

## GRANT AGREEMENT

This grant agreement (“**Agreement**”) is entered into as of the date of the last signature of this Agreement (“**Effective Date**”) and commences on 01 December 2023 (“**Commencement Date**”) by and between

**MEDICINES PATENT POOL**, Rue de Varembe 7, 1202 Geneva, Switzerland (“**MPP**”)

and

**AFRIGEN BIOLOGICS (PTY) LTD**, Unit 5 and 6 Kestrel Park, Longclaw Drive Montague Gardens, Cape Town, Western Cape, 7441, South Africa (“**Afrigen**”).

Afrigen and MPP are referred hereto collectively as “**Parties**” and individually each the “**Party**”.

### PREAMBLE

WHEREAS, the World Health Organisation (“**WHO**”), MPP, Afrigen and other organisations have established an mRNA technology transfer programme (“**Programme**”) to increase the manufacturing capacity of mRNA-based vaccines for infectious diseases in low- and middle-income countries (“**LMICs**”).

WHEREAS, as part of the Programme, Afrigen will develop an mRNA vaccine platform technology for infectious diseases and establish a technology transfer and training hub for partners of the Programme to receive technology transfer and training to increase their capacity to manufacture mRNA-base vaccines.

WHEREAS, Afrigen wishes to leverage of the Programme to develop an mRNA-based vaccine for neisseria gonorrhoeae and to provide technology transfer and training on that vaccine to the partners of the Programme to increase the manufacture and availability of that vaccine in LMICs.

WHEREAS, MPP has received funding from third parties (“**Funders**”) to accelerate the availability of mRNA-based vaccines for *Neisseria gonorrhoeae* and wishes to provide funding to Afrigen to develop an mRNA-based vaccine for *Neisseria gonorrhoeae*.

NOW THEREFORE, the Parties hereby agree to the following terms and conditions:

#### 1. **Project**

- 1.1. Scope of Work. Afrigen will perform the scope of work described in Annexure 1 to this Agreement (“**Project**”). The Project may be modified solely by mutual agreement between the Parties.
- 1.2. Key Personnel. The Project will be performed by Afrigen under the direction of the Afrigen principal investigator (“**Afrigen PI**”) and with the participation of the other key individuals identified in Annexure 1 (collectively with the Afrigen PI, the “**Key Personnel**”). No substitution of Key Personnel will be permitted for the first six months of the Project, except as necessitated by the sudden illness, death or termination of employment of the employee, in which case such employee will be replaced with a mutually agreeable substitute. In the event the Afrigen PI becomes unavailable to continue with the Project, the parties will attempt to find a mutually acceptable substitute. In the event a mutually acceptable substitute is not found, the Agreement may be terminated in accordance with Section 11.
- 1.3. Subcontractors. Afrigen shall not delegate, whether by subcontract or otherwise, any of its obligations hereunder without the prior written consent of MPP. If a delegation is approved, Afrigen shall flow down all obligations of this Agreement in an enforceable agreement with the delegee and shall remain liable for the performance or non-performance/breach of this Agreement by such delegee.

## 2. **Grant Payment**

- 2.1. Grant for the Project. Subject to the terms and conditions of this Agreement, and Afrigen's compliance therewith, MPP will fund Afrigen USD\$150,000.00 ("**Grant**") to perform the Project in accordance with the approved budget set out in Annexure 1 ("**Budget**").
- 2.2. Budget. The Grant provided under this Agreement are to be spent by Afrigen exclusively in accordance with the Budget. Afrigen shall have the right to perform Budget revisions on a quarterly basis. Afrigen shall request MPP's prior written approval if there is a variance of +/- 5% between the main budget categories. Any request for Budget modification must include sufficient documentation to justify such request. For the avoidance of doubt, no Budget revision or variance of the Budget's categories that is permitted under this Clause 2.2 shall result in Spoke spending in excess of the total Grant. Any overspending on Budget will be at the cost of Afrigen, unless otherwise agreed between the Parties.
- 2.3. Payment Schedule. MPP shall make payments of the grant to Afrigen in accordance with the payment schedule set out in Section 4 of Annexure 1 ("**Payment Schedule**"). MPP shall pay the amounts in accordance with the Payment Schedule within 30 days from the completion of the relevant milestone of the Payment Schedule via a bank transfer to the Afrigen account set forth in Section 6 of Annexure 1.

