1. **Announcement Number:** Open Broad Agency Announcement Number (OBAA) 14-003/Call 0012

2. **FBO Solicitation Number:** HSHQDC-14-R-B0009

3. **Solicitation Event Dates/Time (Local Eastern Time):**

    - Full Proposal Due Date– August 22, 2015- 1:00 PM EST

There will be no exceptions to the time and date on which responses are due, unless determined otherwise by the Government. Full Proposals received after the designated closing date/time will not be considered.

Note: This Call will be conducted in accordance with the Single-Phased Evaluation Process as described under Section 1.6 of the OBAA. The OBAA Solicitation HSHQDC-14-R-B00009 was posted on Federal Business Opportunities on June 16, 2014. See Link:

https://www.fbo.gov/index?s=opportunity&mode=form&id=3935288433485a6ee877134ac7d2a8a9&tab=core&_cview=1

This Call will consist of the solicitation, receipt, and evaluation of a Full Proposal, limited to 30 pages, excluding the Formal Transmittal Letter, Cover Page, Summary of Costs and Related Information, Table of Contents and resumes/biographical information for proposed performers. Once the Full Proposal peer/scientific review process has been completed, offerors will be notified via e-mail, or in writing, that its proposal has been selected, selected but not funded, or not selected for award.

4. **OBAA Call Technical Topic Area (TTA) of Interest:**

Chemical and Biological Research and Development CBD.07 Vaccines and Therapeutics: New, cost-effective, biological-based countermeasures for foreign animal disease (FAD) and zoonotic pathogens affecting major domestic livestock species. Specific areas of interest are cattle and swine product candidates based on molecular or recombinant vaccine platforms previously shown to be safe and effective against other infectious animal or human biodefense disease targets, panvalent vaccines and novel biological-derived broad spectrum antiviral agents with an established immune-based mechanism of action.

(1) New, molecular-based or recombinant vaccine candidates that improve the onset of protective immunity and can differentiate infected from vaccinated animals.
(2) Novel immunostimulants, adjuvants, or biological-based agents with an immune-based mechanism of action that can improve pathogen-specific vaccine efficacy and/or vaccine potency.
(3) New molecular or recombinant-based vaccines that can increase spectrum of cross-protection against related strains.
(4) New molecular or recombinant-based vaccines based on innovative state- of-the-art technologies (e.g., nanovaccines, VLPs).
(5) New biological-based broad spectrum anti-viral therapeutics (small molecule drugs excluded) that can be used in combination with pathogen-specific vaccines

(6) Novel high throughput vaccine or biological delivery systems for livestock.

NOTE: Influenza countermeasure proposals will not be considered.

4.1. Research Opportunity Description

4.1.1. DHS S&T: African Swine Fever Antigen Production and Antigen Presentation Vector Platform

Background

The Department of Homeland Security (DHS) is committed to using cutting edge technologies and scientific talent in our quest to make America safer. DHS' Science & Technology (S&T) Directorate is tasked with researching and organizing the scientific, engineering and technological resources of the United States and leveraging these existing resources into technological tools to help protect the homeland.

In HSPD-9, DHS is identified as the lead agency to coordinate federal activities to "accelerate and expand development of current and new countermeasures against intentional introduction or natural occurrence of catastrophic animal, plant, or zoonotic diseases." DHS carries out this responsibility in close collaboration with its sector-specific agency partners, especially the United States Department of Agriculture (USDA). In the case of African Swine Fever Virus (ASFV), this has been recently recognized as an emerging, threatening agricultural pathogen and thus is of high priority for biological countermeasure (e.g., vaccines) research and development (R&D).

African swine fever (ASF) is a devastating hemorrhagic fever of pigs with mortality rates approaching 100 percent. ASF is endemic to Sub-Saharan Africa and maintains a life cycle in the wild through infection between soft ticks and feral pigs (wild pigs, bush pigs, warthogs). It causes major economic losses, threatens food security, and limits pig production in affected countries. A large DNA virus, African swine fever virus (ASFV), causes ASF. The threat for an introduction of African Swine Fever (ASF) in the United States is significant. ASF is a highly contagious viral disease of domestic pigs, wild boar, and wild suids. ASF was considered an infection that was eradicated in the European Union (EU) at the end of the 1990s. The appearance of the 2007 outbreak in the Caucasus region demonstrated that there is a constant threat of the re-introduction into a country. Its current widening distribution in Western Russia and Eastern EU made in the short time since its introduction in the Caucasus region represent a threat not only to Europe but also to Asia where swine represent the main source of animal protein and where the introduction and consequent high mortality caused by ASF would have devastating effects.

