

**AMENDMENT AND RESTATEMENT AGREEMENT
to the MPP–Afrigen Grant Agreement of 21 January 2022**

THIS AMENDMENT AND RESTATEMENT AGREEMENT TO THE MPP–AFRIGEN GRANT AGREEMENT (this “**Amendment**”) is made and entered into as of 17 January 2025 (the “**Amendment Effective Date**”) by and between:

MEDICINES PATENT POOL FOUNDATION, a non-profit foundation registered under the laws of Switzerland, and having a principal place of business at Rue de Varembe 7, CH-1202 Geneva (the “**MPP**”); and

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

RECITALS

WHEREAS, MPP and Afrigen entered into a grant agreement dated 21 January 2022 (the “**Grant Agreement**”) in order to collaborate on the Program;

WHEREAS, MPP and Afrigen entered into agreements to amend the Grant Agreement on 11 October 2022 (“**First Amendment**”), on 24 January 2024 (“**Second Amendment**”), and on 12 December 2024 (“**Third Amendment**”); and

WHEREAS, the Parties now wish to amend and restate the Grant Agreement to (i) amend certain provisions of the Grant Agreement and (ii) amend or insert certain Attachments to the Grant Agreement, in order to assist in the Project being carried out in accordance with the objectives of the Program.

NOW THEREFORE, based on the foregoing premise and in consideration of the mutual covenants and obligations contained herein and other good and valuable consideration, the receipt, adequacy, and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Definitions.** All capitalised terms not otherwise defined herein shall have the meaning assigned to them in the Restated Agreement.
2. **Amendment.** The Grant Agreement is, with effect from the Amendment Effective Date, amended to take the form set out in Schedule 1 to this Amendment, which restates the Grant Agreement as amended by this Amendment (“**Restated Agreement**”).
3. **General.**
 - 3.1 Amendments. No provision of this Amendment may be modified or amended except expressly in writing signed by all parties.
 - 3.2 Governing Law and Jurisdiction. The provisions of Section 13.1 (*Governing Law*) and 13.2 (*Dispute Resolution*) of the Restated Agreement are hereby incorporated into this Amendment as if set out herein.

3.3 Counterparts. This Amendment may be executed in one or more counterparts, each of equal value, which, when joined, shall together constitute one agreement. A signature of a Party transmitted on a scanned copy of this Third Amendment is deemed as an original signature. Any photocopy or electronic facsimile (including pdf format) of this Third Amendment, or of any counterpart, shall be deemed the equivalent to an original.

IN WITNESS WHEREOF, the Parties have executed this Amendment by their duly authorised representatives.

Signed for and on behalf of
MEDICINES PATENT POOL FOUNDATION

Signed for and on behalf of
AFRIGEN BIOLOGICS (PTY) LTD

DocuSigned by:

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Name Charles Gore
Title Executive Director
Date 16 January 2025

DocuSigned by:

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Name Petro Terblanche
Title Chief Executive Officer
Date 17 January 2025

DocuSigned by:

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Name Marie-Paule Kieny
Title Chair of the Board
Date 16 January 2025

SCHEDULE 1

Restated Agreement

GRANT AGREEMENT

This grant agreement ("**Agreement**") is entered into as 21 January 2022 ("**Effective Date**") and is amended and restated on 17 January 2025 ("**Amendment Effective Date**") by and between:

MEDICINES PATENT POOL FOUNDATION, rue de Varembé 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 desire to strengthen regional health security and respond more equitably to the current Covid-19 pandemic and future pandemics;

WHEREAS, they agreed to establish a sustainable mechanism that will increase vaccine manufacturing capacity in Africa and elsewhere in low- and middle-income countries, through the establishment of a Covid-19 technology transfer hub;

WHEREAS, MPP has received funding from third parties ("**Funders**") to accelerate the availability of COVID-19 related vaccines and therapies by establishing the mRNA Technology Transfer Program ("**Program**"); and

WHEREAS, Afrigen wishes to participate in the Program and would like to carry out the Project hereunder;

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 as part of the Program described in Attachment 1, attached and incorporated herein ("**Project**"). The Project may be modified solely by mutual agreement between the Parties. Afrigen shall not disclose any technology transfer package or other information, material or results generated or otherwise arising from its performance of the scope of work set out in Attachment 1 of this Agreement, including any data or Inventions, to any third party unless it is either an entity designated by WHO as an eligible recipient of the mRNA technology platform under the Program ("**Program Partner**") or as otherwise agreed to in writing by 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 Attachment 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.

