



# **Agenda Item 1**

**Featured Start-Up –  
Profectus BioSciences,  
Inc.**



**BOARD OF REGENTS**

SUMMARY OF ITEM FOR ACTION  
**INFORMATION** OR DISCUSSION

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**TOPIC:** Featured Start-Up – Profectus BioSciences, Inc. (information item)

**COMMITTEE:** Economic Development and Technology Commercialization

**DATE OF COMMITTEE MEETING:** November 20, 2014

**SUMMARY:** Profectus BioSciences, a clinical-stage biotechnology company, has been selected as the featured start-up for the November 20<sup>th</sup> Committee meeting. The company is a spin-off from UMB's Institute of Human Virology and was previously located in the Life Sciences Incubator at bwtech@UMBC.

Notably, on October 22<sup>nd</sup>, Profectus received an \$8.6 million contract from the U.S. Department of Health and Human Services to accelerate the advancement of the company's candidate Ebola vaccine into human clinical studies.

**ALTERNATIVE(S):** This item is for information purposes.

**FISCAL IMPACT:** This item is for information purposes.

**CHANCELLOR'S RECOMMENDATION:** This item is for information purposes.

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COMMITTEE RECOMMENDATION:

DATE:

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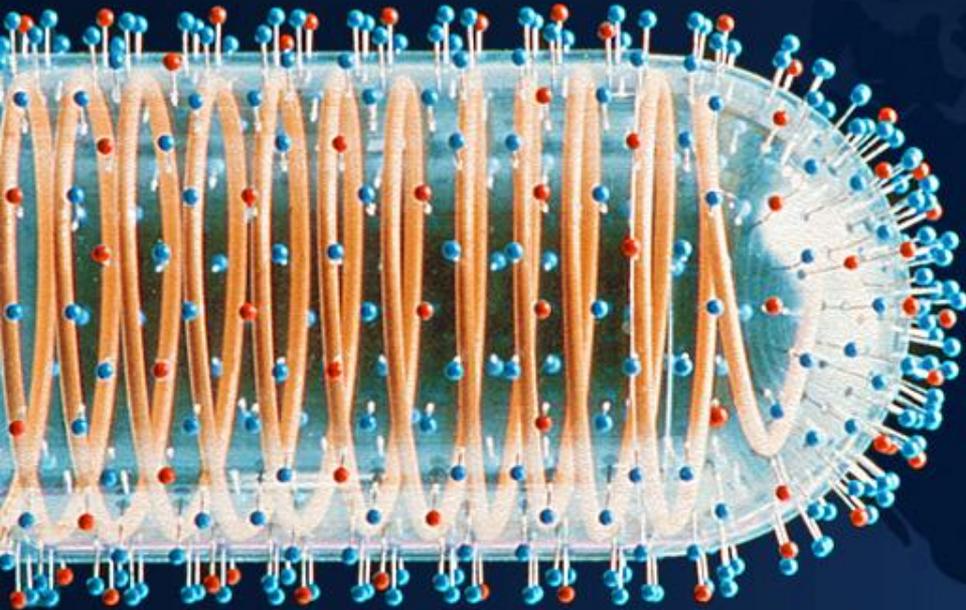
BOARD ACTION:

DATE:

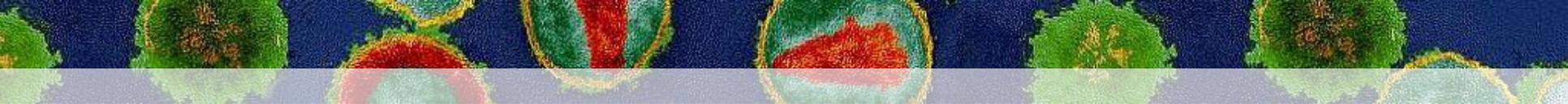
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SUBMITTED BY: Joseph F. Vivona (301) 445-2783

