PUBLIC HEALTH SERVICE

PATENT LICENSE-NON-EXCLUSIVE

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

This Cover Page identifies the Parties to this Agreement:

The U.S. Department of Health and Human Services, as represented by

The National Cancer Institute

an Institute or Center (hereinafter referred to as the "IC") of the

FDANIH

and

Bullrun Capital, Inc., hereinafter referred to as the "Licensee",

having offices at Suite 915 – 700 West Pender Street, Vancouver, BC, Canada V6C 1G8,

created and operating under the laws of Canada.

Tax ID No.: 842028912RT0001

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For the IC internal use only:

License Number: L-123-2019-0

License Application Number: A-493-2018

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

U.S. Patent Application Serial No 15/010,830, filed January 29, 2016, **HHS** Reference Number E-048-2010-0-US-05, titled "Agonist/antagonist compositions and methods of use";

U.S. Patent 9,277,748 (Application No. 13/634,447) filed March 11, 2011, issued March 8, 2016, titled "Agonist/antagonist compositions and methods of use", **HHS** Ref. No.: E-048-2010-0-US-04;

Canada Patent Application Serial No. 2,792,878, filed March 11, 2011, HHS Reference Number E-048-2010-0-CA-03 titled "Agonist/antagonist compositions and methods of use";

PCT Patent Application Serial No. PCT/US2011/028132, filed March 11, 2011, now abandoned, **HHS** Reference Number E-048-2010-0-PCT-02 titled "Agonist/antagonist compositions and methods of use"; and

U.S. Provisional Patent Application No. 61/340,063, filed March 12, 2018, now abandoned, titled "Agonist/Antagonist Compositions and Methods of Use", **HHS** Ref. No.: E-048-2010-0-US-01.

Licensee: Bullrun Capital, Inc.

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

Additional Remarks: N/A

Public Benefit(s): This technology may fill a public health need by improving safety over currently available pepper sprays.

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

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The IC and the Licensee agree as follows:

1. BACKGROUND

- 1.1 In the course of conducting biomedical and behavioral research, the **IC** investigators made inventions that may have commercial applicability.
- 1.2 By assignment of rights from the IC employees and other inventors, HHS, on behalf of the Government, owns intellectual property rights claimed in any United States or foreign patent applications or patents corresponding to the assigned inventions. HHS also owns any tangible embodiments of these inventions actually reduced to practice by the IC.
- 1.3 The Secretary of HHS has delegated to the IC the authority to enter into this Agreement for the licensing of rights to these inventions under 35 U.S.C. §§200-212, the Federal Technology

 Transfer Act of 1986, 15 U.S.C. §3710(a), and the regulations governing the licensing of Government-owned inventions, 37 C.F.R. Part 404.
- 1.4 The IC desires to transfer these inventions to the private sector through commercialization licenses to facilitate the commercial development of products and processes for public use and benefit.
- 1.5 The **Licensee** desires to acquire commercialization rights to certain of these inventions in order to develop processes, methods, or marketable products for public use and benefit.

2. **DEFINITIONS**

- 2.1 "Affiliate(s)" means a corporation or other business entity, which directly or indirectly is controlled by or controls, or is under common control with the Licensee. For this purpose, the term "control" shall mean ownership of more than fifty percent (50%) of the voting stock or other ownership interest of the corporation or other business entity, or the power to elect or appoint more than fifty percent (50%) of the members of the governing body of the corporation or other business entity.
- 2.2 "Benchmarks" mean the performance milestones that are set forth in Appendix D.
- 2.3 "Commercial Development Plan" means the written commercialization plan attached as Appendix E.
- 2.4 "First Commercial Sale" means the initial transfer by or on behalf of the Licensee of Licensed Products or the initial practice of a Licensed Process by or on behalf of the Licensee in exchange for cash or some equivalent to which value can be assigned for the purpose of determining Net Sales.
- 2.5 "FDA" means the Food and Drug Administration.
- 2.6 **First Responder Inc.** means a corporation having an address of Suite 915 700 West Pender Street, Vancouver, BC, Canada V6C 1G8, a company of which **Licensee** is the initial founding shareholder having all of the issued and outstanding shares upon organization and the right to appoint the initial directors of same.

