



National Heart, Lung,
and Blood Institute

NHLBI Regional Innovation Conference - Southeast

September 22, 2014 • NC Biotechnology Center
Research Triangle Park, NC



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**North Carolina
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Agenda

- 9:30am Welcome Remarks and NHLBI Overview
- 10:00am Company Presentations A
Translational Sciences
CorInnova
BioMarck Pharmaceutical
- 10:45am Refreshments and Partnering
- 11:15am NHLBI Resources
- 11:35am NCI SBIR Opportunities
- 11:45am Company Presentations B
Savara Pharmaceutical
Parion Sciences
AlgorithmRx
- 12:30pm Lunch and Partnering
- 1:30pm The Influence of Payer Decisions on Life Sciences Development Strategy
- 2:00pm Company Presentations C
Pulmotect
Stellarray
HemoSonics
- 2:45pm Partnering Break
- 3:15pm Investor Perspective Panel
- 4:45pm Closing Remarks
- 4:50pm Reception

Speakers



Kurt Marek, PhD

Dr. Marek is the Deputy Director of the Office of Translational Alliances and Coordination (OTAC) at the National Heart, Lung, and Blood Institute (NHLBI). OTAC is charged with developing trans-NHLBI programs to foster the translation of early stage discoveries into commercial products. The Office coordinates the NIH Centers of Accelerated Innovations and the Institute's small business program. Dr. Marek oversees the Institute's efforts to support small businesses performing research and development on innovative biomedical products and to facilitate partnerships between small businesses, investors and strategic partners.



Chris Sasiela, PhD, RAC

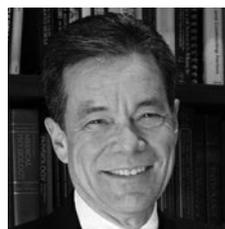
Dr. Sasiela is Regulatory Specialist in the NHLBI Office of Translational Alliances and Coordination. She provides consultative advice and develops regulatory affairs educational content for NHLBI small businesses, clinical investigators, and program staff. She also facilitates communication between NHLBI-funded investigators and the FDA.



Mark Johnson

Mr. Johnson is Vice President of payer marketing policy at GlaxoSmithKline (GSK). In GSK's Payer and Vaccines Division, he develops payer value strategies for both pipeline and approved products, as well as promotional programming for marketed brands.

Moderator



Stephen Flaim, PhD

Dr. Flaim is Special Advisor in the NHLBI Office of Translational Alliances and Coordination and Chairman, Tech Coast Angels. He is Founder and President of Flaim Partners Consulting and a board member of Pivotal Biosciences Inc. and AnaBios Corp. Dr. Flaim is Chairman of the Board for Leading Biosciences Inc.; technology and business adviser to the William J. von Liebig Center for Entrepreneurism and Technology Advancement at UC San Diego; Chairman of the Board of Directors for the John G. Watson Foundation; Cofounder/CEO of CardioCreate Inc.; and Chairman/CEO of OncoFluor, Inc.

Panelists



Charles Baldwin, JD

Mr. Baldwin is a Partner at Brooks, Pierce, McLendon, Humphrey & Leonard, LLP, one of North Carolina's oldest law firms. He represents companies across a broad spectrum of industries and scale, from start-ups to multi-nationals. Mr. Baldwin's specialties include business and corporate law and planning; LLCs and start-ups; capital investment; international law and trade; arbitration and litigation; non-compete and trade secrets; and municipal law.



Walter Plunkett, PhD

Dr. Plunkett performs scientific licensing of worldwide business development at GSK, where he conducts due diligence for both in-licensing and out-licensing of assets. Dr. Plunkett has more than 25 years of experience in the pharmaceutical industry, focusing mainly on drugs that treat cardiovascular and metabolic diseases.



