Company Overview

We are launching Monument Biosciences to bring forward the next generation of disease modifying drugs for Alzheimer's Disease and Related Dementias (ADRD). The company is being launched from leading National Institute on Aging (NIA) & National Institute of Health (NIH) ADRD initiatives for next generation AD research (TREAT-AD & MODEL-AD). These programs have been awarded >$100M to date, and are setting the standard for next generation novel disease models and drug discovery for ADRD. Our discovery programs are anchored in **human patient genetics**, recent discoveries around tau homeostasis and **tau seeding**, and the role of microglia in **neuroinflammation**. Our approach relies on **translational biomarkers** to treat the right patients and follow their disease progress in response to therapy – informing clinical strategy, safety, and patient benefit. Based in Indianapolis, Indiana, the team is comprised of leading neuro focused scientists, clinicians, and entrepreneurs from Eli Lilly, Stark Neuroscience Research Institute, and Luson Bioventures with a proven track record in venture creation & drug development.

Problem or Market Opportunity

Alzheimer's disease is a progressive neurological disorder that affects memory, thinking, and behavior. As the disease progresses, it can significantly impact a person's ability to perform daily tasks and can eventually lead to total dependence on caregivers. It is estimated that there are over six (6) million people living with Alzheimer's Disease in the US, and this number is expected to double by 2050. There are also many forms of related dementia pathologies that add significantly to this burden. The economic impact of Alzheimer's and Related Dementias is substantial, with the cost of care estimated to be over $1 trillion globally. The burden of dementia underscores the urgent need for effective prevention, treatment earlier in the course of disease, and care strategies to mitigate its impact on patients, caregivers, and society.

Technical & Competitive Advantage

Recently, the FDA approved the first novel AD therapeutics in nearly 20 years in aducanumab and lecanemab, from Biogen and Eisai, respectively. These showed promise of reducing disease progression by 27% over two years of therapy, which is a clinically meaningful advance for patients. However, there were significant side effects and the drugs are far from a cure. Our approach to next generation programs in ADRD is based on the learnings from these approved agents, and we have potential advantages to all programs currently in development. Our initial targets are cutting edge new targets in **tau seeding** and **neuroinflammation** – now considered the hallmark biologies toward curing these diseases. Monument has exclusive rights through Indiana University – the leading institution in these major NIH-Funded programs (top 3 in the world).

Regulatory Strategy & Intellectual Property

Our regulatory strategy will employ a custom approach for each program to maximize clinical trial design efficiency. Using Monument's translational biomarker platform, our goal is to identify blood based biomarkers of neuroinflammation to assess target engagement in early stage clinical trials (healthy volunteers). This effort will allow us to move into early proof of concept (POC) trials in genetically driven patient populations of Alzheimer's Disease with an informed dose selection. After achieving POC, we will broaden development into stratified ADRD populations.

Key Milestones

Milestone Description	Objective
Expected Seed Milestones	Establishment of expanded scientific R&D team and supporting infrastructure, completion of Candidate Selection (CS) with start of IND enabling studies for neuroinflammation program 1 (INPP5D/SHIP1), and completion of CS for the second NI program (PLCG2), and first tau seeding program Bassoon (BSN)
Expected Series A Milestones	One-to-two IND candidates from internal pipeline; clinical readiness for one-to-two in-licensed programs; biomarker and clinical strategies detailed for lead programs – this would be a leading position in the field

Capitalization History

Year	Grant or Equity Type	Description	Amount
2016 & 2022	NIH/NIA U54	MODEL-AD 1 ($38M) 2016 & MODEL-AD 2 ($49M) 2022	$87M
2019	NIH/NIA U54	TREAT-AD 1 (TREAT-AD 2 in process)	$38M
2023	Seed Preferred	Founding Seed Round	$5-$10M

Current Round, Terms, and Use of Proceeds

Monument Biosciences is being built upon a NIH/NIA consortium that has been awarded over $100M to date, and more in process. We are currently putting together the founding Seed Financing for Monument with $5-$10M ahead of a planned Series A financing likely toward early 2024. The founding seed round is being led by Luson Bioventures, which has incubated the company since 2021. Luson has founded and launched several new biotech ventures since 2007, and raised >$1B to date for these ventures, of which several have gone public or been acquired.

Key Team Members and Advisors

Monument's founding team members have deep drug discovery experience from industry, academia, and biotech, as well as an extended founding science team who are leaders in their fields.

Derek A. Small, CEO and Chairman - Experienced CEO executive with 20+ years in industry, drug development and venture capital roles; Founding managing director of Luson Bioventures

Alan Palkowitz, PhD, Director and SAB Co-Chair - President & CEO of Indiana Bioscience Research Institute (IBRI); TREAT-AD Lead PI and Co-Director; with 25+ years leading the discovery chemistry program at Eli Lilly and Company

Timothy Richardson, PhD, Chief Scientific Officer - Scientific Director Molecular Innovation of IBRI; Medicinal Chemistry and Chemical Biology Core Leader at TREAT-AD IUSM-Purdue; with 20+ year of discovery chemistry research from Eli Lilly and Company

Bruce Lamb, PhD, SAB Co-Chair - Executive Director of Stark Neuroscience Research Institute; Professor of Psychiatry, Medical & Molecular Genetics, & Alzheimer's Disease Research, IU School of Medicine; MODEL-AD – Director and TREAT-AD Center – Co-Director

Jeff Dage, PhD, Head of Translational R&D – Head of biomarkers and translation research at Stark Neuroscience Research Institute; TREAT-AD PI; with 20+ years at Eli Lilly and Company as Research Fellow and Group Leader of Translational Research

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