National Heart, Lung, and Blood Institute

NHLBI Innovation Conference - West

November 17, 2015 • UCI Applied Innovation
Irvine, CA

PARTNERS

ANGEL CAPITAL ASSOCIATION

Agenda

9:00am Welcome Remarks and NHLBI Overview and Resources
Richard Sudek, Gary Robinson, Jennifer Shieh

9:40am Company Presentations
Adient Medical
Correlia Biosystems
Vanguard Therapeutics

10:25am Refreshments and Partnering Break

11:10am Keynote Presentation
Stanton J. Rowe

11:40am Company Presentations
Ventrix
480 Biomedical
Targazyme, Inc.
Accel Diagnostics

12:40pm Lunch and Partnering

1:40pm UC CAI Presentation
William Boyle

2:10pm Company Presentations
Targeson, Inc.
OrPro Therapeutics
Xfibra, Inc.

2:55pm Partnering Break

3:40pm Investor Perspective Panel
Stephen Flaim (Moderator), Lawrence B. Cohn, Don Kasle, Linda Marbán, Monty Mars, Timothy Wollaeger

4:40pm Closing Remarks

4:50pm Reception

Speakers

Richard Sudek
Dr. Richard Sudek is the Executive Director of Applied Innovation at UC Irvine, Emeritus Chairman of Tech Coast Angels and Assistant Professor of Entrepreneurship at George L. Argyros School of Business and Economics at Chapman University. Dr. Sudek's primary research interests are in the area of entrepreneurial finance, entrepreneurial leadership, and team leadership.

Gary Robinson
Dr. Gary Robinson is the business development specialist for the Office of Translational Alliances and Coordination (OTAC) at NHLBI. Prior to joining OTAC, Dr. Robinson was the co-founder and the Chief Business Officer of Celek Pharmaceuticals, headed business development at Panacos Pharmaceuticals, and held business and corporate development positions at IGEN International.

Jennifer Shieh
Dr. Jennifer Shieh is the small business coordinator at the NHLBI Office of Translational Alliances and Coordination (OTAC). Previously, she was a Program Director and AAAS Science & Technology Policy Fellow at the National Cancer Institute (NCI) SBIR Development Center, and Biology Associate at precision medicine startup Syapse Inc. She is co-author of the textbook Guide to Research Techniques in Neuroscience.

Stanton J. Rowe
Mr. Stanton Rowe is the Chief Scientific Officer at Edwards Lifesciences and also serves as Corporate Vice President, advanced technology. He joined the company in 2004 when Edwards acquired Percutaneous Valve Technology, of which he was President and CEO and helped to found in 1999. Previously, Mr. Rowe was Corporate Vice President of business development and strategic planningfor Datascope and was Vice President of business development for Johnson & Johnson's interventional systems division (JJIS).

William Boyle
Dr. William Boyle is an Associate Professor in the Department of Medicine in the David Geffen School of Medicine (DGSOM) at University of California, Los Angeles Dr. Boyle leads a consultation service for Clinical and Translational Science Institute DGSOM faculty related to the discoveries-to-products pipeline. Dr. Boyle has experience in translational medicine, project management, target selection, pipeline management, and platform translation.

Investor Perspective Panelists

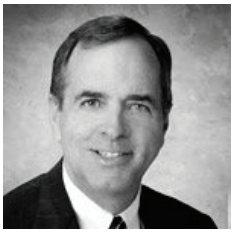
Stephen Flaim (Moderator)
Dr. Stephen Flaim is a Senior Special Advisor and Investor-in-Residence at the NHLBI Office of Translational Alliances and Coordination (OTAC), Chairman Emeritus of Tech Coast Angels, and Director of the Angel Capital Association. He is Founder and President of Flaim Partners Consulting and a board member of Pivotal Biosciences Inc., CardioCreate, Inc., Leading Biosciences, Inc. and Chairman of the Board of OncoFluor, Inc. Dr. Flaim is also a technology and business advisor to the William J. von Liebig Center for Entrepreneurism and Technology Advancement at University of California, San Diego.

