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KEYNOTE SPEAKERS

My entrepreneurial journey at HandyLab and DeNovo Sciences

Kalyan Handique, Ph.D.

CEO

DeNovo Sciences

This talk will go through the entrepreneurial journey of HandyLab, a University of Michigan molecular diagnostics start-up, from its inception in 2000 to its eventual sale to Becton Dickinson in 2009. The talk will focus on the experience of developing and commercializing HandyLab's microfluidics technology, securing funding from various sources including venture capital, building a world-class team, developing and selling a molecular diagnostic product platform in a regulated medical market, and eventual exiting through the sale of HandyLab to BD for \$275MM. Key lessons learnt related to the commercialization of the microfluidic technology as well as building the Company will be discussed. Dr. Handique will also touch upon how he applied some of the lessons learnt earlier to the new cancer diagnostics start-up called DeNovo Sciences.

Biography: Dr. Kalyan Handique is currently the President and CEO at DeNovo Sciences, the Grand Prize winner of 2011 Accelerate Michigan. DeNovo Sciences is developing a microfluidic platform for detection of cancer from blood as an alternative to painful biopsies. Prior to joining DeNovo, he was VP of R&D Systems Development at Becton Dickinson (BD) Diagnostic Systems. He became a part of BD as result of a landmark deal valued at above \$275 Million, where BD acquired HandyLab, a company he co-founded in 2000. Handy played a pivotal role in forming the vision, the core technical team as well as envisioning the positive, v lture of HandyLab, a molecular diagnostic company. He started HandyLab while completing his doctoral degree in Microfluidics at University of Michigan. Under his leadership, the highly motivated HandyLab team successfully launched a series of integrated molecular diagnostic products in the hospital testing market. Handy is the author of numerous journal articles, such as in Science, as well as the inventor of over 50 patents and patent applications.

Bringing wearable body monitoring to the masses

Ivo Stivoric

CTO

BodyMedia

For several years, high-tech armbands have been helping contestants on NBC's "The Biggest Loser" and thousands of other consumers track calorie burn, activity levels and sleep patterns to assist with weight management. Now wearable body monitors are getting smaller, wireless, affordable and even disposable, paving the way for mass adoption. This session by BodyMedia, a pioneer in the space, will address the MEMS, flexible, and converging electronics and other technology underly

roductions that are expanding the appeal as well as the health-related applications for body monitoring, the strategy being used to drive adoption, and its vision for utilizing MEMS and "flexible" technology in future products.

Biography: As an innovator and visionary in multi-sensor wearables, Ivo Stivoric is internationally recognized for helping to develop today's consumer body monitoring category. In 1999, as one of the original founders of BodyMedia, he applied his vision for the life-changing BodyMedia technology to catalyze the application of body monitoring in the medical and consumer lifestyle management industries. Today, as CTO and Vice President of New Products for BodyMedia, Ivo is spearheading the rapid expansion of the product line across a wide-range of healthcare applications such as disease management and remote care. By integrating new technologies and enhancements that build upon the product's proven efficacy and robust clinical outcomes, BodyMedia is ushering in the next evolution in the category with product innovation and industry partnerships that will play an important role in the future of healthcare.

SESSION 1

An Overview of the Market for MEMS Sensors and Sports Applications

Session Leader: Louis Ross, CEO, Virtus Advanced Sensors, Inc.

The market for MEMS motions sensors continues to climb as new applications are developed by a growing cadre of researchers and companies large and small. The introduction of 6DoF devices over the next 3 years will be a key enabler for healthcare/medical related applications, as well as sports. There are various factors associated with sensor and complete systems development which are key to help push the type of volume needed for sports applications to go beyond a highly specialized niche to a growing commercial market. It is quite likely this market will reach over \$1B in revenue within the next five years. This session will cover some recent advancements in the industry's leading motion sensor technology.

Biography: Louis Ross has worked as an industry analyst, strategist and in operations at the start up level over the past 18 years working with Fortune 500 companies, governments and technology venture companies in the microtechnology space. Mr. Ross was previously a Managing Partner for Obsidian Capital, a New York based



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venture capital advisory firm and also served as an Assistant Vice President at Merrill Lynch Japan where his team managed Merrill's Japan Portfolio as a member of the Global Strategy Team based in Tokyo. Mr. Ross is a frequent invited speaker at emerging technology and finance related conferences and workshops, and has been a contributing editor to various related publications. He has frequently appeared in the news media including AP Newswire, Bloomberg News, Bloomberg TV, CNN, MSNBC, Reuters Television, Reuters Newswire, Nihon Keizai Shimbun, Voice of America, among others. Mr. Ross has served as a Commercial Reviewer for the U.S. National Science Foundation's SBIR (Small Business Innovation Research) funding program for companies commercializing emerging micro and nanotechnologies.

Mr. Ross received a BA in Economics from Rollins College, and a Masters in Finance from Johns Hopkins University and studied as a Research Fellow and Rotary International Japan Ambassadorial Scholar in Japan at Keio University and the University of Tokyo and is fluent in Japanese.

MEMS Sensor Fusion: Applications Stories in Sports Science

Saumitra Sinha Ray, Specialist – Movement Science, Xsens Technologies North America Inc.

Motion capture has evolved rapidly over the years and the use of MEMS technology in this field has provided researchers with significant advantages over alternate technologies. Xsens sensor fusion algorithms allow the use of multiple MEMS sensor signals together to obtain accurate drift free 3D orientation data. Xsens sensor fusion and full body inertial motion capture will be discussed. Application cases demonstrating the use of MEMS sensors with Xsens sensor fusion in sports science research will be discussed. The first example studies 3D joint loading within the lower extremities during snowboarding. Another application uses this technology to study differences between experienced and inexperienced wheelchair users during sport. The last application case demonstrates MEMS sensors and Xsens sensor fusion used for real time tracking of the scapula movement for baseball pitchers.

Biography: Saumitra Sinha Ray, M.S. is a Business Developer with Xsens North America at their US office in Los Angeles. He holds a degree in Industrial Electronics engineering and Master's in Biomedical Engineering, and has 8+ years of experience working with a large variety of medical devices used for research and commercial applications, particularly in the field of rehabilitation engineering. Saumitra has experience in various motion tracking technologies and a variety of MEMS sensors used in medical applications. Saumitra has successfully implemented motion tracking technologies for use in applications including: rehabilitation, ergonomics, biomechanics research and sports science.

The Revolutionary Change in Sports from MEMS and Sensor Enabled Products

David DiPaola is Managing Director for DiPaola Consulting

MEMS and sensors in sports are seeing explosive growth. Enabling factors such as their unobtrusive micro size, reduced cost, accuracy, use of smart algorithms, low power consumption, wireless connectivity, simplified interfaces for data interpretation and mobile computing are making this available to everyone not just elite professional athletes in an expensive laboratory setting. As a result, revolutionary changes are occurring in how we learn, our overall understanding of humans in sports and our resulting behavior enabling us to increase performance and achieve our goals in shorter intervals. In addition, sensors and MEMS products are providing useful data to help engineers make sport protection gear more effective, people lose unwanted pounds and athletes avoid health danger zones. Examples includes arrow mounted ballistic measurement systems, stoke information from tennis rackets and golf clubs, a quarterback's eye movement, vital sign monitoring, head impact intensity, motion of balls and more. This presentation provides an overview of these innovative products and technologies that make them work.