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- 2.7 "Government" means the Government of the United States of America.
- 2.8 "Licensed Fields of Use" means the fields of use identified in Appendix B.
- 2.9 "Licensed Patent Rights" shall mean:
 - (a) Patent applications (including provisional patent applications and PCT patent applications) or patents listed in Appendix A, all divisions and continuations of these applications, all patents issuing from these applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all these patents;
 - (b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a):
 - (i) continuations-in-part of 2.9(a);
 - (ii) all divisions and continuations of these continuations-in-part;
 - (iii) all patents issuing from these continuations-in-part, divisions, and continuations;
 - (iv) priority patent application(s) of 2.9(a); and
 - (v) any reissues, reexaminations, and extensions of all these patents;
 - (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.9(a): all counterpart foreign and U.S. patent applications and patents to 2.9(a) and 2.9(b), including those listed in Appendix A; and
 - (d) **Licensed Patent Rights** shall *not* include 2.9(b) or 2.9(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.9(a).
- 2.10 "Licensed Processes" means processes, which in the course of being practiced, would be within the scope of one or more claims of the Licensed Patent Rights that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.
- 2.11 "Licensed Products" means tangible materials, which in the course of manufacture, use, sale, or importation, would be within the scope of one or more claims of the Licensed Patent Rights that have not been held unpatentable, invalid or unenforceable by an unappealed or unappealable judgment of a court of competent jurisdiction.

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- 2.12 "Licensed Territory" means the geographical area identified in Appendix B.
- "Net Sales" means the total gross receipts for sales of Licensed Products or practice of Licensed Processes by or on behalf of the Licensee, and from leasing, renting, or otherwise making Licensed Products available to others without sale or other dispositions, whether invoiced or not, less returns and allowances, packing costs, insurance costs, freight out, taxes or excise duties imposed on the transaction (if separately invoiced), and wholesaler and cash discounts in amounts customary in the trade to the extent actually granted. No deductions shall be made for commissions paid to individuals, whether they are with independent sales agencies or regularly employed by the Licensee, and on its payroll, or for the cost of collections.
- 2.14 "Practical Application" means to manufacture in the case of a composition or product, to practice in the case of a process or method, or to operate in the case of a machine or system; and in each case, under these conditions as to establish that the invention is being utilized and that its benefits are to the extent permitted by law or Government regulations available to the public on reasonable terms.

3. **GRANT OF RIGHTS**

- 3.1 The IC hereby grants and the Licensee accepts, subject to the terms and conditions of this Agreement, a nonexclusive license under the Licensed Patent Rights in the Licensed Territory to make and have made, to use and have used, to sell and have sold, to offer to sell, and to import any Licensed Products in the Licensed Fields of Use and to practice and have practiced any Licensed Processes in the Licensed Fields of Use.
- This **Agreement** confers no license or rights by implication, estoppel, or otherwise under any patent applications or patents of the **IC** other than the **Licensed Patent Rights** regardless of whether these patents are dominant or subordinate to the **Licensed Patent Rights**.

4. **SUBLICENSING**

4.1 The **Licensee** has no right to sublicense

5. STATUTORY AND NIH REQUIREMENTS AND RESERVED GOVERNMENT RIGHTS

- 5.1 Prior to the **First Commercial Sale**, the **Licensee** agrees to provide the **IC** with reasonable quantities of **Licensed Products** or materials made through the **Licensed Processes** for **IC** research use.
- The **Licensee** agrees that products used or sold in the United States embodying **Licensed Products** or produced through use of **Licensed Processes** shall be manufactured substantially in the United States, unless a written waiver is obtained in advance from the **IC**.

6. ROYALTIES AND REIMBURSEMENT

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

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- 6.3 The Licensee agrees to pay the IC earned royalties as set forth in Appendix C.
- 6.4 The Licensee agrees to pay the IC benchmark royalties as set forth in Appendix C.
- A patent or patent application licensed under this **Agreement** shall cease to fall within the **Licensed Patent Rights** for the purpose of computing earned royalty payments in any given country on the earliest of the dates that:
 - (a) the application has been abandoned and not continued;
 - (b) the patent expires or irrevocably lapses; or
 - (c) the patent has been held to be invalid or unenforceable by an unappealed or unappealable decision of a court of competent jurisdiction or administrative agency.
- 6.6 No multiple royalties shall be payable because any **Licensed Products** or **Licensed Processes** are covered by more than one of the **Licensed Patent Rights**.
- 6.7 On sales of **Licensed Products** by the **Licensee** made in other than an arms-length transaction, the value of the **Net Sales** attributed under this Article 6 to this transaction shall be that which would have been received in an arms-length transaction, based on sales of like quantity and quality products on or about the time of this transaction.
- With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights and paid by the IC prior to the effective date of this Agreement, the Licensee shall pay the IC, as an additional royalty, not to exceed seventy thousand Dollars (\$70,000), within sixty (60) days of the IC's submission of a statement and request for payment to the Licensee, an amount equivalent to the unreimbursed patent expenses previously paid by the IC. With regard to unreimbursed expenses associated with the preparation, filing, prosecution, and maintenance of all patent applications and patents included within the Licensed Patent Rights and paid by the IC on or after the effective date of this Agreement, the IC, at its sole option, may require the Licensee:
 - (a) to pay the IC on an annual basis, within sixty (60) days of the IC's submission of a statement and request for payment, a royalty amount equivalent to these unreimbursed expenses paid during the previous calendar year(s); said expenses being divided amongst all licensees to the Licensed Patent Rights, should any other such licenses be executed;
 - (b) to pay these unreimbursed expenses directly to the law firm employed by the IC to handle these functions. However, in this event, the IC and not the Licensee shall be the client of the law firm; or