## 3. **Use of Grant**

- 3.1. Grant. Afrigen acknowledges and agrees that the Grant is provided to Afrigen solely for the purposes of Afrigen performing the Project. Afrigen shall enter into the necessary sub-agreements and perform the necessary administrative activities to ensure the performance of the Project. Afrigen shall not use the Grant to perform activities outside the Project unless as otherwise agreed to in writing by the Parties.
- 3.2. Use of Equipment, Materials or Goods. During the Project, Afrigen shall use the equipment, materials or goods, purchased or generated with the Grant primarily for the purpose of the Project. Afrigen may use such equipment, materials or goods for purposes other than the Project provided that such use does not interfere with, compete with or delay the Project. If MPP reasonably suspects or becomes aware that Afrigen's use of such equipment, materials or goods has interfered with, competed with or delayed the Project, upon the request of MPP, Afrigen shall promptly provide MPP with documentary evidence demonstrating such has not occurred or such has been remedied.
- 3.3. Ownership. Title to any equipment, materials or goods purchased or generated with the Grant shall vest in Afrigen provided Afrigen uses such in accordance with Section 3.2. Notwithstanding any other section in this Agreement, if Afrigen does not use such equipment, materials or goods in accordance with Section 3.2, MPP may direct Afrigen to sell, donate or otherwise transfer such equipment, materials or goods, and reimburse MPP the fair market value of such, if applicable. Without limiting the foregoing, subject to MPP's prior written consent, during or after the Project, Afrigen may:
  - (a) replace or substitute any equipment, materials or goods purchased or generated with the Grant with new or improved equipment, material or goods; or
  - (b) sell, donate or otherwise transfer any equipment, materials or goods purchased or generated with the Grant, and reimburse MPP the fair market value of such equipment, materials or goods, if applicable.

## 4. **Reporting**

- 4.1. Reports. Afrigen shall provide MPP with the following reports:
  - (a) quarterly and final financial reports in a format agreed with MPP, which shall:
    - (i) for quarterly reports

- A. be sent within 10 working days after the end of each calendar quarter (with the first quarterly financial report covering the period from the 01 December 2023 until the end of the first calendar quarter after the Effective Date); and
  - B. contain the comparison between the actual spending of the Grant versus the Budget during the preceding quarter(s) accumulatively, in USD currency;
- (ii) for the final financial report:
- A. be sent by 31 January 2025 or within ten (10) working dates from the completion of the Project or exhaustion of the Grant, the earlier of which to occur; and
  - B. contain the comparison between the actual spending of the Grant versus the Budget during the term of the Agreement; and
- (iii) be sent to the address set forth in Section 7 of Annexure 1,
- (“Financial Report”)**. All financial payments reported this Section 4.1 shall be provisional and subject to adjustment within the total estimated cost under this Agreement in the event such adjustment is the result of a finding against Afrigen pursuant to Section 6.3.
- (b) quarterly and final technical report, which shall:
- (i) for quarterly technical reports:
    - A. be sent within 10 working days after the end of each calendar quarter (with the first quarterly technical report covering the period from the 01 December 2023 until the end of the first calendar quarter after the Effective Date); and
    - B. describe the status and progress on the Project during the preceding quarter(s) accumulatively, including detail (i) the activities performed and achievements, (ii) any delayed and/or overdue activities, and (iii) the activities to be performed and/or completed during the next quarter;
  - (ii) for the final technical report:
    - A. be sent by 31 January 2025 or within ten (10) working dates from the completion of the Project or exhaustion of the Grant, the earlier of which to occur; and
    - B. describe all activities performed and achievements of the Project during the term of the Agreement; and
  - (iii) be sent to the address set forth in Section 7 of Annexure 1,

**(“Technical Report”)**,

(each a **“Report”**, and together, the **“Reports”**).

#### 4.2. Submission and Revision.

- (a) Before submitting any Report to MPP, Afrigen must ensure that the Report meets all applicable requirements for that Report.
- (b) MPP shall, within ten (10) working days after submission of a Report (or such other period agreed in writing by the Parties), notify Afrigen that it either approves or rejects the Report. If MPP rejects the

Deliverable, MPP shall supply Afrigen with its comments, including a list of the deficiencies, at the time of rejection.

- (c) Afrigen shall, within ten (10) working days (or such other period agreed in writing by the Parties) of receipt of MPP's comments, prepare a revised Report that addresses MPP's comments and re-submit it to MPP for approval, in which event sub-Sections (a) and (b) above and this sub-Section (c) shall apply to that revised Report.