Biography: David DiPaola is Managing Director for DiPaola Consulting a company focused on engineering and management solutions for electromechanical systems, sensors and MEMS products. A 16 year veteran of the field, he has brought many products from concept to production in high volume with outstanding quality. His work in design and process development spans multiple industries including automotive, medical, industrial and consumer electronics. As an authorized external user of the Center for Nanoscale Science and Technology at NIST, David conducts R&D in micro fabrication and FESEM. Furthermore, he also provides management solutions that compliment engineering when technology is not the best answer. Previously he has held engineering management and technical staff positions at Texas Instruments and Sensata Technologies developing sensors and MEMS products. He has authored numerous technical papers, has been featured in prominent journals and holds 5 patents.

MEMS in Sports Applications: A New Era Has Begun

Jay Esfandyari, MEMS Product Marketing Manager, STMicroelectronics

MEMS (Micro-Electro-Mechanical-Systems) is a technology based on silicon micromachining fabrication processes and is used to fabricate a variety of sensors. The key component of a MEMS sensor is a micron-sized mechanical sensing element integrated into a single package together with an advanced ASIC with embedded smart functionalities.

MEMS based sensors surpass other technologies in performance, size, cost, and current consumption. These advantages have enabled the use of MEMS sensors in a large number of applications in sports.

For many applications such as a pedometer, simple motion detection, and tracking, for example, a 3-axis accelerometer has been sufficient. However, for more advanced applications such as concussion detection or human body tracking, a combination of MEMS sensors is required to provide higher performance and faster response time.

This presentation will discuss MEMS sensors such as accelerometers, gyroscopes, magnetometers, and pressure sensors, and the major technical sensor parameters that are required for sports applications. The most popular and emerging applications of these sensors in sports will also be discussed.

Biography: Jay Esfandyari has more than 20 years of industry experience in Semiconductor Technology, Integrated Circuits Fabrication Processes, MEMS development and fabrication, and strategic MEMS market and business development. In the capacity of MEMS Product Marketing Manager at STMicroelectronics, Jay Esfandyari has developed new markets for MEMS products and achieved multi-million dollar business

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opportunities. In his previous roles, Jay worked closely with customers to develop custom MEMS products, developed models to describe the physics of defect generation in silicon wafer during device fabrication processes, created solutions to perform analysis and computer simulation to improve the quality of silicon wafers. Jay Esfandyari holds a master's degree and a Ph.D. in Electrical Engineering from the University of Technology of Vienna, Austria.

SESSION 2

Microtechnologies for Neural Interfaces and Prostheses

Session Leader: Peter Gilgunn, Research Fellow, Institute for Complex Engineered Systems, Carnegie Mellon

This session will focus on microsystem technologies that are impacting the field of neural prostheses. The speakers will highlight present and future opportunities in that field by presenting three applications at different stages of their technological life. The session will cover exciting opportunities and to examine streamlining the commercialization of MEMS-enabled neural prostheses. Topics covered in this session will include a neural prosthetic on the mass market (the cochlear implant) that is being re-engineered using MEMS microfabrication technologies to improve performance, reduce cost and increase clinical deployment, a neural prosthetic in the midst of translation to the mass market that began development during the MEMS boom of the late 1990s and benefited from the engineering and design insights of the MEMS field (Shawn Kelly of Boston Retinal Implant and CMU), and a neural prosthetic in its infancy (the vestibular implant) that is integrating MEMS sensors and microfabricated electrodes in a single implantable system.

Biography: Peter Gilgunn is a research fellow in the Institute for Complex Engineered Systems at Carnegie Mellon University, an inventor, author and budding entrepreneur. He received his PhD in Electrical and Computer Engineering from Carnegie Mellon in May, 2010 for his dissertation on the design and fabrication of electrothermally actuated MEMS micromirror arrays. He is currently working to design and fabricate an ultra-compliant intracortical neural probe embedded in a biodegradable delivery vehicle that has the potential to overcome the chronic inflammatory response associated with Si-based and microwire neural probes.

Restoring the Sixth Sense in 3D: Progress and Challenges in Development of a Multichannel Vestibular Prosthesis

Kristin Hageman, Ph.D. student, Biomedical Engineering, Johns Hopkins Department

The vestibular organs of the inner ear provide essential sensation of head velocity and acceleration to maintain stable vision and posture during head movements. Many individuals with profound bilateral vestibular hypofunction often cannot maintain stable vision even after vestibular rehabilitation. The Johns Hopkins Multichannel Vestibular Prosthesis (MVP) is a semi-implantable device that is stimulating vestibular nerve firing rates to encode rotational head movements in vestibular deficient animals. The current implementation of the MVP follows a semi-implantable approach, similar to cochlear implants: implanted electrodes coupled to an external component including velocity and acceleration sensors, processing circuitry, and the power source. This talk will discuss the progress and challenges in the development of the next-generation MVP as it moves toward a fully implantable, commercialized product.

Biography: Kristin Hageman is a Ph.D. student in the Johns Hopkins Department of Biomedical Engineering. She completed her undergraduate degree in Biomedical Engineering at Case Western Reserve University in 2011. During her time as an undergraduate, Kristin worked at Medtronic, Inc. for an eight-month cooperative education program which ignited her interest in the development of biomedical devices. For her PhD, Kristin joined the Johns Hopkins Vestibular NeuroEngineering Lab of Dr. Charles Della Santina, PhD. MD., where her research is focused on the development of the third generation of the Multichannel Vestibular Prosthesis.

A Thin-Film Cochlear Electrode Arrays for Clinical Use

Angelique Johnson, Ph.D., Founder, MEMStim LLC

Neurostimulator devices for the treatment of neurological diseases and disorders provide an effective treatment when pharmaceutical and surgical treatments are not enough. However, the technology is greatly limited by hand-assembly manufacturing. As such, the electrode arrays cannot be fully miniaturized for low risk surgeries, and are impossible to update with innovative materials and structures, which have been shown to significantly improve the positive outcomes of stimulation therapies. Alternatively, thin-film MEMS arrays can offer higher site densities for increased nerve/neuron specificity, a minimal array size for atraumatic implantation, and the ability to incorporate smart structures for drug delivery, visual feedback, in-vivo neural communication. Harnessing many of these benefits, MEMStim LLC is currently developing a thin-film cochlear electrode array. The array is comprised solely of clinical grade materials; it is robust enough for surgical placement; it is stiff enough for deep insertion into the cochlea; it can contain built-in curvature to position the sites close to the neuronal processes; and it is compatible with surgical insertion techniques. Through the development of a cochlear electrode array, MEMStim is addressing many of the challenges that have, thus far, prevented MEMS microelectrode arrays from achieving clinical use.

