InFlame[™] Therapeutics, Inc.

Discovering drugs that protect the brain

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Company Profile

Industry Sector: Development of Brain Neuroprotective Drugs Diagnostic Biomarkers for Brain Inflammation

Company Overview: The team at *InFlame™ Therapeutics* has discovered cellular and biochemical pathways that account for memory loss and dementia caused by brain inflammation. Such inflammation, involving cells called microglia, occurs in both Alzheimer's disease and HIV brain infection, afflicting more than 4.5 million patients in the US alone. Currently, there are no effective disease-modifying drugs to treat these brain disorders. Through the use of unique microglia-based assays and animal models, we screen for brain protective drugs; by monitoring a disease biomarker, we accelerate the pace of clinical testing.

Target Markets: Drug developers who want efficacy measures of a candidate drug prior to human testing. Pharmaceutical companies that evaluate risk/benefits of a new drug undergoing human clinical trials. Clinics and hospitals that treat early stages of Alzheimer's disease or HIV-associated cognitive disorders.

Management and Structure

Laura A. Jacobus, CEO, *InFlame™ Therapeutics*

Dana Giulian, M.D., Ph.D., CSO, *InFlame[™] Therapeutics*

Funding: STTR awards (R42NS046997, R42AG022805) SBIR Awards (R43NS051120, R43NS052068, R44NS52068)

Collaboration: Guy Schiehser, Ph.D., Director of Chemistry at JPC Former Director of Medicinal Chemistry at Wyeth-Ayerst Research

National Institutes of Health



Key Value Drivers

Technology*: Chronic brain inflammation generates neural poisons. **ENCEPHALOTOXIN™** is one such poison discovered by *InFlame™* that is closely associated with memory losses found in Alzheimer's disease and HIV-associated cognitive disorders. **ENCEPHALOTOXIN™** serves as a novel diagnostic biomarker to detect early stages of disease in patients at-risk for memory loss and dementia. To serve this at-risk population, *InFlame™* has created a preclinical testing program using specific cell-based assays and novel animal models to facilitate identification of new chemical entities that prevent brain degeneration.

Competitive Advantage: There are no approved disease-modifying therapeutics for Alzheimer's disease or HIV-associated cognitive disorders despite a US market valued at more than \$5 billion annually. The *InFlame[™]* combination of novel investigative tools and a clinical biomarker allows faster pre-clinical drug development and more rapid, less expensive, and safer clinical trials. We guarantee confidentiality.

Plan & Strategy: 1) seek partners to develop novel brain-protecting therapeutics 2) license novel technologies 3) seek partners to develop diagnostic kits

Pipeline and Product Development

Cell-Based Screening Assays: tools to identify drug leads for neuroprotection; US Patents 6,071,493; 6,475,742; and 6,475,745.

ENCEPHALOTOXIN[™] : biomarker of brain inflammation; US Patent 7,344,852 for composition and use; Phase 2 clinical trial initiated.

Novel Animal Models: for preclinical testing of Alzheimer's disease therapeutics; program has successfully identified 3 novel treatment regimens.

Sustained-Release Drug Formulation: drug combination for treatment of brain inflammation occurring in HIV cognitive disorders; Phase 1 clinical trial completed; Phase 2 study to begin. US patent filed.

Novel Drugs for Brain Protection: novel agents that prevent brain injury in Alzheimer's disease. Pre-clinical testing phase to be completed by end of year.