- 4.3. Approval. The Parties must repeat the process of Section 4.2, a maximum two (2) times in order for MPP to approve the Report. Without limiting MPP's rights or remedies, if MPP does not approve the Report on the second repeat of Section 4.2, MPP may (a) terminate this Agreement, (b) grant Afrigen a new deadline in order to meet the applicable requirements, or (c) initiate the dispute resolution process provided for in Section 13.1(a). For the avoidance of doubt, the dispute resolution process shall not include 13.1(b). For the avoidance of doubt, no act or omission of MPP in connection with this Section constitutes deemed approval of a Report, and approval of a Report does not occur until MPP notifies Afrigen in writing that the Report has been approved. Upon acceptance of a Report by MPP, Afrigen will certify and sign the Report as complete and accurate, and provide MPP with a copy.
- 4.4. Informal Reporting and Communication. Notwithstanding the provision of a Report, upon reasonable request by MPP, Afrigen shall provide MPP with information on the status and progress of the Project and any other information requested by MPP. The Parties shall engage in routine, collaborative communications as required throughout the performance of the Project.

## **5. Delay and Suspension**

- 5.1. Delays. If there is an actual or anticipated delay in the completion of an activity or deliverable of the Project within the timeframe specified in Annexure 1 of this Agreement, Afrigen undertakes to (a) promptly inform MPP in writing in case of such delay; and (ii) take all steps reasonably required by MPP to prevent, limit, or rectify such delay. Without limiting MPP's other rights or remedies it may have against Afrigen in connection with the delay caused by Afrigen, MPP may specify a revised timeline for the completion an activity or deliverable of the Project.
- 5.2. Other Delays. To the extent that a delay is caused by MPP or at no fault of Afrigen, Afrigen will be entitled to a reasonable extension of time consistent with the duration of the delay for the completion of an activity or deliverable of the Project. Afrigen may request an extension of time for the completion of an activity or deliverable of the Project by submitting to MPP a written proposal to that effect, which must not be unreasonably withheld.
- 5.3. Resolution. The Parties shall in good faith agree on the way to resolve any delay under this Section 5. To the extent that the Parties cannot reach an agreement on an extension of time referred to in Section 5.2, the Parties shall resolve the dispute in accordance with the dispute resolution process set out in Section 13.1(a). For the avoidance of doubt, the dispute resolution process shall not include 13.1(b). If the Parties are unable to resolve such dispute in accordance with Section 13.1(a), any Party may terminate this Agreement.

## **6. Financial Records, Inspection and Audits**

- 6.1. Records. Afrigen shall maintain supporting documentation for all costs associated with the Project, including records substantiating time and/or percentage of effort for all salaries paid or funds expended with funds provided under this Agreement. All records and documentation related to this Agreement shall be maintained in accordance with applicable laws and regulations and generally accepted accounting principles for a period of five years from completion of the Project.
- 6.2. Inspections. MPP, or its nominees and experts, shall have the right to inspect and review the progress of the Project at the location(s) where the Project has been performed, upon reasonable notice and at mutually agreeable times and locations. Access to facilities, relevant data, test results and computations used or generated hereunder shall be made reasonably available when such inspections are conducted.

Inspections by MPP shall be conducted in a manner as to not unduly delay the progress of the Project or any other activities of Afrigen.

- 6.3. Audit. MPP or its authorized representative shall have the right to review and audit all costs alleged to have been incurred hereunder and those records required by Section 6.1 at agreed upon times and locations. Afrigen shall provide MPP with copies of any audit report which presents any instance of non-compliance with laws or regulations relating to the performance or administration of this Agreement. Afrigen shall also provide copies of any response to any such report and a plan for corrective action. Afrigen shall maintain a separate accounting cost code specific to this grant, and all costs and income properly relating to this grant shall be accounted for through that cost code. Afrigen shall ensure that appropriate records are kept supporting the entries made on the cost code.

## 7. Confidentiality

- 7.1. Definition. “**Confidential Information**” means information which is marked with “confidential” or a similar legend upon disclosure, or if disclosed orally or observed, is designated as confidential at the time of disclosure and provided by one Party, a “**Disclosing Party**” to the other Party, a “**Receiving Party**”. Confidential Information does not include information that is: (a) already known to the Receiving Party prior to disclosure under this Agreement; (b) publicly known or becomes publicly known other than through acts or omissions of the Receiving Party, or anyone that obtained the information or materials from the Receiving Party; (c) lawfully disclosed to the Receiving Party without restriction by a third party; (d) independently developed by employees of the Receiving Party without knowledge of or access to Confidential Information; or (e) approved by release by written authorization of the Disclosing Party.