Biography: As a Meyerhoff Scholar and member of Tau Beta Pi, in 2005 Dr. Angelique C. Johnson (PhD) received her B.S. and B.A. degrees in Computer Engineering and Mathematics, respectively, from the University of Maryland, Baltimore County. Prior to attaining her PhD at the University of Michigan in 2011, she worked briefly at the Cleveland Clinic, Massachusetts Institute of Technology, and California Institute of Technology on devices and software for neural interfaces. Her PhD dissertation was on "An Active Thin-Film Cochlear Electrode Array with Monolithic Curl and Backing". The work from her dissertation resulted in two patent applications, a feature on the cover of Hearing Research, and a new startup, MEMStim LLC. Dr. Johnson is presently working to build MEMStim LLC into a formidable company with the mission of providing higher performance electrode arrays for the treatment of neurological diseases and disorders.

MEMS Challenges for a Visual Prosthesis for the Blind

Shawn K. Kelly, Ph.D., Electrical/Biomedical engineer and Senior Systems Scientist, Institute for Complex Engineered Systems at Carnegie Mellon University / Research Biomedical Engineer, Department of Veterans Affairs

Several research groups and companies worldwide are working to develop visual prostheses to restore useful

blind. These devices deliver electrical stimulation to nerves in the visual pathway (or sometimes other areas, like the tongue) to create the representation of pixelated images.

The Boston Retinal Implant Project is developing and testing a chronically-implantable subretinal visual prosthesis that will stimulate retinal nerves of patients blinded by retinitis pigmentosa and macular degeneration. This talk will cover the early design decisions for the retinal implant, especially those relating to our MEMS electrodes, as well as current MEMS designs and future electrode and packaging challenges.

Biography: Dr. Shawn K. Kelly is an electrical/biomedical engineer and Senior Systems Scientist in the Institute for Complex Engineered Systems at Carnegie Mellon University, as well as a Research Biomedical Engineer with the Department of Veterans Affairs. He is developing a retinal prosthesis for the blind, as well as other implantable neurostimulation medical devices. He received the S.B., M.Eng., and Ph.D. in electrical engineering from the Massachusetts Institute of Technology in 1996, 1998, and 2003, respectively. He joined the Boston Retinal Implant Project in 1996 and designs circuits for stimulation and wireless power and data telemetry.

SESSION 3

Micro and Meso Technologies for Diagnosis

Session leader: Gregory J. Galvin, Ph.D., Chairman and CEO, Rheonix, Inc.

Microfluidics – the use of microscale structures to manipulate micro- and nanoliter volumes of fluids – has been an active topic of research for decades. One of applications most expected to benefit from microfluidics is diagnostics. Microfluidic technologies offer the potential of replacing an entire laboratory with a handheld device. This session will explore the current state of microfluidics and examples of how the long envisioned potential of these technologies are being realized in commercial products. Along the way we will find that microfluidics in the end is not so micro after all.

Biography: Dr. Greg Galvin is President and CEO of Kionix, a wholly owned subsidiary of ROHM Co., Ltd. and one of the world's top three suppliers of micro-electromechanical (MEMS) inertial sensors. He is also Chairman and CEO of Rheonix, Inc., a company developing microfluidic-based molecular diagnostic systems. Dr. Galvin was elected to the Cornell University Board of Trustees in 2011; he also serves on the Advisory Council of Cornell's College of Engineering. He has a B.S. in Electrical Engineering from the California Institute of Technology, a Ph.D. in Materials Science and an M.B.A. from Cornell University.

Big answers from small structures

Richard Montagna, Ph.D., Senior Vice President for Corporate Business Development and Scientific Affairs, Rheonix, Inc.

The growing wealth of genetic information provides a means to more effectively deliver healthcare. With both industry and the FDA moving away from a "one size fits all" approach to drug delivery toward a more personalized one, this paradigm shift will be further accelerated as more effective, less costly and easier methods are developed to acquire and report genetic information. Such information can be used to predict if a patient will be responsive to a particular drug and, if so, at what dosage? Microfluidic technologies, coupled with automation, are playing an important role in this paradigm shift by dramatically simplifying what would otherwise be very complex and sophisticated assays to perform. Data will be presented to describe a fully automated, unattended microfluidic molecular diagnostic platform that meets the technical challenges of personalized medicine. The value of this technology will also be discussed with respect to the challenges of gaining reimbursement.

Bio: Dr. Montagna serves as Senior Vice President for Corporate Business Development and Scientific Affairs for Rheonix, Inc. and was President of Innovative Biotechnologies International, Inc. prior to its acquisition by Rheonix in 2008. Earlier, he served as Director of Biological Operations of Associated Biomedic Systems and President of Cellular Products, both of Buffalo, NY. With over 30 years of corporate administrative and scientific development experience, he has led the commercialization of over 40 biotechnology products, including multiple FDA-approved human biologics and in vitro diagnostics. He has considerable experience in the design and performance of nationwide clinical studies, as well as the preparation of FDA regulatory submissions. He has also presented data to multiple FDA Advisory Committees in support of those submissions.

In 1988 he testified before President Reagan's Presidential AIDS commission, providing data in support of a recommendation that the U.S. initiate mandatory screening of its donated blood supply for the presence of antibodies to HTLV-1. Nationwide testing was initiated shortly thereafter. In 2008, he was also nominated for the National Research Initiative Discovery Award for developing a MEMS biosensor for the direct detection of prions in serum specimens. During the recent past, Dr. Montagna has also been an invited speaker at multiple international meetings.

Dr. Montagna earned a Ph.D. in Molecular Biology from the University of Buffalo and served postdoctoral fellowships at NYU Medical Center as an NIH Fellow in Experimental Pathology and at the University of Texas System Cancer Center, M.D. Anderson Hospital and Tumor Institute, in the area of chemical carcinogenesis. Dr. Montagna has published 40 scientific papers in molecular biology and holds a number of patents in the biosensor area. He also holds an Adjunct Professorship at Cornell University in the Department of Biological Environmental Engineering and has won over \$5.5 Million of grant funding as Principal Investigator.

Closing the Window on HIV Detection Using Microfluids

R Sam Niedbala, Dept of Chemistry, Lehigh University

The detection of HIV is challenged by the progression of the infection. The initial stages may include a latent period followed by rapid viral replication and later an ineffective immune response. Although the immune response is unable to fight the infection, the antibodies generated are useful in developing a diagnostic test to identify the presence/absence of the HIV infection. Once antibodies appear the virus will for a time subside. The timeline for this progression from viral replication to immune response can be weeks or months. Therefore an effective diagnostic test would ideally identify both markers in a single analysis thereby closing the window of detection. Our laboratory has worked to develop such a test in a microfluidic platform using blood and oral fluids. This seminar will present the challenges faced and potential solutions. Such approaches may be applicable to other analytes as microfluidic technology begins to provide a platform for complicated analysis in a

point of care location.

Biography: Dr. Sam Niedbala is on the Faculty of Lehigh University's Chemistry Department. His laboratory continues to work in the areas of HIV and Tuberculosis detection. Dr. Niedbala is the former CSO and a founder of OraSure Technologies. OraSure developed the first FDA approved rapid HIV test that uses both blood and oral fluids. Dr. Niedbala has over 60 publications in the field of diagnostics.