- (c) under exceptional circumstances, the **Licensee** may be given the right to assume responsibility for the preparation, filing, prosecution, or maintenance of any patent application or patent included with the **Licensed Patent Rights**. In that event, the **Licensee** shall directly pay the attorneys or agents engaged to prepare, file, prosecute, or maintain these patent applications or patents and shall provide the **IC** with copies of each invoice associated with these services as well as documentation that these invoices have been paid.
- 6.9 The IC agrees, upon written request, to provide the Licensee with summaries of patent prosecution invoices for which the IC has requested payment from the Licensee under Paragraphs 6.8 and 6.9. The Licensee agrees that all information provided by the IC related to patent prosecution costs shall be treated as confidential commercial information and shall not be released to a third party except as required by law or a court of competent jurisdiction.
- 6.10 The Licensee may elect to surrender its rights in any country of the Licensed Territory under any of the Licensed Patent Rights upon sixty (60) days written notice to the IC and owe no payment obligation under Paragraph 6.9 for patent-related expenses paid in that country after the effective date of the written notice.

7. PATENT FILING, PROSECUTION, AND MAINTENANCE

7.1 The IC agrees to take responsibility for the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights, but to consult with, the Licensee in the preparation, filing, prosecution, and maintenance of any and all patent applications or patents included in the Licensed Patent Rights and shall furnish copies of relevant patent related documents to the Licensee.

8. RECORD KEEPING

8.1 The Licensee agrees to keep accurate and correct records of Licensed Products made, used, sold, or imported and Licensed Processes practiced under this Agreement appropriate to determine the amount of royalties due the IC. These records shall be retained for at least five (5) years following a given reporting period and shall be available during normal business hours for inspection, at the expense of the IC, by an accountant or other designated auditor selected by the IC for the sole purpose of verifying reports and royalty payments hereunder. The accountant or auditor shall only disclose to the IC information relating to the accuracy of reports and royalty payments made under this Agreement. If an inspection shows an underreporting or underpayment in excess of five percent (5%) for any twelve (12) month period, then the Licensee shall reimburse the IC for the cost of the inspection at the time the Licensee pays the unreported royalties, including any additional royalties as required by Paragraph 9.7. All royalty payments required under this Paragraph shall be due within sixty (60) days of the date the IC provides the Licensee notice of the payment due.

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

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

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- 9.2 The Licensee shall provide written annual reports on its product development progress or efforts to commercialize under the Commercial Development Plan for each of the Licensed Fields of Use within sixty (60) days after December 31 of each calendar year. These progress reports shall include, but not be limited to: progress on research and development, status of applications for regulatory approvals, manufacture, marketing, importing, and sales during the preceding calendar year, as well as, plans for the present calendar year. The IC also encourages these reports to include information on any of the Licensee's public service activities that relate to the Licensed Patent Rights. If reported progress differs from that projected in the Commercial **Development Plan** and **Benchmarks**, the **Licensee** shall explain the reasons for such differences. In any annual report, the Licensee may propose amendments to the Commercial Development Plan, acceptance of which by the IC may not be denied unreasonably. The Licensee agrees to provide any additional information reasonably required by the IC to evaluate the Licensee's performance under this Agreement. The Licensee may amend the Benchmarks at any time upon written approval by the IC. The IC shall not unreasonably withhold approval of any request of the Licensee to extend the time periods of this schedule if the request is supported by a reasonable showing by the Licensee of diligence in its performance under the Commercial Development Plan and toward bringing the Licensed Products to the point of Practical Application.
- 9.3 The Licensee shall report to the IC the dates for achieving Benchmarks specified in Appendix D and the First Commercial Sale in each country in the Licensed Territory within thirty (30) days of such occurrences
- 9.4 The Licensee shall submit to the IC, within sixty (60) days after each calendar half-year ending June 30 and December 31, a royalty report, as described in the example in Appendix F, setting forth for the preceding half-year period the amount of the Licensed Products sold or Licensed Processes practiced by or on behalf of the Licensee in each country within the Licensed Territory, the Net Sales, and the amount of royalty accordingly due. With each royalty report, the Licensee shall submit payment of earned royalties due. If no earned royalties are due to the IC for any reporting period, the written report shall so state. The royalty report shall be certified as correct by an authorized officer of the Licensee and shall include a detailed listing of all deductions made under Paragraph 2.13 to determine Net Sales made under Article 6 to determine royalties due.
- 9.5 Royalties due under Article 6 shall be paid in U.S. dollars and payment options are listed in Appendix G. For conversion of foreign currency to U.S. dollars, the conversion rate shall be the New York foreign exchange rate quoted in *The Wall Street Journal* on the day that the payment is due, and any loss of exchange, value, taxes, or other expenses incurred in the transfer or conversion to U.S. dollars shall be paid entirely by the Licensee. The royalty report required by Paragraph 9.4 shall be mailed to the IC at its address for Agreement Notices indicated on the Signature Page.
- 9.6 The **Licensee** shall be solely responsible for determining if any tax on royalty income is owed outside the United States and shall pay this tax and be responsible for all filings with appropriate agencies of foreign governments.