Lawrence B. Cohn
Mr. Lawrence Cohn is chair of Stradling Yocca Carlson & Rauth life sciences practice. Mr. Cohn represents medical device, pharmaceutical, and biotechnology companies and investors in their corporate transactions, private, venture capital and public securities financings, mergers and acquisitions, licensing, strategic alliances, and technology transfers. He was recognized as one of “America’s Leading Lawyers” in Life Sciences: Commercial by Chambers USA in 2009 through 2015. He was also named “Top 25 Biotech Lawyer in California” by the Daily Journal in 2011.

Don Kasle
Mr. Don Kasle is the Chairman Emeritus of Tech Coast Angels where he is an active investor and coach for start-up companies. Mr. Kasle is also a Senior Consultant for TriTech Small Business Development Center (SBDC), providing free consulting to high-growth, highly-scalable companies. Mr. Kasle is currently a member of four Boards of Directors and serves as Chairman on two of the four. Over the course of his career, Mr. Kasle has served on 33 Boards of Directors in the private, public, and not-for profit sectors.

Linda Marbán
Dr. Linda Marbán, co-founded Capricor, Inc. in 2005 and has served as Chief Executive Officer since 2010. She combines her background in research with her business experience to lead Capricor and create a path to commercialization for its novel stem-cell cardiac therapies. From 2003-2009, Dr. Marbán was with Excigen, Inc. where she was responsible for business development, operations, pre-clinical research, and supervising the development of gene therapy products in a joint development agreement with Genzyme Corp.

Monty Mars
Mr. Monty Mars has over twenty years of experience in corporate development in the medical device and biotechnology industries. Mr. Mars joined the corporate development group at Edwards Lifesciences in 2008 where he focuses on acquisitions, divestitures and early stage investing.
Mr. Mars holds a BS in Biochemistry from the University of California at Davis, a JD from the University of Southern California and an MBA from the Wharton School of Business.



Timothy Wollaeger
Mr. Timothy Wollaeger has more than forty years of experience in the medical products and biotechnology fields in both corporate management and venture capital. Mr. Wollaeger joined Sanderling Ventures as a Managing Director in 2002, and opened the firm’s San Diego office. Mr. Wollaeger serves on the Board of Directors for several Sanderling portfolio companies, including CalciMedica and Chimerix (NASDAQ: CMRX). He is Chairman of the Board of Directors for Sotera Wireless and Asteres. Prior to joining Sanderling, Mr. Wollaeger founded the venture capital firm Kingsbury Capital Partners.

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Showcase Companies

Diagnostics

Correlia Biosystems develops next generation protein measurement platforms for diagnostic and research applications. Correlia's versatile electronic lateral flow test (eLFT) is under development for rapid, low-cost, and quantitative disease diagnosis at the point-of-care. Addressing the huge unmet need for accurate confirmatory assays in global health, our first eLFT product is a rapid test for sickle-cell disease in neonates and adults. Correlia's eLFT technology will use a fraction of the time of traditional centralized lab tests to provide confirmatory diagnosis in 10 minutes - instead of days or weeks - enabling doctors to make immediate and informed treatment decisions that improve patient outcomes.

Accel Diagnostics employs proprietary technologies to transform the patient blood testing paradigm, from lab-centered to near-patient - bringing significant advantages in terms of simplicity, time-to-result, care delivery, and cost over standard lab-based diagnostics. The technology enables physicians and patients to perform biomarker diagnostic tests directly in the doctor's office and/or home. The entire test is contained in a disposable credit card size chip, without compromising test accuracy. A companion app enables physicians to remotely review test results of home patients. First product is being developed, and entering the pilot phase at three leading institutes, for near-patient diagnosis of heart failure - an untapped opportunity of $3+B.

Targeson, Inc. is a world leader in targeted microsphere technology for use as tools in the medical research markets. To date, the company has: (1) initial sales revenue; (2) grant funding; (3) partner milestone income; and (4) a robust research market pipeline. Targeson manufactures several commercial products (including first-in-class angiogenesis targeted ultrasound imaging agents and targetable transfection agents), and is developing a clinical product to help complement the diagnosis of Acute Coronary Syndrome. Targeson's business model is to develop and market products in the research markets for revenue generation, then leverage this expertise to expand into larger clinical market opportunities.