Integrated Fluidic Strategies in Food Safety Testing

Dan Kephart, PhD, Director of R&D, Life Technologies

The human microbiome is composed of around 10,000 species of commensal bacteria, yeast, and other microorganisms that colonize external and internal niches within the human body. While normal flora are critical for maintaining human health, each year approximately 1 in 6 Americans are affected by pathogenic microbes that lead to foodborne-related illness. Producers want to screen for pathogens in their raw and processed materials to ensure the safety and quality of their food products and make high stakes product release decisions as quickly as possible. However, the testing of food matrices is complex due to their composition and complexity of associated flora. We are addressing this need by automating the entire molecular testing workflow using a fluidic CARD™ approach that has a number of advantageous features. Our research into customer needs will be presented along with the constraints and processes that were used to formulate a product concept. Results from real-life testing of food samples and our lessons learned will be presented.

Biography: Dan Kephart, PhD is the Director of research and development for animal health and food safety testing at Life Technologies. He holds a degree in biochemistry and the biotechnology development field for 20 years, where he has launched over 100 reagent and instrumentation products for nucleic acid isolation, human diagnostic testing, human identification, and animal and food testing. Previous to Life Technologies he led global scientific applications development at Promega Corporation. Dan works closely with customers to uncover inspirational unmet needs, develop product concepts, and deliver commercial and custom solutions. His international team is currently investigating novel methods for analyzing animal and food samples. He is the author of numerous publications and holds 11 patents related to molecular analysis of genetic material.

SESSION 4

Microtechnologies for Health Monitoring

Matt Apanius, Director, The Richard Desich SMART Commercialization Center for Microsystems, Lorain County Community College

There is huge growth potential for MEMS and sensor devices that enable products for monitoring human health. With the "commoditization" of MEMS in the consumer electronics arena, the opportunities for microtechnologies applications for health monitoring seem to be endless as the potential for low cost devices can drive down the soaring costs of healthcare. This session will provide insights to the regulatory environment for new products in established markets, a commercialization pathway for new disruptive technologies, and glimpses of the commercial and technical challenges associated with products that hope to leverage the performance and economic gains of miniaturization.

Biography: Matthew Apanius is the Director of the Richard Desich SMART Commercialization Center for Microsystems at Lorain County Community College. He has commercial MEMS product development experience working with applications that include telecommunications, aerospace, automotive, industrial controls, hand-held displays, biomedical devices, and life science. His work with academic and government research projects include state-change physics in microgravity, anisotropic thermal behavior of nanomaterials, and nanomechanical structures for switches and acoustic wave devices. With over a decade of experiences committed to understanding and defining unique MEMS requirements, Matthew developed the concept for a national center focused on commercializing these technologies – the SMART Commercialization Center for Microsystems. Prior to joining the SMART Center at Lorain County Community College, Matthew was the President of Microfabrication Solutions, Inc., a successful MEMS prototyping company located in Cleveland, Ohio since 2002. During 2000-2002, Matthew was a MEMS Process Engineer at Goodrich-Advanced MicroMachines where he led a technical team developing a MEMS-based optical switch.

Micropillars and Microfluidic Channels for Liquid Crystal-Based Gas Sensors

Bharat R. Acharya, Ph.D., Platypus Technologies LLC, Madison, Wisconsin USA

Sensors based on various existing technologies have suboptimal performance in the sense that they lack the sensitivity and selectivity required for practical applications and are prone to potential interference from environmental fluctuations. Performance specifications of liquid crystals (LC)-based gas sensors comprising a thin film of nematic LC supported on chemically functionalized substrates with polymer micropillars/microchannels are reported. By engineering surfaces with specific chemical functional groups at the interface and designing microfluidic channels to allow controlled diffusion of the target analytes above the LC film, the sensors based on these microstructures have been demonstrated to detect various gases with sensitivities relevant in industrial hygiene, environmental monitoring, and biomedical applications. The MEMS based technologies has potential of solved related to fabrication of these microstructures to enable commercialization of the LC-based sensing technology in these markets.

Biography: Bharat R. Acharya received his doctoral degree in Physics in 2001 from Kent State University, Kent OH, in liquid crystal (LC) alignment on polymer surfaces used for LC displays. After his graduate work, Dr. Acharya joined Bell Laboratories in Murray Hill, NJ, as a NSF-GOALI post-doctoral fellow. While at Bell Labs, he developed LC-based devices for telecommunication applications. He then joined Platypus Technologies LLC, as a Research Scientist to develop LC-based chemical and biological sensors. Currently, Acharya is the Director of Sensor Development leading an interdisciplinary group of scientists and engineers pursuing development of biological and chemical sensors that exploit the unusual behavior of LCs in contact with different interfaces.

BioMEMS in Continuous Glucose Monitoring

Disha B. Sheth, Ph.D. and Irada Isayeva, Ph.D., Office of Science and Engineering Laboratories, Center for

Devices and Radiological Health, Food and Drug Administration

The incidence of diabetes is increasing, with approximately 25 million with diabetes in the USA today compared to 0.5 million in 1958. In spite of > \$170 bln/year spent, diabetes and its complications are the 7th leading cause of death. Studies have shown that a tight glycemic control is critically important in successful diabetes management and prevention of diabetes-related complications. One tool to help manage diabetes is a continuous glucose monitor (CGM). These devices measure glucose levels in subcutaneous tissue with an implantable enzymatic electrochemical sensor, and have an implantation life of 3 to 7 days. Biological responses and technological limitations (e.g., potential interferences) limit the use of these devices for longer term and artificial pancreas usage. BioMEMS approaches to miniaturized sensors, including measurement redundancies and novel fabrication techniques, are important technologies that could be used for developing novel accurate sensors and artificial pancreas devices.

Biography: Disha Sheth is a Staff Postdoctoral Fellow at the U.S. Food and Drug Administration. She has a PhD in Biomedical Engineering from Case Western Reserve University, specializing in sensors and instrumentation. She worked at SMART Microsystems as a BioMEMS Engineer prior to joining FDA. Her specialties include MEMS - clean room microfabrication, Biosensors, Electrochemical - amperometric and potentiometric sensors and Optical.

Nanowire biosensors –when size matters, big promises and little impact

Nima Jokilaakso, Proactive Researcher, Molecular Biotechnology, Royal Institute of Technology (KTH), Sweden

Scientists are driven by goals and goals are built on ideas, such as understanding how things are connected on a system level or searching for the smallest elements, atoms to get the pieces of the puzzle at hands. Miniaturization is not a new idea but we have in the last few decades in the field of miniaturization made science fiction to reality and modern man could hardly explain how most of his everyday tools function. Biomedical MEMS and Sensors have the potential to revolutionize healthcare in the same way as the internet and smartphones have for communications but so far the successes are few. Nanowire biosensors, nanometer-thin wires composed of silicon used as Field Effect Transistors that can be functionalized for selective capture and sensing of disease biomarkers are examples of inventions that still have not reached commercial success. This talk will focus on key issues such as technological risk, market risk and business risk and how to facilitate failures into success.