Kevin Schimelfenig

Mr. Schimelfenig is a Managing Partner at McGeever, LLC, a private holding company and angel investment company, and he is a member of the Wilmington Investor Network. He advises C-level executives in the medical device, life-science, and health care arenas about innovative solutions to accelerate revenue, mitigate risk, and adapt to market challenges. Previously, Mr. Schimelfenig spent more than 25 years in the medical products industry, with companies including Johnson & Johnson and Steris Corporation.



Christy Shaffer, PhD

Dr. Shaffer is Venture Partner at Hatteras Venture Partners and Managing Director of Hatteras Discovery. She serves as the board chair of two Hatteras portfolio companies: G1 Therapeutics and Clearside Biomedical. A seasoned entrepreneur and biotech executive, Dr. Shaffer has more than 20 years of life-science industry experience. Previously, she worked at Burroughs Wellcome Co., and in 1995 joined Inspire Pharmaceuticals (recently acquired by Merck in 2011) as the first full-time employee. In 2000, Dr. Shaffer oversaw Inspire's initial public offering.



Brian Wamhoff, PhD

Dr. Wamhoff co-founded HemoShear, co-invented its technology, and is currently its Vice President of Research and Development. He is also on the University of Virginia (UVA) faculty and leads an NIH-funded laboratory investigating smooth-muscle cell phenotypic switching in vascular disease. Before joining UVA, Dr. Wamhoff was a lead scientist at Setagon, Inc, where he helped develop a novel drug-eluting stent to treat blood-vessel stenosis in humans.



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Showcase Companies

Therapeutics



Translational Sciences, Inc. (TSI) transforms scientific insights into first-in-class therapeutic agents to reduce morbidity, mortality, and health care costs for cardiovascular diseases caused by thrombosis. Its monoclonal antibody therapy, LysiMab, safely dissolves thrombi, and it is also a platform therapeutic being developed for the treatment of other acute thrombotic diseases such as heart attacks and ischemic stroke. **Poster 5 10:00AM Presentation**



BioMarck Pharmaceuticals is a privately held drug discovery and development company with an advanced indication for chronic obstructive pulmonary disease (COPD). BioMarck also intends to advance one of its novel N-terminal peptide-inhibitors of the MARCKS protein as a new potential treatment of Acute Respiratory Distress Syndrome (ARDS).

Poster 2 10:30AM Presentation



Savara Pharmaceuticals develops and commercializes therapies for rare respiratory diseases with high unmet medical need. The company's lead product is a dry powder inhaler of vancomycin, AeroVanc, to treat pulmonary methicillin-resistant *Staphylococcus aureus* (MRSA) infection in cystic fibrosis patients. AeroVanc is currently in Phase II clinical development.

Poster 4 11:45AM Presentation



Pulmotect is developing a clinical stage, inhaled immunomodulator that provides broad protection against airborne viral, fungal, and bacterial pathogens. PUL-042 is a synthetic inhaled drug that locally activates innate immune defenses in lung epithelial lining. It elicits host-based, antimicrobial responses that prevent or attenuate infection by a broad range of inhaled pathogens (demonstrated against viral, bacterial and fungal challenges).

Poster 3 2:00PM Presentation



BioLink Life Sciences is a biopharmaceutical technology company developing innovative drug treatments that target major diseases. BioLink's drug therapies support disease-management initiatives to enhance patient care and quality of life while improving tolerability and decreasing costs. The company is developing a robust pipeline of novel treatments for iron deficiencies, kidney disease, diabetes, and seizure disorders. **Poster 1**

Devices



CorInnova is a medical device company developing a non-blood contacting biventricular cardiac assist device to treat end-stage heart failure. The product promises to eliminate 40 percent of adverse events associated with left ventricular assist devices (LVADs) while also promoting heart recovery. **Poster 6 10:15AM Presentation**



Parion Sciences is dedicated to improving and extending the lives of patients with innate mucosal surface defense deficiencies of the eye or airway. Parion has a diverse pipeline of pre-clinical and clinical candidates to treat these diseases via distinctive mechanisms of action and approaches. **Poster 7 12:00PM Presentation**