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- 9.7 Additional royalties may be assessed by the **IC** on any payment that is more than ninety (90) days overdue at the rate of one percent (1%) per month. This one percent (1%) per month rate may be applied retroactively from the original due date until the date of receipt by the **IC** of the overdue payment and additional royalties. The payment of any additional royalties shall not prevent the **IC** from exercising any other rights it may have as a consequence of the lateness of any payment.
- 9.8 All plans and reports required by this Article 9 and marked "confidential" by the **Licensee** shall, to the extent permitted by law, be treated by the **IC** as commercial and financial information obtained from a person and as privileged and confidential, and any proposed disclosure of these records by the **IC** under the Freedom of Information Act (FOIA), <u>5 U.S.C. §552</u> shall be subject to the predisclosure notification requirements of <u>45 C.F.R. §5.65(d)</u>.

10. PERFORMANCE

- 10.1 The Licensee shall use its reasonable commercial efforts to bring the Licensed Products and Licensed Processes to Practical Application. "Reasonable commercial efforts" for the purposes of this provision shall include adherence to the Commercial Development Plan in Appendix E and performance of the Benchmarks in Appendix D.
- 10.2 Upon the First Commercial Sale, until the expiration or termination of this Agreement, the Licensee shall use its reasonable commercial efforts to make Licensed Products and Licensed Processes reasonably accessible to the United States public.
- 10.3 The Licensee agrees, after its First Commercial Sale, to make reasonable quantities of Licensed Products or materials produced through the use of Licensed Processes available to patient assistance programs.
- 10.4 The **Licensee** agrees, after its **First Commercial Sale** and as part of its marketing and product promotion, to develop educational materials (e.g., brochures, website, etc.) directed to patients and physicians detailing the **Licensed Products** or medical aspects of the prophylactic and therapeutic uses of the **Licensed Products**.
- 10.5 The Licensee agrees to supply, to the Mailing Address for Agreement Notices indicated on the Signature Page, the Office of Technology Transfer, the NIH with inert samples of the Licensed Products or Licensed Processes or their packaging for educational and display purposes only.

11. INFRINGEMENT AND PATENT ENFORCEMENT

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

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

12. NEGATION OF WARRANTIES AND INDEMNIFICATION

- 12.1 The IC offers no warranties other than those specified in Article 1.
- 12.2 The IC does not warrant the validity of the Licensed Patent Rights and makes no representations whatsoever with regard to the scope of the Licensed Patent Rights, or that the Licensed Patent Rights may be exploited without infringing other patents or other intellectual property rights of third parties.
- 12.3 THE IC MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OF ANY SUBJECT MATTER DEFINED BY THE CLAIMS OF THE LICENSED PATENT RIGHTS OR TANGIBLE MATERIALS RELATED THERETO.
- 12.4 The IC does not represent that it shall commence legal actions against third parties infringing the Licensed Patent Rights.
- 12.5 The **Licensee** shall indemnify and hold the **IC**, its employees, students, fellows, agents, and consultants harmless from and against all liability, demands, damages, expenses, and losses, including but not limited to death, personal injury, illness, or property damage in connection with or arising out of:
 - (a) the use by or on behalf of the Licensee, its directors, employees, or third parties of any Licensed Patent Rights; or
 - (b) the design, manufacture, distribution, or use of any Licensed Products, Licensed Processes or materials by the Licensee, or other products or processes developed in connection with or arising out of the Licensed Patent Rights.
- 12.6 The **Licensee** agrees to maintain a liability insurance program consistent with sound business practice.

