EX-10.9 14 a2236234zex-10_9.htm EX-10.9

Exhibit 10.9

Portions of this Exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

CONFIDENTIAL

FORMULATION DEVELOPMENT AGREEMENT

This FORMULATION DEVELOPMENT AGREEMENT (this "***Agreement***") is entered into as of June l, 2007 (the *"**Effective Date**"*) by and between Aridis Pharmaceuticals, LLC, a California corporation with its business at 5941 Optical Court, San Jose, CA 95138 *("**Aridis**"*) and PATH Vaccine Solutions, a nonprofit organization and affiliate of PATH organized as a separate legal entity under the laws of the State of Washington, having a primary place of business at 1455 NW Leary Way, Seattle, WA 98107 *("**PVS**"*).

RECITALS

WHEREAS, PATH is an international, nonprofit, non-governmental organization whose mission is to improve the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors. PATH identifies, develops and applies appropriate and innovative solutions to public health problems, especially in low-resource settings, and shares knowledge, skills, and technologies with governmental and nongovernmental partners in developing countries and with groups in need;

WHEREAS, the mission of PVS is to accelerate the development of a rotavirus vaccine for pediatric indications and ensure its availability, affordability and accessibility for the developing world. The objective of the PATH rotavirus program is to reduce the number of deaths and hospitalizations of children in the developing world due to rotavirus infection through advanced development and introduction of safe, affordable and efficacious new rotavirus vaccines;

WHEREAS, Aridis has expertise in the field of formulation development for vaccines and holds proprietary rights in technology for such formulation development;

WHEREAS, if a rotavirus vaccine formulation is successfully developed in accordance with the provisions of this Agreement, Aridis shall make available to PVS and its designated vaccine manufacturers the selected rotavirus vaccine formulations for use by such manufacturers in the manufacture and distribution of a rotavirus vaccine in accordance with PVS' mission in Developing Countries; and

WHEREAS, Aridis and PVS wish to enter into an Agreement to formalize their collaboration on the development of select rotavirus vaccine formulations under conditions as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the representations, warranties and covenants set forth in this Agreement, Aridis and PVS agree as follows:

1. DEFINITIONS

1.1 ***"Affiliate"*** shall mean, with respect to any Party, any other individual or entity directly or indirectly controlling, controlled by or under common control with such Party. For

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purposes of this Section 1.1, "control" means the beneficial ownership, directly or indirectly, of fifty percent (50%) or more of the equity or the outstanding voting shares or securities, or the right to receive fifty percent (50%) or more of the profits or earnings of an entity, or the ability to direct or cause the direction of the management or policies of an entity.

1.2 ***"ATCC License"*** shall have the meaning as set forth in Section 5.3 herein.

1.3 ***"Background Intellectual Property"*** shall mean any and all information, data (including research data), know-how, methods, formulas, formulations, compositions, materials, manufacturing know-how (including methods and standard operating procedures), computer programs, test results and trade secrets, owned or controlled by Aridis as of the Effective Date of this Agreement for which a license is required in order to practice the Project Intellectual Property for the manufacture, use or sale of the Primary Formulation or Optional Formulation developed under the scope of the Project. Specifically excluded from this definition are (i) those rights held by Aridis under license to the U.S. DHHS National Institute of Health technology known as "Multivalent Human Bovine Rotavirus Vaccine," DHHS reference No. E-015-98/0; (ii) those intellectual property rights owned, controlled or licensed by Aridis where the practice of such intellectual property would require the payment of consideration or fulfillment of obligations to a third party; (iii) rights to technologies unrelated to formulation which cover distinct therapeutic compounds, methods or product types (such as a Shigella vaccine form, for example); and (iv) clinical data.

1.4 ***"Budget'*** shall mean the budget for performing the Project, including payment schedule and deliverables, as mutually agreed upon by the Parties, a copy of which is attached hereto as Appendix A, and incorporated herein.

1.5 ***"Developing Countries"*** shall mean those countries identified by the World Bank as of the Effective Date as having "low income economies," or "lower-middle income economies" or "upper-middle income economies," and which are set forth in Appendix C, attached hereto, as may be amended from time to time by the World Bank.

1.6 ***"Dispute"*** shall have the meaning as set forth in Section 13.6 herein.

1.7 ***"Electing Party"*** and ***"Non-Electing Party"*** shall have the meaning as set forth in Section 12.4 herein.

1.8 ***"Enabling Technology"*** shall have the meaning as set forth in Section 4.2 herein.

1.9 ***"Milestones"*** shall mean the goals, go-no-go decision points, deadlines and deliverables for the development of select rotavirus vaccine formulations as set forth in Appendix B of this Agreement and incorporated herein.

1.10 ***"Notice of Breach"*** and ***"Notice of Termination"*** shall have the meaning as set forth in Section 12.2 herein.

1.11 ***"Optional Formulation"*** shall have the meaning as set forth in Section 2.1 herein.

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1.12 ***"Parties"*** shall mean Aridis and PVS together and ***"Party"*** shall mean any one of them.

1.13 ***"Patent Rights"*** shall mean (i) all patents and patent applications owned by Aridis and/or its Affiliates or sublicensees, or to which Aridis and/or its Affiliate(s) or sublicensees otherwise have the right to grant licenses, existing as of the Effective Date or coming into existence at any time thereafter, which generally or specifically claim or cover processes or formulations for Rotavirus Vaccine; (ii) all patents issued with respect to the applications described above; and (iii) all divisionals, continuations, continuations-in-part, re-examinations, re-issues and extensions of such patents and applications. A list of Aridis' Patent Rights as of the Effective Date is attached hereto as Appendix D and incorporated into this Agreement. Aridis shall provide PVS with written updates of the list of Patent Rights or more frequent updates when, in Aridis' reasonable judgment, modifications may have bearing on or be relevant to the Project.

1.14 ***"Primary Formulation"*** shall have the meaning as set forth in Section 2.1 herein.

1.15 ***"Private Sector"*** shall mean those entities not included within the definition of Public Sector as defined herein.

1.16 ***"Project Plan*** " shall mean the scope of work to be undertaken by Aridis in performance of its obligations under this Agreement as defined in Appendix B and incorporated herein as may be amended from time to time upon mutual written approval of the Parties.

1.17 ***"Project Intellectual Property"*** shall mean any and all inventions (whether patentable or not), proprietary information, know-how, technology, formulae, processes (including all SOPs), trade secrets, materials, technical data and any other information for or related to the formulations developed for Rotavirus Vaccine, or as invented, developed or acquired by, or come into the possession or control (by licensure or otherwise) of Aridis, all where arising out of performance by Aridis of the work under the Project Plan.

1.18 ***"Public Sector"*** shall mean governmental health ministries and other governmental agencies of Developing Countries, the Global Fund for Children's Vaccines, the WHO, World Bank, UNICEF and other governmental and non-profit charitable agencies or organizations, including PATH, and shall include without limitation United States and European governmental agencies (e.g. USAID, DANIDA, DFID and GTZ) that may purchase vaccines for delivery, distribution and/or sale to Developing Countries.

1.19 ***"Rotavirus Vaccine"*** shall mean a multivalent vaccine for the prevention of rotavirus infection having a bovine parenteral virus backbone developed under license from the U.S. DHHS National Institute of Health technology known as "Multivalent Human Bovine Rotavirus Vaccine," DHHS reference No. E-015-98/0 NIH, select formulations of which shall be as developed under this Agreement.

1.20 ***"SOPs"*** shall mean standard operating procedures for the development of selected formulations of the Rotavirus Vaccine.

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1.21 ***"Term"*** shall have the meaning as set forth in Section 12.1 herein.

2. PROJECT PLAN

2.1 The Scope of Work. The Parties shall mutually develop and agree upon Milestones, including decision points as part of the Project Plan, attached hereto and made a part of this Agreement as Appendix B, which sets forth the scope of work for the vaccine formulation development activities to be conducted under this Agreement, it being understood that Appendix B shall initially include the scope of work for Phase I of the Project Plan, Phase II to be agreed upon by the Parties upon successful completion of Phase I and included as part of Appendix B at such time. The Project Plan may be modified from time to time by the mutual agreement of the Parties as select formulations for Rotavirus Vaccine are identified. The Project Plan will be comprised of two Phases, Phase I will include the identification and development of both a liquid formulation and one or more powder formulations. Phase II will be the optimization of the formulation as selected by PVS upon the completion of Phase I. It is anticipated by the Parties that the formulation to be initially selected by PVS for optimization may be a liquid formulation, and once selected this formulation will be referred to as the "Primary Formulation" in this Agreement. It being under stood that prior to the start of Phase II, PVS will determine the formulation to be taken forward for optimization by Aridis and such formulation shall be designated as the Primary Formulation, and PVS may select a second formulation to be used as an optional formulation for Rotavirus Vaccine in Developing Countries (***"Optional Formulation"***).