Biography: Nima Jokilaakso is a proactive researcher in Molecular Biotechnology at the Royal Institute of Technology (KTH), Sweden. Nima is currently working on developing a silicon nanowire biosensor for the healthcare setting by combining the advances made in MEMS industry with the needs in the Life Science market. Nima believes in open source innovation and the ability to transform our world to the better with applied science and has initiated two projects for mobile healthcare and has worked previously in the biotech industry. Nima has during his undertakings met other entrepreneurial scientists, healthcare professionals and providers, SME and Big Pharma representatives, Technology Transfer Officers, Patent Attorneys and Venture Capitalists in order to understand stakeholder perspectives and the value chain. Nima is now devoted to spreading ideas by networking and sharing expertise to catalyze the innovation process.

SESSION 5

MEMS and Microfluidics for Drug Delivery

Ellis Meng, Associate Professor of Biomedical and Electrical Engineering, Viterbi School of Engineering, University of Southern California

Drug delivery technologies have evolved since ancient Egyptian times from simple pills to the intravenous infusion devices to the recently approved “digital medicines” consisting of pills with integrated ingestible microelectronic sensors. This long history of innovations in delivery of medicines is spurred by the need for efficient and effective drug management of health conditions. Recent advances over past few decades in drug delivery and infusions harness both MEMS and microfluidics technologies. This timely panel focuses on the use of such novel technologies as reviewed by leading experts and covers the current status of development of different drug delivery strategies. These recent advances seek to achieve maximal efficacy of drug therapy to meet the requirements of various clinical needs.

Biography: Ellis Meng is an Associate Professor of biomedical and electrical engineering at the Viterbi School of Engineering of the University of Southern California. She completed her graduate work in electrical engineering at the California Institute of Technology in 2003. Dr. Meng directs the Biomedical Microsystems Laboratory which specializes in focuses on advancing biocompatible poly technology and micromachining, sensors and actuators, microfluidics, implantable MEMS and bioMEMS. She is a recipient of the National Science Foundation CAREER and Wallace H. Coulter Foundation Early Career Awards. Ellis was recognized as a 2009 TR35 Young Innovator Under 35 for her work in next generation drug delivery pumps. She also an active educator and authored a textbook on bioMEMS. Her professional memberships include Tau Beta Pi, IEEE, ASME, ASEE, and BMES.

Curved and folded Bio-MEMS for drug delivery and surgery

David Gracias, Associate Professor of Chemical and Biomolecular Engineering, Johns Hopkins University

The human body is three dimensional and structured from the nano to the macroscale. Hence, there is a pressing need for the development of tiny 3D devices that can access nano to microscale conduits, deliver therapeutics selectively and on-demand, retrieve biologic samples, and perform less invasive surgical procedures. In addition, to fulfill the promise of regenerative medicine and live-cell therapeutics, there is a need to develop synthetic poly ly curved, folded and vascularized geometries observed in native tissues. In this talk, I will describe self-assembly strategies that leverage the precision of planar lithographic patterning techniques allowing the creation of precisely patterned curved and folded devices for biomedical applications. These include multifunctional capsules, curved microfluidic scaffolds, reconfigurable stimuli-responsive devices and miniaturized mimics of macro surgical tools such as grippers or drillers. I will also discuss results of the first ever biopsy in a live animal using sub-millimeter scale, untethered surgical grippers.

Biography: Prof. David Gracias is an Associate Professor of Chemical and Biomolecular Engineering at the Johns Hopkins University (JHU). He has additional appointments in the Department of Chemistry and the Institute for Nanobiotechnology at JHU. Prof. Gracias received his Ph.D. from the University of California at Berkeley, did his post-doctoral research at Harvard University and worked at Intel Corporation prior to starting his independent laboratory at JHU in 2003.

Dr. Gracias' research has resulted in 137 scientific articles, including 88 in research journals and 22 issued patents. His research has been published or highlighted in prominent academic journals such as Science, Nature Communications, Nature Nanotechnology, Nature Photonics, Nature Physics, Nature Chemistry, PNAS and press portals such as the Wall Street Journal, the New York Times, Forbes and Discover Magazine. His notable awards include the NIH Director's New Innovator Award, NSF Career Award, Beckman Young Investigator Award, Camille Dreyfus Teacher Scholar Award, Maryland Academy of Sciences Outstanding Young Engineer Award and the DuPont Young Professor Award.

Smart MEMS micropumps for infusion and injection medical devices

Laurent Montes, Associate Professor, IMEP-Lahc Minatec / Grenoble INP, France

MEMS micropumps for infusion and injection medical devices have been developed, but also for biological microfluidics (lab-on-chip). While most actual micropumps use piezoelectric based actuators, we present an original approach based on bimetallic effect used for large deflection of a flexible silicon membrane. Analytical and numerical models have been used to simulate and optimize the performance of the actuated diaphragm. It predicts the deflection behavior under definite power actuation and pressure. The technological process is fully IC compatible. A specific test bench has been developed for wafer level characterization, showing very large membrane displacements (~80µm). This presentation will also introduce an original method for rapid prototyping, especially for making plug-and-flow microfluidic channels. The micropumps include several fully integrated temperature, pressure and flow sensors. Such sensors allow for a very precise measurement and control of the micropump parameters, such as ultra-precise dose delivery and smart functioning by retroaction control.

Bio: Laurent Montès received the M.S. degree in electrical engineering and the Ph.D. in micro and nanoelectronics from the Université Joseph Fourier de Grenoble in 1995 and in 1999 respectively. In 2000, he was a postdoctoral fellow at the University of Rochester, NY-USA, in the group of Prof. P.M. Fauchet and L. Tsybeskov. In 2001 he became an Assistant Professor at INP-Grenoble, where he became an Associate Professor in 2002. Since 2004, he is director of the International Summer School on Advanced Microelectronics (MIGAS) and Research Program Officer of MicroNanoTechnologies development at Minatec/INP-Grenoble.

His research interests at the Institute of Microelectronics, Electromagnetism and Photonics (IMEP-LAHC) / Minatec-Grenoble, where he is team leader of the group 'Nanostructures and NEMS', include advanced microelectronic devices, nanotechnologies, nanosilicon memories, nanowire devices and micro-nano-systems (MEMS/NEMS). He is also scientific advisor of EVEON, a startup developing MEMS for medical devices. He has advised or is advising more than 10 PhD thesis (some with strong industrial partnership), and is author or co-author of more than 60 journal or conference peer-reviewed papers.

Affinity-Based Drug Delivery

Horst von Recum, Associate Professor of Biomedical Engineering at Case Western Reserve University

While many research groups have explored the use of polymers for the controlled release of therapeutic agents, this release is typically primarily dependent on diffusion, and thus scales poorly with extremely thin coatings such as on microfabricated devices. Our research group has been exploring the use of molecular interactions between drug and polymer to be substantially longer and more linear than that capable by diffusion-based drug delivery, attaining delivery from essentially molecularly-thin coatings. In our research novel materials made from poly(ethylene glycol) and dextran were fabricated and explored for the controlled release of small molecule drugs. This presentation will include recent work on the antibiotic presentation and delivery platform. Similar results have been translated to antimicrobial delivery in orthopedic devices, wound dressings, and other biomedical applications. Additionally this platform has been extended to the delivery of therapeutics toward cancer, HIV, and ophthalmological applications.

