National Heart, Lung, and Blood Institute

NHLBI REGIONAL INNOVATION CONFERENCE SAN FRANCISCO SEPTEMBER 10, 2013

@NHLBI_SBIR #NHLBIshowcase

Genentech Hall, UCSF
600 16th Street
San Francisco, CA 94158

Janssen Labs
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BAYBIO

Entrepreneurship at UCSF Center
Office of Innovation, Technology & Alliances

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Agenda

9:00 - 10:00 a.m.
Registration & Partnering

10:00 - 10:15 a.m.
Welcome Remarks

10:15 - 10:30 a.m.
NHLBI Office of Translational Alliances and Coordination: Speeding Discoveries from Lab to Market

10:30 - 11:15 a.m.
Company Presentations

11:15 a.m. - 12:20 p.m.
Lunch & Partnering

12:20 - 12:35 p.m.
NHLBI Small Business Program: Accelerating Innovation

12:35 - 1:20 p.m.
Company Presentations

1:20 - 1:50 p.m.
Partnering Break

1:50 - 3:20 p.m.
Investor Perspectives Panel

3:20 - 5:00 p.m.
Closing Remarks & Networking Reception

Speaker Bios

Jodi Black, PhD

Deputy Director, Division of Extramural Research Activities, NHLBI

Dr. Black is the Deputy Director, DERA, National Heart, Lung, and Blood Institute, where she provides scientific and management leadership and oversight of extramural research and training programs. Dr. Black develops and oversees programs designed to derive the greatest possible benefit from the Institute's basic science and clinical research investment by enabling, facilitating, and catalyzing the translation of research discoveries and innovations into new diagnostics, devices, therapeutics, and tools. She created the NHLBI Office of Translational Alliances and Coordination (OTAC) which enhances translation of technologies from the bench to the market by developing initiatives that enable continued R&D guided by commercialization requirements and by providing access to resources.

Kurt Marek, PhD

Program Director and SBIR Coordinator, NHLBI

Dr. Marek is a Program Director at the National Heart, Lung, and Blood Institute where he coordinates the Small Business Innovation Research (SBIR) program. In this role, he develops, manages, and evaluates scientific programs to support small businesses performing research and development on innovative biomedical products. Dr. Marek provides advice to small businesses on all aspects of the SBIR program, including funding opportunities, the application process, and commercializing technologies. Dr. Marek was instrumental in the development of the Office of Translational Alliances and Coordination, the NHLBI office charged with developing trans-NHLBI programs to foster the translation of early stage discoveries into commercial products.

Chris Sasiela, PhD, RAC

Regulatory Specialist, Office of Translational Alliances & Coordination, NHLBI

Dr. Sasiela serves as the Institute's FDA regulatory requirements expert on matters related to new translational technology development and commercialization of advanced technology platforms for research, diagnosis, treatment, control, and prevention of cardiovascular, lung, and blood diseases. She provides guidance to small businesses in navigating initial interactions with FDA and developing their regulatory strategy. She held a Fellowship position at FDA's Center for Drug Evaluation & Research and served as Director of the Regulatory Affairs & Services team for Social & Scientific Systems, Inc. She earned her Regulatory Affairs Certificate (RAC-US) from the Regulatory Affairs Professional Society.

Speaker Bios

Stephen Flaim, PhD **Special Advisor, NHLBI ,& Chairman, TCA (MODERATOR)**

Dr. Flaim is Special Advisor to the Office of Translational Alliances and Coordination in the Division of Extramural Research Activities, NHBLI of the NIH, and Chairman of TCA. He is also Founder & President of Flaim Partners Consulting, a Fellow of the American College of Cardiology, the AHA, the American College of Clinical Pharmacology, and the Royal Society of Medicine. Dr. Flaim is a board member of Pivotal Biosciences and AnaBios Corporation, Chairman of the Board for Leading Biosciences, on the Editorial Board of the Journal of Pharmacology and Experimental Therapeutics, a Technology and Business advisor to the William J. von Liebig Center for Entrepreneurism and Technology Advancement at UCSD, and Chairman of the John G. Watson Foundation. He is Cofounder & CEO of CardioCreate and Chairman & CEO of OncoFluor.