2.2 Conduct of the Project Plan. Aridis shall allocate a sufficient amount of time and effort, using personnel with sufficient skills and experience, together with sufficient equipment, supplies and facilities to perform its obligations for the vaccine formulation development work as identified in the Project Plan, including without limitation, (i) in a good scientific manner; (ii) in accordance with all applicable laws and regulations (including those pertaining to animal or human use or testing); (iii) in accordance with good research practices incorporating mutually agreed standards and procedures; and (iv) with diligence, using reasonable best efforts to meet all Milestones under the Project Plan. Successful completion of Phase I of the Plan shall be the selection by PVS of a Primary Formulation developed by Aridis under Phase I of the Plan and within the Budget for Phase I as specified in Appendix A.

2.2.1 For the avoidance of doubt, it is understood and agreed by the Parties that Aridis' obligation under this Agreement is to use reasonable best efforts as described in this Section 2.2 to perform in accordance with the Project Plan, and such reasonable best efforts shall not include an obligation to expend resources in excess of that specified in the Budget or Project Plan without the mutual prior written agreement of the Parties.

2.2.2 Aridis shall be obligated to use reasonable best efforts to meet the Milestone completion dates as set forth in Appendix B, it being understood and agreed that completion of a Milestone by the designated date does not guarantee that completion

of such Milestones will result in a successful formulation acceptable for use with the Rotavirus Vaccine; provided that, the steps undertaken by Aridis in completion of a Milestone meet the criteria as set forth in this Section 2.2.

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2.2.3 It is agreed that the deliverables to be provided to PVS or its designees by Aridis in accordance with the Project Plan, shall include data, information, study reports, and certain formulation test materials and/or reagents. It is not anticipated that biological materials will be a part of the deliverables provided to PVS or its designees hereunder.

2.3 Scientific/Technical Management Committee. PVS and Aridis shall form a Scientific/Technical Management Committee. The purpose of such Committee shall be to review, evaluate and offer input with respect to the efforts and activities under the Project Plan on an ad hoc basis. Without limiting the foregoing, the Committee shall be responsible for overseeing the Project Plan in a manner consistent with the Agreement, including, but not limited to, (i) reviewing the progress of the Project Plan, including by way of example, review of Aridis activities and progress; (ii) providing technical guidance and recommendations in support of the selected formulations; and (iii) such other matters as from time to time the Parties consider necessary for the advancement of the Project Plan.

2.4 Reports.

2.4.1 Regular Progress Reports. Aridis shall submit to PVS bi-annual written progress and financial reports. Such reports shall also summarize the financial expenditures incurred by Aridis in implementing the Project Plan. Upon completion of Phase I of the Project Plan, Aridis shall promptly submit a written report to PVS summarizing Aridis' progress and results in implementing the Plan. In addition, Aridis shall submit to PVS a final written progress and financial report, with substantiating documentation, within three (3) months following the completion of the Plan or termination of this Agreement if termination occurs prior to completion of the Plan. The form of financial report is as set forth in Appendix E.

2.4.2 Disclosure of Inventions and Improvements; Disclosure of Data and Information. In addition to the foregoing reporting requirements, Aridis shall promptly disclose to PVS in writing (i) Project Intellectual Property; (ii) Background Intellectual Property; and (iii) all data, information and other documentation developed, acquired, controlled or otherwise obtained by Aridis, rights to which are specifically excluded from the definition of Background Information under Subsection l .3(ii) to the extent such data, information and other documentation is used or included by Aridis in the Project Plan.

2.5 Books and Records. Aridis shall keep complete and accurate books and records, including financial records, pertaining to its implementation of the Project Plan for a minimum of five (5) years after the completion or termination of this Agreement. Such books and records shall be made available to PVS or its designee upon request. PVS shall have the right, with at least seven (7) days written notice, to conduct audits of the activities undertaken by Aridis in implementing the Project Plan.

3. PAYMENTS BY PVS; INDIRECT SUPPORT

3.1 PVS Funding. In consideration of Aridis' performance of its obligations under this Agreement and the Project Plan, PVS shall pay to Aridis, subject to the terms of this Agreement, an amount not to exceed the total Budget as set forth in Appendix A during the Term

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of the Agreement, subject at all times to PVS' right, described in Section 12.2 below, to terminate this Agreement and the funding of the Project Plan. The agreed upon Budget including payment schedule and deliverables is as set forth in Appendix A. PVS shall only be obligated to pay those sums as set forth in the Budget that are the responsibility of PVS in accordance with schedule of payment and

deliverables as set forth therein, it being understood that prior to commencement of Phase II, the statement of work for Phase II shall be agreed to by the Parties in conformance with the Budget for Phase II as set for in Appendix A.

3.2 Indirect Support by PVS. In addition to the funding provided by PVS directly to Aridis as set forth in Section 3.1 hereunder, PVS shall provide certain materials, either itself or through its designee, as set forth in the Project Plan. Such materials are included within the definition of Enabling Technology as specifically set forth in Section 4.2.

3.3 Use of PVS Funds. Aridis shall use all funds received from PVS hereunder, including any interest earned on funds advanced, in accordance with the Budget and the Plan. Without the prior express written permission of PVS, the total payments to Aridis under this Agreement shall not exceed the Budget agreed in advance by PVS. PVS shall only pay Aridis for actual expenses (including overhead where specifically noted in the approved Budget) incurred up to the approved budgeted amounts as set forth in the Plan. To the extent funds provided by PVS remain unspent due to modification of the Budget or termination of the Agreement, such unexpended funds shall be returned to PVS as set forth in Section 12.6.

3.4 No Other Payments. Other than the payments as set forth in Section 3.1 herein, all costs and expenses incurred in connection with the performance of the Project Plan and other obligations of Aridis hereunder shall be borne exclusively by Aridis without further reimbursement or compensation directly or indirectly by PVS, unless PVS in its discretion elects in writing to undertake additional funding commitments due to a modification or amendment to the Plan.

4. OWNERSHIP OF INTELLECTUAL PROPERTY, DATA AND INFORMATION

4.1 Ownership of Inventions and Prosecution of Patents.

4.1.1 Subject to the provisions of this Agreement, as between PVS and Aridis, title to any inventions conceived or reduced to practice solely by an Aridis employee in the course of implementing the Project Plan shall be owned by Aridis, shall be included within the definition of Project Intellectual Property hereunder, and shall be subject to the grant of rights specified herein. Inventions developed jointly by employees, Affiliates or consultants of PVS and employees and Affiliates of Aridis shall be jointly owned in accordance with U.S. patent laws and regulations and shall be included within the definition of Project Intellectual Property. Aridis may file patent applications on any such inventions at their sole cost and expense. If Aridis chooses not to file for patent protection with respect to any jointly owned inventions developed hereunder, Aridis shall notify PVS in writing of such decision within sufficient time to allow action to be taken by PVS without the loss of potential patent rights, and shall provide PVS with the opportunity to file, at PVS' sole cost and expense, patent applications on any such jointly owned invention conceived or reduced to practice in the course of the Project Plan.

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4.1.2 Aridis shall not abandon any patent application, patent or other right included within the scope of the Project Intellectual Property or the Background Intellectual Property, the effect of which would be to limit or prevent PVS from practicing the intellectual property rights licensed to PVS under this Agreement, without disclosure to PVS and arrangement by mutual agreement with PVS for the protection of PVS license rights.

4.1.3 Except as expressly provided in this Agreement, PVS shall receive no rights under the Aridis Background Intellectual Property and Project Intellectual Property.

4.2 Enabling Technology. It is understood and agreed to by Aridis that Project Intellectual Property and the underlying Background Intellectual Property as licensed to PVS by Aridis hereunder shall be used by PVS for the advancement of the Primary Formulation and/or the Optional Formulation developed by Aridis under the Project Plan and shall be made available in accordance with Article 5 to PVS designated manufacturers for the advancement of a Rotavirus Vaccine in Developing Countries.