- 7.2. No Disclosure or Use. The Receiving Party will use reasonable efforts to safeguard the confidentiality of the Confidential Information and will not disclose or use the Confidential Information except for the purpose of performing its obligations or exercising its rights under this Agreement. For clarity, MPP shall have the right to share the reports and any other Confidential Information provided hereunder with the Funders and the WHO. If the Receiving Party is required by law, regulation or court order to disclose Confidential Information, then the Receiving Party may furnish this required Confidential Information, provided the Receiving Party has promptly notified the Disclosing Party and reasonably assisted the Disclosing Party in its efforts to seek and/or obtain a protective order or other remedy of the Disclosing Party’s election.

- 7.3. Survival. The obligations of nondisclosure and non-use will survive termination or expiration of this Agreement for a period of three years. Receiving Party agrees to return or destroy all Confidential Information, as requested by Disclosing Party, except that, subject to the terms and conditions herein, Receiving Party may retain one copy of Confidential Information solely to evidence its compliance and those electronic files maintained for archival purposes.

- 7.4. Privacy Laws. Afrigen shall take all appropriate action to protect the privacy and confidentiality of all human research subjects in accordance with all applicable laws and regulations. Investigators, Data Safety Monitoring Boards, IRBs and other appropriate entities should ensure that policies and procedures are in place that protect identifying information and that they oversee compliance with those policies and procedures in accordance with all applicable laws and regulations. Afrigen shall notify MPP immediately (within 24 hours) in case of any issues regarding compliance with this Section 7.4.

## 8. Intellectual Property

- 8.1. Background Rights. Except as expressly provided in Section 8.3, neither MPP nor Afrigen transfers by operation of this Agreement or otherwise any intellectual or tangible property right, including patent right, copyright, or any other proprietary right owned as of the Commencement Date or arising outside of the Project. Nothing to the contrary shall be implied and all such rights, titles and interests are reserved.

- 8.2. Inventions. “**Inventions**” means all ideas, inventions or discoveries conceived, first created or made in the performance the Project, and if solely by MPP shall be owned by MPP, solely by Afrigen shall be owned by Afrigen, or jointly by Afrigen and MPP shall be jointly owned by the Parties. In case of joint ownership, both MPP and Afrigen shall ask for the other Party’s prior written consent for the exercise of such joint

ownership including, without limitation any disposal, protection, sale, management or security over such rights. Afrigen will provide MPP with a disclosure of all the data generated under this Agreement and each Invention in such detail as MPP may reasonably require in the reports provided in accordance with Section 6.1.

- 8.3. Grant to MPP. Afrigen hereby grants to MPP a non-exclusive, transferable, sublicensable, irrevocable, fully paid-up, royalty-free, worldwide, license to practice and have practiced the data and the Inventions for the purposes of fulfilling its mission to facilitate the development and equitable access of health technologies in low- and middle-income countries (as defined by the World Bank). In the event that MPP wishes to make such Inventions available for other purposes, MPP and Afrigen will enter into good-faith negotiations. Afrigen agrees to provide to MPP a licence in relation to its background rights, as referred to in Section 8.1. only to the extent necessary to enable the use and exercise of the Inventions made by Afrigen hereunder. MPP shall have the right to share the data generated under the Program with WHO for further sharing with any third parties for the purposes of fulfilling its mission to facilitate the development and equitable access of mRNA technologies in low- and middle-income countries.
- 8.4. Infringement. Afrigen shall immediately give notice to MPP if Afrigen (or any of its relevant administrative, technical and business development staff involved in monitoring the Project) becomes aware of, or if the Afrigen receives notice from any third party on:
- (a) any infringement of the background intellectual property and/or Invention, or
  - (b) any claim by a third party that an action carried out under the Project infringes the intellectual property or other rights of any third party.
- 8.5. Publications. Each Party may freely publish, present, use or otherwise disseminate any results arising out of the performance of this Agreement for its own purposes, provided that the publication, presentation or use does not disclose any Confidential Information of the other Party and the publishing Party has submitted any proposed publication or presentation of Inventions to the non-publishing Party for review at least 30 days prior to submission for publication or presentation. All publications or other disclosure of the Inventions and/or results generated hereunder shall properly acknowledge the support provided by MPP and, if applicable, the Funders.

## 9. Notices

- 9.1. All notices under this Agreement shall be in writing, properly addressed as below or as otherwise provided in accordance herewith and shall be deemed to have been duly given or received upon the earlier of: (a) actual receipt, (b) the date of confirmed delivery according to the records of a commercially recognized express courier with tracking capabilities; or (c) the date of confirmed transmission if sent by email with confirmation of delivery.