Biography: Horst von Recum is an Associate Professor of Biomedical Engineering at Case Western Reserve University where he has been since 2004. He began his career in Chemical Engineering and Biochemistry at Rice University, obtained a PhD in Bioengineering at the University of Utah, and was a postdoctoral fellow both at MIT (where he worked on drug delivery microchips in the laboratory of Bob Langer), and at the University of Washington. His research interests are in polymers for biomedical applications. He holds one of the top cited references in electrospinning for tissue engineering and drug delivery. A current focus of his lab is the use of intentional molecular interactions between drug and device to control the rate of release beyond that capable of diffusion alone. Termed "affinity-based" drug delivery, Dr. von Recum has applied this toward uses in device infections, cancer therapy, cardiovascular disease, HIV, and ophthalmological applications.

BioMEMS for Transdermal Drug Delivery

Babak Ziaie, Professor, School of Electrical and Computer Engineering, Birck Nanotechnology Center Purdue University

Low cost microdevices for transdermal and subcutaneous drug delivery is slated to have a major impact on next generation devices for administration of biopharmaceuticals and other emerging new formulations. These devices range in complexity from simple microneedle arrays to more complicated systems incorporating micropumps, micro-reservoirs, on-board sensors, and electronic intelligence. In this presentation, devices currently in the market and those in the earlier stages of research and development will be reviewed. Also presented will be several examples of research in the laboratory towards using phase change liquids and microorganisms in polymer-based low-cost disposable transdermal micropumps.

Biography: Babak Ziaie received his doctoral degree in Electrical Engineering from the University of Michigan in 1994. From 1995-1999 he was a postdoctoral-fellow and an assistant research scientist at the Center for Integrated Microsystems (CIMS) of the University of Michigan. He subsequently joined the Electrical and Computer Engineering Department of the University of Minnesota as an assistant professor (1999-2004). Since

Jan 2005, he has been with the School of Electrical and Computer Engineering at Purdue University where he is currently a professor. His research interests are related to the biomedical applications of MEMS and Microsystems (BioMEMS).

Panel -- Today's technology race: Win, place, or show?

Moderator: Colin K. Drummond, Director of the Coulter-Case Translational Research Partnership (CCTRP), Department of Biomedical Engineering, Case Western Reserve University

Biomedical sensors are part of a rapidly growing and ever-changing commercial sensor market, where the new sensor applications offer the hope for improved patient care. Technological developments with the promise as a "game changer" must be weighed against the pragmatic need for technology "good enough" today, in today's investment climate. It can seem like a horse-race: Could a "disruptive innovation" be the long-shot winner that stands out in field with an edge over the competition? Will patent law changes stemming from the America Invents Act foster a more conservative taste for "second place" technologies? Or will only the proven technologies that are long-standing members of "show" be the real winners in today's race? Our distinguished panel of investors and advisors have "been there and done that" and will be part of a stimulating discussion on technology today.

Moderator bio:

Colin K. Drummond is the Director of the Coulter-Case Translational Research Partnership (CCTRP) in the Department of Biomedical Engineering at CWRU. He received his Ph.D. degree in Mechanical Engineering from Syracuse University in 1985 and an MBA in Technology Management from the Weatherhead School of Management in 1997. For over two decades Colin has worked in the application of science and technology to the creation of products and services and in the past 8 years has been a co-founder of two medical device start-up companies. Dr. Drummond holds an appointment in the Masters of Engineering and Management program, teaching several courses in the area of entrepreneurship, finance, and information technology.

Panelist bios:

Mike Bunker

Managing Director, Early Stage Partners, Life Sciences

Mike has many areas of expertise but has recently focused a lot of time on the treatment of stroke and on catheter-related technologies, particularly those that reduce the incidence of nosocomial infection. Among Mike's investments are Juventas Therapeutics, CardioX, Histosonics, Great Lakes Pharmaceuticals, and CytoPherx. Prior to joining Early Stage Partners as Managing Director in 2008, Mike held roles in sales management and corporate acquisitions for C.R. Bard Access Systems (NYSE: BCR). As Director of Corporate Development, he created the process to evaluate medical technology investments for Bard's six centralized divisions and successfully executed 14 acquisitions, licenses, and divestitures. Later, Mike managed a field sales force and negotiated multiple contracts with hospitals.

Grant McGimpsey, Ph.D.

Vice President for Research and Sponsored Programs, Kent State University

Grant McGimpsey is Vice President for Research at Kent State University. Prior to his current role, he spent 22 years as Professor of Chemistry at Worcester Polytechnic Institute (WPI) in Massachusetts. Throughout his tenure at WPI he also served as Associate Provost for Research and Director of the WPI Bioengineering Institute. In 2009 he was also appointed Professor of Biomedical Engineering. His research interests include surface chemistry and sensors. He has published over 80 journal articles and holds 7 patents. In 2005 he founded Active Surface Technologies Inc. (ASTI) to commercialize sensor and surface technologies. In January 2012, ASTI became AT Biosciences Inc.

Wayne Hawthorne

Senior Licensing Manager, Case Western Reserve University/Technology Transfer Office

Wayne is a Senior Licensing Manager and facilitates the commercialization of technologies and discoveries from the Biomedical Engineering Department in the Case School of Engineering, and is the Office's liaison with the Coulter Translational Research Partnership. Current projects range from neurological blocking/stimulating to tissue engineering to medical imaging to radiation therapy technologies. Wayne has over 10 years of experience in technology commercialization and 30 year of total experience in medical devices and instrumentation, as well as information technologies. Mr. Hawthorne has taken a "hands on" approach, working directly with researchers, clinicians, engineers and other technicians over his career.

Raymond F. Vennare

Principal, Venture Entrepreneur Group

Raymond F. Vennare is an accomplished founder, senior executive and venture entrepreneur with more than two decades of hands-on experience creating, launching and building biotechnology and information technology companies across diverse markets. Acting on behalf of inventors, investors, research institutions and C-level executives, Raymond plays a key role in sourcing, assessing and cultivating novel discovery and emerging technologies around which companies can be formed, product pipeline developed or deal flow advanced.

CALL FOR SPEAKERS

If you'd like to participate as a speaker, please call Dr. Mike Pinelis at 734.277.3599 or send a brief email with your proposed presentation topic to mike@memsjournal.com. All speakers will receive a complimentary pass to the conference.

Conference scope includes topics related to BioMEMS and sensors such as:

- Fabrication process design and modeling
- Device modeling and simulation
- Fabrication technologies

- Materials and material processing
- Testing including test equipment and methods
- Interface and calibration circuits
- Devices with substantially improved performance
- System integration and end use applications
- Component and wafer-level packaging technologies
- Reliability testing and methods
- Non-electronic interfaces
- Environmental effects and compensation methods
- Diagnostics
- Health screening
- Individualized treatment
- Drug delivery system
- Tissue engineering
- Organ prosthesis
- R&D tools
- Surgery and minimally invasive procedures

SPEAKERS

Many thanks to our BioMEMS 2012 speakers (listed below).

