

## SPONSORED RESEARCH AGREEMENT

This Agreement (“Agreement”) is between Northeast Ohio Medical University (“NEOMED”), an instrumentality of the State of Ohio and an Ohio Institution of Higher Education having corporate powers under the laws of the State of Ohio, with administrative offices located at 4209 State Route 44, Rootstown, Ohio 44272 and COMPANY INC. (“Company”), a corporation having a principal place of business at \_\_\_\_\_.

NEOMED and the Company are collectively known as the “Parties”. The Effective Date of this Agreement is \_\_\_\_\_.

### 1. RESEARCH PROGRAM

- 1.1 **Performance of the Research Program.** NEOMED will use reasonable efforts to perform the Research Program described in Exhibit A, which is hereby incorporated and made part of this Agreement.
- 1.2 **Objectives.** The performance of the Research Program is of mutual interest to Company and NEOMED, and is consistent with the instructional, scholarship, and research objectives of NEOMED as a nonprofit, tax-exempt, Ohio institution of higher educational. This Agreement does not limit the freedom of individuals participating in this Research Program to engage in any other research.
- 1.3 **Principal Investigator.** The Principal Investigator will be responsible for performance and supervision of the Research Program. If for any reason the Principal Investigator cannot conduct or complete the Research Program, NEOMED will appoint a successor, subject to Company approval. If the Parties cannot agree on a successor, either party may terminate this Agreement in accord with the terms of Section 6 (Early Termination).
- 1.4 **Period of Performance.** The Agreement is effective as of the Effective Date and terminates as of the End Date.

### 2. PAYMENT

- 2.1 **Designation.** This Agreement is designated as \_\_\_\_\_ in accordance with the descriptions set forth below in 2.1 (A) and (B).

(A) **“Cost-Reimbursable”.** If this Agreement is designated as “Cost-Reimbursable,” Company will reimburse NEOMED for the Cost of conducting the Research Program. The Parties estimate that the Cost is sufficient to support the Research Program, but NEOMED may submit to Company a revised budget requesting additional funds if costs are reasonably projected to exceed the Cost. Company is not liable for any payment in excess of the Cost except on Company’s written agreement. NEOMED has the authority to rebudget Costs from time to time, at the discretion of the Principal Investigator, as long as the rebudgeting is consistent with the goals of the

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Research Program. At the end of the Research Program, if the balance owed to Company is \$100 or less, NEOMED may keep the balance.

- (B) **Fixed-Price.** If this Agreement is designated as “Fixed Price,” Company will pay NEOMED the Cost indicated in the budget as set forth in Exhibit A. The Parties estimate that the Cost is sufficient to support the Research Program. NEOMED may submit to Company a revised budget requesting additional funds if Company requests a change in the Research Program scope of work. Company will not be liable for any payment in excess of the Cost except on Company’s written agreement. NEOMED has the authority to rebudget costs at the discretion of the Principal Investigator, as long as the rebudgeting is consistent with the goals of the Research Program. Company is not entitled to any refund of unspent funds if all Research Program commitments have been met. NEOMED will provide its customary final financial report upon Company’s written request.

2.2 **Schedule.** Company will pay NEOMED in accord with the Payment Schedule as set forth in Exhibit A. Company will pay within 60 days of receipt of an invoice

2.3 **Payment by Check.** Payments are to be made payable to NEOMED and mailed to the Office of Research and Sponsored Programs with the project identifying information included on the check to the address below.

(A) **Electronic Copy.** A PDF copy of the check should be forwarded to the Office of Research and Sponsored Programs at NEOMED to ensure that the check is received.

(B) **Reference Information.** Each check payment must reference: the research project title, invoice number, SPO number, and the name of the Principal Investigator

(C) **Payment Addresses.** Company will send checks directly to the Sponsored Receivables Lockbox at one of the following addresses:

Office of Research and Sponsored Programs  
NEOMED  
4209 State Route 44, P.O. Box 95  
Rootstown, Ohio 44272

2.4 **NEOMED Payment Contact.**

Grants Accounting Manager  
Office of Research and Sponsored Programs  
NEOMED  
4209 State Route 44, P.O. Box 95  
Rootstown, Ohio 44272

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2.5 **Company Payment Contact.** Invoices to Company will be sent to:

Name \_\_\_\_\_

Address \_\_\_\_\_

Email \_\_\_\_\_

2.6 **Purchase Orders.** To the extent any conflict arises between the terms of this Agreement and the terms of any purchase order issued by Company for payment, the terms of this Agreement shall govern.