1A. Technology Transfer.

1A.1 Definition. “**Technology Transfer**” refers to a logical procedure that controls the transfer of any process together with its documentation and professional expertise from development to manufacture or between manufacturing sites. It is a systematic procedure that is followed in order to pass the documented knowledge and experience gained during development and or commercialization to an appropriate, responsible and authorized party. In this Agreement, Technology Transfer embodies both the transfer of documentation and the demonstrated ability of Program Partners to effectively perform the critical elements of the transferred technology, to the satisfaction of all parties and any applicable regulatory bodies.

1A.2 Afrigen’s obligations. Afrigen will take all necessary steps, and will provide all necessary assistance to MPP and/or WHO, to cause the Technology Transfer to Program Partners to be conducted in accordance with the Project and the roadmap set out in Attachment 4 and will provide the documentation detailed in Attachment 5 (Technology Transfer Package 1).

1A.3 MPP’s obligations. MPP shall take all reasonable steps to ensure that Afrigen receives the documentation detailed in Attachment 6 (Technology Transfer Package 2) from the Biologicals and Vaccines Institute of Southern Africa (“**Biovac**”), as referred to in the roadmap at Attachment 4.

1A.4 Materials. Technology Transfer Package 1 shall include the transfer of materials as specified in Attachment 7.

2. Project Management.

The Parties will form a joint project management committee (the “**Project Committee**”) to oversee and facilitate the implementation and execution of the Project, to receive and review technical reports, and to review proposed changes to the Project scope, timeline and/or Budget. Each Party will have the right to designate its representatives (which may be consultants or adviser subject to the relevant terms and conditions set out herein) to the Project Committee and may replace its representatives upon notice to the other Party. The Project Committee may meet virtually or in person at mutually agreeable times and locations. All decisions at the Project Committee shall be taken unanimously. In the event the consensus cannot be reached, the matter shall be submitted to the executive director of each Party and in case the issue remains unsolved for 3 months from its first referral, the matter shall be resolved in accordance with Section 13.2 “Dispute Resolution”.

3. Grant Payment.

3.1 Grant for the Project. Subject to the terms and conditions of this Agreement, and Afrigen’s compliance therewith, MPP will fund Afrigen for performing the Project in accordance with the approved budget attached as Attachment 2 and incorporated herein (“**Budget**”). The maximum amount hereunder shall not exceed the amount of USD 49.5 million for the Project (except the Revised Objective 3 Activity) and ZAR 24.5 million for the Revised Objective 3 Activity. Subject to Section 11.2 “Grant Reduction”, MPP shall have the right to increase or decrease the total amount of the grant in accordance with the needs and the performance of the Project.

3.2 Loan Agreement. MPP shall deduct the amounts provided to Afrigen under the Bridge Loan Agreement between the Parties dated 30 September 2021 (“**Loan Agreement**”) from grant amount set out in Section 3.1 hereabove. Prior to the first payment request under this Agreement, Afrigen shall submit a financial and technical report(s) in relation to the use of the amounts provided under the Loan Agreement, covering the period from the 29th of September 2021 till the first Disbursement Request under this Agreement.

3.3. Budget. The funds provided under this Agreement are to be spent by Afrigen exclusively in accordance with the Budget. The Parties 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% versus annual amounts set out in the Budget. Any request for Budget modification must include sufficient documentation to justify such request.