Complex molecular diagnostics made easy and practical through MEMS

Gregory J. Galvin, Ph.D.
Chairman and CEO
Rheonix, Inc.

Polymer microfluidic technology has enabled the development of fully automated tools capable of carrying out very complex molecular diagnostics. Complete processing from the introduction of a raw sample to final result is achieved on a disposable microfluidic "chip" or "card." Moreover, the economics of this technology allows for test pricing well below that of conventional bench top molecular diagnostics. Although long promised and expected, MEMS is now delivering on its potential for medical diagnostics. Several companies have, or will soon have, products in this market. Adoption and growth are expected to be rapid and merger and acquisition activity is brisk.

Biography: Dr. Gregory J. Galvin pioneered a novel micromechanical technology by researchers at Cornell University. From 1993 to 2000, Kionix grew from its two founders to over 40 employees and developed products in inertial sensors, microfluidics, data storage, micro-relays, and micro-optics. Late in 2000, Kionix was acquired for its optical switching technology by Calient Networks of San Jose, CA and renamed Calient Optical Components. Just prior to the acquisition, a new company was spun out to the then Kionix shareholders to pursue inertial sensor, microfluidics, and data storage markets. This company regained the Kionix name post acquisition. From the acquisition until June 2002, Dr. Galvin served as President and CEO of Calient Optical Components and on the boards of both Calient Networks and the new Kionix. In July 2002, he returned full time to Kionix as President and CEO and advanced the Company to its 2009 acquisition as a wholly owned subsidiary by ROHM Co., Ltd. of Japan. In addition to continuing service as Kionix's President and CEO, Dr. Galvin also serves as CEO and Chairman of Rheonix, Inc., a corporate entity established in December 2008 to commercialize a unique polymer microfluidic technology developed by Kionix scientists.

Dr. Galvin received his S.M. from the California Institute of Technology in Electrical Engineering and a Ph.D. in Materials Science and M.B.A. from Cornell University. Dr. Galvin worked at the Cornell Nanofabrication Facility (CNF) in which the Cornell micromechanical research was conducted. Prior to founding Kionix, he was employed by Cornell University as Director of Corporate Research Relations, focusing on transferring technology from the university to industry. Dr. Galvin's graduate research was in the areas of thermodynamics of silicon under ultrafast melting, ion beam analysis, and thin film technologies. He is a member of several scientific societies, has published over 20 technical papers, and holds 58 patents. Dr. Galvin is a founding member, and former chairman, of the Finger Lakes Entrepreneurs Forum. On July 1, he will begin a four-year term on the Cornell University Board of Trustees. He is a member of the Cornell University Council, Advisory Council of the Cornell Engineering College, and serves as a Director of the Boyce Thompson Institute for Plant Research, Tompkins County Area Development, Inc., the Kensa Group, the El Portal de Belin Foundation, and Ithaca's Sciencenter. In June 2010, Dr. Galvin was named a winner of the Ernst & Young Entrepreneur Of The Year® award. A leading authority on MEMS product innovation, Dr. Galvin is frequently invited to speak at meetings and conferences in the United States, Europe, and Asia.

Mind over MEMS: how MEMS technology is coming to a neuron near you!

Peter Gilgunn, Ph.D.
Microsystems Research Fellow
The Institute for Complex Engineered Systems

In our technological society, people rely on the cognitive extension provided by technologies like smart phones and other wirelessly connected computing devices. The trend is decisively toward greater and more intimate integration with our technology and naturalistic interaction with it – for example, consider the impact of Siri on iPhone4. Research on neural and other tissue interfaces promises to bridge the final gap between us and our technology and by doing so enable applications in physical, cognitive and sensory enhancement. MEMS design, fabrication and assembly techniques are key to realizing the robust, high channel-count neural interfaces

necessary to make this connection stable and reliable over decades-long service periods. This talk will present the current state-of-the-art in commercial neural interfaces and identify application areas that will become accessible as the current generation of neural interfaces are cycled out of the research community and into the commercial health and consumer environment.

Biography: Peter Gilgunn is a research fellow in the Institute for Complex Engineered Systems at Carnegie Mellon University, an inventor, author and budding entrepreneur. He received his PhD in Electrical and Computer Engineering from Carnegie Mellon in May, 2010 for his dissertation on the design and fabrication of electrothermally actuated MEMS micromirror arrays. He is currently working to design and fabricate an ultra-compliant intracortical neural probe embedded in a biodegradable delivery vehicle that has the potential to overcome the chronic inflammatory response associated with Si-based and microwire neural probes.

MEMS and nano hybrid systems for topical and transdermal delivery of drugs

Nena Golubovic, Ph.D.

President

Agigma, Inc.

Delivery of drugs and active compounds to and through the skin has gained increasing attention in recent years in both therapeutic and skin care market segments. Many innovative delivery systems incorporating micro or nanostructures are being used today. The major benefits from using novel skin delivery systems are: (1) improved efficiency of transfer of drugs, (2) optimal use of high cost drugs, (3) improved stabilization of drugs, (4) minimization of any skin irritation associated with drugs, (5) improved ease of product application and removal and (6) improved visible appearance and esthetic quality of the skin after the product is applied.

In addition to major topical and transdermal delivery technologies available today, there is a need for "hybrid" delivery systems that effectively protect active compounds in a matrix until the matrix is rapidly disrupted in order to release its payload directly onto the skin surface. Advanced therapies and treatments are often based on bioactive compounds that are potentially at risk for loss of activity in environments that involve exposure to air and room temperature. Fortunately, strategies are becoming available to protect these molecules from damage from the elements by shielding them in polymeric nanomatrices that are fully biocompatible and can be very rapidly disrupted in order to release the drugs directly onto the skin surface. The protection provided by such nanomatrices has a second potential advantage: bioactive agents may be formed in situ on the skin surface by packaging the components that generate the active species in separate nanomatrices. Disruption of the matrices upon application to the skin allows the components to combine and react to produce the desired products without any potential loss of biological activity. Additionally

livery systems have extremely high loading capacity and they show potential to enable fully integrated monitoring and control delivery solutions for the most effective outcome of selected therapies.

Biography: Dr. Nena Golubovic has 15 years of global technical and business leadership experience in developing MEMS from concept to market, including MEMS and nanotechnology product design, semiconductor process R&D and manufacturing, silicon wafer fabrication, integration, packaging and testing. Nena actively participated in development of commercial MEMS pressure sensors for automotive applications and MEMS acoustic devices. Nena pioneered bulk silicon microneedle technology and implemented range of standardized process modules for high throughput, low cost manufacturing of MEMS devices. Over the last decade Nena has led development and commercialization of innovative MEMS and nanotechnologies for medical device and drug delivery business segments.

