Development of Novel, Cost-Effective and Minimally Invasive Blood Antibody Biomarker Tests for Alzheimer's Disease Diagnosis and Early Detection

BioPegasus, LLC

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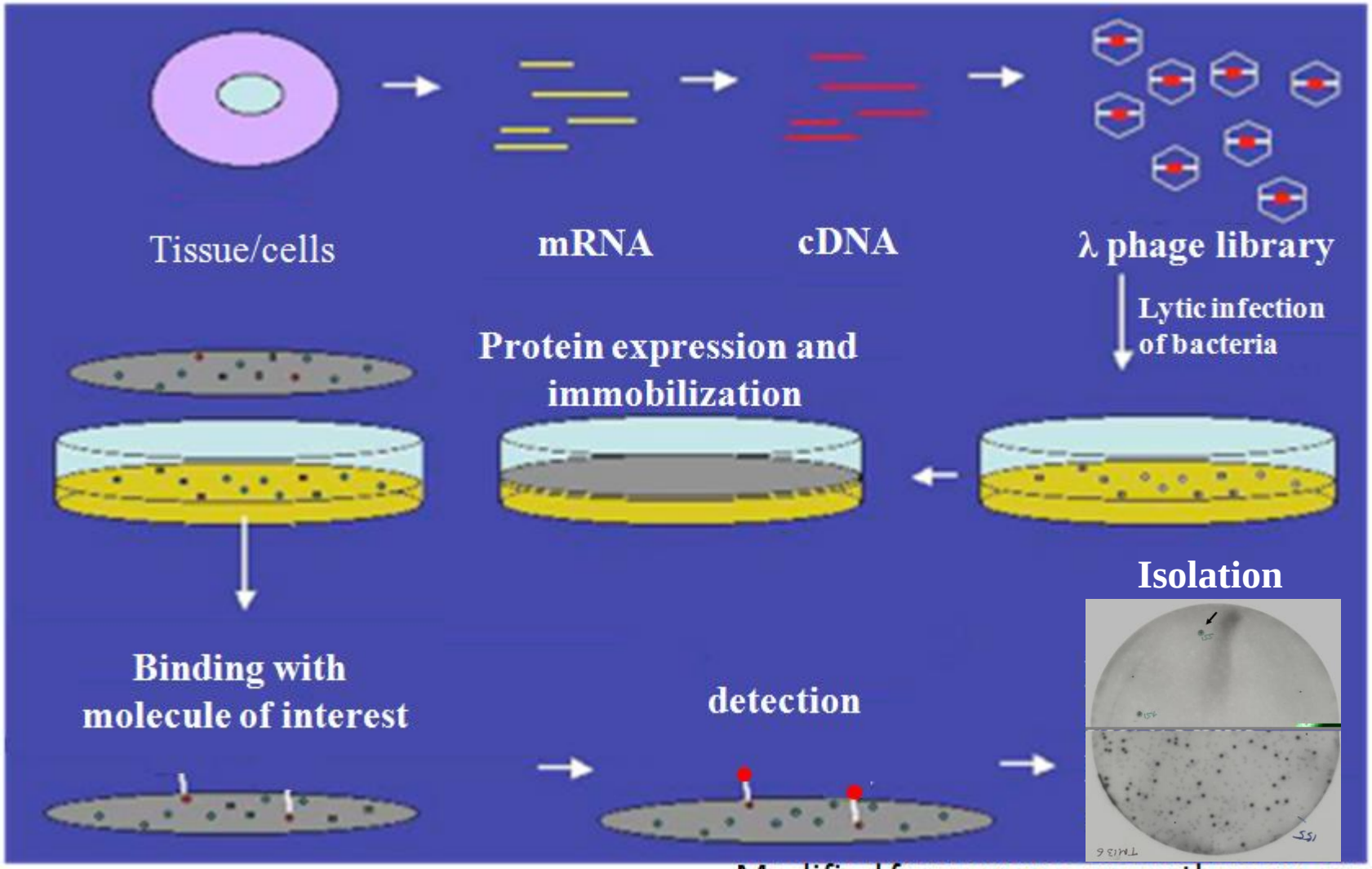
Mission

BioPegasus specializes in a unique and transformative biomarker and target discovery and identification technology platform. This proprietary platform is cost-effective and robust, allowing systematically and thoroughly to discover, identify and isolate tissue-specific and disease-specific autoantigens and key disease drivers/proteins and their genes, and disease-specific antibodies in order to solve some most challenging problems of our time. It aims to accelerate novel therapeutic and diagnostic development for some devastating diseases to improve our health and quality of life. These diseases include autoimmune diseases, cancer and, in particular, Alzheimer's disease (AD).

Core Technology



Modified from www.cancer-therapy.org

Proprietary phage cDNA expression library construction and screening

Positive clones will be identified by DNA sequencing. These proteins/genes identified with molecule of interest are the basis for further therapeutic and/or diagnostic development.

