

REIMBURSABLE SPACE ACT AGREEMENT  
BETWEEN  
EPIOMED THERAPEUTICS, INC.  
AND THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION,  
NASA LYNDON B. JOHNSON SPACE CENTER  
FOR  
FURTHER DEVELOPMENT OF INSTRANASAL SCOPOLAMINE (INSCOP)

ARTICLE 1. AUTHORITY AND PARTIES

In accordance with the National Aeronautics and Space Act (51 U.S.C. § 20113), this Agreement is entered into by the National Aeronautics and Space Administration, Lyndon B. Johnson Space Center, located at 2101 NASA Parkway, Houston, Texas 77058 (hereinafter referred to as "NASA") and Epiomed Therapeutics, Inc. located at 25 Mauchly, Suite 316, Irvine, CA 92618 (hereinafter referred to as "Epiomed" or "Partner"). NASA and Partner may be individually referred to as a "Party" and collectively referred to as the "Parties."

ARTICLE 2. PURPOSE

NASA and Epiomed wish to collaborate on further development and commercialization of the NASA-developed INSCOP formulation for motion sickness. The Parties eventually intend to make the Product available to NASA and to market and distribute it to military personnel and civilians.

ARTICLE 3. DEFINITIONS

1. "IND" means Investigational New Drug Application No. 33,983.
2. "INSCOP" means the scopolamine product being developed by NASA under Investigational New Drug Application No. 33,983.
3. "Product" means INSCOP in final form for use by end-users.

ARTICLE 4. RIGHTS & RESPONSIBILITIES

This agreement is provided on an exclusive basis consistent with the specific activities set forth as part of NASA's responsibilities. Specifically, Epiomed will assume responsibility for further development and commercialization of INSCOP. Epiomed has been identified as a suitable partner because it has sufficient resources to provide the additional corporate pharmaceutical and regulatory expertise necessary to execute effective communication and documentation with the FDA, to ensure completion of clinical trials under the existing IND, and, if further development is warranted, pursue subsequent approval of a NDA and subsequent market release of the new drug.

NASA will use reasonable efforts to:

1. Collaborate in the conduct of safety/efficacy trials of INSCOP.
2. Provide results from clinical trials conducted thus far for evaluation and forward plan of completing FDA requirements.
3. Advise on further development and continue collaboration to complete the clinical evaluation of INSCOP for the treatment of motion sickness.
4. Provide Epiomed with historical FDA correspondence and compliance documentation for INSCOP.
5. Transfer IND sponsorship to Epiomed to enable implementation of future clinical trials and FDA approvals.

Epiomed will use reasonable efforts to:

1. Provide resources and corporate, pharmaceutical and regulatory expertise to develop and commercialize deliver the Product to NASA and any other end users.
2. Secure FDA approval for transfer of IND sponsorship.
3. Apply for patent protection at least in the U.S. for future joint inventions between the Parties.
4. Support clinical evaluation of INSCOP, and conduct required activities for market release of the Product.
5. Supply INSCOP for use by NASA and other end users. Distribution for testing and use will be made to astronauts and study subjects through normal pharmacy procedures that include stock and dispensing compliance oversight and documentation, maintenance of stock records, and storing and disposal in accordance with DEA guidelines.

#### ARTICLE 5. SCHEDULE AND MILESTONES

The planned major milestones for the activities defined in the "Responsibilities" clause are as follows:

Transfer of IND to Epiomed by JSC.

Upon execution of the Agreement

Completion of safety/efficacy/PK trials for INSCOP by  
Epiomed

Within [REDACTED] of the  
transfer of the IND

Delivery of the Product to NASA by Epiomed

Within [REDACTED] of  
transfer of the IND

#### ARTICLE 6. FINANCIAL OBLIGATIONS

1. Partner agrees to reimburse NASA an estimated cost of [REDACTED] for NASA to carry out its responsibilities to complete testing of INSCOP under this Agreement. NASA will not initiate work under this Agreement until NASA has received Partner's payment(s) for that work. In no event will NASA transfer any U.S. Government funds to Partner under this Agreement. Payment must be made by Partner in advance of initiation of NASA's efforts.

Advance payments shall be scheduled to ensure that funds are resident with NASA before Federal obligations are incurred in support of this Agreement.