4.2.1 Information, reagents and materials, including but not limited to (a) qualified cell lines, (b) production processes and formulations, (c) assay design and reagents, and (d) packaging design, some or all of which may be made available to Aridis by PVS or its designees or, in the case of a formulation, developed by Aridis under the Project Plan is defined as ***"Enabling Technology."***

4.2.2 Should Aridis elect to develop and manufacture a Rotavirus Vaccine, PVS shall, upon such written notification from Aridis and to the extent reasonable based on good faith negotiations by the Parties, provide Aridis with access to Enabling Technology with the right to use such Enabling Technology in the commercial development of a Rotavirus Vaccine. Acceptance and use of Enabling Technology shall obligate Aridis to the global access provisions as set forth in Article 6.

4.3 No Impairment of Rights. Neither Party shall grant any rights or licenses, or enter into any contract, agreement or transaction that would impair or be inconsistent with the rights and licenses that may be granted to the other Party under this Agreement.

5. GRANT OF LICENSE; FIELD OF USE

5.1 Grant of Rights to PVS. In consideration for the funding and indirect support provided by PVS to Aridis hereunder, Aridis hereby grants to PVS a non-exclusive license, with right to sublicense, at no additional fee, charge or royalty obligation, under the Aridis Project Intellectual Property and underlying Aridis Background Intellectual Property to the extent necessary for PVS, its Affiliates and sublicensees to make, use and sell the Primary Formulation and the Optional Formulation in the Field within the Territory and with the Scope as specified in Table I below. Table I herein summarizes the rights granted by Aridis to PVS hereunder, where the license granted to PVS as implemented for use in Developing Countries shall include the right to have manufactured the selected formulations worldwide for use solely in Developing Countries. License rights as granted by Aridis to PVS hereunder as applied to the Field of pneumococcal disease and enteric disease shall be limited to Developing Countries; however,

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Aridis shall discuss with PVS in good faith possible partnering or licensing opportunities with designated PVS commercial collaborators to extend the license rights proposed by PVS to such commercial collaborator to include Developed Country rights to the extent such rights are available from Aridis at that time.

Table I

Field	Territory	Scope
Rotavirus Vaccine	Developing Countries	Non-exclusive
Pneumococcal disease and enteric disease: Shigellae (all forms) Entertoxogenic E. coli (multiple components of ETEC)	Developing Countries	Non-exclusive

5.2 Grant of Rights to Aridis. Pursuant to Section 4.1, ownership of Project Intellectual Property shall be held by Aridis, provided however, use of the Project Intellectual Property and the underlying Background Intellectual Property by Aridis shall be in conformance with the license rights granted to PVS as set forth in Section 5.1 and as further defined by the terms of this Agreement. Should Aridis elect to make, use or sell a Rotavirus Vaccine in Developing Countries as formulated using the Enabling Technology, Aridis shall undertake the commercial terms for global access as set forth in Article 6. Table II summarized the obligations of Aridis hereunder.

Table II

Field	Territory	Scope
Rotavirus Vaccine	Developed Countries	Exclusive (non-exclusive with respect to PVS manufacturing rights asset forth in Section 5. I)
Rotavirus vaccine	Developing Countries	Non-exclusive (subject to commercial terms for global access as set forth in Article 6)
Pneumococcal and enteric disease vaccines	Worldwide	Non-exclusive (*exclusive as to Developed Countries rights but subject to good faith discussion obligations as set forth in Section 5.1*)
Other diseases and other fields of use	Worldwide	Exclusive

5.3 Sublicense under PVS-ATCC License Agreement. In order to facilitate the work to be conducted by Aridis under the Project Plan, PVS may by mutual agreement with Aridis provide certain ATCC materials to Aridis. Such ATCC materials would be

provided to Aridis as a sublicensee of PVS under the PVS-ATCC License Agreement dated as of February 7, 2007 (the ***"ATCC License")***, and the use of such ATCC materials would be limited to those activities as set forth in the Project Plan.

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5.3.1 In conformance with the terms of the ATCC License, Aridis will agree in writing prior to receipt of such ATCC materials to be bound by all applicable terms, conditions, obligations (including reporting, and inspections) and other restrictions of the rights granted by ATCC to PVS under the ATCC License that protect or benefit ATCC's rights and interests.

5.3.2 Prior to the receipt of ATCC materials by Aridis hereunder, Aridis shall execute a material transfer agreement with ATCC, substantially in the form attached hereto as Appendix F, before any ATCC material is transferred to Aridis. The transfer of ATCC material from ATCC to Aridis shall be direct from ATCC's storage facility.

6. COMMERCIAL TERMS FOR GLOBAL ACCESS

6.1 Obligations of Global Access. In the event that Aridis elects to commercialize a Rotavirus Vaccine in the Developing Countries under terms as set forth in Section 5.2 of this Agreement development of which incorporates or utilizes the Enabling Technology, Aridis shall negotiate in good faith with PVS to insure that the terms under which Aridis is introducing a Rotavirus Vaccine into Developing Countries, either itself or through a commercial partner, provides for availability of a Rotavirus Vaccine to Public Sector purchasers in or for Developing Countries at a preferential price and supply to that provided to Private Sector purchasers in the Developing Countries. The following provisions in this Article 6 shall be used as the basis for the good faith negotiation of an agreement for the commercialization and supply of a Rotavirus Vaccine in Developing Countries by Aridis. Such negotiations shall be undertaken between Aridis and PVS upon written notice by Aridis to PVS of Aridis' intent to enter the Developing Countries market with a Rotavirus Vaccine. In such negotiations PVS shall in its reasonable discretion take into account the degree to which Enabling Technology has enabled the Aridis Rotavirus Vaccine.

6.2 Supply for Commercial Sale. Upon an election to make and sell a Rotavirus Vaccine to Public Sector purchasers in Developing Countries, Aridis shall manufacture, supply and sell, or cause to be manufactured, supplied and sold, the Rotavirus Vaccine for use in designated Developing Countries for a period of time to be agreed upon by the Parties following licensure of a Rotavirus Vaccine in a Developing Country. Aridis shall fill, or cause to be filled, Developing Country requirements for Rotavirus Vaccines by using commercially reasonable efforts to supply Rotavirus Vaccines to Public Sector purchasers in such quantities and timeframes sufficient to fulfill the purchase orders for use in Developing Countries.

6.3 Public Sector Pricing. Aridis shall provide Rotavirus Vaccine to Public Sector purchasers at a price to be determined by the Parties, it being understood that in accordance with achievement of the mission of PVS to make available to Developing Countries a Rotavirus Vaccine that is safe, efficacious, accessible and affordable, the Public Sector price for such Rotavirus Vaccine shall be at a substantial discount to the Private Sector price for the same Rotavirus Vaccine.

6.4 Selection of Developing Countries by Aridis. Should Aridis intend to deliver Rotavirus Vaccine into Developing Countries classified as "upper middle income" countries by the World Bank, Aridis may petition PVS for full or partial exclusivity in those territories with

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respect to the rights otherwise granted to PVS under Section 5.1, subject to determination in PVS's sole discretion that such exclusivity would not be inconsistent with any PVS obligations and in accordance with its objectives (including its mission to accelerate the development of a rotavirus vaccine and ensure its availability, affordability and accessibility for the developing world).

7. CONFIDENTIALITY

7.1 Exchange of Confidential Information. During the course of this Agreement, Aridis and PVS (the ***"Disclosing Party,"*** as the case may be) may provide the other Party (the ***"Receiving Party")*** with certain information, data or material in writing that the Disclosing Party has prominently marked or otherwise prominently identified as confidential or proprietary in nature (***"Confidential Information"***). Without limiting the Parties' rights under this Agreement, the Receiving Party will use its commercially reasonable efforts to hold such Confidential Information in confidence and to prevent disclosure to third parties in the manner the Receiving Party treats its own similar confidential information (except that disclosure may be made to third parties working with the Receiving Party in connection with development of the Rotavirus Vaccine who are under similar confidentiality obligations).