3.4. Disbursement Request. MPP shall make payments of the grant hereunder on a quarterly basis upon receipt of collectively the following:

- a. the disbursement request from Afrigen based on the Project requirements ("**Disbursement Request**"), plus an estimated rolling advance of one month.
- b. financial report in accordance with this Agreement regarding the previous payment, showing the extent of the previous payment spent in accordance with the Budget.
- c. satisfactory technical report in accordance with Section 5 herebelow.

3.5. Payments. MPP shall pay the amounts in accordance with each Disbursement Request within 30 days from its receipt via a bank transfer to the Afrigen account set forth in Attachment 2.

3.6. Financial Reports. Each financial report shall:

- a. be sent within 10 working days after the end of each calendar quarter (quarter month – 1st quarter ending March 2022) in a format to be shared by MPP, which may be updated from time to time;
- b. with regards to the Budget (excluding the Revised Objective 3 Activity), as revised from time to time, be issued in USD currency;
- c. with regards to the Revised Objective 3 Budget, be issued in ZAR currency;
- d. contain the comparison between the actual spending versus the budgeted amounts;
- e. be certified as complete and accurate by an authorized official of Afrigen for the activities performed.
- f. be sent to the address set forth in Attachment 2.

3.7. Annual Financial Statement. In addition to quarterly financial reports under this Agreement as per Section 3.6, Afrigen shall provide to MPP:

- a. by no later than 20 January of each year, a letter relating to MPP's preceding financial year (ending 31 December) which includes:
 - (i) MPP's open position as of 31 December; and
 - (ii) a detailed summary of expenditures incurred by Afrigen, by nature of expense, during the period from 1 January to 31 December; and
- b. by no later than 15 March of each year:
 - (i) an audited annual Project financial report of Afrigen; and
 - (ii) a questionnaire, in a format to be provided by MPP, regarding the use of funds under this Agreement. Such questionnaire shall be signed by an auditor mutually agreed upon by the Parties.

3.8. Final Statement. A final audited statement of cumulative costs incurred marked "FINAL" must be submitted to MPP no later than 60 days after completion or termination of the Project. The final statement of costs shall constitute the final financial report of Afrigen. All payments hereunder 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 6.2.

4. **Use of Funds.**

4.1 Afrigen acknowledges and agrees that the grant hereunder is provided for non-commercial purposes only. During the term of this Agreement, Afrigen shall use the funds for the execution of the Project and the activities listed in the scope of work set out in Attachment 1. As such, Afrigen shall enter into the necessary sub-agreements and perform the necessary administrative activities to ensure that the activities listed in the scope of work set out in Attachment 1 are funded and executed. Afrigen shall not use the funds to perform activities outside the scope of work set out in Attachment 1 unless as otherwise agreed to in writing by the Parties.

4.2 During the Project term, Afrigen and / or the sub-grantees funded hereunder with MPP funds through Afrigen shall use the equipment, materials or goods, purchased or generated with the grant provided hereunder, for the purpose of the Project. Any other use of the equipment, materials or goods, purchased or generated with the grant provided hereunder shall be restricted to not-for-profit, academic use and shall not interfere with, compete with or delay the activities funded hereunder (with documentary evidence upon MPP's request).

- 4.3 Title to any equipment, materials or goods purchased or generated with the MPP grant provided hereunder shall vest in Afrigen and / or sub-grantee(s), as applicable, during the Project provided Afrigen and / or sub-grantee(s) uses such in accordance with Section 4.2. Upon completion of the Project or termination of this Agreement, if Afrigen and / or sub-grantee(s) wish to:
- a. use any equipment, goods or materials purchased through this grant for commercial purposes; or
 - b. either sell, donate or otherwise transfer the said equipment, goods or materials,
- Afrigen and / or sub-grantee(s) shall request a prior written consent from MPP. Should MPP provide such consent, Afrigen agrees and / or shall procure that the sub-grantee(s) agrees to reimburse MPP for fair market value of such commercial use. Afrigen and / or sub-grantee(s) may upon completion of the Project or termination of this Agreement (except in case of termination pursuant to Section 11.3 hereof) use any equipment, goods or materials purchased through this grant for not-for-profit, academic purposes.