If to MPP: MEDICINES PATENT POOL  
FOUNDATION  
rue de Varembé 7  
1202 Geneva, Switzerland  
Attention: General Counsel  
Email:  
legal@medicinespatentpool.org

If to Afrigen: AFRIGEN BIOLOGICS (PTY) LTD  
Unit 5 and 6 Kestrel Park Longclaw  
Drive Montague Gardens  
Cape Town, Western Cape, 7441,  
South Africa  
Attention: Prof Petro Terblanche  
Email: petro.terblanche@afrigen.co.za

## 10. Indemnity and Insurance

- 10.1. Indemnification. Afrigen shall indemnify, hold harmless and defend MPP, its affiliates, and their respective officers, directors, employees, independent contractors and agents (“**Indemnitees**”) from and against any and all claims, losses, damages, and/or liability of whatsoever kind or nature, as well as all costs and expenses, including reasonable attorneys’ fees and court costs (“**Losses**”) which arise or may arise at any time out of or relating to Afrigen’s and/or its independent contractor’s or agent’s performance or breach of this Agreement and/or any act or omission of negligence or willful misconduct by Afrigen or its independent

contractor or agents; except to the extent of such Losses that are attributable solely to MPP's breach of this Agreement, gross negligence or willful misconduct. Afrigen shall not settle or compromise any claim or allegation subject to indemnification hereunder in a manner that imposes any material obligation on, or makes any admission of fault by, Indemnitees. Indemnitees will cooperate as reasonably requested, at the expense of Afrigen, in the defense of the action.

- 10.2. Insurance. Afrigen shall continuously maintain at its own expense sufficient insurance levels throughout the term of this Agreement and beyond to ensure its obligations under this Agreement and will provide evidence of adequate insurance coverage upon request.
- 10.3. Limitation of Liability. NEITHER PARTY SHALL 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 THIS AGREEMENT OR ITS SUBJECT MATTER, REGARDLESS OF WHETHER THEY SHALL BE ADVISED, SHALL HAVE OTHER REASON TO KNOW, OR IN FACT SHALL KNOW, OF THE POSSIBILITY OF SUCH DAMAGES.

## **11. Term and Termination**

- 11.1. Term. The term of this Agreement commences on 01 December 2023 and continues until the completion of all activities of the Project and the acceptance by MPP of all Reports, unless earlier terminated in accordance with this Section 11.
- 11.2. Grant Reduction. In the event the Funders reduce the funding for the Program or the Project, the Parties will enter into good faith negotiations to determine if the Project can be completed as originally anticipated or its scope must be modified. In the event of the Parties cannot agree to a modified Project and Budget reasonably acceptable to the Funders, MPP may suspend this Agreement immediately. In the event of suspension of the Project, Afrigen will immediately cease incurring expenses and take every reasonable measure to cancel outstanding expenses. In the event Funders discontinue support of the Program or if funding is reduced to the extent that MPP, in consultation with Afrigen, determines it is not practicable to continue funding this Project, MPP may terminate this Agreement effective immediately upon notice. In such event, to the extent funds are allowable by and available from Funders, MPP shall pay reasonable and allowable costs incurred up to and including the effective date of termination, and for reasonable and allowable non-cancelable obligations made consistent with the Budget prior to Afrigen's receipt of notice of termination.
- 11.3. Termination by MPP. MPP may terminate this Agreement: (a) if Afrigen commits a breach and fails to remedy such breach within 30 days after receiving written notice; or (b) to the extent not prohibited by applicable law, Afrigen enters liquidation, has a receiver or administrator appointed over any assets related to this Agreement, makes any voluntary arrangement with any of its creditors, or ceases to conduct its business, or any similar event under the law of any foreign jurisdiction, effective as of the date of such event.
- 11.4. Project Data. Afrigen shall deliver to MPP, within 60 days of the date of termination of this Agreement, complete and unredacted copies of all data and Inventions, including any further information or documentation requested that was created in the performance of the Project and/or prepared for and/or submitted for all regulatory approvals. MPP may use the foregoing for any purpose in furtherance of its mission. If applicable, Afrigen agrees to cooperate with MPP in the transfer of the Project to another contractor.
- 11.5. Surviving Rights and Obligations. The termination or expiration of this Agreement does not relieve either Party of its rights and obligations that have previously accrued. Terms and conditions of this Agreement that by their nature prescribe continuing rights and obligations shall survive the termination or expiration of this Agreement.
- 11.6. Other effects of termination.

