnitee on account of any injury or death of persons, damage to property, or any other damage or loss whatsoever (1) arising out of or in connection with this Agreement; (2) arising out of or in connection with the exercise or practice of the rights granted hereunder by or under authority of Licensee, its Affiliates or their Sublicensees, or third party wholesalers or distributors, or physicians, hospitals or other healthcare providers who purchase a Licensed Product; or (3) relating in any way to the manufacture, use and sale of the Licensed Products. This indemnification shall include, without limitation, (i) any product liability claim or other claim of any kind related to the use by a third party of a Licensed Product that was manufactured, sold or otherwise disposed of by Licensee, its assignees, Sublicensees, vendors, or other third parties, (ii) a claim by a third party that the Licensed Patents or the design, composition, manufacture, use, sale or other disposition of any Licensed Product infringes or violates any patent, copyright, trademark or other intellectual property rights of such third party; and (iii) clinical trials or studies conducted by or on behalf of Licensee relating to the Licensed Patents or Licensed Products.

(b) Licensee understands, acknowledges and agrees that Licensor is an institution operated pursuant to authority conferred by the State of Ohio and as a State institution pursuant to Article VIII, Section 3; Licensor is prohibited from incurring any debt not expressly authorized by the Ohio Constitution. The Ohio Constitution Article II, Section 22, requires that any money drawn from the treasury must be pursuant to an act of the Ohio General Assembly. This restriction has been held by the Ohio Supreme Court and Ohio Attorney General to apply to indemnification agreements. Licensee acknowledges that it expressly understands this Agreement does not confer upon it any right or claim to indemnification by Licensor be it expressed or implied.

#### 13.2 Insurance.

- (a) Throughout the Term, Licensee, at Licensee's sole cost, shall procure and maintain in full force and effect a policy or policies of comprehensive commercial general liability insurance, including broad form and contractual liability, in a minimum amount of \$2,000,000 combined single limit per occurrence and in the aggregate as respects personal injury, bodily injury, and property damage however occasioned arising out of this Agreement.
- (b) Commencing at a time prior to the Licensed Product being used or sold, whichever occurs first, and continuing throughout the Term, Licensee at Licensee's sole cost and expense shall procure and maintain in full force and effect a policy or policies of product liability insurance in a minimum amount of \$3,000,000 combined single limit per occurrence and in the aggregate as respects bodily injury and property damage however occasioned arising out of this Agreement.
- (c) The policy or policies of insurance described in this Section 13.2 shall be issued in such form as is reasonably acceptable to Licensor and shall be issued by a carrier with an A.M. Best rating of "A(VIII) or better. The policy or policies shall be endorsed to (i) name Licensor, Inventor, and their respective trustees, officers, directors, managers, employees, and agents as additional insureds on a primary and non-contributory basis; and (ii) to provide Licensor with at least thirty (30) days prior written notice of cancellation or material change in coverage. Within thirty (30) days following the Effective Date and thereafter no less than thirty days prior to expiration of the policy, Licensee shall provide Licensor with certificates of insurance, copies of endorsements and portions of the policy, where necessary, to evidence the required coverage and any renewals thereof for a period of at least one year.

- (d) Licensor, in Licensor's sole discretion, may at any time during the Term review the insurance limits required above and adjust the limits to be consistent with commercially reasonable requirements for similar agreements.
- Limitation of Liability. IN NO EVENT SHALL LICENSOR, INVENTOR, AND THEIR OFFICERS, EMPLOYEES, STUDENTS, TRUSTEES, AGENTS OR AFFILIATED ENTERPRISES, BE LIABLE FOR ANY INDIRECT, SPECIAL, CONSEQUENTIAL, INCIDENTAL, EXEMPLARY, OR PUNITIVE DAMAGES (INCLUDING, WITHOUT LIMITATION, DAMAGES FOR LOSS OF PROFITS OR REVENUE) ARISING OUT OF OR IN CONNECTION WITH THE AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER ANY SUCH PARTY KNOWS OR SHOULD KNOW OF THE POSSIBILITY OF SUCH DAMAGES.
- 14. Assignment. The Agreement may not be assigned by Licensee without the prior written consent of Licensor. A merger or other transaction in which the equity holders of Licensee prior to such event hold less than a majority of the equity of the surviving or acquiring entity shall be considered an assignment of the Agreement. For any permitted assignment to be effective, (a) Licensee shall be in good standing under this Agreement, (b) the assignee shall assume in writing (a copy of which shall be promptly provided to Licensor) all of Licensee's interests, rights, duties and obligations under the Agreement and agree to comply with all terms and conditions of the Agreement as if assignee were an original party to the Agreement.
- **15. Use of Name.** Licensee shall not use the name, trademarks or other marks of Licensor without the advance written consent of Licensor, which may be withheld in Licensor's sole discretion. Licensor may use Licensee's name and logo for annual reports, brochures, website, internal reports and other marketing materials and publications without Licensee's prior consent.
- 16. Notice. All notices to be given under this Agreement shall be in writing and delivered either personally or sent by United States mail, certified, postage prepaid, or by pre-paid nationally recognized overnight courier service, and in each case addressed as set forth in this Section 16. Notices given under this Agreement will be deemed to have been given when received or when receipt is refused or when delivery is first attempted but cannot be made. Either party may change the location at which it receives notices to another location within the United States of America upon not less than ten (10) days' prior written notice to the other pursuant to this Section 15.
  - (a) All notices to Licensee are mailed to:

    [Company Contact and Information]
  - (b) All notices to Licensor are mailed to:
    Office of the General Counsel
    4209 State Route 44

P.O. Box 95 Rootstown, Ohio 44272 Attn: Maria R. Schimer

#### 17. General Provisions.

- **17.1 Governing Law.** The Agreement will be construed and enforced in accordance with laws of the State of Ohio, without regard to choice of law and conflicts of law principles.
- **17.2 Compliance with Laws.** Licensee will comply with all applicable federal, state and local laws and regulations, including, without limitation, all export laws and regulations.
- **17.3 Sovereign Immunity.** Nothing in the Agreement shall be deemed or treated as any waiver of Licensor's sovereign immunity.
- 17.4 Court of Claims/Forum. Licensee acknowledges that any claim for breach of the Agreement asserted by Licensee against Licensor shall be brought in the Ohio Court of Claims and this is Licensee's sole and exclusive process for seeking money damages for any and all alleged breaches of the Agreement by Licensor.
- **17.5 Binding Effect.** The Agreement is binding upon and inures to the benefit of the parties hereto, their respective executors, administrators, heirs, permitted assigns, and permitted successors in interest.
- **17.6 Force Majeure**. In the event any party shall be delayed, hindered, or prevented from performing any act required by this Agreement by reason of labor strikes, lock-outs, inability to procure materials, failure of power, restrictive governmental laws or regulations, riots, insurrections, war or any reason of similar nature, not the fault of the delayed party, then the performance of such act shall be excused and extended for a period equal to the period of such delay.
- 17.7 Construction of Agreement. Headings are included for convenience only and will not be used to construe the Agreement. The parties acknowledge and agree that both parties substantially participated in negotiating the provisions of the Agreement; therefore, both parties agree that any ambiguity in the Agreement shall not be construed more favorably toward one party than the other party, regardless of which party primarily drafted the Agreement.
- **17.8 Modification**. Any modification of the Agreement will be effective only if it is in writing and signed by duly authorized representatives of both parties. No modification will be made by email communications.
- **17.9 Severability.** 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 the law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.
- **17.10 Waiver.** Neither party will be deemed to have waived any of its rights under the Agreement unless the waiver is in writing and signed by such party. No delay or

omission of a party in exercising or enforcing a right or remedy under the Agreement shall operate as a waiver thereof.

- **17.11 Entire Agreement.** This Agreement, including all Exhibits attached hereto and incorporated herein, constitutes the entire understanding between the parties. This Agreement supersedes any and all prior understandings and agreements between the parties, oral and written.
- **17.12 Counterparts and Signatures.** The Agreement may be executed in multiple counterparts, each of which shall be deemed an original, but all of which taken together shall constitute one and the same instrument. A party may evidence its execution and delivery of the Agreement by transmission of a signed copy of the Agreement via facsimile or email.

[Remainder of page blank/Signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Patent License Agreement as of the day first written above.

LICENSOR:

# NORTHEAST OHIO UNIVERSITY MEDICAL UNIVERSITY

BY:	_
Steven P. Schmidt, Ph.D.	_
Vice President for Research	
Dean of the College of Graduate Studies	
Professor and Chair, Department of Pharmaceutica	l Sciences
BY:	
John Wray	_
Vice President of Administration and Finance	
Reviewed by:	
Maria R. Schimer, Esq. General Counsel, NEOMED	
General Coursel, NEOWLED	
LICENSEE:	
[Company Contact]	
Ву:	
Name/Its:	

# NORTHEAST OHIO MEDICAL UNIVERSITY Quarterly Royalty Report Exhibit A

R	e	V	e	n	u	e
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(a)	Quantity of Sales of Licensed Product (Segregated by Product)			
(b)	Gross Sales (Segregated by Product)			
Itemize	ed Dedu	ctions - Attach Supporting Documenta	ntion	
	(1)	Discounts and Rebates Actually Granted		
	(2)	Excise and Sales Taxes Actually Paid		
	(3)	Import, Expert and Custom Duties Paid		
	(4)	Freight, Transit and Insurance Charges	Total	
		Net Sales	 Total	

# Performance Milestones Exhibit B

- 1. Financing in excess of \$X within one (1) year of the effective date of this Agreement, or such other event as agreed upon, in writing, by the Parties within three (3) years of the effective date of this Agreement.
- 2. Financing in excess of \$X within three (3) years of the effective date of this Agreement, or such other event as agreed upon, in writing, by the Parties within three (3) years of the effective date of this Agreement.
- 3. Commencement of Phase II Study within three (3) years of the effective date of this Agreement. [Or other TBD]