5. Project Reports and Inspections.

5.1 Reports. In addition to meetings of the Project Committee, Afrigen shall provide quarterly technical reports describing progress on the Project, including the pre-clinical, clinical, regulatory data and other information as otherwise reasonably requested by MPP. Afrigen shall also submit to MPP:

- a. two interim technical reports in the middle of the Project performance, the date of such report shall be targeted for 31 December 2022 and 31 December 2023 and can be modified by mutual agreement between the Parties; and
- b. a final technical report within 60 days of completion of the Project or termination of this Agreement, whichever first occurs,

in both cases containing the summary of the pre-clinical and clinical data generated under the Project, and all deliverables and achievements under the Project in detail.

5.2. Continuous Information. Afrigen shall notify MPP promptly in case of any significant issues in the performance of the Project.

5.3 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. Financial Records 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 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 noncompliance 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, the WHO, Program Partners, or any other entity agreed to in writing by the Parties. 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 of this Agreement 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.

- a. In the case of data and Inventions created in the performance of the previous and Revised Objective 3 Activity, Afrigen, subject to any necessary approvals in terms of the IPR Act and any other applicable legislation and regulations, and through a separate agreement, undertakes to grant to MPP a non-exclusive, transferable, sublicensable, irrevocable,

worldwide, license to practice and have practiced the data and the Inventions, for the purposes of fulfilling its mission to facilitate the development and affordable and equitable access of mRNA technologies in low- and middle-income countries (as defined by the World Bank), which license may include a royalty sacrifice. For clarity, no royalty may be imposed with respect to data or Inventions licensed to MPP under Section 8.3(b) below. In the event that Afrigen is provided with access to any third-party intellectual property for the purposes of the Project, Afrigen undertakes to use reasonable efforts to negotiate a licence to MPP for such third-party intellectual property under the same or similar terms as either 8.3(a) or 8.3(b), as applicable.

- b. For all data and Inventions other than those to which Section 8.3(a) apply, 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).
- c. In the event that MPP wishes to make such Inventions available for purposes other than those referred to in Section 8.3(a) and (b) herein, MPP and Afrigen will enter into good-faith negotiations.
- d. 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.
- e. 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 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.

8.6. Grant to Afrigen. MPP hereby grants to Afrigen the option to utilize the Inventions to commercially produce and distribute products provided that such option should it be exercised by Afrigen does not conflict with the MPP's mission as described in section 8.3. To ensure that such conflicts are avoided, Afrigen will consult with the MPP at the time of such commercial interest in order to receive support on Afrigen's commercial plan. Should such Invention be solely or jointly owned by the MPP, then upon such support being received by Afrigen from the MPP, the MPP will grant Afrigen a license for the use of such Invention on terms to be negotiated in good faith between the Parties.

9. **Notices.** 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 Varembe 7, Fifth Floor
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:
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. **Termination.**

11.1 Term. The term of this Agreement commences on the Effective Date and continues until the completion of the Project, 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 insufficient funding and 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.

11.6.1. Exit meeting. The Project Committee shall hold a final meeting as soon as reasonably practicable just before or following termination and shall be dissolved after all final reporting has been completed.

11.6.2. Unspent funds. Upon termination prior to the end of the Project pursuant to Section 11 hereof, 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).

11.6.3. Post-exit reporting. In the event that the Agreement terminates for any reason (including expiry) and provided that Afrigen continues to work on the Program, Afrigen shall continue to provide MPP with an annual progress update as follows:

- (i) state of development of the technology regarding the mRNA vaccine, including the information regarding the progression and outcomes of any clinical trial;
- (ii) a sales report in a format to be agreed between the Parties; and
- (iii) a report regarding the training, licensing and technology transfer to any third party regarding the mRNA vaccine.

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 trials 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 11.1.

12.2 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 11.2.

12.3 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 Attachment 3 hereto 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.

12.4 Disclaimer. EXCEPT AS PROVIDED IN SECTIONS 11.1 AND 11.2, 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. **Miscellaneous.**

13.1 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.