2. Payment shall be payable to the National Aeronautics and Space Administration through the NASA Shared Services Center (NSSC) (choose one form of payment):

(1) U.S. Treasury FEDWIRE Deposit System, Federal Reserve Wire Network Deposit System, pay.gov at <https://www.nssc.nasa.gov/portal/site/customerservice/menuitem.bb29c518138071c056969daf4dd72749>; or

(2) Check. A check should be payable to NASA and sent to:

NASA Shared Services Center  
FMD – Accounts Receivable; For the Accounts of: Lyndon B. Johnson Space Center  
Bldg 1111, C Road  
Stennis Space Center, MS 39529

Payment by electronic transfer is strongly encouraged, and payment by check is to be used only if circumstances preclude the use of electronic transfer. All payments and other communications regarding this Agreement shall reference the Center name, title, date, and number of this Agreement.

3. NASA will not provide services or incur costs beyond the existing payment. Although NASA has made a good faith effort to accurately estimate its costs, it is understood that NASA provides no assurance that the proposed effort under this Agreement will be accomplished for the above estimated amount. Should the effort cost more than the estimate, Partner will be advised by NASA as soon as possible. Partner shall pay all costs incurred and has the option of canceling the remaining effort, or providing additional funding in order to continue the proposed effort under the revised estimate. Should this Agreement be terminated, or the effort completed at a cost less than the agreed-to estimated cost, NASA shall account for any unspent funds within (1) year

after completion of all effort under this Agreement, and promptly thereafter return any unspent funds to Partner.

4. Notwithstanding any other provision of this Agreement, all activities under or pursuant to this Agreement are subject to the availability of funds, and no provision of this Agreement shall be interpreted to require obligation or payment of funds in violation of the Anti-Deficiency Act, (31 U.S.C. § 1341).

#### ARTICLE 7. PRIORITY OF USE

Any schedule or milestone in this Agreement is estimated based upon the Parties' current understanding of the projected availability of NASA goods, services, facilities, or equipment. In the event that NASA's projected availability changes, Partner shall be given reasonable notice of that change, so that the schedule and milestones may be adjusted accordingly. The Parties agree that NASA's use of the goods, services, facilities, or equipment shall have priority over the use planned in this Agreement. Should a conflict arise, NASA in its sole discretion shall determine whether to exercise that priority. Likewise, should a conflict arise as between two or more non-NASA Partners, NASA, in its sole discretion, shall determine the priority as between those Partners. This Agreement does not obligate NASA to seek alternative government property or services under the jurisdiction of NASA at other locations.

#### ARTICLE 8. LIABILITY AND RISK OF LOSS

1. Each Party hereby waives any claim against the other Party, employees of the other Party, the other Party's Related Entities (including but not limited to contractors and subcontractors at any tier, grantees, investigators, customers, users, and their contractors or subcontractor at any tier), or employees of the other Party's Related Entities for any injury to, or death of, the waiving Party's employees or the employees of its Related Entities, or for damage to, or loss of, the waiving Party's property or the property of its Related Entities arising from or related to activities conducted under this Agreement, whether such injury, death, damage, or loss arises through negligence or otherwise, except in the case of willful misconduct.

2. Each Party further agrees to extend this cross-waiver to its Related Entities by requiring them, by contract or otherwise, to waive all claims against the other Party, Related Entities of the other Party, and employees of the other Party or of its Related Entities for injury, death, damage, or loss arising from or related to activities conducted under this Agreement. Additionally, each Party shall require that their Related Entities extend this cross-waiver to their Related Entities by requiring them, by contract or otherwise, to waive all claims against the other Party, Related Entities of the other Party, and employees of the other Party or of its Related Entities for injury, death, damage, or loss arising from or related to activities conducted under this Agreement.

#### ARTICLE 9. INTELLECTUAL PROPERTY RIGHTS - DATA RIGHTS

## 1. General

(a) "Related Entity" as used in this Data Rights clause means a contractor, subcontractor, grantee, or other entity having a legal relationship with NASA or Partner that is assigned, tasked, or contracted to perform activities under this Agreement.

(b) "Data" means recorded information, regardless of form, the media on which it is recorded, or the method of recording.