2.7 **Taxes.** NEOMED is a nonprofit, tax exempt, 501(c)(3) entity . Company agrees that if this Agreement is subject to taxation by any governmental authority, Company will pay these taxes in full. NEOMED will have no liability for the payment of these taxes.

### 3. INTELLECTUAL PROPERTY

3.1 **Definition of Technology.** “Technology” means all tangible materials, inventions, works of authorship, software, information, and data conceived or developed in the performance of the Research Program and funded under this Agreement.

3.2 **Ownership of Technology.** NEOMED owns the entire right, title, and interest, including all patents, copyrights, and other intellectual property rights, in and to all Technology developed using NEOMED facilities and by NEOMED personnel under this Agreement (“NEOMED Technology”). Company owns the entire right, title and interest, including all patents, copyrights, and other intellectual property rights, in and to all Technology developed using Company facilities and by Company personnel under this Agreement (“Company Technology”). Technology that is jointly developed by NEOMED and Company personnel will be jointly owned (“Joint Technology”).

3.3 **Patent Filing and Expenses.** NEOMED may file patent applications covering NEOMED Technology (“NEOMED Patents”) at its own discretion and expense, or at the request of Company at Company’s expense. If Company elects to license NEOMED Patents, Company will pay the costs of patent filing, prosecution and maintenance in the United States and any foreign country elected. NEOMED Patents include any foreign patent application corresponding thereto, and any divisional, continuation, or reexamination application, extension, and each patent that issues or reissues from any of these patent applications. Company will notify NEOMED of those countries outside the United States in which it desires a license in sufficient time for NEOMED to satisfy the patent-law requirements of those countries. Company will reimburse NEOMED for out-of-pocket costs for those filings, including patent filing, prosecution, and maintenance fees.

3.4 **Invention Disclosure and License Election.** NEOMED will provide Company with a complete, written, confidential disclosure of NEOMED Technology after the disclosure is received by NEOMED’s Office of Technology Licensing. By giving written notice to

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NEOMED within three months after receipt of the disclosure, Company may elect one of the following alternatives:

- (A) **Non Exclusive License.** Subject to third-party rights, if any, a nonexclusive, nontransferable (without the right to sublicense), worldwide license in a designated field of use to make, have made, use, and sell products covered by the NEOMED Patents on terms to be negotiated. NEOMED may at its option discontinue patent prosecution or maintenance of any such invention licensed to Company for which NEOMED is paying patent-related costs; or
  - (B) **Exclusive License.** Subject to third party rights, if any, a royalty-bearing, limited-term, exclusive, field-of-use license, including the right to sublicense, in the United States or any other country elected by Company (subject to Section 3.3 above) to make, have made, use, and sell products covered by the NEOMED Patents, in exchange for Company's agreement to diligently commercialize the invention.
- 3.5 **License Terms and Conditions.** All licenses of this Section 3 elected by Company are effective as of the date the Parties negotiate and sign a separate license agreement, which will contain, Ohio governing law, insurance, and no-warranty provisions, in addition to other customary terms and conditions. Company agrees all licenses will be subject to applicable laws and regulations. NEOMED is not permitted and will not agree to indemnify or hold Company harmless in any license agreement issued.
- 3.6 **License to Joint Technology.** Company may, at its option under Section 3.4(B), exclusively license NEOMED's rights in Joint Technology.
- 3.7 **Copyright Licenses.** Company may elect to negotiate a nonexclusive or exclusive (subject to third party rights, if any) royalty-bearing license to use, reproduce, display, distribute and perform computer software developed in the course of the Research Program (NEOMED Software) and its documentation for commercial purposes in a designated field of use. Company must elect within three months of notice of NEOMED's disclosure of copyrightable material available for license. Computer software for which a patent application is filed is subject to Section 3.4.
- 3.8 **Negotiation Period and Non-Election.** If Company does not provide written notice of election to NEOMED within three months of a written disclosure under Sections 3.4, 3.6, or 3.7, NEOMED has no further license obligations to Company. If NEOMED and Company fail to complete license negotiations within three months after written election, NEOMED has no further license obligations to Company.
- 3.9 **Assignment.** NEOMED represents that all of its employees, students, and consultants who participate in the Research Program will be obligated to assign to NEOMED all their rights in patentable or copyrightable Technology.

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- 3.10 **Expendables and other equipment.** NEOMED owns all expendables and equipment purchased or fabricated to perform the Research Program.
- 3.11 **Other Intellectual Property.** For the avoidance of doubt, all intellectual property developed outside of this Agreement shall remain the property of its owner. Except as explicitly provided in this Agreement, neither party receives any right to the other's intellectual property developed outside of this Agreement.