- (a) Reports. Afrigen shall provide MPP with all outstanding or due Reports in accordance with the timeframe specified in this Agreement.
- (b) Unspent funds. Upon termination prior to the end of the Project pursuant to this Section 11, Afrigen shall return all funding received from MPP under this Agreement which is unspent at the date of termination (after deduction of costs and non-cancellable commitments incurred prior to the date of termination).

## 12. **Compliance with Law**

- 12.1. Mutual Representations and Warranties. Each Party represents and warrants that it will comply with all applicable laws and regulations, including without limitation those governing conflict of interest, human research, animal research, and export control. Each Party shall reasonably cooperate with the other to identify and manage any export-controlled technology used in meeting its obligations hereunder. Where the clinical trial is to be undertaken under this Agreement, Afrigen shall comply with ICH GCP principles outlined in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice guidelines as laid down in the "ICH Topic E6(R1)" and set out at <http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html>, as amended from time to time. Afrigen shall notify MPP immediately (within 24 hours) in case of any issues regarding compliance with the rules set out this Section 12.1.
- 12.2. Afrigen Further Representations and Warranties. Afrigen further represents and warrants that: (a) it has established policies and procedures to ensure compliance with all applicable laws and regulations pertaining to the conduct of research in humans; (b) that neither it nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded from participation in this transaction by any governmental department or agency; (c) it has reviewed and agreed with the specific donors' requirements, set out in the Annexure 2 of this Agreement and (d) all personnel working on the Project, including Key Personnel, have met all legal and organizational requirements required to perform the work anticipated hereunder with the appropriate level of skill required therefor.
- 12.3. Animal welfare. Afrigen shall procure that any research under the Project that involves animals that is undertaken by Afrigen, or their partners, collaborators or service providers (whether in the South Africa or internationally) shall comply with the UK Animals (Scientific Procedures) Act 1986, to be approved by the local ethical review process and be conducted with due consideration for the 3Rs (replacement, reduction and refinement of the use of animals in research). Afrigen shall notify MPP immediately (within 24 hours) in case of any issues regarding compliance with the rules set out this Section 12.3.
- 12.4. Disclaimer. EXCEPT AS PROVIDED IN SECTIONS 12.1 AND 12.2, NEITHER PARTY MAKES ANY AND EACH EXPRESSLY DISCLAIMS ALL REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, REGARDING ITS PERFORMANCE UNDER THIS AGREEMENT, INCLUDING WITHOUT LIMITATION THE MARKETABILITY, USE OR FITNESS OF THE RESULTS DEVELOPED HEREUNDER FOR ANY PARTICULAR PURPOSE.

## 13. **Dispute Resolution**

- 13.1. Escalation process. The Parties wish to facilitate the resolution of any dispute arising out of or relating to this Agreement including but not limited to the breach, termination, interpretation or validity thereof (a "**Dispute**") in an expedient manner by mutual cooperation and agree to following the procedures to resolve any such Dispute, except where a Party seeks urgent interlocutory relief:
  - (a) The Parties must attempt to resolve any Dispute by negotiation using the following escalation procedure:
    - (i) Upon receiving a written notice by one Party to another of the details of the Dispute, the Parties' contracting managers must first attempt to resolve such Dispute.



- (ii) If the Parties' contracting managers cannot resolve the Dispute within ten (10) working days of the written notice being given, they must refer the Dispute to the Parties' respective executive officers (or their nominee) who must use their best efforts to resolve all issues escalated to them, in a way that attempts to preserve the relationship between the Parties, within ten (10) working days of the Dispute being referred to them.
- (b) Unless otherwise specified in this Agreement, if the Parties cannot resolve the Dispute in accordance with the escalation procedure in (a) above within the timeframes specified, then the Dispute shall be referred to and finally determined by arbitration in accordance with the WIPO Arbitration Rules. The arbitral tribunal shall consist of three arbitrators. The place of arbitration shall be Geneva, Switzerland.