Menssana Research, Inc. develops advanced breath tests for early detection of diseases. These breath tests can detect cancers of lung and breast, infections (e.g. tuberculosis and influenza), transplant rejection, and radiation exposure. Breath testing is painless and non-invasive, but collection and analysis of breath is technically difficult, which is why breath testing has played only a minor role in medical diagnosis until recently. Menssana Research has developed technology for breath analysis in the laboratory and at the point-of-care. The BreathLink system can collect, concentrate, and analyze a breath sample at the point-of-care, and deliver a result in less than ten minutes. The technology is protected with U.S. and international patents, and the lung cancer, breast cancer, and tuberculosis breath tests have a CE Mark. FDA approved the Heartsbreath test for heart transplant rejection with a Humanitarian Device Exemption, and the lung cancer test is currently under review. Poster 3

QT Medical, Inc. is a spinoff of LA BioMed in Torrance, CA. Incorporated in 2013, QT Medical aims to commercialize the QTScreen technology for long QT syndrome (LQTS) screening in newborns. LQTS is a genetic disease occurring 1 per 2,000 babies, and can cause sudden death. QTScreen is a full 12-lead electrocardiogram (ECG) system that enables parents to perform the ECG screening at home. A clinical trial of 4,000 newborns is currently underway. QT Medical will be the leader in the LQTS screening market ($300M annually in the U.S.) and possibly future home use ECG market. Poster 4

Showcase Companies

Diagnostics (cont'd)

SignaBlok, Inc. is a biopharmaceutical company founded in 2009 to develop innovative and first-in-class diagnostics for targeted macrophage imaging through the use of SignaBlok's proprietary multifunctional nanoparticles for targeted delivery of imaging agents and drugs to macrophages. Potential clinical applications include atherosclerosis (primary), cancer, and rheumatoid arthritis (RA). In atherosclerosis, SignaBlok develops an innovative nanotechnology-enabled platform for targeted imaging to detect dangerous vulnerable (unstable) atherosclerotic plaques in coronary and carotid arteries using a non-invasive magnetic resonance imaging (MRI) modality in order to identify high-risk vulnerable individuals, diagnose the disease before symptoms occur, facilitate intervention decision-making process, and monitor response to treatment. Poster 5

Vala Sciences, Inc. (VSI) is a diagnostics and drug discovery and development company providing solutions to clinical labs and pharmaceutical, biotechnology and academic sectors. VSI's patented Kinetic Image Cytometer provides groundbreaking drug discovery and diagnostics for diseases such as heart failure and dementia that manifest abnormalities of kinetics such as in muscle contraction and nerve conuction. Poster 7

Therapeutics

Vanguard Therapeutics is targeting the process that drives sickle cell disease – abnormal blood flow. Sickle cell adhesion to P-selectin on the vascular endothelium is central to this impaired flow. Vanguard is developing an orally available treatment that will block P-selectin, improve blood flow, and avert the painful vaso-occlusive crises that afflict patients with sickle cell disease. Vanguard anticipates lower barriers to marketing our new product because of the proven safety of its parent compound during 19 years treatment of a different entity. Among programs targeting the initial adhesion step of vaso-occlusion, only Vanguard has the important advantage of oral bioavailability.

Ventrix, Inc. provides solutions for the heart. Ventrix is a privately held company and has established a firm foothold in San Diego, CA. In 2012, Ventrix closed a Series A financing round and has received funding from NIH and NSF SBIR awards. Ventrix is focused on delivering a biomaterial scaffold for cardiac repair for heart attack patients who currently have very limited treatment options. Ventrix is interested in partnership opportunities with leading Healthcare Technology companies.