7.2 Disclosure to Third Parties. In support of the PVS rotavirus vaccine program, either Party may disclose, under appropriate confidentiality provision no less restrictive than the confidentiality and non-use provisions under this Agreement, Confidential Information of the other Party to members of PVS supported working groups and technical advisory groups or to consultants or development partners of PVS or Aridis, respectively, as reasonably necessary for consultation directed toward the advancement of the PVS rotavirus vaccine program. Notwithstanding the foregoing, the Receiving Party shall have no such non-disclosure obligations with respect to any information identified as Confidential Information and disclosed by the other party that (i) is or becomes publicly available through no breach of this Agreement; (ii) is rightfully in the Receiving Party's possession prior to the Disclosing Party's disclosure; (iii) is disclosed to the Receiving Party by an independent third party under no obligation of confidentiality; (iv) is independently developed by the Receiving Party as can be demonstrated by documentary evidence; or (v) is required to be disclosed by the Receiving Party under any applicable law, rule or regulation of any government in any country, but only to the extent of such required disclosure. Without limiting the foregoing, PVS shall have the right to include Confidential Information as part of PVS' reports to its donors to the extent such Confidential Information is reasonably necessary to be included within PVS reports of its rotavirus vaccine program activities (in summary or general descriptive form to the extent reasonably feasible, and otherwise so as to minimize disclosure of information not required to be disclosed).

8. REPRESENTATIONS AND WARRANTIES

8.1 PVS Representations and Warranties. PVS represents and warrants that:

8.1.1 PVS has the right, power and authority to enter into this Agreement and to perform PVS' obligations hereunder.

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8.1.2 This Agreement has been duly executed and delivered by PVS and is a legal, valid and binding obligation enforceable against PVS in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, arrangement, moratorium and other laws relating to or affecting creditors' rights generally and equitable principles.

8.1.3 The execution, delivery and performance of this Agreement, and the rights granted hereunder, do not conflict with, violate or breach any agreement to which PVS is a party, and there are no agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement.

8.2 Aridis Representations and Warranties. Aridis represent and warrant that:

8.2.1 Aridis has the right, power and authority to enter into this Agreement and to perform its obligations hereunder and grant the rights granted herein.

8.2.2 This Agreement has been duly executed and delivered by Aridis and is a legal, valid and binding obligation enforceable against Aridis in accordance with its terms, subject to applicable bankruptcy, insolvency, reorganization, arrangement, moratorium and other laws relating to or affecting creditors' rights generally and equitable principles.

8.2.3 The execution, delivery and performance of this Agreement, and the rights granted hereunder, do not conflict with, violate or breach any agreement to which Aridis is a party, and there are no agreements, assignments or encumbrances in existence inconsistent with the provisions of this Agreement. Aridis will not grant any license or other right in the Background

Intellectual Property and/or the Project Intellectual Property that interferes with, conflicts with or is inconsistent with any of or Aridis' obligations or PVS' license, rights or entitlements under this Agreement.

8.2.4 As of the Effective Date, Aridis has no actual knowledge of, and without having performed any investigation as to such likelihood, is not aware of any potential claim by a third party of infringement by Aridis as to its Background Intellectual Property and Aridis will in good faith endeavor not to develop Project Intellectual Property that to its knowledge could infringe the intellectual property rights of a third party.

8.2.5 Should Aridis identify third party technology of possible interest for incorporation into the Project Plan, Aridis will first consult with PVS and the parties shall mutually agree upon a course of action.

8.2.6 Aridis will apply the funding it receives from PVS under this Agreement directly and solely toward implementing and achieving the objectives of the Project.

8.2.7 In the event PVS terminates this Agreement pursuant to Section 12.3 or 12.4, the license granted to PVS under this Agreement shall remain valid and enforceable and shall not be impaired, modified or terminated in any way as a result of such termination.

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8.3 Disclaimer of Certain Warranties. Except as specifically set forth in Section 8.1 and 8.2, ARIDIS AND PVS EACH MAKE NO WARRANTIES TO THE OTHER, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION, ANY WARRANTIES WITH RESPECT TO THE COMPLETION, SUCCESS OR PARTICULAR RESULTS OF THE PROJECT, STABILITY OR VIABILITY OF THE FINAL FORMULATION, OR THE CONDITION, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE PROJECT RESULTS.

9. LIMITATIONS ON LIABILITY

9.1 Aridis Obligations. Aridis shall be liable for its actions in accordance with the terms of this Agreement for (i) the performance of the Project Plan by Aridis; (ii) the acts of Aridis in connection with this Agreement; and (iii) the breach (by act or omission) of any of Aridis' obligations, representations or warranties under this Agreement; except only to the extent such actions were caused by the gross negligence or willful misconduct of PVS. Aridis shall not be liable under a claim of product liability for any product developed, used or sold incorporating the formulation data or information or other deliverable hereunder or Background Intellectual Property rights or Project Intellectual Property rights delivered to PVS under this Agreement.

9.2 Limitation of Liability. IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, EXEMPLARY, PUNITIVE, SPECIAL OR CONSEQUENTIAL DAMAGES (INCLUDING LOSS OF PROFIT) OF ANY KIND WHATSOEVER ARISING FROM THIS AGREEMENT OR AN ACT OR OMISSION BY EITHER PARTY, WHETHER BASED ON BREACH OF CONTRACT, BREACH OF WARRANTY, TORT OR ANY OTHER LEGAL THEORY.

10. INSURANCE

10.1 Form of Insurance Coverage. Aridis shall, at all times during the term of this Agreement, obtain and maintain at its own cost and expense, comprehensive commercial general liability insurance, and other insurance as may be commercially appropriate from time to time, with respect to its activities hereunder and insuring against risks therefrom.

10.2 In the event Aridis elects to receive ATCC materials from PVS under a sublicense to the ATCC License as set forth in Section 5.3 of this Agreement, the insurance maintained by Aridis hereunder shall be in such amounts as Aridis and PVS may agree, based upon standards prevailing in the international vaccine industry at the time, but at least in the following amounts: Three Million US Dollars (US $3,000,000) per occurrence and Ten Million US Dollars (US $10,000,000) in the aggregate for damage, injury and/or death to persons, unless such coverage is not obtainable, in which case the parties will discuss appropriate adjustments.

10.3 Verification of Insurance Coverage. Upon execution of this Agreement and on an annual basis thereafter during the term of this Agreement, Aridis shall provide PVS with certificates of insurance for all relevant current insurance.

Portions of this Exhibit, indicated by the mark "[***]," were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

11. PUBLICATIONS: RELEASE OF INFORMATION

11.1 Publications. Subject to the confidentiality provisions of Section 7 of this Agreement, the Parties shall have the right to publish or present the technical data, clinical data or results of any test or clinical trial relating to the Project, in any peer review journal, similar publication or oral presentation to the general public; *provided* that before making such publication or presentation, each Party shall provide a draft manuscript or abstract to each other Party for its review and comment at least thirty (30) days prior to the proposed date of publication or presentation. A Party may request the removal of any of its Confidential Information contained in the proposed publication or presentation, may request the deletion of its name which the Party, in its sole discretion, considers inappropriate, and, in the event a Party determines a need to delay the publication or presentation to protect or preserve exclusive Patent Rights, request such delay. The non-publishing Party(ies) may comment on the publication and the publishing Party shall consider these comments seriously and give good faith consideration to revising the publication where appropriate. The publishing Party shall delay the publication or presentation for up to ninety (90) days from the date of a non-publishing Party's request as necessary to permit filings to preserve or protect Patent Rights. Scientists at Aridis and PVS will be expected to treat matters of authorship in a proper, collaborative spirit, giving credit where it is due and proceeding in a manner that fosters cooperation and communication, but will not do anything in this regard that will jeopardize the issuance of a valid patent. The provisions of this Section shall survive the termination of this Agreement.

11.2 Use of Names. Neither Party shall use the name of the other in any public documents, publicity or advertising without the prior written consent of the Party. This obligation does not prohibit PVS from disclosing Aridis as a collaborator in the PVS rotavirus program to other PVS collaborators or potential collaborators, nor does it prohibit Aridis from acknowledging the PVS funding received by Aridis under this Agreement to potential partners or investors of Aridis. Unless PVS informs Aridis otherwise, any publication or presentation shall state the following in an appropriate location: "Funded in whole or in part by the PATH Vaccine Solution Rotavirus Vaccine Program."

11.3 Public Statements. Any press release, public statement or public announcement with respect to the Project shall be subject to the mutual written approval of the Parties. PVS shall not refer to Aridis or any of its representative, officer or director in any Rotavirus Vaccine presentation, Rotavirus Vaccine packaging or promotional materials without the prior written approval of Aridis.