Advantages of the Technology Platform

- Unnecessary to have any prior knowledge of either the proteins expressed in a cDNA expression library or the antibodies present in a patient serum
- Overexpression of cellular proteins in soluble and structurally free-folding forms
- Direct *in situ* transfer and immobilization of all the overexpressed proteins from plates to membrane lifts with trivial efforts
- Direct detection of cellular proteins with a molecule(s) of interest
- Reproducible and unambiguous results
- Natural epitope and protein conformational structures and great epitope accessibility
- Retaining of all low and high affinity binders
- Cost-effective and high-throughput
- Easy Isolation of genes of interest for future diagnostic and therapeutic development
- Tissue and disease specific, reducing unnecessary background in analysis

Competing Technologies with Disadvantageous Inherent Limitations

- **λ phage cDNA expression library screening: variations / versions of the technology with perplexing and intractable issues**
- **Protein array: costly, less than 50% human genome gene products, very poor reproducibility based on statistical calculation**
- **Peptoid array: non-natural molecules, statistical calculation and uncertain results**
- **Peptide array: impractical with random peptides at 5-aa ($20^5 = 3.2x10^6$) and up for protein sequence coverage, statistical calculation and uncertain results**
- **Phage display library (M13, T7, λ): loss of both high and low affinity binders, very limited protein sequence coverage and variability, very restricted and un-natural protein conformation**
- **Proteomics 2D / Mass Spec: low sensitivity, very limited protein separation and detection capacity**

Market and Potential

- **No similar competing diagnostics and POCT**
- **Current number of people affected by AD, doubles every 20 years**

	AD Patients (millions)	Seniors (millions)	% Senior in Population	Screening/ Early Detection ($, millions)*	Severity/ Diagnosis ($, millions)**
US	~6	~46	~14.5	1,150	828
China	~10	~123	~9	1,230	1,230
Worldwide	~31***	~448***	~8.5	4,480***	4,480***
Total	~47	~617		6,860	6,538

* Based on $50 per qualitative POC test by 50% seniors (65 years old and better) in the US and 20% seniors in China and Worldwide. The number could be greater because an individual may take more than 1 POC test in life-time and could start testing as early as 50 years old.

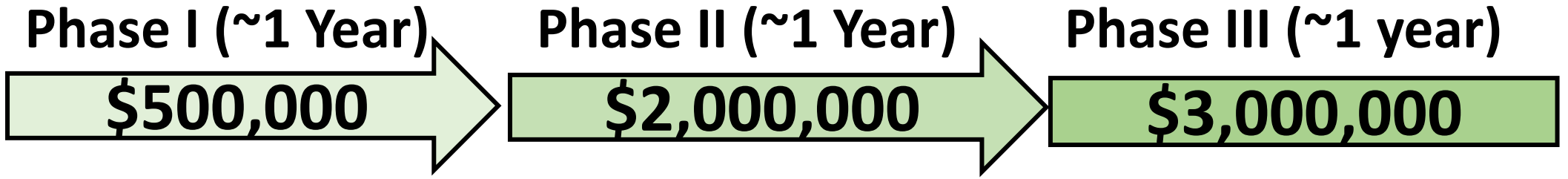
** Quantitative Lab Test based on 10% of AD prevalence in seniors at $200/patient. 90% of patients would take the test in the US and 50% in China and Worldwide.

*** Values do not include numbers from US and China.

To Replace Current ~2.8-Years Battery of Tests and Exams for Ruling-In or Ruling-Out AD

- **Medical Conditions:**
  stroke, tumor, Parkinson's disease, sleep disturbances, side effects of medication, an infection, mild cognitive impairment, vascular dementia
- **Brain Scans:**
  computed tomography (CT), magnetic resonance imaging (MRI), positron emission tomography (PET)
- **Questionnaires:**
  mini-mental state examination (MMSE), functional activities questionnaire , activities of daily living, cognitive incapacity & problem behaviors assessment,
- **Standard Medical Tests:**
  urine tests, CSF tau/p-tau, plasma IP/MS Aβ 42/40
- **Efficacy of Anti-dementia Treatments:**
  ADAS-cog (Alzheimer's Disease assessment Scale-cognitive subscale)
- **Tests in the Pipeline/Awarded for Development:**
  unique RNA in blood, ultra sensitive CSF tau, eye Aβ imaging

Budget ($5,500,000), Timeline (3 Years) and Team



- Management Team
  - Founder: T. Ma, PhD
  - Management/Operation: X. Fang, PhD
  - Biomarkers/Diagnostics: W. Ding, PhD
- Phase I Team
  - Technology: T. Ma, PhD
  - Alzheimer's Disease: E. Trushina, PhD; X. Zhou, MD, PhD
  - 2 Scientists - to be determined
- Phase II and III
  - Antibody biomarker validation
  - Blood antibody test kits (POCT and lab test) development, production, IP and regulatory applications and marketing, etc.