13.2 Dispute Resolution. Any dispute, controversy or claim arising under, out of or relating to this Agreement and any subsequent amendments of this contract, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, 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.

13.3 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 on the Amendment Effective Date. This provision shall also apply to unintended omissions.

13.4 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.

13.5 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.

13.6 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.

13.7 Entire Agreement. This Agreement, including any Exhibit, 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.

Signed for and on behalf of
MEDICINES PATENT POOL FOUNDATION

DocuSigned by:
Charles Gore
Signature 4713D0F59C13482...
Name Charles Gore
Title Executive Director
Date 16 January 2025

Signed for and on behalf of
AFRIGEN BIOLOGICS (PTY) LTD

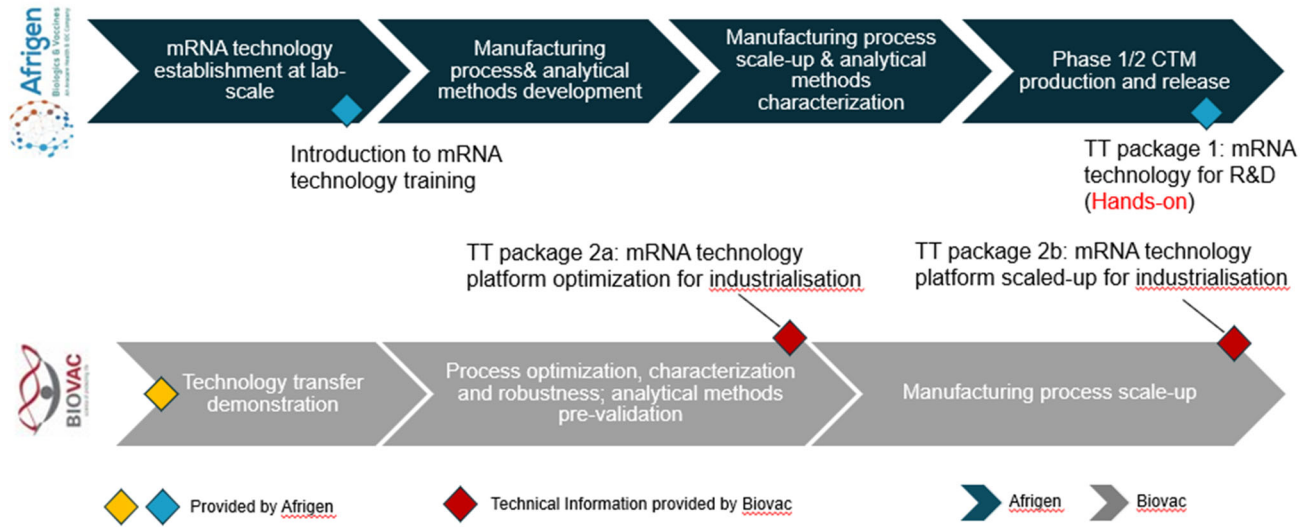
DocuSigned by:
Petro Terblanche
Signature 3DDA01FF5FB3409...
Name Prof. Petro Terblanche
Title Chief Executive Officer
Date 17 January 2025

DocuSigned by:
Marie-Paule Kiény
Signature 331D2E7093C049A...
Name Marie-Paule Kiény
Title Chair of the Board
Date 16 January 2025

LIST OF ATTACHMENTS

- | | |
|---------------------|--|
| Attachment 1 | Project Scope of Work and Key Personnel |
| Attachment 2 | Budget, Payment, and Financial Reporting |
| Attachment 3 | Donor's Specific Requirements |
| Attachment 4 | Technology Transfer Roadmap |
| Attachment 5 | Content of Technology Transfer Packages |
| Attachment 6 | Terms of Material Transfer |

ATTACHMENT 4 Technology Transfer Roadmap



ATTACHMENT 5

Content of Technology Transfer Package 1

Package 1 shall include:

- Technology Transfer Technical Information Package 1 (content listed below)
- Materials (detailed in Attachment 6)