Targazyme, Inc. is a clinical-stage biopharmaceutical company developing and commercializing breakthrough products to improve clinical efficiency outcomes for immunotherapies for cancer and autoimmune diseases, stem cell transplants, gene therapy and regenerative medicine. Targazyme is driving towards a product registration trial in hematopoietic stem cell transplantation and proof of concept clinical trials in immunotherapy. The company's platform technologies improve the therapeutic potential of cells by directing therapeutic cells to sites of inflammation, ischemia and/or tissue damage in the body and improving retention in those tissues. By directing these cells to where they are most needed, Targazyme's technologies can improve the effectiveness of therapeutic cells in numerous disease indications.
Poster 14

OrPro Therapeutics is a San Diego, CA based biopharmaceutical company that is developing a novel enzymatic based therapeutic for the treatment of cystic fibrosis (CF) and other obstructive lung diseases. OrPro's technology is a patent protected, inhaled, non-systemic treatment that is designed to break the disulfide bonds in CF mucus and normalize its viscoelastic properties allowing for improved mobility. The product is currently in IND enabling development.
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Showcase Companies

Therapeutics (cont'd)

Xfibra, Inc. is focused on the development of new therapies to treat fibrotic diseases including liver cirrhosis and lung fibrosis. The initial focus of the company has been to advance a compound into development for liver disease. Key features of the company's technology include: (1) the identification of the unique molecular target (phosphoacceptor C/EBPb-Thr266]) that is essential for the activation and survival of liver myofibroblasts (which are the cells responsible for the production of the scar tissue in cirrhosis); and (2) that drug development candidates have been discovered that act by effectively and selectively blocking this target and inhibit liver scarring.
Poster 17

Elex Biotech, LLC is developing first-in-class NCEs with increased safety and efficacy for the treatment of arrhythmia, an underlying cause of heart failure. The initial focus is on an orphan/rare disease, catecholaminergic polymorphic ventricular tachycardia (CPVT; associated with a genetic mutation in ryanodine receptor 2, RyR2). The NCEs are based on a unique rational approach toward developing new drugs targeting RyR2, the main Ca2+ channel involved in heart muscle contraction. Current data suggest these NCEs normalize mutant RyR2 channels but do not affect normal RyR2 channels. Elex has demonstrated in vivo proof of concept in animal models of CPVT. Poster 8

Fox Chase Chemical Diversity, Inc. The misson of Fox Chase Chemical Diversity Center, Inc. is to advance our collaborators' basic biomedical discoveries by providing value-added early drug discovery and medicinal chemistry research support to translate screening hits to viable preclinical drug and diagnostic candidates. Fox Chase has secured the largest number and dollar amount of currently funded NIH SBIR/STTR projects in Pennsylvania. The company has partnered with the New York Blood Center to develop a novel platform of Platelet Factor 4 tetramer antagonists that could be a first-in-class treatment of heparin-induced thrombocytopenia and thrombosis (HITT).
Poster 9

Molecular Express, Inc. has been conducting research and developing new products and technologies across a spectrum of industries since 1996. The company specializes in the formulation, process development, scale-up and manufacturing of technologies and products based on its expertise in lipid-based nanoparticles. Through an exclusive license to the lung surfactant technology "Minisurf™" from the University of Rochester/Los Angeles Biomedical Research Institute, Molecular Express is pursuing commercialization opportunities in the pharmaceutical and biotechnology markets (US Patent Number 8,563,683 - "Synthetic Lung Surfactant and Use Thereof").
Poster 10

Navigen develops promising early-stage pharmaceutical technologies. Navigen sources its technologies by partnering with innovative academic researchers and through our own in-house discovery efforts. Navigen works side-by-side with inventors to advance their early technologies to the point at which potential investors, corporate partners, or acquirers are more likely to engage. They have crafted a business model that enables them to tailor each partnership to best meet the inventor's objectives and the technology's requirements. The expertise of Navigen's professionals spans the scientific and commercial areas necessary to grow inventions efficiently and effectively.
Poster 11

Rubicon Biotechnology, LLC is located in Orange County, CA. Their mission is to develop novel and cost effective therapies. Rubicon in-licenses biologics and completes preclinical, Phase I and Phase II clinical studies prior to out-licensing to a big pharma company. They have licensed FvHsp70 to treat myocardial infarction, stroke and pulmonary injury. Their small in-house team at Rubicon and UCLA conduct in vitro studies while our world class collaborators at Mt. Sinai Hospital and MRI Global study the drug in vivo. Once licensed to a partner, Rubicon will recognize future development milestones and royalties from worldwide sales. Poster 13