### 4. REPORTS

- 4.1 **Reports.** The Principal Investigator will provide a final report to Company within 90 days of the End Date. The report will summarize the Research Program findings.
- 4.2 **Use of Results.** Company may use NEOMED Technology that is not covered by NEOMED Patents for any lawful purpose.

### 5. PUBLICATION

- 5.1 **Objective.** The basic objective of research activities at NEOMED is the generation of new knowledge and its expeditious dissemination for the public's benefit. Company will cooperate with NEOMED in meeting this objective.
- 5.2 **Confidential Information.** "Confidential Information" means Company-owned, confidential, scientific, business or financial information that is provided in written form and clearly marked as confidential, provided that such information:
- (A) is not publicly known or available from other sources who are not under a confidentiality obligation to the source of the information;
  - (B) has not been made available by its owners to others without a confidentiality obligation;
  - (C) is not already known by or available to NEOMED without a confidentiality obligation;
  - (D) is not independently developed by the receiving party; or
  - (E) does not relate to potential hazards or cautionary warnings associated with the performance of the Research Program, and is not required to be disclosed under operation of law.
- 5.3 **Review.** As a matter of basic academic policy, NEOMED retains the right at its discretion to publish freely the results of the Research Program. NEOMED will provide Company

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with a copy of any manuscript or other publication at the time it is submitted for publication. Company may review the manuscript or publication:

- (A) To ascertain whether Company's Confidential Information would be disclosed by the publication;
- (B) To identify potentially patentable Technology so that appropriate steps may be taken to protect the Technology; and
- (C) To confirm that the privacy rights of individuals are adequately protected.

5.4 **Comments.** Company will provide comments, if any, within 30 days of receiving the manuscript or publication. If patentable Technology is disclosed in the manuscript or publication, Company will promptly advise NEOMED whether it requests NEOMED to file and prosecute a patent application.

5.5 **Acknowledgment.** NEOMED will acknowledge Company in publications for its sponsorship of the Research Project.

## 6. EARLY TERMINATION

6.1 **Termination by either party.** Either party may terminate this Agreement upon 60 days' written notice. If this Agreement is terminated before the End Date, Company will pay the reasonable cost incurred by NEOMED in winding down and terminating the Research Program, including the cost of the Research Program during the wind-down period and all related costs and non-cancelable commitments made before termination. If any NEOMED student is supported under this Agreement, Company will remain responsible for the full cost of the budgeted student support through the end of the academic quarter in which this Agreement is terminated. After termination, NEOMED will submit a final report of all costs incurred and all funds received under this Agreement. The report will be accompanied by a check for funds remaining after allowable costs and non-cancelable commitments have been paid, provided the funds exceed \$100.

6.2 **Termination for failure to pay.** NEOMED reserves the right to cease performance and terminate this Agreement immediately if Company fails to pay any invoice within 60 days of receipt.

## 7. NOTICE

7.1 **All Notices.** All notices under this Agreement are deemed fully given when written, addressed, and sent as follows:

All notices to Company are mailed or emailed to:

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Name \_\_\_\_\_  
Address \_\_\_\_\_  
Email \_\_\_\_\_

All notices to NEOMED are e-mailed or mailed to:  
NEOMED  
Office of Research and Sponsored Programs  
4209 State Route 44, P.O. Box 95NEO  
Rootstown, Ohio 44272

cc: Principal Investigator

NEOMED  
Office of the General Counsel  
4209 State Route 44, P.O. Box 95  
Rootstown, Ohio 44272

7.2 Either party will provide written notice to the other of a change in address.

### 8. PUBLICITY

Company will not use: (i) NEOMED's name or trademarks, (ii) the name or trademarks of any organization related to NEOMED, or (iii) the name of any NEOMED faculty member, employee, student or volunteer without the prior written consent of NEOMED. Permission may be withheld at NEOMED's sole discretion. This prohibition includes, but is not limited to, use in press releases, advertising, marketing materials, other promotional materials, presentations, case studies, reports, websites, software application or interfaces, and other electronic media.