13. TERM, TERMINATION, AND MODIFICATION OF RIGHTS

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

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- 13.2 In the event that the **Licensee** is in default in the performance of any material obligations under this **Agreement**, including but not limited to the obligations listed in Paragraph 13.5, and if the default has not been remedied within ninety (90) days after the date of notice in writing of the default, the **IC** may terminate this **Agreement** by written notice and pursue outstanding royalties owed through procedures provided by the <u>Federal Debt Collection Act</u>.
- 13.3 In the event that the **Licensee** becomes insolvent, files a petition in bankruptcy, has such a petition filed against it, determines to file a petition in bankruptcy, or receives notice of a third party's intention to file an involuntary petition in bankruptcy, the **Licensee** shall immediately notify the **IC** in writing.
- 13.4 The **Licensee** shall have a unilateral right to terminate this **Agreement** in any country or territory by giving the **IC** sixty (60) days written notice to that effect.
- 13.5 The IC shall specifically have the right to terminate or modify, at its option, this **Agreement**, if the IC determines that the **Licensee**:
 - (a) is not executing the Commercial Development Plan submitted with its request for a license and the Licensee cannot otherwise demonstrate to the IC's satisfaction that the Licensee has taken, or can be expected to take within a reasonable time, effective steps to achieve Practical Application of the Licensed Products or Licensed Processes;
 - (b) has not achieved the **Benchmarks** as may be modified under Paragraph 9.2;
 - has willfully made a false statement of, or willfully omitted, a material fact in the license application or in any report required by this **Agreement**;
 - (d) has committed a material breach of a covenant or agreement contained in this **Agreement**;
 - is not keeping Licensed Products or Licensed Processes reasonably available to the public after commercial use commences;
 - (f) cannot reasonably satisfy unmet health and safety needs; or
 - (g) cannot reasonably justify a failure to comply with the domestic production requirement of Paragraph 5.2, unless waived.
- In making the determination referenced in Paragraph 13.5, the IC shall take into account the normal course of such commercial development programs conducted with sound and reasonable business practices and judgment and the annual reports submitted by the Licensee under Paragraph 9.2. Prior to invoking termination or modification of this Agreement under Paragraph 13.5, the IC shall give written notice to the Licensee providing the Licensee specific notice of, and a ninety (90) day opportunity to respond to, the IC's concerns as to the items referenced in 13.5(a)-13.5(g). If the Licensee fails to alleviate the IC's concerns as to the items referenced in 13.5(a)-13.5(g) or fails to initiate corrective action to the IC's satisfaction, the IC may terminate this Agreement.

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- 13.7 The IC reserves the right according to 35 U.S.C. §209(d)(3) to terminate or modify this Agreement if it is determined that the action is necessary to meet the requirements for public use specified by federal regulations issued after the date of the license and these requirements are not reasonably satisfied by the Licensee.
- 13.8 Within thirty (30) days of receipt of written notice of the IC's unilateral decision to modify or terminate this **Agreement**, the **Licensee** may, consistent with the provisions of 37 C.F.R. §404.11, appeal the decision by written submission to the designated the IC official. The decision of the designated IC official shall be the final agency decision. The **Licensee** may thereafter exercise any and all administrative or judicial remedies that may be available.
- 13.9 Within ninety (90) days of expiration or termination of this **Agreement** under this Article 13, a final report shall be submitted by the **Licensee**. Any royalty payments, including those incurred but not yet paid (such as the full minimum annual royalty), and those related to patent expense, due to the IC shall become immediately due and payable upon termination or expiration. Unless otherwise specifically provided for under this **Agreement**, upon termination or expiration of this **Agreement**, the **Licensee** shall return all **Licensed Products** or other materials included within the **Licensed Patent Rights** to the IC or provide the IC with written certification of the destruction thereof. The **Licensee** may not be granted additional IC licenses if the final reporting requirement is not fulfilled.

14. GENERAL PROVISIONS

- 14.1 Neither party may waive or release any of its rights or interests in this **Agreement** except in writing. The failure of the **Government** to assert a right hereunder or to insist upon compliance with any term or condition of this **Agreement** shall not constitute a waiver of that right by the **Government** or excuse a similar subsequent failure to perform any of these terms or conditions by the **Licensee**.
- 14.2 This Agreement constitutes the entire agreement between the Parties relating to the subject matter of the Licensed Patent Rights, Licensed Products and Licensed Processes, and all prior negotiations, representations, agreements, and understandings are merged into, extinguished by, and completely expressed by this Agreement.
- 14.3 The provisions of this **Agreement** are severable, and in the event that any provision of this **Agreement** shall be determined to be invalid or unenforceable under any controlling body of law, this determination shall not in any way affect the validity or enforceability of the remaining provisions of this **Agreement**.
- 14.4 If either party desires a modification to this **Agreement**, the parties shall, upon reasonable notice of the proposed modification by the party desiring the change, confer in good faith to determine the desirability of the modification. No modification shall be effective until a written amendment is signed by the signatories to this **Agreement** or their designees.
- 14.5 The construction, validity, performance, and effect of this **Agreement** shall be governed by Federal law as applied by the Federal courts in the District of Columbia.