This project seeks to build on this legacy of successful DHS S&T Agro Defense transboundary animal disease vaccine and diagnostic African Swine Fever (ASF) program. Previous LRBAA awards were made in 2011 to construct, test and evaluate ASF recombinant vaccine candidates based on replication-deficient adenovirus and host-restricted modified vaccinia viral vectors, and a baculovirus recombinant subunits system. Ongoing and active efforts through an interagency agreement with USDA ARS are focusing on a modified-live, rationale gene knockout, attenuated ASFV approach. Full proposals are accepted, no white papers necessary.

4.1.2. Description Technical Topic Areas (TTA)

There are two technical topic areas being solicited under this BAA Call: African Swine Fever Antigen Production and Antigen Presentation Vector Platform. The first technical topic area is production of recombinant subunit ASF virus (ASFV) antigens. The second technical topic area is vaccine vector platforms for presentation of ASF virus (ASFV) subunit antigens. Recent gap analysis by Agro Defense transboundary animal disease vaccine and diagnostic African Swine Fever (ASF) program; deemed to be lacking and low risk, and the impact of the parameter was deemed high based upon R&D countermeasure needs for TTA 1 and deemed to be lacking and high risk, and the impact of the parameter was deemed high based upon R&D countermeasure needs for TTA 2. This BAA Call seeks antigen productions and vaccine vector platforms for ASF to assist further development of technologies to protect the homeland.

An Offer may submit a full proposal to one or both of the technical topic areas. However, each technical topic areas should have its own technical and price proposal. As a result, if an Offeror submits a proposal for each of the topic areas, each proposal will be evaluated independently.

4.1.2.1 Technical Topic 1

The goal of Technical Topic Area 1 is to express and purify individual ASFV open reading frames (ORFs) of known and more preferably, of unknown function, using a baculovirus expression system that has the co-capability for recombinant ASFV subunit expression in insect and mammalian cells.

To support the objectives of the Agro Defense transboundary animal disease vaccine and diagnostic ASF program, this project will:

- Using the 12 published annotated ASFV genomes (i.e., annotated protein sequences), apply bioinformatics strategies to identify and group the conserved (>90% amino acid identity) ORFs into the following classes/subclasses: (i) confirmed or predicted function (7 subclasses –structural proteins, nucleic acid metabolism, DNA damage prevention and DNA repair, protein modification enzymes, membrane-associated and secreted proteins, immune response modulation, and apoptosis/redox metabolism) and (ii) unknown function.
- Using the annotated ASFV genome for virulent ASFV isolate Georgia/2007/1 (GenBank accession FR682468), apply bioinformatics and in silico strategies to prioritize and down select candidate antigens: (i) within each class/subclass of confirmed/predicted function and (ii) unknown function. The total number of candidates down selected should preferably constitute at least 20% coverage of the ASFV ORF genome, within which at least 70% of the ORFs should preferably represent ASFV proteins of unknown function/class.
- Express and purify each down selected ASFV candidate antigen using a dual function (e.g., insect and mammalian cell) baculovirus or other appropriate expression system.
- Provide sufficient quantities of each down selected ASFV recombinant antigen (and each respective Bacmid) to DHS S&T for further use in in vitro and in vivo testing and evaluation studies.
- Generate hybridoma cell lines secreting monoclonal antibodies specific for each down selected ASFV antigen. The total number of ASFV target antigens for monoclonal antibody production should preferably constitute at least 50% of the down selected antigens, within which at least 70% should preferably represent ASFV proteins of unknown function/class.
- Provide sufficient quantities of each ASFV-specific monoclonal antibody secreting hybridoma cell line to DHS S&T for further use in in vitro and in vivo testing and evaluation studies.

