

# JEFFREY SMITH

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## EXECUTIVE LEADER – ASSAY DEVELOPMENT, BIOMARKERS & TRANSLATIONAL SCIENCE

Visionary scientific leader with 25+ years of groundbreaking innovation in assay development, biomarker assessment, and translational research, driving advancements in oncology and inflammatory disease therapies. Proven track record of leading high-impact R&D programs, pioneering novel diagnostic and therapeutic strategies, and translating innovative science into clinical applications. Proven ability to secure regulatory approvals, drive strategic planning and partnerships, and accelerate drug development, transforming cutting-edge science into breakthrough therapies.

### Career Highlights

- ⇒ *Engineered proprietary immunoassays for pharmacokinetic/pharmacodynamic biomarker analysis*, reducing development timelines and setting standards for diagnostics in inflammatory bowel disease therapies.
- ⇒ *Developed a groundbreaking protease inhibitor cocktail* that stabilized analytes for extended periods, eliminating sample degradation, reducing variability, and enabling ultra-precise biomarker analysis for advanced therapies.
- ⇒ *Co-founded and led R&D for a diagnostics startup*, securing funding, filing multiple patents, and creating a non-enrichment-based blood sample preparation method that boosted cancer cell detection sensitivity and precision.
- ⇒ *Discovered and optimized SL0101*, the first small-molecule p90RSK-specific inhibitor, catalyzing advancements in targeted cancer therapies and laying the foundation for current clinical trials in triple-negative breast cancer.

## PROFESSIONAL EXPERIENCE

**BIORA THERAPEUTICS, INC.** | Irving, TX | 2018-2024

### SENIOR DIRECTOR TRANSLATIONAL SCIENCE & ASSAY DEVELOPMENT(2018 - 2024)

Led a multidisciplinary team to advance biomarker-driven assay development for pharmacokinetic and pharmacodynamic assessments in inflammatory bowel disease therapies. Led the design, validation, and implementation of cutting-edge immunoassays, driving innovation in translational research and accelerating development timelines.

- ♦ **Leadership Excellence:** Built and directed a team of Directors, Assistant Directors, and Scientists, optimizing R&D processes and enhancing assay development capabilities.
- ♦ **Developed Proprietary Assays:** Designed and validated immunoassays for biomarker analysis across multiple sample types, improving diagnostic accuracy and regulatory support.
- ♦ **Enhanced Cross-Functional Collaboration:** Partnered with engineering, preclinical, clinical, and business development teams to align R&D with corporate strategy and clinical objectives.
- ♦ **Optimized Data Analysis:** Streamlined workflows reducing data processing time and improving preclinical decision-making.
- ♦ **Innovated Sample Stability:** Engineered a protease inhibitor cocktail that preserved biomarker integrity for up to seven days, ensuring reliable sample analysis.

**AXON DX, LLC** | Earlsville, VA | 2013-2018

### CHIEF SCIENTIFIC OFFICER

Co-founded and led R&D for a diagnostics startup, pioneering innovative instruments and reagents for minimally invasive detection of circulating tumor cells and other rare biomarkers. Spearheaded product development, secured funding, and patented breakthrough technologies that advanced cancer diagnostics and positioned the company as an industry leader.

- ♦ **Built High-Performing Team:** Recruited and led a team of 8 scientists, fostering a culture of innovation and driving cutting-edge R&D advancements.
- ♦ **Pioneered Breakthrough Technology:** Developed and patented a non-enrichment-based blood sample preparation method, increasing rare biomarker detection sensitivity.
- ♦ **Secured Major Funding:** Raised seed funding by demonstrating scientific and commercial viability to investors.
- ♦ **Enhanced Diagnostic Accuracy:** Improved detection precision over standard assays, solidifying the company's position as a leader in cancer diagnostics.
- ♦ **Accelerated Product Development:** Led end-to-end development, from concept to validation, while ensuring regulatory compliance and forging strategic partnerships.

**UNIVERSITY OF VIRGINIA** | Charlottesville, VA | 2010-2013

## RESEARCH ASSISTANT PROFESSOR – DEPARTMENT OF BIOMEDICAL ENGINEERING

Executed research in pancreatic cancer, focusing on molecular imaging and microvesicle studies to advance diagnostics and therapeutics. Directed a team of researchers, developed novel techniques, and translated laboratory discoveries into clinically actionable innovations.

- ♦ **Led Cutting-Edge Research:** Advanced pancreatic cancer diagnostics through molecular imaging and phage-display biopanning.
- ♦ **Published High-Impact Findings:** Contributed to top-tier scientific journals with groundbreaking pancreatic cancer detection and treatment research.
- ♦ **Mentored Future Scientists:** Guided post-doctoral researchers and graduate students, fostering a productive and innovative research environment.

**LUNA INNOVATIONS, LLC** | Charlottesville, VA | 2005-2010

## PRINCIPAL INVESTIGATOR

Managed drug development and pathogen detection initiatives, managing research funding, advancing targeted cancer therapies, and driving innovation in public health and safety. Mentored and led a team of senior scientists.

- ♦ **Pioneered Cancer Therapeutics:** Co-discovered and optimized SL0101, the first p90RSK-specific inhibitor, securing patents and advancing targeted cancer treatment.
- ♦ **Managed High-Impact Research:** Oversaw a \$750K annual budget and led multiple externally funded programs focused on drug discovery and pathogen detection.
- ♦ **Held Department of Defense security clearance.**

## EDUCATION & CREDENTIALS

**Doctor of Philosophy (PhD) in Molecular Physiology & Biophysics**, Vanderbilt University School of Medicine

**Bachelor of Science (BS) in Biology**, Lipscomb University

### *Patents:*

**Rhamnose substituents of SL0101 and therapeutic uses thereof** | US8426568B2  
**Synthesis and identification of novel RSK-specific inhibitors** | US9040673B2  
**Cell detection, capture, and isolation methods and apparatus** | US10147180B2

Cross-Functional Team Leadership | Drug Discovery | Pharmacology-based Assay Development & Screening  
 Research & Development (R&D) | Biomarkers | Translational Research | Clinical Development | Data Analysis  
 Oncology & Immunology | Biostatistics | Project Management | Regulatory Compliance | Strategic Leadership

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