#### **14. Miscellaneous**

- 14.1. Governing Law. This Agreement shall be governed by the laws of Switzerland, without giving effect to any choice-of-law provision that would require the application of the laws of a different jurisdiction. This Agreement will be construed in the English language.
- 14.2. Severability. The provisions of this Agreement are severable, and if any provision is determined to be invalid or unenforceable in a given jurisdiction, such invalidity or non-enforceability shall not in any way affect the validity and enforceability of the remaining provisions or the validity or enforceability of those provisions in any other jurisdiction. Any invalid or unenforceable provision will be reformed promptly by the Parties to effectuate their intent as evidenced at the time this Agreement was executed. This provision shall also apply to unintended omissions.
- 14.3. Assignment. Neither Party may assign or transfer this Agreement to another without the prior written consent of the other Party. Such successor shall expressly assume in writing the obligation to perform in accordance with the terms and conditions of this Agreement. Any other assignment or transfer shall be void.
- 14.4. Independent Contractors. Nothing in this Agreement shall be interpreted as placing the Parties in an employment, partnership, joint venture or agency relationship and neither Party shall have the right or authority to obligate or bind the other Party on its behalf.
- 14.5. Use of Names. Except for disclosure of the support for the Program and Project in publications or activities directly related to this Agreement, neither Party shall use the name of the other, of Funders or of any staff member, employee or student of any other Party or any adaptation, acronym or name by which any Party is commonly known, in any advertising or sales literature or any publicity not directly related to this project without the prior written approval of the Party or individual whose name is to be used.
- 14.6. Entire Agreement. This Agreement, including any Annexure, constitutes the entire agreement between the parties with respect to the subject matter and supersedes all prior communications, agreements or understandings, written or oral regarding such subject matter including the Loan Agreement. For the avoidance of doubt, the terms and conditions of this Agreement apply to the funding having been made under the Loan Agreement. Any amendment to this Agreement must be in writing and signed by both Parties and Afrigen agrees to revise this Agreement accordingly in line with any request from the Funders. The delay or failure to assert a right or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver, or excuse a similar or subsequent failure to perform any such term or condition. A valid waiver must be executed in writing and signed by the Party granting the waiver. Each Party acknowledges that it was provided an opportunity to seek advice of counsel and as such this Agreement shall not be strictly construed against the drafter.

IN WITNESS WHEREOF, the Parties execute this valid and binding agreement in one or more counterparts, each of which shall be deemed an original and all of which, taken together, constitute one and the same instrument by electronic signature which shall be given the effect of an original signature upon receipt by the other Party.

For: **Afrigen Biologics (PTY) LTD**


Signature:  DocuSigned by:  
Petro Terblanche

Name: Prof Petro Terblanche, CEO

Date: 07 June 2024

Place: Cape Town, South Africa

For: **Medicines Patent Pool Foundation**

Signature:  DocuSigned by:  
Chan Park for Charles Gore, Executive Director

Name: Chan Park, General Counsel

Date: 06 June 2024

Place: Geneva, Switzerland

## Annexure 1 Project Scope of Work

### 1. Background

Gonorrhoea is a STI caused by the bacterium *Neisseria gonorrhoeae*. An estimated 82.4 million new cases of occurred worldwide in 2020.<sup>1</sup> As per Centres for Disease Control and Prevention (CDC), in 2021 gonorrhoea was the second most common notifiable sexually transmitted infection in the United States for that year. Rates of reported gonorrhoea have increased 118% since their historic low in 2009. During 2020 to 2021, the overall rate of reported gonorrhoea increased 4.6%. During 2020 to 2021, rates of reported gonorrhoea increased among both men 6.3%) and women (2.4%). A similar trend is reported from regions of where notifications are accurate.

Inadequate treatment can lead to pelvic diseases, infertility, pregnancy complications, higher risk for HIV transmission and ongoing transmission to sexual partners. Increased emergence of antimicrobial resistance (AMR) has cause for alarm for future untreatable infections. The WHO has set targets for reducing gonorrhoea incidence by 90% by 2030. An effective vaccine will contribute significantly in achieving this target and currently a subunit vaccine (Bexsero) is undergoing clinical trials.

Leveraging off the mRNA technology platform developed as part of the mRNA Technology Transfer Programme, Afrigen, in collaboration with Evaxion Biotech (Denmark) plans to design an mRNA vaccine containing antigens identified by Evaxion's AI-Immunology™ platform.

### 2. Objective

Demonstrate proof of concept feasibility for a *N. gonorrhoeae* mRNA-based vaccine by *in-vitro* screening a number of antigens with the aim of selecting one or more candidates up to animal model immunogenicity studies.

