Agenda Item 1

Featured Start-Up – Profectus BioSciences, Inc.
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 20th 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 22nd, 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.

COMMITTEE RECOMMENDATION: DATE:

BOARD ACTION: DATE:

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

Prime/Boost System of Vaccines (PBS Vax™)

Transition State Vaccines
IHV-01: HIV vaccine development with the Institute Of Human Virology

- 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™ Chikunguya 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
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

| Target                      | Platform Technology | Antigen discovery | Prototype vaccine prepared | Expression confirmed | Immuno- 
|                            |                    |                   |                            |                      | genicity in small animals | Immuno- 
|                            |                    |                   |                            |                      | NHPs              | Efficacy in animal model | IND | Phase 1 | Phase 2 | Phase 3 |
| HIV                        | PBS Vax™           |                   |                             |                      |                   |                   |                 |                   |        |
| HPV                        | PBS Vax™           |                   |                             |                      |                   |                   |                 |        |
| HCV                        | PBS Vax™           |                   |                             |                      |                   |                   |                 |        |
| HBV                        | PBS Vax™           |                   |                             |                      |                   |                   |                 |        |
| HSV                        | PBS Vax™           |                   |                             |                      |                   |                   |                 |        |

**Therapeutic Vaccines for Chronic Infectious Diseases** (7)

**Prophylactic Vaccines for Public Health and Biodefense**

- Ebola/Marburg VesiculoVax™
- Equine Encephalitis VesiculoVax™
- Chikungunya VesiculoVax™
- Lassa/Arena VesiculoVax™

**Additional Prophylactic Vaccines**

- HIV PBS Vax™
- HIV Subunit
- Nipah/Hendra Subunit
- Malaria PBS Vax™