Allan May **Founder, Life Science Angels**

Since 1995, Mr. May has been founder, Chairman, CEO, or investor in more than 50 medtech, biotech, and diagnostic startups. He is now founder of Life Science Angels, the largest angel organization in the U.S. focused solely on early stage medical device and life science start-ups, and comprised solely of high net worth individuals from the medical device or biotech fields. LSA has invested more than $35M in 40 startups and achieved 7 positive exits to date. In 2011, Mr. May launched the Life Science Angel Network, a consortium of 15 angel groups throughout the United States, to focus on increasing the syndication and capitalization of highly vetted healthcare startups.

Gregory Naeve, PhD **Head, Strategic Research Partnerships, San Francisco, Pfizer**

Dr. Naeve is currently the Rinat Lead & Head of Pfizer's SF office for Strategic Research Partnerships in the External Research, Development, & Innovation unit. In this role, Greg is responsible for liaising with Pfizer scientists to identify and institute strategic partnerships that address internal technology and pipeline needs. Prior to Pfizer, he worked as a VC with The Column Group, a venture fund focused on creating biotech companies to develop novel therapeutics and technologies. He was the Co-Founder, President, & Chief Scientific Officer of Parallax Biosystems, a company developing a molecular detection platform with applications in pre-clinical drug discovery and diagnostics. He held positions at Neurocrine Biosciences and Amgen. He received his PhD in Biochemistry from the University of Southern Cali-

Andrew Schwab **Founder & Managing Partner, 5AM Ventures**

Prior to founding 5AM in 2002, Mr. Schwab was a Principal at Bay City Capital. After joining Bay City Capital in 1999, he led the firm's investment and merchant banking activities for such companies as Cubist, Metabolex, PTC Therapeutics, Symyx, and Syrrx. Previously ,Mr. Schwab was VP of Business Development at Digital Gene Technologies and a VP in the life science investment banking group of Montgomery Securities. At 5AM, he has led the firm's investments in and served on the Boards of Directors of Cleave, DVS, Flexion, Ikaria, Ilypsa (acquired by Amgen), Miikana (acquired by EntreMed), Panomics (acquired by Affymetrix), RuiYi, Synosia (acquired by Biotie), and Viveve. Mr. Schwab received a BS with Honors in Genetics & Ethics from Davidson College. He is based in the Menlo Park, CA office.

NHLBI Awardees

AfaSci, Inc. is a biomedical research company based in the San Francisco Bay Area. AfaSci was founded in 2003 with the initial goal of increasing high throughput and reducing the inherent cost of modern drug discovery by creating new research devices and technology platforms.

Aronora, Inc. is a biotech company focusing on the development of proprietary injectable anti-coagulant/antithrombotic agents that do not cause bleeding. The high degree of specificity of its products translates to a superior safety profile.

Astraea Therapeutics is a discovery-stage biopharmaceutical company, focused on the discovery and preclinical development of small-molecule therapeutics for the treatment of drug addiction and central nervous system disorders.

BetaStem's fundamental vision is to cure diabetic retinopathy by repairing and regenerating damaged blood vessels in a patient's eye. The treatment is based on stem cells from a patient's own blood, bone marrow or cord blood, "activated" through a proprietary process.

Cylerus, Inc. —founded by the inventor of the boundary layer drug delivery technology—is developing an implantable, sirolimus-eluting cuff and reservoir system to solve the clinical problem of vascular graft failure.

DRVision specializes in microscopy based inspections, what we call image based decisions. Image based decision applications require broad competence in technologies ranging from high speed computing and image processing to machine learning and pattern recognition.

ELEX Biotech, LLC develops innovative small molecule pharmaceutical drugs for management and cure of cardiovascular and related diseases, with a lead program for ventricular arrhythmia.

Gamma Therapeutics, Inc. is a biotechnology venture developing a novel class of biopharmaceutical and diagnostic test solutions for the cardiovascular disease industry based upon a natural clotting protein in blood called Gamma Prime Fibrinogen.

GMSBiotech's technology streamlines sample collection and processing, to then deliver complex genotyping as a simple bench-top microarray test. The goal is to make complex genetic testing simple and inexpensive enough to be done by hand in any lab.