12. TERMINATION

12.1 Term. The initial Term of this Agreement shall be for a period of eighteen (18) months from the Effective Date, it being understood that the Term of this Agreement is in accordance with the time frame for development through the completion of Phase I of the Project. The Parties will meet prior to the completion of Phase I to determine the scope of work to be continued under Phase II of the Project and shall amend the Budget (Appendix A), Project Plan (Appendix B), and Term of the Agreement accordingly. The Parties may amend the Term of this Agreement by a written instrument signed by both Parties.

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12.2 Termination upon Completion of Phase I. Subject to the provisions of Section 12.6 below, PVS may terminate this Agreement and its funding of the Project at its election upon sixty (60) days written notice to Aridis. Either Party at its election may terminate this Agreement at the completion of Phase I and have no further obligations under this Agreement save for those terms that survive termination including the income rights and obligations as set forth in Sections 5.1 and 5.2. Upon termination of this Agreement as provided hereunder, PVS shall have no further payment obligation to Aridis; provided that PVS shall pay or reimburse Aridis for all activities authorized by PVS and achieved as of the effective date of termination.

12.3 Termination for Breach. Subject to the provisions of Section 12.6 below, in the event that either Party shall breach any of the material terms, conditions or agreements contained in this Agreement and fail to remedy such breach within thirty (30) days of written notice thereof (the ***"Notice of Breach"***) from the non-breaching Party, the non-breaching Party may terminate this Agreement, by giving the breaching Party a second notice (the ***"Notice of Termination"***), which notice shall terminate this Agreement effective ten (10) days following the breaching Party's receipt of such notice.

12.4 Termination in Event of Bankruptcy. Subject to the provisions of Section 12.6 below, a Party (the ***"Electing Party***") shall have the right to terminate this Agreement effective immediately upon written notice to the other Party (the ***"Non-Electing Party***") if: (a) the Non-Electing Party makes an assignment for the benefit of creditors; (b) a receiver is appointed for the Non-Electing Party and is not removed within sixty (60) days, or such assignment is not withdrawn within sixty (60) days; or (c) the Non-Electing Party files a voluntary petition in bankruptcy or is otherwise a party to proceedings in bankruptcy, reorganization or the appointment of a receiver, trustee, or custodian for or over its property and such proceedings, if involuntary are not vacated, set aside or stayed within sixty (60) days after commencement. The termination shall become effective on the date of receipt of the notice by the Electing Party to the Non-Electing Party.

12.5 Mutual Termination. In addition to the foregoing, this Agreement may be terminated upon the mutual written agreement of the Parties only if the Parties set forth their agreement to terminate in a written document signed by a senior executive of each Party.

12.6 Effect of Termination.

12.6.1 If this Agreement is terminated by PVS or Aridis, with respect to any activity not yet completed, Aridis shall promptly refund to PVS all unspent funds paid by PVS to Aridis, less (i) any non-cancelable amounts paid or non-cancelable obligations incurred prior to termination; and (ii) those funds as agreed to by PVS in support of the wind down of Aridis activities upon such notice of termination.

12.6.2 The parties acknowledge and agree that the mission of PVS to accelerate development of a Rotavirus Vaccine and to ensure its widespread and timely availability and accessibility for use in Developing Countries will be substantially impaired if this Agreement is terminated. Therefore, in the event of termination of this Agreement by either Party for any of the reasons as set forth in Section 12.2, 12.3 , 12.4 or 12.5, upon such termination, the following

provisions and terms shall automatically become and/or continue to be effective: (a) except for termination due to breach or voluntary termination by PVS prior to completion of Phase I and through no breach of Arid is, the grant of license by Aridis to PVS pursuant to Section 5.1 shall survive; (b) Aridis promptly shall provide to PVS all know-how, and materials not already provided to PVS necessary for the further development of the selected formulations and rights as granted under Section 4.2 and Section 5.1; and (c) Aridis shall execute and deliver such documents and instruments as PVS may reasonably request to further evidence or give effect to this Section 12.6.2.

12.6.3 In the event of termination of this Agreement by either Party, then upon such termination, the following provisions and terms shall automatically become and continue to be effective: (a) Aridis shall have the right to continue the Project under its own funding and resources and shall have the right to use for commercial purposes all Project Intellectual Property; and (b) PVS shall have the rights as set forth in Sub-Section 12.6.2.

12.6.4 Upon termination of this Agreement, neither Party shall use the name of the other Party without the express written permission of the other Party.

12.7 Termination of Funding Obligations. After fulfilling its financial commitments specified in Section 3.1, PVS shall have no further funding obligations under this Agreement.

12.8 Survival. The provisions of Articles 4, 5 (survival of the licenses granted by Aridis is governed by Section 12.6.2 above), 6, 7, 8, 9 and 13 and Sections 11.2, 12.6 and 12.8 shall survive the expiration or termination of this Agreement to the extent such terms by their nature continue following termination.

13. MISCELLANEOUS

13.1 No Agency or Joint Venture. Nothing in this Agreement shall be deemed to create an agency or partnership relationship or joint venture between the Parties. Each Party shall be solely responsible for all taxes, benefits, withholding, worker's compensation, unemployment insurance and similar requirements pertaining to its own employees. Neither Party's employees shall be deemed agents or employees of the other Party and neither Party shall have the power or authority to obligate or bind the other Party.

13.2 Notices. Any notices required to be given or which shall be given under this Agreement shall be in writing delivered by recognized commercial overnight courier service, personal delivery, confirmed facsimile or by certified or registered mail addressed to the parties as shown below, and shall be deemed to have been given or made as of the date received:

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For PVS:

PATH Vaccine Solutions
(PVS) 1455 NW Leary Way
Seattle, WA 98107
Attention: Director of Legal Affairs
Fax: 206-285-6619
Tel: 206-285-3500

with a copy to:

PVS Rotavirus Vaccine
Program 1455 NW Leary Way
Seattle, WA 98107
Attention: Senior Program Administer
Fax: 206-285-6619
Tel: 206-285-3500

For Aridis:

Aridis Pharmaceuticals, LLC
5941 Optical Court
San Jose, CA 95138
Fax: 408-960-3822
Tel: 408-385-1742

13.3 Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and permitted assigns, collaborators and sublicensees. Neither Party may assign or otherwise transfer this Agreement without the prior written consent of the other Party.

13.4 Governing Law. The validity, interpretation, construction and effect of this Agreement and the legal relationship of the parties to it shall be governed by and in accordance with the laws of the State of California, without regard to it or any other jurisdictions choice of law provisions.

13.5 Voluntary Resolution of Disputes. In the event of any dispute, controversy or claim between the Parties based on, arising out of or related to this Agreement (a ***"Dispute"),*** the Parties shall attempt in good faith to resolve such dispute promptly, voluntarily and amicably. The Vaccine Development Committee shall first attempt to resolve the dispute. If reasonably necessary to promote the prompt resolution of the dispute, either Party may, by written notice to the other, escalate the voluntary dispute resolution process to include the President or Chief Executive Officer of each Party or a senior officer designated by such President or Chief

Executive Officer. The designated officers of each Party shall use reasonable efforts to resolve the dispute within forty-five (45) days after the dispute is referred to them.

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13.6 *Force Majeure*. Aridis shall not be responsible to PVS for delay in performing any of the tasks in the Project where such delay is due to *force majeure* causes beyond the control of Aridis, including fire, flood, explosion, lightning, windstorm, earthquake, civil commotion, riot, war, strikes, or any other cause beyond the control of Aridis. Should the force majeure event continue for a period of more than six (6) months, PVS shall have the right, at its sole discretion, to terminate this Agreement in accordance with Section 12.2.

13.7 Other Documents. From time to time as appropriate, the Parties shall prepare, execute and deliver such other documents as may be reasonably necessary or appropriate to give effect to or implement the intentions, agreements and undertakings of the Parties set forth in this Agreement.

13.8 Severability. In the event any portion of this Agreement shall be held illegal, void or ineffective, the remaining portions hereof shall remain in full force and effect. If any of the terms or provisions of this Agreement are in conflict with any applicable statute or rule of law, then such terms or provisions shall be deemed inoperative to the extent that they may conflict therewith and shall be deemed to be modified to conform with such statute or rule of law. In the event that the terms and conditions of this Agreement are materially altered as a result of this Section 13.8, the parties will renegotiate the terms and conditions of this Agreement to resolve any inequities.