4.1.2.2 Technical Topic 2

The goal of Technical Topic Area 2 is to develop new or next generation (adapted) of previously used vaccine vector platforms (e.g., replication deficient human adenovirus; modified vaccinia)with the potential to simultaneously express and present multiple ASFV open reading frames (ORFs) in a context similar to a natural ASFV infection.

To support the objectives of the Agro Defense transboundary animal disease vaccine and diagnostic ASF program, this project will:

- Identify one or more veterinary vaccine vector platforms hypothesized to present ASFV recombinant ORFs or epitopes in a manner similar to that used by native ASFV.
- Using the annotated ASFV genome for virulent ASFV isolate Georgia/2007/1 (GenBank accession FR682468), apply bioinformatics and in silico strategies to identify and down select a minimum subset of 12 ASFV ORFS that encode for (i): one or more putative swine T cytotoxic cell epitopes and/or (ii) one or more putative swine B-cell epitopes.
- Using an identified vaccine vector(s), construct a set of recombinant vaccine candidates, with each recombinant vaccine expressing a minimum of 3 ASFV ORFs containing several putative T-cytotoxic cell and/or B-cell epitopes.
- Provide sufficient quantities of each recombinant vaccine to DHS S&T for further use in vitro and in vivo testing and evaluation studies.

5. **Number of Selections:** It is anticipated that multiple selections (up to 3) will be made depending on the quality of the Proposals and availability of funds.

6. **Anticipated Ceiling:** Although subject to official fiscal appropriation and availability, it is anticipated that approximately $1.47 million of Fiscal Year (FY) 2015 funds will be available for any resultant awards under this BAA Call. **The Government will reserve the right to incrementally fund any resultant contracts awarded from this BAA Call as provided by the FAR 52.232-22, "Limitation of Funds."** Contracts or other agreements that obligate funds will not have an initial period of performance that exceeds 24 months from the date of contract award. However, Offerors will be able to propose a base year effort with additional option years.

7. **Anticipated Award Type:** Award type is anticipated to be in the form of Cost Reimbursement type contracts however the Government reserves the right to award firm-fixed price contracts, cooperative agreements, Other Transactions (OTs) (if authorized by law at time of award), or interagency agreements to appropriate parties should the situation warrant.

   In the event an offeror or subcontractor is a Federally Funded Research and Development Center (FFRDC), Department of Energy National Laboratory, or other Federally funded entity, DHS/S&T will work with the appropriate sponsoring agency to issue an interagency agreement pursuant to the Economy Act (31 U.S.C. 1535) or other appropriate authority.

8. **Anticipated Award Dates:** The 4rd Quarter of Fiscal Year 2015 is when the government anticipates making any resultant contract awards under this Call for those Proposals are selected. However, the award date for any resultant contract award may vary based on the quality of the proposals received and the availability of funds.

9. **White Paper Instructions:** NA – No white papers are being requested in response to this solicitation.

10. **Full Proposal Instructions:** Offerors shall submit their Full Proposals in accordance with BAA 14-003, Section 5.4 - Format and Content of Full Proposals.

11. **Evaluation Criteria:** Full Proposals will be evaluated in accordance with the following evaluation criteria:

Criterion I: Scientific Merit:

The Offeror must demonstrate understanding of the critical technology and scientific challenges required to achieve the desired performance metrics and strategy as described elsewhere within this announcement. The research, development, testing and evaluation (RDT&E) approach should be scientifically sound, practical, and technically defensible. The RDT&E approach is innovative and has advantages over other solutions, if successfully implemented. The RDT&E must contribute to scientific knowledge in the topic area and must enumerate potential benefits of the proposed research. The proposal shall demonstrate an awareness of the state-of-the-art. The proposal should be well-prepared with supportive information that is self-explanatory. All critical scientific and technical issues and risks are clearly identified, and the planned development approach and risk mitigation efforts are clearly defined and feasible. The merit of the technical approach over other competing approaches should be clearly delineated. Specific considerations will include:

- Working knowledge of ASFV infection, pathogenesis and host immune responses.
- Rationale on the bioinformatics strategies applied to identify and group conserved ASFV ORFs
- Rationale on prioritization and down selection process of ASFV candidates for subunit and/or vaccine vector platform expression
- Rationale on down selection process of ASFV subunit proteins for monoclonal antibody production,