### 9. INDEMNITY

Company will indemnify, defend, and hold harmless NEOMED, its trustees, directors, employees, agents, volunteers, subcontractors, and students ("Indemnitees") from any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses of litigation) incurred by or imposed upon the Indemnitees or any one of them in connection with claims, suits, actions, demands, or judgments arising out of or connected with: (a) Company-provided materials or equipment used in the Research Program, (b) human subjects involved in the Research Program, and (c) Company's use of results of the Research Program, except to the extent that the liability is due to the gross negligence or willful misconduct of NEOMED. NEOMED will promptly notify Company of any claim and will cooperate in the defense of the claim. Company will, at its own expense, provide attorneys reasonably acceptable to NEOMED to defend against any claim for which Company has agreed to indemnify NEOMED. This indemnity will not

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be deemed excess coverage to any insurance or self-insurance NEOMED may have covering a claim. Company's indemnity will not be limited by the amount of Company's insurance.

### 10. INSURANCE

10.1 **NEOMED Coverage.** NEOMED will maintain worker's compensation insurance or other coverage on its employees as required by Ohio law, and will self-insure or maintain insurance covering its liability under this Agreement.

10.2 **Company Coverage.** Company will procure and maintain during the term of this Agreement comprehensive liability and product liability insurance to the full amount of Company insurance limits, but in no event less than \$3,000,000 per occurrence, with a reputable and financially secure insurance carrier. The insurance will include NEOMED, its trustees, directors, employees, agents, subcontractors, volunteers and students as additional insureds with respect to this Agreement. This insurance will be written to cover claims incurred, discovered, manifested, or made during or after the expiration of this Agreement.

(A) **Certificate.** Before executing the Agreement, Company will provide NEOMED with a Certificate of Insurance evidencing primary coverage and requiring 30 days' prior written notice to NEOMED of cancellation or material change. Company will advise NEOMED in writing that it maintains excess liability coverage (following form) over primary insurance for at least the minimum limits set forth in Section 10.2. Conditions of the Certificate of Insurance will be subject to approval in advance by NEOMED's Office of Risk Management.

(B) **Primary Coverage.** Company's insurance will be primary coverage. NEOMED's insurance or self-insurance will be excess and noncontributory.

(C) **Continued Coverage.** If Company's insurance is written on a claims-made basis, as opposed to an occurrence basis, Company will purchase the coverage necessary to ensure continued and uninterrupted coverage of all claims, including those made after the policy expires or is terminated.

### 11. HUMAN SUBJECTS RESEARCH AND PROTECTION

11.1 **Human Research Protection Program.** Company acknowledges that NEOMED has a human research protection program ("HRPP") established in accordance with the principles and standards of the Association for the Accreditation of Human Research Protection Programs that is applicable to all research involving human subjects, including the Research Program, that includes: (i) submittal for prospective and continuing review to NEOMED's institutional review board ("IRB") under the federal regulations governing the protection of human research subjects, (ii) obtaining consent from human research



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subjects as specified in those regulations, (iii) conducting the research in accordance with ethical standards such as the Belmont Report.

**11.2 Communication Concerning Certain Events Affecting Research Participants.** In furtherance of NEOMED's HRPP, Company agrees:

- (A) to notify promptly the Principal Investigator and/ or the NEOMED IRB directly, of (i) non-compliance with the Research Program in Exhibit A or applicable laws, particularly those laws related to human research subjects, that could affect the safety or welfare of participating subjects; (ii) serious adverse events that have been reported to the FDA or other governmental agency in relation to the Research Program at NEOMED or any other site; (iii) unanticipated problems in the Research Program at NEOMED or any other site that could relate to risks to participating subjects; and (iv) circumstances that could affect subjects' willingness to continue to participate in the Research Program or the continued approval of NEOMED's IRB for the Research Program; and,
- (B) to develop a plan of communication to subjects with NEOMED's Principal Investigator that is acceptable to NEOMED's IRB when new findings or results of the Research Program might affect the willingness of subjects to continue to participate in the Research Program or directly affect their current or future safety or medical care.

**11.3 Data and Safety Monitoring Reports.** Company will provide NEOMED with any data and safety monitoring reports related to the Research Program that may: (i) affect the safety and welfare of current or former Research Program participants, or (ii) influence the conduct of the Research Program. NEOMED will submit such reports to the IRB as required. During the Research Program and for at least two (2) years following the completion of the Research Program at all sites, Company will promptly provide NEOMED and Principal Investigator with a written report of any routine monitoring findings in site monitoring reports and data safety monitoring committee reports including, but not limited to, data and safety analyses that may: (i) affect the safety and welfare of current or former Research Program participants, or (ii) influence the conduct of the Research Program.

## **12. NO WARRANTIES**

**12.1 No Guarantee.** Company acknowledges that the Research Program is a scientific undertaking and, consequently, NEOMED will not guarantee any particular outcome or specific yield.