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- All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the Signature Page, or to any other address as may be designated in writing by such other party. **Agreement** notices shall be considered timely if such notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 14.7 This **Agreement** shall not be assigned or otherwise transferred (including any transfer by legal process or by operation of law, and any transfer in bankruptcy or insolvency, or in any other compulsory procedure or order of court) except to the **Licensee's Affiliate(s)** or to **First Responder**, **Inc.** without the prior written consent of the **IC**. The parties agree that the identity of the parties is material to the formation of this **Agreement** and that the obligations under this **Agreement** are nondelegable. In the event that the **IC** approves a proposed assignment, the **Licensee** shall pay the **IC**, as an additional royalty, one percent (1%) of the fair market value of any consideration received for any assignment of this **Agreement** within sixty (60) days of the assignment
- The **Licensee** agrees in its use of any **IC**-supplied materials to comply with all applicable statutes, regulations, and guidelines, including **NIH** and **HHS** regulations and guidelines. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials in the United States without complying with <u>21 C.F.R. Part 50</u> and <u>45 C.F.R. Part 46</u>. The **Licensee** agrees not to use the materials for research involving human subjects or clinical trials outside of the United States without notifying the **IC**, in writing, of the research or trials and complying with the applicable regulations of the appropriate national control authorities. Written notification to the **IC** of research involving human subjects or clinical trials outside of the United States shall be given no later than sixty (60) days prior to commencement of the research or trials.
- The **Licensee** acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the <u>Export Administration Act of 1979</u> and <u>Arms Export Control Act</u>) controlling the export of technical data, computer software, laboratory prototypes, biological materials, and other commodities. The transfer of these items may require a license from the appropriate agency of the **Government** or written assurances by the **Licensee** that it shall not export these items to certain foreign countries without prior approval of the agency. The **IC** neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.10 The Licensee agrees to mark the Licensed Products or their packaging sold in the United States with all applicable U.S. patent numbers and similarly to indicate "Patent Pending" status. All Licensed Products manufactured in, shipped to, or sold in other countries shall be marked in a manner to preserve the IC patent rights in those countries.

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- By entering into this **Agreement**, the **IC** does not directly or indirectly endorse any product or service provided, or to be provided, by the **Licensee** whether directly or indirectly related to this **Agreement**. The **Licensee** shall not state or imply that this **Agreement** is an endorsement by the **Government**, the **IC**, any other **Government** organizational unit, or any **Government** employee. Additionally, the **Licensee** shall not use the names of the **IC**, the **FDA**, **HHS**, or the **Government** or their employees in any advertising, promotional, or sales literature without the prior written approval of the **IC**.
- 14.12 The Parties agree to attempt to settle amicably any controversy or claim arising under this **Agreement** or a breach of this **Agreement**, except for appeals of modifications or termination decisions provided for in Article 13. The **Licensee** agrees first to appeal any unsettled claims or controversies to the designated **IC** official, or designee, whose decision shall be considered the final agency decision. Thereafter, the **Licensee** may exercise any administrative or judicial remedies that may be available.
- 14.13 Nothing relating to the grant of a license, nor the grant itself, shall be construed to confer upon any person any immunity from or defenses under the antitrust laws or from a charge of patent misuse, and the acquisition and use of rights pursuant to 37 C.F.R. Part 404 shall not be immunized from the operation of state or Federal law by reason of the source of the grant.
- 14.14 Paragraphs 8.1, 9.6-9.8, 12.1-12.5, 13.8, 13.9, 14.12 and 14.14 of this **Agreement** shall survive termination of this **Agreement**.
- 14.15 The terms and conditions of this **Agreement** shall, at the **IC's** sole option, be considered by the **IC** to be withdrawn from the **Licensee's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Licensee** and a fully executed original is received by the **IC** within sixty (60) days from the date of the **IC** signature found at the Signature Page.

SIGNATURES BEGIN ON NEXT PAGE

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NIH PATENT LICENSE AGREEMENT – NONEXCLUSIVE

SIGNATURE PAGE

For the IC:	Richard U.	Digitally signed by Richard U. Rodriguez -S	
	Rodriguez -S	Date: 2019.02.14 10:02:13 -05'00'	2-14-19
Associate Di National Car	Rodriguez, MBA irector, TTC ncer Institute titutes of Health		Date
Mailing Add	lress or E-mail Addres	ss for Agreement notices ar	nd reports:
Monitoring Office of Teo National Ins 6011 Execut	npliance and Adminis & Enforcement chnology Transfer titutes of Health tive Boulevard, Suite laryland 20852-3804	325	
E-mail: Licer	nseNotices_Reports@	Pmail.nih.gov	
For the Lice any stateme	nsee (Upon, informatents of the Licensee r	cion and belief, the undersi nade or referred to in this o	gned expressly certifies or affirms that the contents o document are truthful and accurate.):
Printed Nam	Authorized Official All Marine Arman	1/h /	<u>Febry</u> 119. Date
Title			
l. Off	icial and Mailing Add	ress for Agreement notices	::
<u>Kal</u> Nar	Malhi me		
<u>CEC</u> Title			
Ma A-493-2018	iling Address 915-700 Vancan	w fende ver, BC, CA	NADA VEC 142
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	Bullrun Capital	Inc.		
		West Pender Street		
	Vancouver, BC,	Canada		
				