13.9 Entire Agreement. This Agreement embodies the entire understanding and agreement between Aridis and PVS with respect to the subject matter contained herein, and any prior or contemporaneous representations, either oral or written, are hereby superseded. No amendments or modifications to this Agreement (including, without limitation, changes to the Project Plan), or waivers of any rights under this Agreement, shall be effective unless and until made in writing and signed and delivered by authorized representatives of the Parties.

13.10 Execution in Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original as against any party whose signature appears hereon, and all of which shall together constitute one and the same instrument. This Agreement shall become binding when one or more counterparts hereof, individually or taken together, shall bear the signatures of both of the parties.

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IN WITNESS WHEREOF, Aridis and PVS have executed and delivered this Agreement in duplicate originals by and through their duly authorized representatives below.

ARDIS PHARMACEUTICAL, LLC		PATH VACCINE SOLUTIONS	
By:	/s/ Eric Patzer	By:	/s/ Christopher J. Elias
Name:	Eric Patzer	Name:	Christopher J. Elias
Title:	President	Title:	Chair

APPENDICES

Appendix A	Budget (including Deliverables and Payment Schedule)
Appendix B	Project Plan
Appendix C	List of Developing Countries
Appendix D	Aridis Patent Rights
Appendix E	Financial Report Form
Appendix F	Form of MTA for ATCC Materials

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APPENDIX A
Budget
Advancing Rotavirus Vaccine Development (ARVAC) Project

BUDGET CATEGORY	INITIAL PERIOD (18 months)	SECOND PERIOD (18 months)
PERSONNEL	$ 537,195[a]	$ 557,904[a]
(Salary and fringe benefits) [b]		
CONSULTANT COSTS [c]	$ 50,000	—
EQUIPMENT [d]	$ 80,000	$ 40,000
SUPPLIES [e]	$ 60,000	$ 51,000
TRAVEL [f]	$ 42,000	$ 42,000
OTHER EXPENSES [g]	$ 100,600	$ 100,600
SUBTOTAL DIRECT COSTS	$ 869,795	$ 791,504
ADMINISTRATIVE EXPENSES [h]	$ 130,159	$ 108,621
TOTAL COSTS	$ 999,954	$ 900,125

[a] Personnel costs for each 18 month period are itemized on page 2.

[b] Fringe benefits - 18%.

[c] Consultant costs - consultant has extensive experience in analytical characterization of viral vaccines. Consultant will provide analytical and scientific input regarding formulations and will devote the equivalent of 25 days to this project at a per diem rate of $2,000.

[d] A freeze drier will be needed to accommodate the additional capacity requirements of this project and to provide adequate separation between this project and other infectious agents in the lab that utilize a freeze dried formulation. Cost estimates for a freeze drier are $80,000 to be purchased in the initial period. During the second period, milling equipment will be needed to convert bulk dried material to a powder at a cost of $20,000. In addition 4°C and 25°C stability chambers will be needed for scale-up of the liquid and powder processes at a cost of $20,000.

[e] Lab supplies are $15,000 per full time equivalent (FTE), which is the standard rate in NIH grants. In the initial period 4 FTE x 15,000 = $60,000. In the second period 3.4 FTE x $15,000 = $51,000.

[f] Travel expenses include two international meetings per funding period for two key personnel for a total of four meetings. Cost estimate is $8,500 per meeting x 4 = $34,000. Two domestic meetings are included for two personnel to attend scientific meetings and/or visit consultant lab. Cost estimate is $2,000 per trip x 4 = $8,000 total. Total travel costs= $34,000 + $8,000 = $42,000.

[g] Other expenses include grant management costs ($52,000) for record keeping (scientific and financial) and project management. This project will also incur an expansion into an adjacent laboratory at an additional cost of $2,700 per month for a total of $48,600 ($2,700 x 18 month).

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[h] Includes indirect/overhead expenses at -15% of direct costs.

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BUDGET FOR INITIAL (1st) 18 MONTH PERIOD DIRECT COSTS ONLY

ROLE ON PROJECT	EFFORT ON PROJECT(%)	ANNUAL SALARY	SALARY REQUESTED FOR 18 MONTHS	FRINGE BENEFITS (18%)	TOTAL
Principal Investigator	50	158,000	118,500	21,330	139,830
Sr. Manager	100	104,000	156,000	28,080	184,080
Res. Associate	100	53,000	79,500	14,310	93,810
Res. Assistant	100	45,000	67,500	12,150	79,650
Res. Assistant	50	45,000	33,750	6,075	39,825
SUBTOTALS			455,250	81,945	537,195

BUDGET FOR 2nd 18 MONTH PERIOD DIRECT COSTS ONLY

ROLE ON PROJECT	EFFORT ON PROJECT(%)	ANNUAL SALARY	SALARY REQUESTED FOR 18 MONTHS	FRINGE BENEFITS (18%)	TOTAL
Principal Investigator	40	158,000	94,800	17,064	111,864
Sr. Manager	100	104,000	156,000	28,080	184,080
Res. Associate	100	53,000	79,500	14,310	93,810
Tech Transfer Manager	100	95,000	142,500	25,650	168,150
SUBTOTALS			472,800	85,104	557,904

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Payment Schedule

- ***[***]*** upon execution of the contract
- ***[***]*** after six months of implementation upon receipt and approval of the narrative and financial reports
- ***[***]*** after twelve months of implementation upon receipt and approval of the narrative and financial reports
- ***[***]*** Up to $50,000 upon receipt and approval of all end of project deliverables (these being the study reports specified in the Project Plan)

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APPENDIX B
Project Plan
UK Bovine Vaccine Project Plan for Phase I Formulation Development

PROJECT OBJECTIVES AND SCOPE

The goal of this project is to develop a rotavirus formulation using GRAS (Generally Regarded as Safe) ingredients that is superior to the current dosage formulation currently being used which is a single dose lyophilized formulation stored at 2-8°C reconstituted with liquid antacid (citrate and bicarbonate). The criteria for success are defined as follows:

- **Stability**: A vaccine formulation that is stable when stored at 2-8°C for at least one year with 0.5 log FFU/dose per serotype is desirable and should be the goal of project. However if the new formulation has superior attributes to the current lyophilized formulation that enhanced commercial acceptability (e.g. stable at higher temperatures, supports a less expense delivery device, etc.) then virus loss> 0.5 log FFU/dose per serotype may be acceptable.
- **Buffer**: A successful formulation will contain sufficient amount of antacids to buffer against stomach acids and transit through to the gut.
- **Cost effective**: The manufacturing process for a successful formulation must be implementable at commercial scale in a developing world manufacturing setting.
- **Intellectual property**: A successful formulation will not infringe any other patents (prior art for rotavirus vaccines).
- **Vaccine serotypes studied**: A successful formulation must work with UK x Human reassortants for Serotype G1, G2, G4 and G9.

Project execution

Phase I is anticipated to be approximately 18 months in duration. At the completion of Phase I, Aridis will present to PVS and the UK bovine rotavirus vaccine (BRV) manufacturing partners the liquid and powder blend formulations Aridis believes meets the goals of the project. If sufficient data are available that demonstrates one or more formulation options to be superior to the existing formulation, PVS will decide whether to authorize Aridis to continue formulation development (Phase II) in cooperation with the BRV manufacturing partners and a delivery device/packaging company. This phase will evaluate delivery devices for the new formulations.

A superior formulation will include one or more of the following:

- Buffer and vaccine together in one formulation
- Any formulation that is liquid stored at 2-8°C
- A formulation that lends itself to a more convenient delivery device
- A formulation that leads to a cheaper delivery device

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- A formulation process that is determined to be less expense than lyophilization in terms of capital expense or unit cost
- Increased stability resulting in less virus needed at the time of formulation
- Increased stability at temperatures above 25°C

Project milestones and work plan

(All time periods originate from the date Aridis receives materials from PVS to initiate formulation activities)

Liquid Formulation

Month 0- 4	Develop a multidimensional phase diagram using high throughput appropriate analytical tests (possible methods include high resolution 2nd derivative UV spectroscopy, intrinsic and extrinsic fluorescence spectroscopy, circular dichroism, and dynamic light scattering) to map the pH, ionic strength, and temperature regimes where the vaccine is most physically stable. These analytical tests will define solution conditions that avoid viral aggregation, protein structural changes, membrane changes, disassembly, etc. that are potential pathways leading to poor storage stability. Data provided to PVS at the completion of this milestone. If the data from these studies demonstrate that virus serotypes other than G1, G2, G4 and G9 be evaluated in subsequent studies or additional data is obtained from other sources, Aridis and PVS will work together to make the necessary adjustments in the virus serotypes evaluated.
Month 4 and 5	Select excipients, formulations, and additives to develop a refrigerator stable liquid formulation. Stabilizer classes that have been successfully used previously include non-reducing polysaccharides (sucrose, trehalose, etc.), synthetic polymers and biopolymers (hydrolyzed gelatin, polyvinyl pyrrolidone, etc.), small charged amino acids (arginine, lysine, etc.) and surfactants (pluronics, Tweens). Candidate antacids (citrate, sodium bicarbonate, etc.) will also be screened together with stabilizers. The stabilizers selected and formulations to be studies provided to PVS.
Month 6 to 11	A minimum of 15 formulations combinations will be tested using monovalent vaccine preparations of G9 and G1 serotype viruses for stability under 2-8°C, and 25°C (accelerated) storage conditions.
Month 12 to 17	Up to 5 lead formulation candidates will be tested as a tetravalent vaccine consisting of G1, G2, G4 and G9 for stability under real-time at 2-8°C storage condition.
Month 18	Present final results to PVS on lead candidate.