(c) "Proprietary Data" means Data embodying trade secrets developed at private expense or commercial or financial information that is privileged or confidential, and that includes a restrictive notice, unless the Data is:

(i) known or available from other sources without restriction;

(ii) known, possessed, or developed independently, and without reference to the Proprietary Data;

(iii) made available by the owners to others without restriction; or

(iv) required by law or court order to be disclosed.

(d) Data exchanged under this Agreement is exchanged without restriction except as otherwise provided herein.

(e) Notwithstanding any restrictions provided in this clause, the Parties are not restricted in the use, disclosure, or reproduction of Data provided under this Agreement that meets one of the exceptions in (c) above. If a Party believes that any exceptions apply, it shall notify the other Party before any unrestricted use, disclosure, or reproduction of the Data.

(f) The Parties will not exchange preexisting Proprietary Data under this Agreement unless authorized herein or in writing by the owner.

(g) If the Parties exchange Data having a notice that the Receiving Party deems is ambiguous or unauthorized, the Receiving Party shall tell the Providing Party. If the notice indicates a restriction, the Receiving Party shall protect the Data under this clause unless otherwise directed in writing by the Providing Party.

(h) The Data rights herein apply to the employees and Related Entities of Partner. Partner shall ensure that its employees and Related Entity employees know about and are bound by the obligations under this clause.

(i) Disclaimer of Liability: NASA is not restricted in, or liable for, the use, disclosure, or reproduction of Data without a restrictive notice under paragraphs 1 (c), 2 or 8 of this clause or for Data Partner gives, or is required to give, the U.S. Government without restriction.

(j) Partner may use the following or a similar restrictive notice under paragraphs 1(c), 2 and 8 of this clause. Partner should also mark each page containing Proprietary Data with the following or a similar legend: "Proprietary Data – use and disclose only under the notice on title or cover page."

### Proprietary Data Notice:

The data herein include Proprietary Data and are restricted under the Data Rights provisions of Space Act Agreement [provide applicable identifying information].

## 2. Data First Produced by Partner Under this Agreement

If Data first produced by Partner or its Related Entities under this Agreement is given to NASA, and the Data is Proprietary Data, and it includes a restrictive notice, NASA will use reasonable efforts to protect it. The Data will be disclosed only to partner U.S. Government and U.S. Government contractor employees and used (under suitable protective conditions) only for U.S. Government purposes.

### 3. Data First Produced by NASA Under this Agreement

If Partner requests that Data first produced by NASA or its Related Entities under this Agreement be protected, and NASA determines it would be Proprietary Data if obtained from Partner, NASA will mark it with a restrictive notice and use reasonable efforts to protect it for 2 Years after its development. During this restricted period the Data may be disclosed and used (under suitable protective conditions) for U.S. Government purposes only, and thereafter for any purpose. Partner must not disclose the Data without NASA's written approval during the restricted period. The restrictions placed on NASA do not apply to Data disclosing a NASA owned invention for which patent protection is being considered.

### 4. Publication of Results

The National Aeronautics and Space Act (51 U.S.C. § 20112) requires NASA to provide for the widest practicable and appropriate dissemination of information concerning its activities and the results thereof. As such, NASA may publish unclassified and non-Proprietary Data resulting from work performed under this Agreement. The Parties will coordinate publication of results allowing a reasonable time to review and comment.

### 5. Data Disclosing an Invention

If the Parties exchange Data disclosing an invention for which patent protection is being considered, and the furnishing Party identifies the Data as such when providing it to the Receiving Party, the Receiving Party shall withhold it from public disclosure for a reasonable time (one (1) year unless otherwise agreed or the Data is restricted for a longer period herein).

### 6. Copyright

Data exchanged with a copyright notice and no indication of restriction under paragraphs 1(c), 2, 3, or 8 of this clause (i.e., Data has no restrictive notice) is presumed to be published. The following royalty-free licenses apply.

(a) If indicated on the Data that it was produced outside of this Agreement, it may be reproduced, distributed, and used to prepare derivative works only for carrying out the Receiving Party's responsibilities under this Agreement.

(b) Data without the indication of (a) is presumed to be first produced under this Agreement. Except as otherwise provided in paragraph 5 of this clause, and in the Inventions and Patent Rights clause of this Agreement for protection of reported

inventions, the Data may be reproduced, distributed, and used to prepare derivative works for any purpose.