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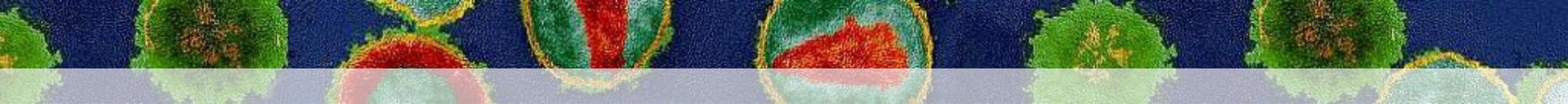


# Profectus BioSciences



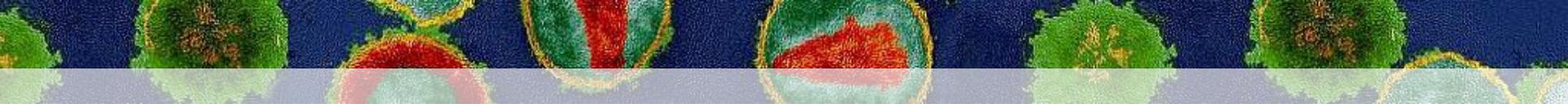
# Who is Profectus BioSciences

**Profectus BioSciences is a clinical-stage biotechnology company pioneering a major evolutionary step in the design and development of preventive and therapeutic vaccines.**



# Profectus BioSciences has strong ties to the state of Maryland

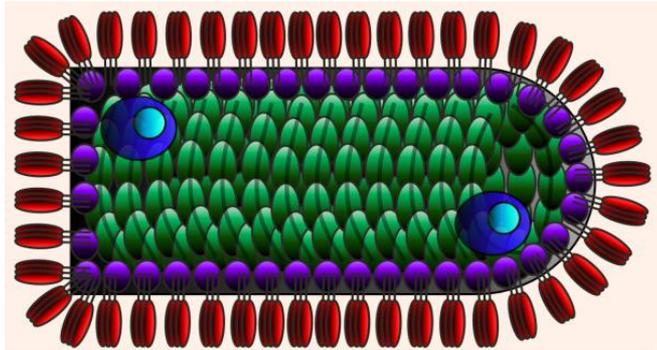
- **2005: Company founded**
  - Spun-Out from the Institute of Human Virology
  - Incubator space at the TechCenter at UMBC
  - In-Licensed IP for HIV Prophylactic Vaccine from IHV/UMB/UMBI
  - Partnered with Wyeth Vaccines to advance our HIV program
- **2005: Financing**
  - Cross Atlantic Capital Partners
  - Maryland based investors
- **2005-6: Awarded 2 MIPS grants**
  - Led to 6 Fulltime jobs in MD
  - Generated \$7M in NIH (SBIR) grants
- **2008: Spin-Out from Wyeth Vaccines research**
  - In-License the PBS Vax™ Platform
  - \$24 Million in NIAID contracts Novated from Wyeth to Profectus



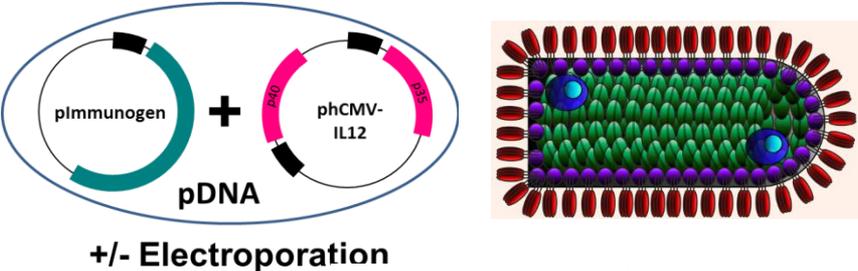
# Profectus BioSciences Today

- **Extensive Patent Estate**
- **Team of scientists** with experience in vaccine discovery through phase III development and licensure
- **Financing (>\$120 M)**
  - Equity = \$21.5 M
  - Government = \$91 M
  - Other = \$9 M
- **The PBS Vax™ Platform** systematically validated in a series of 7 clinical trials in HIV in both uninfected and infected volunteers