### 3. Activities and Deliverables

#### (a) Type of Activities

Afrigen will perform the following activities in accordance with the specified timeline, unless otherwise agreed between the Parties:

Activities	Timelines
Evaxion antigen sequences supplied to Afrigen	12/2023
Design of mRNA cassettes and plasmid constructs:	12/2023 – 03/2024
Lab scale synthesis of mRNA DS (100 µL IVT scale)	03/2024 – 05/2024
In vitro characterization and screening of encoded antigens	03/2024 – 06/2024
LNP formulation of screened candidates and stability testing	04/2024 -07/2024
In-vivo mice immunogenicity tests at Evaxion	07/2024 – 12/2024

<sup>1</sup> Web Annex 1. Key data at a glance. In: Global progress report on HIV, viral hepatitis and sexually transmitted infections, 2021. Accountability for the global health sector strategies 2016–2021: actions for impact. Geneva: World Health Organization; 2021. Licence: CC BY-NC-SA 3.0 IGO.

## Annexure 2 Specific donors' requirements

### 1. Fraud and Corruption

Afrigen declares and guarantees that no offer, gift or payment, consideration or benefit of any kind, which constitutes an illegal or corrupt practice, has been or will be made to anyone by Afrigen, either directly or indirectly, as an inducement or reward for the award or execution of the Agreement.

Afrigen declares and guarantees that neither Afrigen, nor its Employees or delegee involved in the Project:

- a. were convicted during a period of three (3) years prior to and since the submission of the Project proposal, by a court of law in Canada or in any other jurisdiction for an offence involving fraud, bribery or corruption;
- b. are under sanction, for an offence involving fraud, bribery or corruption, imposed by a government, an international governmental organization or an organization providing development assistance.

Afrigen declares and guarantees that it has taken all reasonable steps to assure itself that neither its local partners, its subcontractors, nor its local partners' or subcontractors' employees involved in the Project:

- were convicted during a period of three (3) years prior to and since the submission of the Project proposal, by a court of law in Canada or in any other jurisdiction for an offence involving fraud, bribery or corruption;
- are under sanction, for an offence involving fraud, bribery or corruption, imposed by a government, an international governmental organization or an organization providing development assistance.

### 2. Economic Sanctions and Other Trade Controls

Afrigen declares and guarantees that funding for the purposes of the Project will not be knowingly used, either directly or indirectly, in a manner that contravenes economic sanctions imposed by Canada and enforced by regulations under the United Nations Act (R.S.C. (1985), c. U-2); the Special Economic Measures Act (S.C. (1992), c. 17); the Justice for Victims of Corrupt Foreign Officials Act (S.C. (2017), c. 21) as they are amended from time to time, or for activities that would contravene the provisions of the Export and Import Permits Act (R.S.C. (1985), c. E-19). Information on Canadian sanctions and export and import controls can be found at the following links:

[https://www.international.gc.ca/world-monde/international\\_relations-relations\\_internationales/sanctions/index.aspx?lang=eng](https://www.international.gc.ca/world-monde/international_relations-relations_internationales/sanctions/index.aspx?lang=eng)  
[https://www.international.gc.ca/world-monde/international\\_relations-relations\\_internationales/sanctions/types.aspx?lang=eng](https://www.international.gc.ca/world-monde/international_relations-relations_internationales/sanctions/types.aspx?lang=eng)  
<https://www.international.gc.ca/controls-controles/index.aspx?lang=eng>

### 3. Anti-Terrorism

Afrigen declares and guarantees that the funding for the purposes of the Project will not knowingly be used to benefit terrorist groups or individual members of those groups, or for terrorist activities, either directly or indirectly, as defined in the Criminal Code R.S.C., 1985, c. C-46 or those appearing on the Consolidated United Nations Security Council Sanctions List, as modified during the term of this Agreement.

Afrigen is responsible for consulting all relevant lists, even if the web addresses provided are no longer valid, in order to stay informed of the listed terrorist groups and their members and must ensure that the Contribution of the Department does not benefit any listed terrorist entity and their members, any sanctioned groups or persons. Entities or individuals listed as terrorists can be found at the following web addresses:

A. Criminal Code of Canada list - <https://www.publicsafety.gc.ca/cnt/ntnl-scr/cntr-trrrsm/lstd-ntts/crrnt-lstd-ntts-en.aspx>

B. Regulations implementing the Voted Nations Resolutions on the Suppression of Terrorism - <https://laws-lois.justice.gc.ca/eng/regulations/SOR-2001-360/page-3.html#h-673021>

C. The United Nations Security Council Consolidated Sanctions List is available on the United Nations Security Council website (<https://www.un.org/securitycouncil/>). to implement the sanction measures imposed by the United Nations Security Council pursuant to resolutions 1267 (1999), 1989 (2011) and 2253 (2015) concerning ISIL (Da'esh), Al-Qaida, and associated individuals, groups, undertakings and entities, and pursuant to resolution 1988 (2011) concerning the Taliban and associated individuals.