Showcase Companies

Devices

Adient Medical develops medical devices that serve a useful purpose, then vanish from the body. Adient Medical is developing the first absorbable Inferior Vena Cava filter for the prevention of pulmonary embolism (PE). PE accounts for 100K-300K annual deaths in the U.S., the 3rd leading cause. The filter protects those at risk by trapping blood clots destined for the lungs. Uniquely, the Adient filter is absorbable — maintains 80% strength for 35 days then decomposes into CO2 and H2O after clots resorb in the filter. The filter obviates retrieval, and is inherently safer since the polymer is incapable of penetrating the IVC. Poster 19

480 Biomedical is a medical technology company focused on providing therapeutic solutions through the use of its unique bioresorbable platform technology. They have created a pipeline of novel implantable devices for adult and pediatric patients with vascular and respiratory conditions. Through innovations in material science, 480 Biomedical's products transform medicine by treating diseases locally while also eliminating the adverse consequences of permanent implants.

Biopico Systems is an early stage company that develops, manufactures and markets innovative biological testing technologies with applications throughout the clinical diagnostic and life science industries. The company's focus is on developing innovative approaches to improve the therapeutics and diagnostics of serious diseases and conditions. Their technologies enable high throughput assays to be conducted and analyzed quickly, cost-effectively and accurately using micro/nano systems.

CytoSorbents Corporation is a publicly-traded, critical care focused medical device company working to save lives through blood purification. CytoSorbents' purification technologies are based on biocompatible, highly porous polymer beads that remove toxic substances from blood and other bodily fluids by pore capture and surface adsorption. CytoSorb®, the company's flagship product, is approved in the European Union as a safe and effective cytokine filter for treating critical inflammatory illnesses. HemoDefend™ is a development-stage technology platform for the blood transfusion industry intended to reduce serious and potentially fatal transfusion reactions by removing antibodies, potassium, free hemoglobin and inflammatory mediators from blood products. Poster 21

Ension, Inc. is a medical device product incubator that focuses on designing, manufacturing, and testing medical devices with specialized biological surfaces to ensure biocompatibility, infection resistance and other desired clinical outcomes. Ension's Infection Resistant Surface technology is designed to promote normal healing for application to the transcutaneous drivelines of ventricular assist devices. The surface incorporates a three-pronged approach to infection resistance; a low adhesion surface to prevent microbial attachment, controlled release of antimicrobials, and a natural collagen surface that promotes tissue integration. The innovation lies in engineering a specialized surface that promotes an optimal healing response from the host tissue. Poster 22

Nanoshell Company is a Salt Lake City, UT based nanobiotech company that provides innovative, accessible technologies to improve human health. FastReact is an extracorporeal system that utilizes innovative nanotechnology and fluidics to recover targeted substances in biofluids. Many high value, and potentially therapeutic molecules are unavailable due to high process costs. Clinical therapies and drug development benefit from the acquisition of selected substances from complex biological fluids. Dialysis, blood transfusion, chelation therapy, and other current clinical technologies have limitations in efficiency and targeting. FastReact is an alternative technology for the separation and purification of high value substances that offers selectivity, reduced costs, and simplified procedures. It can be used aseptically during blood donation or in industrial labs to process plasma once cells and platelets are recovered.