# Technology to tailor the vaccine response to the target



**Vesiculovax™ Virus-Vectored Vaccines**

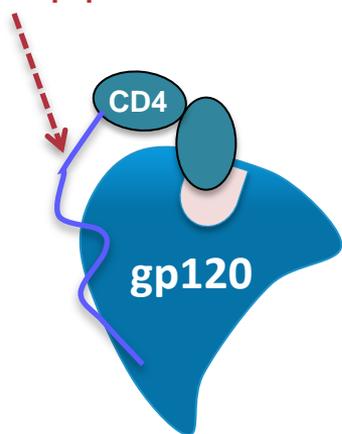


Transition State Vaccines

**Prime/Boost System of Vaccines (PBS Vax™)**

# IHV-01: HIV vaccine development with the Institute Of Human Virology

Flexible peptide linker



**IHV-01 Subunit**

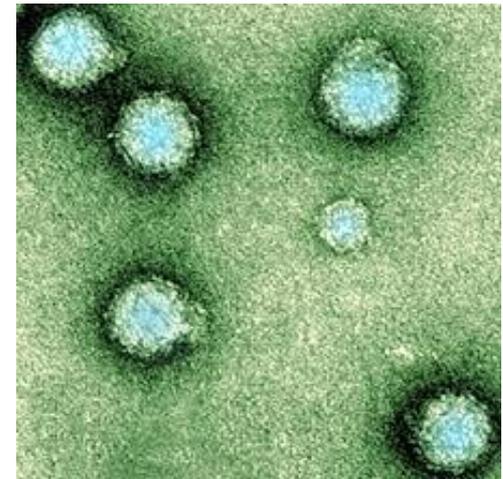
- **IHV-001 is genetic fusion of HIV gp120 and human CD4 – a transition state vaccine.**
- **How it works**
  - The HIV virus hides its vulnerable parts
  - Altering envelope structure (envelope-receptor) exposes the “vulnerable parts”
- **Partners**
  - Institute of Human Virology (IHV)
  - Bill and Melinda Gates Foundation
  - Henry Jackson Foundation
  - NIAID/NIH
- **Vaccine Development**
  - Vaccine manufactured and released under cGMP
  - IND enabling toxicology studies ongoing
  - Phase I clinical testing to start 2Q/2015 at IHV

# Vesiculovax™ for Chikungunya Fever

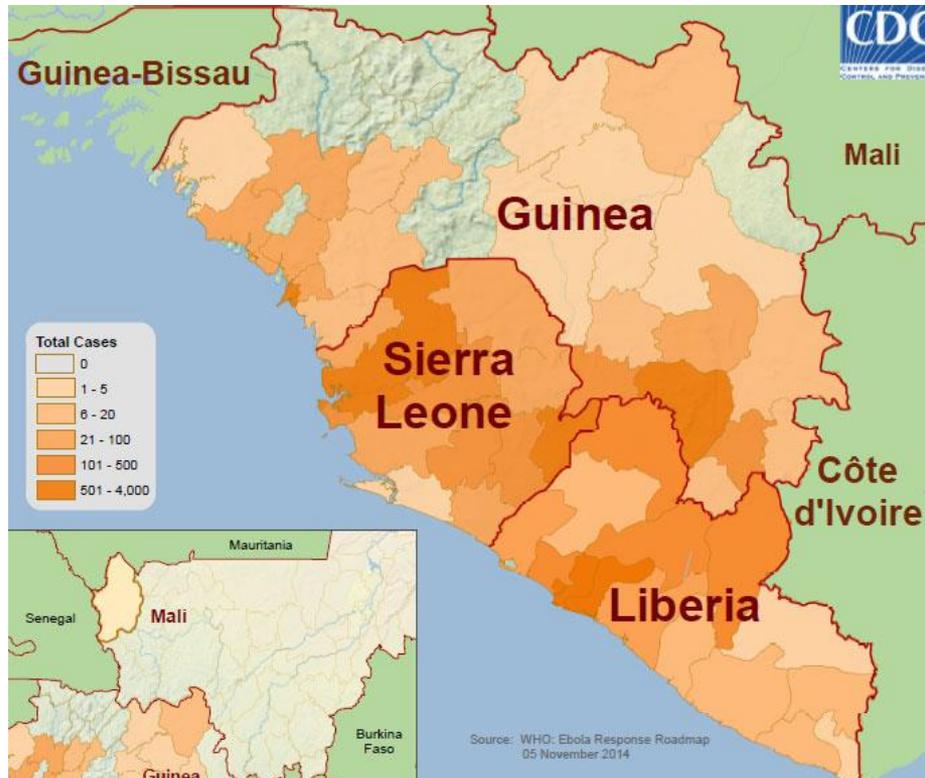
- Mosquito-borne disease caused by Chikungunya virus (CHIKV) endemic in Africa, Asia, and the Indian subcontinent that has recently moved to the Americas
- As of Oct 31, 2014:
  - 780,206 suspected cases reported in the Caribbean and Americas.
  - 11 cases of local transmission documented in the US.
- Transmitted by mosquitoes that are native to the eastern half of the US... Recently observed in Southern CA
- **Vesiculovax™ Chikungunya vaccine**
  - **Preclinical development complete**
  - **100% protection demonstrated with a single dose in animal models of disease**
  - **Phase 1 clinical trials projected to begin in 1Q/2016**