	Email Address:	kal@bullruncapital.ca		_
	Phone:	604-805-4602		
	Fax:			-
				•
II.	Official and Mai	ling Address for Financial notices (the	Licensee's contact	person for royalty payments)
	10 10 0 H			, , , , , , , , , , , , , , , , , , , ,
	Name		_	
	CEO			
	Title		_	
	Mailing Address	:		
	Bullrun Capital I	nc.		
			<u>-</u>	
	Suite 915 -700 V	Vest Pender Street	-	
	Vancouver, VC, (Canada		
			-	
			-	
	Email Address:	kal@bullruncapital.ca		
	Phone:	604-805-4602		
	Fax:			

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

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

Patent(s) or Patent Application(s):

- U.S. Patent Application Serial No 15/010,830, filed January 29, 2016, HHS Reference Number E-048-2010-0-US-05, titled "Agonist/antagonist compositions and methods of use";
- II. U.S. Patent 9,277,748 (Application No. 13/634,447) filed March 11, 2011, issued March 8, 2016, titled "Agonist/antagonist compositions and methods of use", **HHS** Ref. No.: E-048-2010-0-US-04;
- III. Canada Patent Application Serial No. 2,792,878, filed March 11, 2011, **HHS** Reference Number E-048-2010-0-CA-03 titled "Agonist/antagonist compositions and methods of use";
- IV. PCT Patent Application Serial No. PCT/US2011/028132, filed March 11, 2011, now abandoned, **HHS**Reference Number E-048-2010-0-PCT-02 titled "Agonist/antagonist compositions and methods of use"; and
- V. U.S. Provisional Patent Application No. 61/340,063, filed March 12, 2018, now abandoned, titled "Agonist/Antagonist Compositions and Methods of Use", **HHS** Ref. No.: E-048-2010-0-US-01.

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APPENDIX B - LICENSED FIELDS OF USE AND TERRITORY

I. Licensed Fields of Use:

(a) Generation of compositions containing a transient receptor potential cation channel subfamily V member 1 (TRPV1) antagonist combined with a TRPV1 agonist for the temporary incapacitation of a subject.

II. Licensed Territory:

(a) Worldwide

APPENDIX C - ROYALTIES

Royalties:

- I. The Licensee agrees to pay to the IC a noncreditable, nonrefundable license issue royalty in the amount of twenty thousand Dollars (\$20,000) within sixty (60) days from the effective date of this Agreement.
- II. The **Licensee** agrees to pay to the **IC** a nonrefundable minimum annual royalty in the amount of ten thousand Dollars (\$10,000) as follows:
 - (a) The first minimum annual royalty is due within sixty (60) days of the effective date of this **Agreement** and may be prorated according to the fraction of the calendar year remaining between the effective date of this **Agreement** and the next subsequent January 1; and
 - (b) Subsequent minimum annual royalty payments are due and payable on January 1 of each calendar year and may be credited against any earned royalties due for sales made in that year.
- III. The Licensee agrees to pay the IC earned royalties of:
 - (a) Five percent (5%) on **Net Sales** by or on behalf of the **Licensee** in the US and Canada; and
 - (b) Three percent (3%) on **Net Sales** by or on behalf of the **Licensee** in all jurisdictions other than Canada or the United States.
- IV. The Licensee agrees to pay the IC Benchmark royalties within sixty (60) days of achieving each Benchmark:
 - (a) Eight thousand Dollars (\$8,000) upon Completion of Pre-Clinical Acute Dermal/Ocular Toxicity Studies.
 - (b) Eight thousand Dollars (\$8,000) upon Completion of a Phase I Clinical Trial.
 - (c) Ten thousand Dollars (\$10,000) upon First Commercial Sale.