Technology Transfer Technical Information Package 1 content:

Package 1a: mRNA Technology Platform Overview

1. Preliminary Process overview.
2. Preliminary GMP facility layout including materials, personnel and waste flows.
3. Preliminary Equipment lists for Drug Substance (DS, purified mRNA - 1L *in-vitro* transcription (IVT) reaction) and bulk Drug Product (bDP, mRNA encapsulated in Lipid Nano Particles (LNPs) at 3.7L of final product) manufacturing process and analytical methods (manufacturer, catalogue number, grade and supplier).
4. Preliminary Raw materials and consumables for DS and bDP manufacturing process and analytical methods (manufacturer, catalogue number, grade and supplier).

Package 1: – mRNA Technology Platform Description

1. GMP facility layout including materials, personnel and waste flows.
2. Shake flask cultivation and purification protocols for the manufacture of pDNA.
3. mRNA-based vaccine manufacturing of DS, bDP and final DP (manually filled and frozen DP): process descriptions (including equipment list, process parameters, process mass balances); manufacturing master batch records; equipment operation, maintenance and cleaning SOPs.
NOTE: Process descriptions scales: mRNA *in-vitro* transcription -IVT- (100mL, 1L), bulk DP (100ml, 3.7 L).
4. Sampling plan for DS, bDP and final DP including the analytical testing performed and each process step and the type of tests (characterization test, in process test, in process control, release test).
5. Analytical methods for in-process and final quality control: development reports, SOPs, qualification protocols and reports (according to ICH Q2 R1) and laboratory book templates for non-compendial methods and corresponding Pharmacopoeia chapter for the compendial methods. Protocols and, where available, qualification reports for outsourced analytical methods.
6. Primary packaging specifications (including vials, caps and stoppers) and container closure integrity report for -80°C storage.
7. Control Strategies, including proposed DS, bulk DP and final DP acceptance criteria and their rationale based on regulatory requirements and experimental results.
8. Process development support data capturing key experience/product knowledge:
 - a. Manufacturing instructions (including manufacturing process flows, process parameters, hold points, process mass balances) for DS and bDP manufacturing at 20uL, 1mL, 5mL and 10 mL IVT scales;
 - b. Process development report that also outlines the manufacturing process rationale. It includes:
 - i. Justified potential critical manufacturing process parameters/steps identification based on data or risk analysis;
 - ii. Historical data including evolution of the process through the development phases (hereby comprising successes and failures);
 - iii. Analytical results, including stability of DS, bDP and final DP obtained from pivotal batches representative of the final process (preclinical / technical/engineering) and technical interpretation of the results (at least 3 batches at 100mL IVT scale and at least 3 batches at 1L IVT scale);
 - iv. Appropriate comparison between preclinical/technical/engineering batches showing any process differences and comparability of yields and analytical results.

9. Technical reports
 - a. Stability reports for DS, bDP and final DP for batches representative of the final process (at least 3 batches at 100mL IVT scale and at least 3 batches at 1L IVT scale);
 - b. Sterile filtration bacterial challenge, filterability and specific bubble point reports;
 - c. Executed batch records for DS, bDP and final DP for batches representative of the final process (at least 3 batches at 100mL IVT scale and at least 3 batches at 1L IVT scale).
10. Pre-clinical (mice, hamsters, non-human primates) study protocols, study reports and analytical methods description.
11. Toxicology (rat animal model) study protocol and study report.

ATTACHMENT 6
Content of Technology Transfer Packages 2a & 2b

Package 2 shall include:

- Technology Transfer Technical Information Package 2 (content listed below)
- Technical assistance (as defined by Partner needs)

NOTE: Documentation to be provided in a CTD-like format

Technology Transfer Technical Information Package 2 content:

Package 2a: mRNA Technology Platform Optimization for Industrialisation

1. DS and bulk DP GMP facility layouts including personnel, materials and waste flows.
2. Catalogue number and supplier of raw materials, consumables including primary packaging.
3. Catalogue number, supplier, commissioning reports and maintenance plans of equipment.
4. Process optimisation, characterisation and robustness capturing key experience/product knowledge (conducted on process up to 1L IVT/3-6L bulk DP):
 - a. Process optimisation development report, batch records and analytical results for DS, bulk DP and final DP (sterilizing filtration, manual filling and freezing) manufacturing.
 - b. Process description of optimised process at 1L IVT/3-6L bulk DP.
 - c. Sterilizing filter selection rationale and bacterial retention efficacy verification.
 - d. Process characterization and robustness study reports. Critical manufacturing process parameters (CPP) and Key Process Parameters (KPP) identified with associated acceptable ranges.
 - e. Hold times study protocols and reports for the end-to-end process up to final DP.
 - f. Template and executed manufacturing batch records and analytical results of post-optimisation demonstration batches and consistency batches at 1L IVT/3-6L bulk DP.
 - g. Product specifications for DS, bulk DP and filled DP.
 - h. Process performance qualification (PPQ) protocol executed on consistency batches.
5. Analytical procedures for Raw materials, DS, bulk DP and final DP, IPC and IPT in place and pre-validated:
 - a. Analytical strategy and sampling plan with tests categorisation (release test, in process controls (IPC), in-process testing (IPT), characterization).
 - b. Pre-validation protocols and reports for each method (according to ICH Q2 R1 guidelines).
 - c. Trend summaries (where applicable).
 - d. For modified methods: amended SOPs, method development report describing method modifications implemented and their rationale.
 - e. Elemental impurities rationale document.
6. Results of accelerated stability studies conducted in representative conditions (i.e., temperature, humidity, container materials) for DS, bulk DP, filled DP.
7. Appropriate immunogenicity evaluation in pre-clinical animal model studies of batches manufactured at Biovac with optimised process.
8. Process development report (PDR) reflecting optimisation of the manufacturing process (DS, bulk DP and filled DP) and rationale thereof, characterisation and robustness and comparison with the process as received from Afrigen (including pre-clinical results).
9. Updated Target Product Profile.
10. Process description of automated bulk DP filling.

Package 2b: mRNA Technology Platform Scaled-Up for Industrialisation

1. Manufacturing process scale-up: DS at 5-10 L, bulk DP 30-60L, final DP.
 - a. Manufacturing Batch records (template and executed) and analytical results on at least 2 batches at scale.
 - b. Process descriptions for DS, bulk DP and final DP manufacturing process.
 - c. Product specifications for DS, bulk DP and filled DP.
 - d. Hold times, time out of refrigeration (TOR) and time out of freezing (TOF) study protocols and results for the end-to-end process up to final DP.
2. Catalogue number and supplier of raw materials, consumables including primary packaging.
3. Catalogue number and supplier, commissioning reports and maintenance plans of equipment.
4. Cleaning validation strategy plan for non-single use equipment (for DS, bulk DP and final DP manufacturing).
5. Reports of accelerated and real time stability studies (according to ICH Q1 R2 guidelines) conducted in representative conditions (i.e., temperature, humidity, container materials) for DS, bulk DP, final DP.
6. Appropriate immunogenicity evaluation in pre-clinical animal model studies of batches manufactured at Biovac with scaled-up process.
7. Process development report (PDR) on evolution and rationale of the manufacturing process (DS, bulk DP and final DP) and comparison (including pre-clinical results) along the product development across process as received from Afrigen up to scaled-up process.
8. Updated Target Product Profile.

ATTACHMENT 7
Terms of Material Transfer

Afrigen will provide the **Program Partners** with: reference material manufactured at Afrigen to be used to confirm the successful technology transfer of the analytical methods; starting material pDNA sufficient to manufacture technology transfer demonstration batches at the Program Partners; GMP Master Cell Bank vials for the Program Partners requiring them; 60mL of Drug Substance and 80mL bulk Drug Product of the demonstration batch manufactured at Afrigen during the Program Partner training. Detailed list including sources and amounts will be included in the Technical Transfer Plans signed with each Program Partner before technology transfer execution.