#### 7. Data Subject to Export Control

Whether or not marked, technical data subject to the export laws and regulations of the United States provided to Partner under this Agreement must not be given to foreign persons or transmitted outside the United States without proper U.S. Government authorization.

#### 8. Handling of Background, Third Party Proprietary, and Controlled Government Data

(a) NASA or Partner (as Disclosing Party) may provide the other Party or its Related Entities (as Receiving Party):

(i) Proprietary Data developed at Disclosing Party's expense outside of this Agreement (referred to as Background Data);

(ii) Proprietary Data of third parties that Disclosing Party has agreed to protect or is required to protect under the Trade Secrets Act (18 U.S.C. § 1905) (referred to as Third Party Proprietary Data); and

(iii) U.S. Government Data, including software and related Data, Disclosing Party intends to control (referred to as Controlled Government Data).

(b) All Background, Third Party Proprietary and Controlled Government Data provided by Disclosing Party to Receiving Party shall be marked by Disclosing Party with a restrictive notice and protected by Receiving Party in accordance with this clause.

(c) Disclosing Party provides the following Data to Receiving Party. The lists below may not be comprehensive, are subject to change, and do not supersede any restrictive notice on the Data.

(i) Background Data:

none

(ii) Third Party Proprietary Data:

none

(iii) Controlled Government Data:

Intranasal Scopolamine (INSCOP) - Federal Food and Drug Administration (FDA)  
Investigational New Drug (IND) 33,983

(iv) NASA software and related Data will be provided to Partner under a separate Software Usage Agreement (SUA). Partner shall use and protect the related Data in accordance with this clause. Unless the SUA authorizes retention, or Partner enters into a license under 37 C.F.R. Part 404, the related Data shall be disposed of as NASA directs:  
none

(d) For Data with a restrictive notice and Data identified in this Agreement, Receiving Party shall:

(i) Use, disclose, or reproduce the Data only as necessary under this Agreement;

(ii) Safeguard the Data from unauthorized use and disclosure;

(iii) Allow access to the Data only to its employees and any Related Entity requiring access under this Agreement;

- (iv) Except as otherwise indicated in (d)(iii), preclude disclosure outside Receiving Party's organization;
- (v) Notify its employees with access about their obligations under this clause and ensure their compliance, and notify any Related Entity with access about their obligations under this clause; and
- (vi) Dispose of the Data as Disclosing Party directs.

#### 9. Oral and visual information

If Partner discloses Proprietary Data orally or visually, NASA will have no duty to restrict, or liability for disclosure or use, unless Partner:

- (a) Orally informs NASA before initial disclosure that the Data is Proprietary Data, and
- (b) Reduces the Data to tangible form with a restrictive notice as required by paragraphs 1(c), 2 and 8 of this clause, and gives it to NASA within ten (10) calendar days after disclosure.

### ARTICLE 10. INTELLECTUAL PROPERTY RIGHTS - INVENTION AND PATENT RIGHTS

1. "Related Entity" as used in this Invention and Patent Rights clause means a contractor, subcontractor, grantee, or other entity having a legal relationship with NASA or Partner assigned, tasked, or contracted with to perform activities under this Agreement.
2. The invention and patent rights herein apply to employees and Related Entities of Partner. Partner shall ensure that its employees and Related Entity employees know about and are bound by the obligations under this clause.
3. NASA has determined that 51 U.S.C. § 20135(b) does not apply to this Agreement. Therefore, title to inventions made (conceived or first actually reduced to practice) under this Agreement remain with the respective inventing party(ies). No invention or patent rights are exchanged or granted under this Agreement, except as otherwise set forth herein. NASA and Partner will use reasonable efforts to report inventions made jointly by their employees (including employees of their Related Entities). The Parties will consult and agree on the responsibilities and actions to establish and maintain patent protection for joint invention, and on the terms and conditions of any license or other rights exchanged or granted between them.

### ARTICLE 11. USE OF NASA NAME AND EMBLEMS

#### 1. NASA Name and Initials

Partner shall not use "National Aeronautics and Space Administration" or "NASA" in a way that creates the impression that a product or service has the authorization, support, sponsorship, or endorsement of NASA, which does not, in fact, exist. Except for releases under the "Release of General Information to the Public and Media" clause, Partner must

submit any proposed public use of the NASA name or initials (including press releases and all promotional and advertising use) to the NASA Assistant Administrator for the Office of Communication or designee ("NASA Communications") for review and approval. Approval by NASA Communications shall be based on applicable law and policy governing the use of the NASA name and initials.