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APPENDIX D - BENCHMARKS AND PERFORMANCE

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

- 1. Select a first TRPV1 agonist/antagonist compounds for product development (Q1 2019)
- II. Identify a manufacturer of the TRPV1 agonist/antagonist compound (Q2 2019)
- III. Conduct pre-clinical acute dermal/ocular toxicity studies (Q3 2019)
- IV. Conduct a Phase I clinical trial (Q2 2020)
- V. First commercial sale of the first TRPV1 agonist/antagonist compound (Q1 2021)

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<u>APPENDIX E – COMMERCIAL DEVELOPMENT PLAN</u>

Licensee intends to develop short acting pepper sprays that are effective at incapacitating a subject while also having the built-in ability to minimize the duration of the effects after exposure. The products would contain both a TRPV1 receptor agonist such as capsaicin, which would cause the typical pepper spray reaction, along with a TRPV1 receptor antagonist that would be used to counteract the effect of the agonist. **Licensee**'s development plans are as follows:

Since none of the agonist/antagonist combinations have been tested *in vivo*, the first step for **Licensee** will be to confirm which antagonists will work as needed. Following selection of specific combinations of agonists and antagonists to initially develop into commercial products, **Licensee** will explore the regulatory pathway needed to bring the product(s) to market. Although conventional pepper spray formulations do not require **FDA** approval, the addition of the antagonist may cause the product(s) to be viewed as a device containing a drug, such that there is a reasonable chance that the **FDA** will require oversight. Therefore, the company is already planning to manufacture their formulation(s) under cGMP standards while they investigate whether or not **FDA** approval or clearance will be required. The company will engage regulatory consultants who are experts in this area and will also apply directly to the **FDA** for guidance.

Once specific antagonists have been chosen for advancement, **Licensee** plans to identify a contract manufacturer. As noted above, given the chance that the product may require **FDA** review, **Licensee** intends to manufacture the antagonist material under cGMP regulations in order to produce clinical grade material. **Licensee** also realizes that the opinion of the **FDA** could change, and therefore, the company believes it is necessary to manufacture the anatomist under cGMP conditions, even if the initial decision from the **FDA** is that the formulation does not require clearance.

As part of the development process, **Licensee** intends to conduct pre-clinical acute dermal/ocular toxicity studies. These studies are acute one-time exposures that would likely be conducted on rabbits to measure lacrimation (crying/tears), followed by pathology tests on eye tissue after the animals are given a period of time to recover. Study costs will range depending on the number of different formulations and concentrations of agonist/antagonist being used in the study.

As part of finalizing the formulation(s), **Licensee** will conduct product stability studies, looking at how the product(s) manages at higher temperature (42°C) over a period of several months. **Licensee** expects these stability studies, which are used to determine shelf-life, to be ongoing, and will depend somewhat on what the **FDA** requires as well as on the number of concentrations and different liquid formulations to be tested.

Finally, **Licensee** plans to conduct a phase I clinical trial, although this could be run concomitantly with the stability studies. After a final or near-final formulation (or formulations) has been selected, **Licensee** will approach the **FDA** and/or Health Canada about clinical testing. The company anticipates that a single-dose related exposure study is what will be needed. Testing protocols will likely include eyes, skin and respiratory (inhalation) function.

Per the diagram below, **Licensee** expects that it will take about two years to develop the formulation(s) into a sales-ready product.

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Milestone (Month) 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24

Confirm Antagonist(s) for Development FDA Route & Initial Manufacturing Initial Manufacturing Pre-clinical GLP tox Formulation & Stability Solvent & Propellant Canister Selection Valve Selection Actuator Selection Actuator Selection Valve Leakage Stability Study Phase I Study Product Labelling Design Component Procurement & Delivery Digital Promotional Materia-

Manufacturing Large Scale Marketing and Advertisement Sales

Development



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APPENDIX F - EXAMPLE ROYALTY REPORT

Required royalty report information includes:

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

Example

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

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

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APPENDIX G – ROYALTY PAYMENT OPTIONS

New Payment Options Effective March 2018

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

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

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

The IC encourages its licensees to submit electronic funds transfer payments through the Automated Clearing House (ACH). Submit your ACH payment through the U.S. Treasury web site located at: https://www.pay.gov/public/form/startJ28680443 Please note that the "C "only" accepts ACH payments through this U.S. Treasury web site.

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

Drawn on a U.S. bank account via FEDWIRE:

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

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

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

Drawn on a foreign bank account via FEDWIRE:

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

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

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

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

^{**}Anything other than the 12 digit gateway account # will cause the Fedwire to be returned – SWIFT CODE:

Fedwire	Fedwire Field Name	Required Information	
Field Tag	T COVITE TIEID HUITE		
FRNYUS33			

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Agency Contacts:

Office of Technology Transfer (OTT)

(301) 496-7057

OTT-Royalties@mail.nih.gov

Checks

All checks should be made payable to "NIH Patent Licensing"

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

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

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

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

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

National Institutes of Health Office of Technology Transfer License Compliance and Administration Royalty Administration 6011 Executive Boulevard Suite 325, MSC 7660

Rockville, Maryland 20852

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