Showcase Companies

Health IT

Asthma Management Systems was founded by Dr. Andrew Weinstein, a renowned asthma researcher, to commercialize the techniques he developed and utilized in his own practice/research. His adherence program, Asthma Adherence Pathway (AAP) significantly and demonstrably improves patient adherence and reduces the costs associated with poor adherence. The mission of the company is to provide healthcare practitioners effective tools to treat severe asthma patients. The AAP consists of four components: (1) an app system of software; (2) in person and remote patient-centered communication training; (3) internet enabled adherence monitors; and (4) follow up services to responsible organizations for delivering cost-effective care. Poster 24

Cytobank, Inc. is a privately held corporation located in Mountain View, CA. Cytobank provides scientific, informatics, and software solutions built on Cytobank – a cloud-computing platform focused on single cell technologies and big data. The founding team includes leaders from Stanford University with deep expertise in informatics and single cell technologies. Cytobank was built out of a need to address a problem faced in the founders' work – how to manage and extract insight from the vast amount of single cell information measured in the lab. Cytobank is in use by thousands of researchers worldwide including 10 of the top 15 pharma. Poster 25

UC CAI Innovators

The University of California Center for Accelerated Innovation (UC CAI) program translates NHLBI- and NIDA- funded discoveries to improve health and health care to address unmet medical needs. The NCAI Center in California, which includes UC Davis Health System, UC Irvine Health, UCLA Health, UC San Diego Health Sciences, and UC San Francisco, is one of three Centers in the country.

Arash Kheradvar – A Bio-Inspired Transcatheter Mitral Valve
This proposed project will develop and test the first transcatheter bileaflet mitral valve with dynamic annulus, and its delivery system for transapical implantation. This bio-inspired mitral valve system will offer most of the advantages that a native bileaflet mitral with dynamic annulus has to offer for left ventricular function. Poster 26

Arash Kheradvar – Development of a Self-Regenerative Hybrid Heart Valve
This project aims to develop and test the first hybrid tissue-engineered heart valve. The hybrid heart valve leaflets are composed of a super-thin mesh of Nitinol that is tightly enclosed by multiple layers of patient's own cells making a living implant possible within the heart. Poster 27

Elliot Botvinick – Continuous Lactate Monitor for Early Indication of Resuscitation in Trauma and Sepsis
High mortality rates continue to persist in many patients with critical conditions such as sepsis, and trauma. Treatment in these cases is often aimed at stabilizing patient parameters such as vital signs. However, by the time these parameters change, it is often too late to intervene effectively.
Evidence has shown that lactate concentration is one of the most powerful early predictors of outcome in many critical conditions, and that lactate concentration can be used to improve patient survival by directing therapy more effectively. Lactate-guided therapy is difficult or impossible to utilize in clinical practice however because current technologies allow only intermittent lactate measurements, thus failing to provide adequate and timely information about lactate changes. As such, a continuous measurement of lactate is desired to provide real-time lactate concentration.This project advances the development of our technology that will provide hands-free continuous lactate monitoring.
Poster 28

UC CAI Innovators

Vasan Venugopalan – Optical Platform for Rapid High-Throughput Screening of Cellular Mechanotransduction

The initiation and/or progression of numerous pathologies has been linked to the dysregulation of cellular mechanotransduction. These pathologies include arteriosclerosis, hypertension, cardiomyopathy, and asthma. This project aims to develop and deploy a novel high-throughput screening (HTS) technology that is compatible with standard image cytometry based HTS platforms, to screen for the efficacy of compounds to modulate cellular mechanotransduction processes in 2D cell cultures. The project's objective is to use its technology to identify drugs that display the ability to modulate mechanosignaling as opposed to biochemical activity alone. Poster 29

Abbas Ardehali – Lung Assist Device

Patients with acute lung failure who are refractory to mechanical ventilation have poor prognosis and utilize significant healthcare resources. Veno-venous Extra-Corporeal Membrane Oxygenation (vv-ECMO) is being increasingly used to salvage such patients, as accumulating data indicate that it is effective and may improve survival. However, the currently used vv-ECMO catheter has two major shortcomings that render it subject to positional changes and re-circulation of oxygenated blood, thereby affecting its efficiency. The goal of this project is to develop a newly designed/improved catheter system for removal and return of blood for patients in respiratory failure in need of vv-ECMO. Poster 30

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NIH SBIR Workshop at Radiological Society of North America (RSNA)
November 28, Chicago, IL

Life Sciences Summit
December 1 - 2, New York, NY

RegMed Capital Conference and World Stem Cell Summit
December 10 - 12, Atlanta, GA

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.