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Powder Formulation

Month 0-1	Review data from PVS on the Wyeth powder blend formulation process.
Month 2 to 4	Prepare spray dried and bulk lyophilized preparations of two rotavirus serotypes, G1 and G9 serotypes. Prepare antacid buffer salts.
Month 5 to 6	Prepare powder blends of bivalent virus with and without antacid buffer salts for stability evaluation under l 5°C, and 25°C (accelerated) storage conditions.
Month 7 to 10	Evaluate the stability of all 4 powder formulations: Gl/G9 bulk lyophilized; Gl/G9 spray dried; Gl/G9 with buffer salts; Gl/G9 without buffer salts.
Month 11 to 13	Prepare a tetravalent powder blend (G1, G2, G4 and G9) using one manufacturing process (spray dried or bulk lyophilized) and evaluate stability at 2-8°C.
Month 18	Present the manufacturing process and stability data to PVS.

Materials to be provided by PVS (or through its designee):

1. 5 liters of post filtered monovalent bulk of serotypes G1, G2, G4 and G9 and 50 ml of G3 and GS stored at -70°C from Shantha, Biotech. If more vaccine bulks is needed, Shantha Biotech will supply to Aridis upon request.

2. 1ml of 1:100 dilution of monoclonal antibodies to G2, G3 and 20 vials of 1 ml each of G1, G4. Reagent supplies for GS and G9 will be determined later by PVS. If more reagent is needed, PVS or its affiliates will supply to Aridis upon request.

Deliverable at the end of Phase I

Aridis will provide PVS with an abbreviated technology transfer package of sufficient detail to allow a third party to implement the final liquid and powder formulation which has demonstrated to be an improvement over the existing formulation. Aridis will also provide in this abbreviated technology transfer package all stability data used to support the formulation selected for Phase II as well as data from formulations that were not selected. The written package will include the raw materials and solutions that were used in the final formulations studies, a brief description of the manufacturing process, any special equipment used in the formulation; unique facility requirements; process flow diagrams, process operating ranges such as mixing times, temperature conditions, etc. needed to prepare the formulation. All of the above information will

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be provided on the formulation or formulations that Aridis and PVS agree warrant further development.

For clarification, the Phase 1 program comprises formulation development and stability testing but not process optimization or scale-up, and the abbreviated data package is not expected to be a manufacturing grade technology transfer package sufficient to allow third party manufacture without further development. Such manufacturing process, process flow and process operating ranges as are developed per this Project Plan - in addition to formulation and stability data - shall be shared.

Formulation, stability and other related data regarding formulations other than the Primary Formulation and Optional Formulation may be provided in summary form.

Scope of Work for Phase II Formulation Development

Prior to commencement of Phase II of the Project Plan, the Parties will develop a mutually agreeable Phase II Project Plan in accordance with the following objectives:

There are two objectives of the Phase II formulation development proposal: First, to continue the development at Aridis of a single formulation selected from the Phase I development program (either liquid or powder blend formulation) in sufficient detail to allow for a smooth transfer of the formulation technology to the developing country rotavirus vaccine manufacturer. Second, to work closely with PVS in selecting a contractor to develop a delivery device that is compatible with the formulation selected for Phase II and meets the needs of the developing world manufacturer.

Activities that will be included in the first objective include scale up of the formulation process in sufficient scale to permit the selection of appropriate equipment and identification of raw material suppliers to carry out the formulation process at commercial manufacturing scale. This objective will also include conducting real time stability studies at the recommended storage conditions and one higher temperature for a shorter duration on 3 pentavalent vaccine formulations containing the GI, G2, G3, G4 and G9 serotypes that were produced at a larger scale of production.

The second objective will involve providing samples of the formulation selected to the delivery device contractor. These samples will match as closely as possible to the final vaccine formulation selected for Phase II development except no live virus will be present. The chemical properties, ingredients and concentrations will be provided to the contractor to assist in the development of the delivery device. Aridis will work closely with the delivery device contractor to evaluate minor changes in the formulation that may be necessary to allow the formulation to adapt to the delivery device. Arid is will be expected to conduct stability studies in the delivery device selected, the extent to which will be dependent on the ability of Aridis or a contract manufacturing organization to fill the live virus vaccine formulation into the delivery device selected for development.

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APPENDIX C
World Bank List of Developing Countries

Low-income economies (59)

Afghanistan	Haiti	Pakistan
Bangladesh	India	Papua New Guinea
Benin	Kenya	Rwanda
Bhutan	Korea, Dem Rep.	Sao Tome and Principe
Burkina Faso	Kyrgyz Republic	Senegal
Burundi	Lao PDR	Sierra Leone
Cambodia	Lesotho	Solomon Islands
Cameroon	Liberia	Somalia
Central African Republic	Madagascar	Sudan
Chad	Malawi	Tajikistan
Comoros	Mali	Tanzania
Congo, Dem. Rep.	Mauritania	Timor-Leste
Congo, Rep.	Moldova	Togo
Cote d'Ivoire	Mongolia	Uganda
Eritrea	Mozambique	Uzbekistan
Ethiopia	Myanmar	Vietnam
Gambia, The	Nepal	Yemen, Rep.
Ghana	Nicaragua	Zambia
Guinea	Niger	Zimbabwe
Guinea-Bissau	Nigeria	

Lower-middle-income economies

Albania	El Salvador	Namibia
Algeria	Fiji	Paraguay
Angola	Georgia	Peru
Armenia	Guatemala	Philippines
Azerbaijan	Guyana	Romania
Belarus	Honduras	Samoa
Bolivia	Indonesia	Serbia and Montenegro
Bosnia and Herzegovina	Iran, Islamic Rep.	Sri Lanka
Brazil	Iraq	Suriname
Bulgaria	Jamaica	Swaziland
Cape Verde	Jordan	Syrian Arab Republic
China	Kazakhstan	Thailand
Colombia	Kiribati	Tonga
Cuba	Macedonia, FYR	Tunisia
Djibouti	Maldives	Turkmenistan
Dominican Republic	Marshall Islands	Ukraine
Ecuador	Micronesia, Fed. Sts.	Vanuatu
Egypt, Arab Rep.	Morocco	West Bank and Gaza

***Portions of this Exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended**

Upper-middle-income economies (40)

American Samoa	Grenada	Poland

Antigua and Barbuda	Hungary	Russian Federation
Argentina	Latvia	Seychelles
Barbados	Lebanon	Slovak Republic
Belize	Libya	South Africa
Botswana	Lithuania	St. Kitts and Nevis
Chile	Malaysia	St. Lucia
Costa Rica	Mauritius	St. Vincent and the Grenadines
Croatia	Mayotte	Trinidad and Tobago
Czech Republic	Mexico	Turkey
Dominica	Northern Mariana Islands	Uruguay
Equatorial Guinea	Oman	Venezuela, RB
Estonia	Palau	
Gabon	Panama	

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APPENDIX D
Aridis Patent Rights

This Appendix is to list Aridis Patent Rights as of the Effective Date pursuant to section 1.13 of the Agreement. Certain patent applications are under consideration by Aridis and will be included in this Appendix D by amendment to be completed by Aridis promptly upon filing with the U.S. Patent Office or any equivalent foreign agency.

The Appendix shall note all relevant application numbers, application types, filing dates, inventors, assignees, government or other reserved rights noted in the application, and application titles.