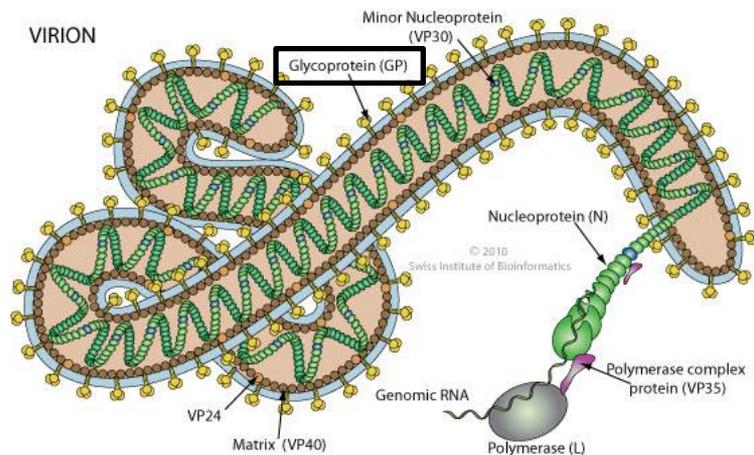
*Aedes aegypti* mosquito.



# Largest Ebola epidemic in history

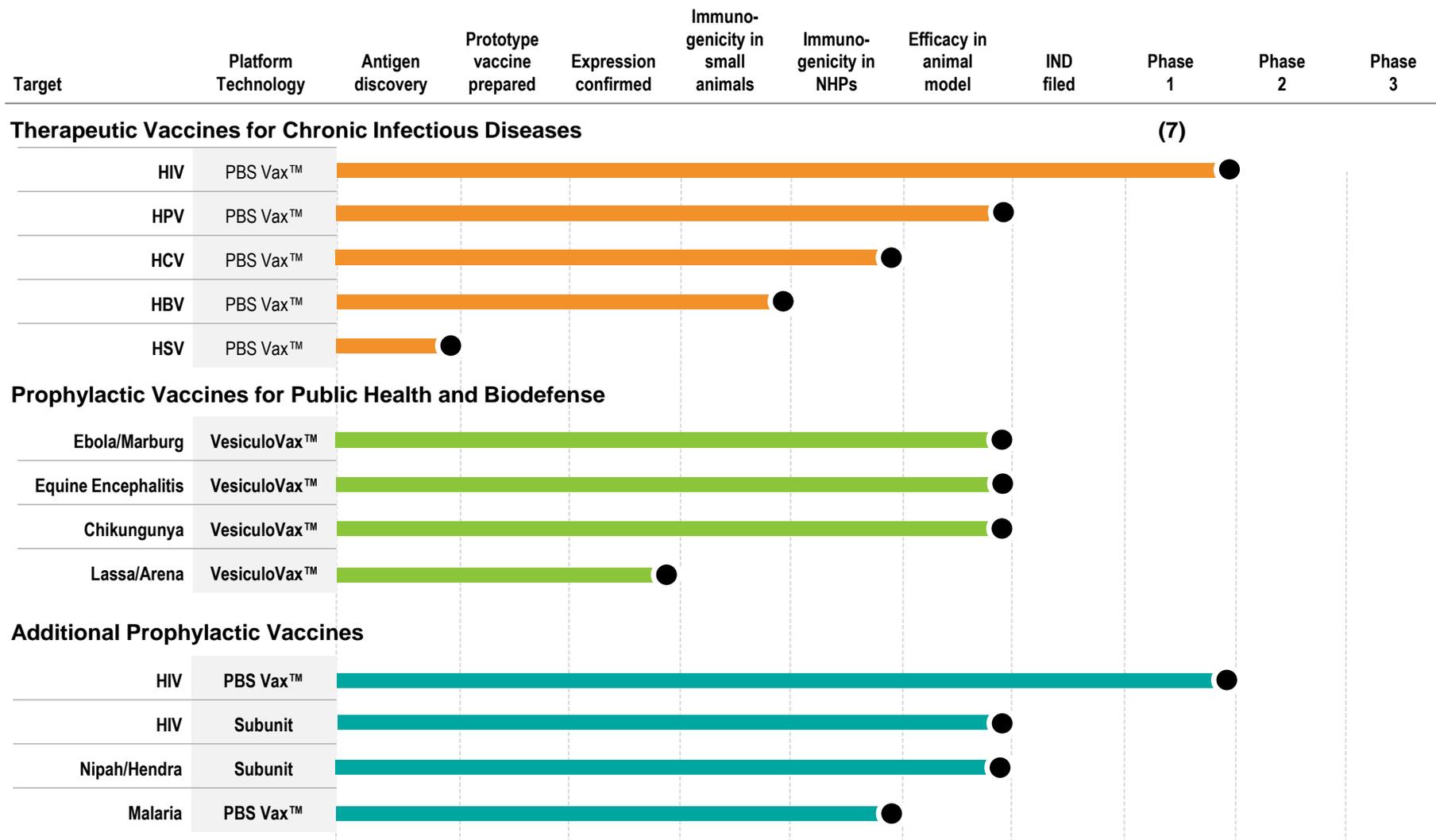


# VesiculoVax™ Ebola/Marburg Vaccine



- **Provides 100% protection** after a single dose in monkey models
- Vesiculovax™ Zaire product – **Phase I clinical trails 2Q/2015**
- Trivalent Vesiculovax™ (Ebola Zaire, Ebola Sudan, Marburg,) – **3Q/2015**
- **\$40M government funding**
- **Partners:** DoD/JVAP, BARDA, NIAID

# PBS Product Development Pipeline



# Collaborations



INSTITUTE OF HUMAN VIROLOGY



ACTG



NATIONAL CANCER INSTITUTE



ichor  
medical systems



DUKE UNIVERSITY SCHOOL OF MEDICINE  
Duke Human Vaccine Institute  
dhvi.duke.edu



HIV VACCINE TRIALS NETWORK



National Institute of Allergy and Infectious Diseases



ABL inc.  
ADVANCED BIOSCIENCE LABORATORIES



INFECTIOUS DISEASE RESEARCH INSTITUTE



UNIVERSITY OF MARYLAND  
18 56



BARDA



Catalent



New Iberia Research Center  
THE UNIVERSITY OF LOUISIANA AT LAFAYETTE



charles river



YALE UNIVERSITY



utmb



Joint Biological Defense  
Joint Vaccine Acquisition Program  
JVAP  
Product Management Office  
Protecting the Force



ALTHEA



HENRY M. JACKSON FOUNDATION FOR THE ADVANCEMENT OF MILITARY MEDICINE



National Institute of Neurological Disorders and Stroke



novasep  
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SIU Southern Illinois University  
CARBONDALE



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PROFECTUS BIOSCIENCES