Stellarray develops and commercializes proprietary radiation sources and systems that use these sources in pre-clinical, clinical and other types of imaging. The company developed two main versions of x-ray source – a plain flat-panel x-ray source used in sterilization and irradiation applications and a pixilated, digitally addressable x-ray source, for stationary computed-tomography systems. **Poster 9 2:15PM Presentation**

Showcase Companies

Devices (cont'd)



Weinberg Medical Physics LLC, is a medical device design company with special competence in medical imaging and image-guided therapy. The company has proprietary methods for ultra-fast high-resolution MRI, which have formed the basis for ongoing joint ventures in dentistry and cancer imaging. **Poster 10**

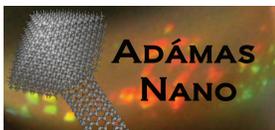
Diagnostics



HemoSonic is a medical device company that develops and commercializes innovative diagnostics to assess and guide the rapid treatment of bleeding and clotting disorders. Its mission is to save lives and improve quality of life while reducing costs, through the use of its products in all applicable clinical settings. The company's first product, aimed at critically ill patients in surgical, trauma, and intensive-care settings, is an in vitro diagnostic device using a consumable test cartridge. **Poster 12** **2:30PM Presentation**



OTC Biotech has established a complete platform of technologies to exploit disruptive capabilities of DNA aptamers for applications in human and animal medicine. These include therapeutics, diagnostics, biosensors, drug discovery, biomarker discovery, research and industrial applications. The company sells DNA aptamers targeted against a wide variety of molecular and cellular targets. **Poster 13**



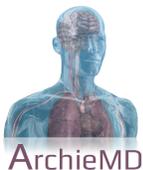
Adamas Nanotechnologies, Inc. develops and produces nanodiamond particles and serves diverse markets, ranging from bioimaging and quantum-information applications to advanced lubrication. One of the company's core technologies is the manufacturing on a commercial production level bright fluorescent nanodiamonds with sensing capabilities. These nanodiamonds can be labeled with a wide variety of selective linking agents for cell labeling and targeting, making them multimodal theranostic agents. **Poster 11**

Health IT



algorithmRx, LLC (aRx) develops and delivers innovative, predictive, point-of-care health care algorithms. Its computer-based clinical decision-support systems provide busy clinicians with up-to-date, evidence-based guidance to enhance medication management. The company is focused on common chronic diseases and health conditions that affect large segments of the U.S. population, such as high blood cholesterol (hypercholesterolemia or elevated LDL-C).

Poster 14 **12:15PM Presentation**



ArchieMD is a company that creates innovative educational products for a wide range of audiences within the health sciences. The company's 3D animations simplify concepts with visual explanations, and its interactive applications enhance many types of training and simulation. **Poster 15**



Intelligent Automation, Inc. is a technology innovation company. It developed mSMART, a smartphone app to improve medication adherence through the use of multiple Adherence-Enhanced Interventions including educational intervention, medication adherence behavior assessment, psychosocial behavior assessment, and provider set reminders. **Poster 16**

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 **AdvaMed MedTech Conference**
October 6-8 Chicago, IL

 **16th Annual NIH SBIR/STTR Conference**
October 21-23 Albuquerque, NM

 **National SBIR/ STTR Conference**
November 12-13 Austin, TX

The NHLBI Office of Translational Alliances and Coordination

The Office of Translational Alliances and Coordination (OTAC) helps to move basic discoveries from laboratory to market to improve health. OTAC does this by providing leadership for the NHLBI small business program and developing trans-NIH SBIR/STTR funding opportunities, supporting universities' efforts to create new technology development models, providing expert regulatory and commercialization advice to the NHLBI community, and developing strategic partnerships.

The National Heart, Lung, and Blood Institute

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

The National Institutes of Health

The National Institutes of Health (NIH), a part of the U.S. Department of Health and Human Services, is the nation's medical research agency—making important discoveries that improve health and save lives.

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