Criterion II: Sound Technical Approach:

Of importance is how the proposed technology or deliverable will meet or exceed the performance requirements for this program and be commercially applicable (how the proposed technology will be transitioned into a regulatory-based product development program conducted by the veterinary biologics industry private sector). Specific considerations will include:

- Rationale on selection of dual function expression system(s) (if applicable to the technical topic area).
- Rationale on selection of veterinary vaccine platform(s) (if applicable to the technical topic area).
- List of key Go/No Decision criteria levels for transition into a regulatory-based product development program

Dual function refers to the platforms that allow for an antigen to be expressed in a tissue culture/bacterial system, AND to be expressed within the target species for MHC processing.

Criterion III: Sound Management Approach:

Presentation of a sound managerial approach to the proposed work, including a demonstrated understanding of the issues and challenges associated with achieving the goals of the topic, and a strategy to address those issues and challenges. A successful team will possess multidisciplinary expertise to address the complexity of the effort. Specific considerations will include:

- Potential pitfalls and alternative solutions
- Timetable and key milestones (e.g., GANTT)

Criterion IV: Capability to Perform and History of Performance:

Demonstration of a capability to perform the proposed work, including history of previous performance in developing related solutions and technologies. Specific considerations will include:

- Previous experience in the identification of recombinant vaccine candidates for swine viral diseases or acute hemorrhagic diseases.
- Previous experience in the cloning and expression of large ORFs from large animal viral DNA genomes
- History is the production of antibody reagents to track expression of heterologous genes in recombinant expression systems.
- History in the transition of recombinant vaccine candidates to industry partners for further development and clinical testing

Criterion V: Cost Realism/Reasonableness:

Presentation of accurate, well-founded and reasonable estimates of all costs related to performance of the proposed effort, including an appropriate allocation of labor resources. Members of the Peer Review panel will be looking for overall best value to the government.

Evaluation of Full Proposals will be based on an assessment of the overall best value to the government based on the aforementioned criteria. Awards will be made based upon Full Proposal evaluation, funds availability, and other programmatic considerations, including awards to lesser rated proposals where orthogonal or alternative approaches and technologies are deemed to be more technically advantageous. Once the proposal evaluation process is complete, Offerors will be notified of selection or non-selection for an award. Offerors not selected for an award may request feedback regarding the evaluation findings of submitted proposals. A written request to the Contracting Officer must be received within 3 calendar days of notification of non-selection.

12. **Proprietary Information:** The Government will be utilizing non-federal employees for both subject matter expertise and administrative assistance in accordance with Section 6.2 of the OBAA. As a reminder, it is the sole responsibility of the contractor to initiate and submit the completed company-to-

company agreement for this BAA Call. The company-to-company agreement is due at the time of proposal due date. If company-to-company agreement is not received with the proposal, the proposal will not be further evaluated for award.

The list below contains Points of Contact (POC) within each Government support company who can facilitate the negotiation of the company-to-company agreement.

Company: Nobilis
POC: Andrew Rak - Andrew.rak@noblis.org

Company: Leidos
POC: Lee E. Haff - lee.e.haff@leidos.com

13. **Foreign Concerns**: Foreign persons are advised that their participation may be subject to Export Control restrictions. Any such restrictions shall be reviewed on an individual award basis.

14. **Questions**: Any questions concerning this call must be submitted via email to the Contract Specialist at jigisha.patel@hq.dhs.gov and copy the Contracting Officer at Michael. Jones@hq.dhs.gov no later than **August 7, 2015 10:00 AM EST** in the following format**:**

Question #	Reference	Contractors' Question
1	General (if there is no specific document reference)	
2	(Example) BAA 14-003, page 15, Section 5.2, first paragraph, second sentence	
3	(Example) BAA 14-003/Call 0012, page 4, Section 11, first sentence	

Please include "Questions for BAA 14-003/ Call 0012" in the subject line. All questions and responses will be posted on the Federal Business Opportunities website http://www.fbo.gov and https://baa2.st.dhs.gov . Questions will only be accepted or answered electronically.