***Portions of this Exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended**

APPENDIX E
Financial Report Form

Recipient: Aridis Pharmaceuticals
Period of Agreement:
Period of this Report: From , 20 , to , 20
Dated Submitted:

	A	B	C	D	E
Budget Categories	**Budget (in U.S. dollars)**	**Expenses this Report**	**Total Expenses Previous Reports**	**Total Expenses (8 + C)**	**Budget Balance (A- D)**
Personnel	537,195				
Consultants	50,000				
Supplies	60,000				
Travel and per diem	42,000				
Equipment	80,000				
Other project costs	100,600				
Indirect Expenses	130,159				
TOTAL COSTS (US$)	999,954			(*)	

Status of Cash on Hand
Payments Received to Date
Expenses to Date (*)
Balance

Status of Interest Earned
Total Interest Earned Previous Reports
Interest Earned this Reporting Period
Total Interest Earned to Date

Signature: _____
Title: _____
Date: _____

CERTIFICATION

The undersigned hereby certifies:

a. That payment of the sum claimed under the cited Agreement is proper and due and that appropriate refund to PVS will be made upon request by PVS in the event of misrepresentation and/or nonperformance, in whole or in part, under the Agreement or for any breach of the terms of the Agreement, the amount of the refund to reimburse PVS for such misrepresentation, nonperformance, or breach; and

b. That information in the Financial Report is correct and such detailed supporting information as PVS may require will be furnished to PVS on request; and

c. That all requirements called for by the Agreement to the date of this certification have been met

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Portions of this Exhibit, indicated by the mark "[***],"* were omitted and have been filed separately with the Securities and Exchange Commission pursuant to the Registrant's application requesting confidential treatment pursuant to Rule 406 of the Securities Act of 1933, as amended

Appendix F
(Form of Material Transfer Agreement)

Material Transfer Agreement

This Material Transfer Agreement (hereafter "Agreement") is between you (" Sublicensee" or "you") and American Type Culture Collection, a not-for-profit organization ("ATCC" or "we" or "us").

The parties are entering into this Agreement in connection with your sublicense agreement (the "Sublicense") with PATH Vaccine Solutions ("PVS"). PVS and ATCC have entered into a License Agreement dated as of , 2006 (the "License").

Scope of Use

YOU MAY MAKE AND USE THE MATERIAL PROVIDED TO YOU UNDER THE SUBLICENSE ("MATERIAL") AND ALL REPLICATES AND DERIVATIVES *FOR PURPOSES PERMITTED IN THE SUBLICENSE ONLY.* THE MATERIAL IS NOT INTENDED FOR USE IN HUMANS. SUBLICENSEE AGREES THAT MATERIAL DESIGNATED AS BIOSAFETY LEVEL 2 OR 3 CONSTITUTES KNOWN PATHOGENS AND THAT OTHER MATERIAL NOT SO DESIGNATED AND REPLICATES OR DERIVATIVES MAY BE PATHOGENIC UNDER CERTAIN CONDITIONS. SUBLICENSEE ASSUMES ALL RISK AND RESPONSIBILITY IN CONNECTION WITH THE RECEIPT, HANDLING, STORAGE, DISPOSAL, TRANSFER AND USE OF THE MATERIAL INCLUDING WITHOUT LIMITATION TAKING ALL APPROPRIATE SAFETY AND HANDLING PRECAUTIONS TO MINIMIZE HEALTH OR ENVIRONMENTAL RISK.

Sublicensee shall not distribute, sell, lend or otherwise transfer the Material, Replicates, or Derivatives (the "Biological Material") for any reason. Except as expressly permitted in the Sublicense, any commercial use of the Biological Material is prohibited without ATCC's prior written authorization. Your use of the Biological Materials requires a sublicense from PATH.

For purposes of this Agreement, "Replicate" means any biological or chemical material that represents a substantially unmodified copy of the Material such as, but not limited to, material produced by growth of cells or microorganisms or amplification of Material. "Derivative" means material created from the Material that is substantially modified to have new properties.

Warranty; Warranty Disclaimer

The Material provided to you under this Agreement is subject to a warranty provided by ATCC to PVS in the License. EXCEPT AS EXPRESSLY PROVIDED TO PVS IN THE LICENSE, THE MATERIAL AND ANY TECHNICAL INFORMATION AND ASSISTANCE PROVIDED BY ATCC ARE PROVIDED AS IS, WITHOUT WARRANTIES OF ANY KIND, EXPRESS OR

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IMPLIED, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TYPICALITY, SAFETY, AND ACCURACY.

Compliance With Laws

SUBLICENSEE IS SOLELY RESPONSIBLE FOR COMPLIANCE WITH ALL APPLICABLE FOREIGN AND DOMESTIC, FEDERAL, STATE AND LOCAL LAWS, STATUTES, ORDINANCES AND REGULATIONS. Without limiting the generality of the foregoing, any shipment of the Material to countries outside the United States must comply with all applicable U.S. laws, including the U.S. export control laws and related regulations.

Indemnification

Sublicensee hereby agrees to indemnify, defend and hold harmless ATCC, its officers, agents, employees and its contributors, against all third party claims, losses, expenses and damages (including reasonable attorneys' fees) arising out of or relating to the use, receipt, handling, storage, transfer, disposal and other activities relating to the Biological Material or products related to the Biological Material. All non-monetary settlements will be subject to ATCC's consent.

Limitation of Liability

IN NO EVENT WILL ATCC OR ITS CONTRIBUTORS BE LIABLE FOR ANY INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT, BIOLOGICAL MATERIALS OR PRODUCTS RELATED TO BIOLOGICAL MATERIALS (WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT LIABILITY, STATUTE OR OTHERWISE) EVEN IF ATCC HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES. IN NO EVENT SHALL ATCC'S CUMULATIVE LIABILITY IN CONNECTION WITH OR ARISING OUT OF THIS AGREEMENT, THE SUBLICENSE, BIOLOGICAL MATERIALS OR PRODUCTS RELATED TO BIOLOGICAL MATERIALS EXCEED THE FEES PAID BY PVS TO ATCC UNDER THE LICENSE. THE PROVISIONS OF THIS SECTION SHALL SURVIVE THE EXPIRATION OR TERMINATION OF THIS AGREEMENT.

Sublicensee agrees that the limitations of liability set forth in this Agreement shall apply even if a limited remedy provided hereunder fails of its essential purpose.

Intellectual Property; Identification

ATCC shall retain ownership of all right, title and interest in the Biological Material. ATCC also retains rights to any intellectual property it owns in the Biological Material. Sublicensee retains ownership of those substances created through the use of the Biological Material, but which do not contain Biological Material. Sublicensee will notify ATCC of any Derivatives it creates from ATCC Material and make such Derivatives available to ATCC. The Biological Material is subject to the restrictions noted in the "Scope of Use" section above. ATCC retains all right, title and interest in the trademarks registered or owned by the ATCC and any and all ATCC catalog numbers or ATCC specific designations of Material sold by the ATCC. ATCC also retains rights to any intellectual property it owns in the Material.

Sublicensee is responsible for ensuring that all permits required for Sublicensee to receive Material are obtained and that sufficient proof of such permits is provided to ATCC.

Termination:

This Agreement shall survive the termination of the Sublicense provided that said Sublicense is

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assigned to ATCC. In all other instances, or upon termination of any assigned Sublicense, this Agreement shall terminate and Sublicensee shall destroy all stocks of Biological Material and provide by ATCC with written notification of that fact. The following provisions shall survive termination of this Agreement: Indemnification, Limitation of Liability, and Intellectual Property; Identification.

Miscellaneous

This Agreement shall be governed by the laws of the State of New York, without reference to its choice of law rules. Sublicensee may not assign or otherwise transfer this Agreement or any rights or obligations under this Agreement, whether by operation of law or otherwise. Any attempted assignment or transfer will be void and of no force or effect. This Agreement and all documents incorporated herein by reference constitute the entire agreement between ATCC and Sublicensee with respect to the Biological Material and supersede all previous agreements or representations; This Agreement may not be modified, changed or terminated orally. No change, modification, addition or amendment shall be valid unless in writing and signed by an authorized representative of each of the parties hereto.

This Agreement shall be signed in two counterparts each of which shall be deemed to be an original, and both of which taken together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed by their respective duly authorized officers.

For ATCC	**For Sublicensee**
Signature	Signature
Title	Title
Date	Date