HeartVista, Inc. has been developing an MRI software platform with an advanced CMR software package. It provides high quality images for the analysis of cardiac function and an interactive interface that improves the workflow with real-time image navigation.

NHLBI Awardees

Kestrel Labs, Inc. is a medical device R&D company that has invented a new laser-based technology that provides a replacement for—and dramatic improvement over—the omnipresent Pulse Oximeter, a product with current worldwide annual revenues of more than $2 billion.

Klein Buendel, Inc. develops and evaluates targeted public health programs in collaboration with academic, public and private partners by bringing together a dynamic multimedia development team and leading research scientists.

Nanoshell Company, LLC's name originally reflected its primary interest in shelled particles that could enclose unique molecules inside of a small cage. However, after developing research-driven products, its focus has shifted to solving unmet biomedical problems, such as artificial oxygen carriers.

Nortis, Inc. has developed technologies for growing functional units of tissues and organs in disposable microfluidic chips. Model systems of the human vasculature, blood-brain barrier, cancer metastasis, kidney, liver, intestine and a platform for malaria-vaccine testing are in the pipeline.

NuvOx focuses on improving oxygenation to body tissues. Its technology is based upon a unique material that transports hundreds of times more oxygen per unit dose than any other material that has been previously studied for this application, including red blood cells.

PlaSalus LLC is a biotechnology research company developing technologies to obtain, preserve and use fetal stem cells from the term human placenta. Its business model is first based upon the growing need for stem cells used in regenerative medicine.

Sharklet Technologies, Inc. is a biotechnology company that develops and brings to market surface technologies that manage microorganisms to make the world a healthier, environmentally safer and better place.

Silicon BioDevices has developed the next generation point-of-care in vitro diagnostics: a handheld, disposable device that measures multiple analytes directly from a finger stick of blood and instantly transfers the results to a mobile device or wireless server accessed EMR system.

Syntrix Biosystems, Inc. is clinical stage pharmaceutical company which has three drugs in its pipeline, with its most advance-stage drug candidate in Phase 2 clinical trials. It is developing a new once-daily oral therapy for the treatment of chronic obstructive pulmonary disease.

VPDiagnostics, Inc.'s mission is to provide non-invasive imaging technology, products and service with evidence-based validations to quantitatively characterize high-risk atherosclerotic plaque before rupture and therefore to better stratify who is at high risk and who gets what treatment.

Hosts and Sponsors

National Heart, Lung, and Blood Institute

www.nhlbi.nih.gov

National Heart, Lung, and Blood Institute

The NHLBI provides global leadership for research, training, and education to promote the prevention and treatment of heart, lung, blood, and sleep diseases and disorders and to enhance the health of all individuals so that they can live longer and more fulfilling lives. The NHBLI is the third largest research organization at the National Institutes of Health (NIH), and has a 2012 budget of more than $3 billion. The NHLBI provides grant and contract funding opportunities to support small businesses performing research and development on technologies related to its mission.

PRESCIENCE INTERNATIONAL

www.prescienceintl.com

Prescience International

Prescience International is dedicated to the global adoption of life science, cleantech and other high-growth technologies which generate sustainable economic results and have a positive social impact. Prescience engages with private and public clients to create and operate unique innovation centers, design and deliver world-class educational programs, and provide targeted commercialization support services.

Janssen Labs

Janssen Research & Development, LLC

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Janssen Labs

Janssen Labs is a life science innovation center providing emerging companies with many of the advantages of being in a big company, without the capital investment. The flagship facility opened in early 2012 in San Diego at Janssen's West Coast Research Center and, through recent expansion, the Janssen Labs has established satellite locations in additional life science hubs around the globe. Janssen Labs is an open innovation model, and the agreement for space does not grant Janssen any stake in the companies, nor will the companies have a guaranteed future affiliation with Janssen.

Johnson & Johnson INNOVATION

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Johnson & Johnson Innovation

Johnson & Johnson Innovation, a division of Johnson & Johnson Finance Corporation, focuses on accelerating early innovation and enhancing opportunities for collaboration and investment across Johnson & Johnson's global healthcare businesses.