## 2. NASA Emblems

Use of NASA emblems (i.e., NASA Seal, NASA Insignia, NASA logotype, NASA Program Identifiers, and the NASA Flag) is governed by 14 C.F.R. Part 1221. Partner must submit any proposed use of the emblems to NASA Communications for review and approval.

### ARTICLE 12. RELEASE OF GENERAL INFORMATION TO THE PUBLIC AND MEDIA

NASA or Partner may, consistent with Federal law and this Agreement, release general information regarding its own participation in this Agreement as desired.

### ARTICLE 13. DISCLAIMER OF WARRANTY

Goods, services, facilities, or equipment provided by NASA under this Agreement are provided "as is." NASA makes no express or implied warranty as to the condition of any such goods, services, facilities, or equipment, or as to the condition of any research or information generated under this Agreement, or as to any products made or developed under or as a result of this Agreement including as a result of the use of information generated hereunder, or as to the merchantability or fitness for a particular purpose of such research, information, or resulting product, or that the goods, services, facilities or equipment provided will accomplish the intended results or are safe for any purpose including the intended purpose, or that any of the above will not interfere with privately-owned rights of others. Neither the government nor its contractors shall be liable for special, consequential or incidental damages attributed to such equipment, facilities, technical information, or services provided under this Agreement or such research, information, or resulting products made or developed under or as a result of this Agreement.

### ARTICLE 14. DISCLAIMER OF ENDORSEMENT

NASA does not endorse or sponsor any commercial product, service, or activity. NASA's participation in this Agreement or provision of goods, services, facilities or equipment under this Agreement does not constitute endorsement by NASA. Partner agrees that nothing in this Agreement will be construed to imply that NASA authorizes, supports, endorses, or sponsors any product or service of Partner resulting from activities conducted under this Agreement, regardless of the fact that such product or service may employ NASA-developed technology.

ARTICLE 15. COMPLIANCE WITH LAWS AND REGULATIONS

(a) The Parties shall comply with all applicable laws and regulations including, but not limited to, safety; security; export control; environmental; and suspension and debarment laws and regulations. Access by a Partner to NASA facilities or property, or to a NASA Information Technology (IT) system or application, is contingent upon compliance with NASA security and safety policies and guidelines including, but not limited to, standards on badging, credentials, and facility and IT system/application access.

(b) With respect to any export control requirements:

(i) The Parties will comply with all U.S. export control laws and regulations, including the International Traffic in Arms Regulations (ITAR), 22 C.F.R. Parts 120 through 130, and the Export Administration Regulations (EAR), 15 C.F.R. Parts 730 through 799, in performing work under this Agreement or any Annex to this Agreement. In the absence of available license exemptions or exceptions, the Partner shall be responsible for obtaining the appropriate licenses or other approvals, if required, for exports of hardware, technical data and software, or for the provision of technical assistance.

(ii) The Partner shall be responsible for obtaining export licenses, if required, before utilizing foreign persons in the performance of work under this Agreement or any Annex under this Agreement, including instances where the work is to be performed on-site at NASA and where the foreign person will have access to export-controlled technical data or software.

(iii) The Partner will be responsible for all regulatory record-keeping requirements associated with the use of licenses and license exemptions or exceptions.

(iv) The Partner will be responsible for ensuring that the provisions of this Article apply to its Related Entities.

(c) With respect to suspension and debarment requirements:

(i) The Partner hereby certifies, to the best of its knowledge and belief, that it has complied, and shall comply, with 2 C.F.R. Part 180, Subpart C, as supplemented by 2 C.F.R. Part 1880, Subpart C.

(ii) The Partner shall include language and requirements equivalent to those set forth in subparagraph (c)(i), above, in any lower-tier covered transaction entered into under this Agreement.

ARTICLE 16. TERM OF AGREEMENT

This Agreement becomes effective upon the date of the last signature below ("effective date") and shall remain in effect until the completion of all obligations of both Parties hereto, or 3 years from the effective date, whichever comes first.