**12.2 Disclaimer of Warranties.** NEOMED provides Company the rights granted in this Agreement AS IS and WITH ALL FAULTS. NEOMED makes no representations and

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extends no warranties of any kind, either express or implied. Among other things, NEOMED disclaims any express or implied warranty:

- (A) of merchantability, of fitness for a particular purpose,
- (B) of non-infringement or,
- (C) arising out of any course of dealing.

### 13. GENERAL PROVISIONS

- 13.1 **Laws and Regulations.** Both Parties are subject to all local, state and federal laws and regulations applicable to its obligations under this Agreement.
- 13.2 **Export Control.** Both Parties agree to adhere to U.S. export laws and regulations, where applicable. Company agrees that it will not disclose Confidential Information that contains technology or technical data identified on any U.S. export control list, including the Commerce Control List ("CCL") at 15 C.F.R. 774 and the U.S. Munitions List ("USML") at 22 C.F.R. 121. Proposed disclosures of Confidential Information by Company that include technology or technical data other than that classified as EAR99 will be negotiated pursuant to a separate agreement.
- 13.3 **Animal Studies.** NEOMED does not conduct animal studies that are intended to support applications for research or marketing permits for FDA-regulated products (as described in Title 21, Code of Federal Regulations (CFR) Part 58-Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies).
- 13.4 **Dispute Resolution.** If any dispute arises between the Parties in connection with payments due under this Agreement that cannot be resolved by mutual agreement after meetings between the Parties, it will be finally settled through mediation and/or litigation in the Ohio Court of Claims or other court of competent jurisdiction.
- 13.5 **Assignment.** Neither party may assign this Agreement without prior written notice to the other party.
- 13.6 **Severability.** If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, the provision will be divisible from this Agreement and deemed to be deleted from this Agreement. If the deletion substantially alters the basis of this Agreement, the Parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent of the Parties.
- 13.7 **Independent Contractors.** NEOMED and Company are independent contractors and neither is an agent, joint venturer, or partner of the other.

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- 13.8 **Governing Law.** This Agreement is governed by the laws of the State of Ohio, without regard to its conflict of laws doctrine. Any legal action involving this Agreement or the Research Program will be adjudicated in the State of Ohio.
- 13.9 **Non-Discrimination.** NEOMED shall follow its normal employment policies, which prohibit discrimination against any employee or applicant for employment on the basis of race, color, creed, religion, national origin, sexual preference, sexual identity, marital status, age, gender, or handicap (except where bona fide occupational qualification so requires), with respect to this Agreement. Qualified individuals will not be denied the opportunity to contribute to the work conducted at NEOMED under this Agreement on the basis of citizenship.
- 13.10 **Force Majeure.** NEOMED is not liable for any failure to perform as required by this Agreement if the failure to perform is caused by circumstances reasonably beyond NEOMED's control, such as labor disturbances or labor disputes of any kind, accidents, failure of any governmental approval required for full performance, civil disorders or commotions, acts of aggression, acts of God, energy or other conservation measures, explosions, failure of utilities, mechanical breakdowns, material shortages, disease, theft, pandemics, or other occurrences.
- 13.11 **Prevailing Terms.** In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated into this Agreement, the terms of this Agreement prevail.
- 13.12 **Entire Agreement.** This Agreement represents the entire agreement and understanding between the Parties with respect to its subject matter. It supersedes all prior or contemporaneous discussions, representations, or agreements, whether written or oral, of the Parties regarding its subject matter.
- 13.13 **Amendments or Changes.** Amendments or changes to this Agreement must be in writing and signed by the Parties' authorized representatives.
- 13.14 **Electronic Signatures.** The Parties to this Agreement agree that a copy of the original signature (including an electronic copy) may be used for any and all purposes for which the original signature may have been used. The Parties further waive any right to challenge the admissibility or authenticity of this Agreement in a court of law based solely on the absence of an original signature.
- 13.15 **Counterparts.** This Agreement and any amendment to it may be executed in counterparts and all of these counterparts together shall be deemed to constitute one and the same agreement.

(The remainder of this page left blank intentionally.)

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The duly authorized party representatives execute this Agreement, including all its terms and conditions.

NEOMED

COMPANY

Signature:

Signature:

Name:

Name:

Title:

Title:

Date:

Date:

I acknowledge that I have read this Agreement in its entirety and will use reasonable efforts to uphold my obligations and responsibilities under this Agreement.

PRINCIPAL  
INVESTIGATOR

Signature:

Name:

Title:

Date:

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### Exhibit A

Scope of Work

Budget

Essential Personnel

Schedule