ARTICLE 17. RIGHT TO TERMINATE

Either Party may unilaterally terminate this Agreement by providing thirty (30) calendar days written notice to the other Party; however, such termination shall not affect the rights and responsibilities of each Party which accrued prior to termination. In the event of such termination, Partner will be obligated to reimburse NASA for all costs for which the Partner was responsible and that have been incurred in support of this Agreement up to the date the termination notice is received by NASA. Where Partner terminates this Agreement, Partner will also be responsible for termination costs.

ARTICLE 18. CONTINUING RIGHTS & OBLIGATIONS

The rights and obligations of the Parties that, by their nature, would continue beyond the expiration or termination of this Agreement, e.g., conducting the clinical investigations or regulatory follow-up thereto, "Liability and Risk of Loss," "Intellectual Property Rights," "Financial Obligations," and related clauses shall survive such expiration or termination of this Agreement.

ARTICLE 19. POINTS OF CONTACT

The following personnel are designated as the Points of Contact between the Parties in the performance of this Agreement.

Management Points of Contact

<u>NASA Lyndon B. Johnson Space Center</u>	<u>Epiomed Therapeutics, Inc.</u>
Lakshmi Putcha, PhD, FCP	David R. Helton
Chief Pharmacologist, Technical Manager	Chief Executive Officer
Mail Stop: SK	25 Mauchly
2101 NASA Parkway	Suite 316
Houston, Texas 77058	Irvine, CA 92618
Phone: 281-483-7760	Phone: 949-398-7359
Fax: 281-483-2888	Fax: 949-348-7775
lakshmi.putcha-1@nasa.gov	drhelton@epiomed.com

ARTICLE 20. DISPUTE RESOLUTION

Except as otherwise provided in the Article entitled "Priority of Use," the Article entitled "Intellectual Property Rights – Invention and Patent Rights" (for those activities governed by 37 C.F.R. Part 404), and those situations where a pre-existing statutory or regulatory

system exists (e.g., under the Freedom of Information Act, 5 U.S.C. § 552), all disputes concerning questions of fact or law arising under this Agreement shall be referred by the claimant in writing to the appropriate person identified in this Agreement as the "Points of Contact." The persons identified as the "Points of Contact" for NASA and the Partner will consult and attempt to resolve all issues arising from the implementation of this Agreement. If they are unable to come to agreement on any issue, the dispute will be referred to the signatories to this Agreement, or their designees, for joint resolution. If the Parties remain unable to resolve the dispute, then the NASA signatory or that person's designee, as applicable, will issue a written decision that will be the final agency decision for the purpose of judicial review. Nothing in this Article limits or prevents either Party from pursuing any other right or remedy available by law upon the issuance of the final agency decision.

#### ARTICLE 21. MODIFICATIONS

Any modification to this Agreement shall be executed, in writing, and signed by an authorized representative of NASA and the Partner.

#### ARTICLE 22. ASSIGNMENT

Neither this Agreement nor any interest arising under it will be assigned by the Partner or NASA without the express written consent of the officials executing, or successors, or higher- level officials possessing original or delegated authority to execute this Agreement, except that Partner may assign this agreement in connection with the sale of all or substantially all of the assets of its business with which this Agreement is associated.

#### ARTICLE 23. APPLICABLE LAW

U.S. Federal law governs this Agreement for all purposes, including, but not limited to, determining the validity of the Agreement, the meaning of its provisions, and the rights, obligations and remedies of the Parties.

#### ARTICLE 24. INDEPENDENT RELATIONSHIP

This Agreement is not intended to constitute, create, give effect to or otherwise recognize a joint venture, partnership, or formal business organization, or agency agreement of any kind, and the rights and obligations of the Parties shall be only those expressly set forth herein.

#### ARTICLE 25. SIGNATORY AUTHORITY

The signatories to this Agreement covenant and warrant that they have authority to execute this Agreement. By signing below, the undersigned agrees to the above terms and conditions.

NATIONAL AERONAUTICS AND      EPIOMED THERAPEUTICS, INC.

SPACE ADMINISTRATION  
LYNDON B. JOHNSON SPACE  
CENTER

BY: *Jeffrey R. Davis*  
Jeffrey R. Davis, M.D.  
Director, Space Life Sciences

BY: *David R. Helton*  
David R. Helton  
Chief Executive Officer

DATE: *8/22/2012*

DATE: *August 16, 2012*