Cells in action: measuring cellular motility in health and disease

Daniel Irimia, M.D., Ph.D.

Assistant Professor in Surgery and Bioengineering

Harvard Medical School

All cells in our body have the ability to move, and their motility is rarely random. Most often, cells follow directional cues in the form of biochemical and mechanical stimuli, to participate in critical processes during health and disease conditions. To better understand the role of cell motility in situations like trauma or cancer, we are designing microfluidic tools to measure the directionality and speed characteristics of moving inflammatory and epithelial cells with unprecedented precision. Using such tools, we were able, for example, to define a set of "normal values" for directional decisions and speed in neutrophils from healthy people. In patients with burn injuries, we measured transient alterations of neutrophil motility, favoring infections and other complications. In pancreatic cancer patients, we uncovered some surprising abilities of the cancer cells to efficiently navigate complex microenvironments and respond to conditions of mechanical and chemical confinement. Ultimately, our engineered tools and the unexpected findings enabled by them could lead to new therapeutic approaches for conditions that span from acute to chronic inflammation, and from cancer to regeneration.

Biography: Dr. Irimia was educated as a physician in Iasi, Romania and received a Ph.D. in Bioengineering from the University of Illinois at Chicago where he pioneered the use of microfabricated devices for research in the fields of cryopreservation and cryosurgery. He is currently an Assistant Professor in the Department of Surgery at the Massachusetts General Hospital and Harvard Medical School, and Senior Investigator at the Boston Shriners Burns Hospital for Children. Dr. Irimia is a leader in designing novel microfluidic tools for the quantitative studies of cell migration and the integration of engineering principles into biological research and medical diagnostic.

Advances in tip based lithography for BioMEMS applications

Saju Nettikadan, Ph.D.

Director of Application Development

NanoInk Inc.

The last couple of decades have witnessed an explosion of interest in miniaturization technologies for life science applications. Reducing domain sizes has distinct advantages in several bioscience arenas. In the field of protein detection, smaller feature sizes will have the benefit of drastically reduced sample size requirements, potentially higher detection sensitivity, reduced assay time, and better compatibility with lab-on-a-chip technologies. In addition, construction of sub-cellular scaled features of biological and biocompatible materials

enables the interrogation of cellular processes at single cell levels. The advantages of miniaturization have already been realized in genomic analysis and to a certain extent in proteomics.

Dip Pen Nanolithography® (DPN®) is one of the techniques that have been recently developed for miniaturization of biomolecular assays. The advantages of this novel technique for biomolecular printing include precise placement of a wide range of materials at defined locations, working at ambient conditions and the ability to maintain the biomolecules in a hydrated state. This enables the functionalization of prefabricated microstructures including MEMS based sensing elements and microfluidic devices.

Biography: Dr. Nettikadan received his doctoral degree in 1998 from The Ohio State University in medical biochemistry. Upon graduation, he joined Bioforce Nanosciences, where his research activities were focused on the development of miniaturized biomolecular assays. Dr. Nettikadan was involved in the initial design, prototype and early testing of the Nano eNabler (BioForce's flagship product). He was responsible for directing the development of novel applications using the Nano eNabler, a desktop instrument for fabrication of miniaturized protein arrays. He joined NanoInk in 2009 as the director of application development and since then has been developing applications for tip based lithography techniques. He has authored over 20 peer-reviewed publications and filed over 8 patent applications.

MEMS sensors for healthcare, medical and sports applications

Louis Ross

President & CEO

Virtus Advanced Sensors

An overview of existing and new potential applications for MEMS technology in the life science (healthcare, medical device) area will be discussed. An emphasis will be placed on dealing with the pressing issue of health care reform and the need to reduce costs as the business model for hospitals and health care providers evolve. The rise of industry and knowledge clusters for medtech in Asia will also be reviewed, including recent government initiatives.

Biography: Louis Ross is the CEO of Virtus Advanced Sensors, Inc., a developer of next-generation MEMS inertial sensor technology and related applications, including in the healthcare, medical and sports performance industries. His background includes nearly 20 years of working in the microtechnology/MEMS/nanotechnology fields in various capacities including think tank researcher, investment banking strategist/analyst, and advisor to Fortune 500 companies, start-ups and government agencies. Mr. Ross obtained a Masters (Finance) from John Hopkins University, a BA (Economics) from Rollins College and was a visiting Research Fellow at Keio University and the University of Tokyo in Japan. He is fluent in Japanese, has a working knowledge of Mandarin and has worked in Asia for 18 years.

Overview of micropump technologies and applications

Paul Rubel

VP of Product Development

Innovative Micro Technology

The life science industry is experiencing a wave where technology targeted at improving patient healthcare and comfort is occurring at break-neck pace. This is a result of scientists and engineers conceiving new ideas and developing products that were not possible even several years ago.

Micropump devices represent a key component in MEMS microfluidics and the technology is helping revolutionize the medical industry by enabling enterprising companies to make quantum leap advances in applications ranging from minimally invasive drug delivery to "lab on a chip" drug discovery. This presentation will address a number of approaches and underlying technologies utilized in MEMS micropumps along with advantages and disadvantages of each. In addition, this presentation will take a look at how several of applications are making use of micropump technology today as well as what's possible for the future.

Biography: Paul Rubel is the VP of Product Development and a co-founder of Innovative Micro Technology (IMT), a developer and manufacturer of micro-electromechanical systems (MEMS). He is currently in charge of developing MEMS product platforms to facilitate MEMS implementation for IMT customers. He has 11 years of experience in the MEMS industry including device design, process development, test, and sales. Mr. Rubel was previously the VP of Post wafer development for Applied Magnetic Corporation, with development and prototype manufacturing responsibilities. Mr. Rubel has over 23 years of experience in the Magnetic Recording Head industry including product development, process development, test & equipment development, operational management, and business development. Mr. Rubel holds a BS in Mechanical Engineering from California Polytechnic State University, San Luis Obispo and is the holder of 19 patents.

Commercialization Panel

Colin Drummond, Ph.D., MB — Panel Moderator

Director, Coulter-Case Translational Research Partnership

Department of Biomedical Engineering

Case Western Reserve University

Biography: Colin K. Drummond is the Director of the Coulter-Case Translational Research Partnership (CCTRP) in the Department of Biomedical Engineering at CWRU. He received his Ph.D. degree in Mechanical Engineering from Syracuse University in 1985 and an MBA in Technology Management from the Weatherhead School of Management in 1997. Dr. Drummond has conducted research in the areas of medical device design, microfabrication packaging, sensor systems, and cross-platform software systems integration. For over two decades Colin has worked in the application of science and technology to the creation of products and services and in the past 5 years has been a co-founder of two medical device start-up companies. Colin co-authored the introductory chapter on "Medical Implant Applications" for the Handbook of Materials for Medical Devices, to be released in 2012.

Prior to joining CWRU, Colin was a partner with the consulting firm Avia Group, LLC, leading the analysis and development of advanced technologies for medical devices. Colin's project work involved the refinement of a technique for indirect mucosal blood flow measurement at a local hospital, the strategic development (f

assessment & business development) of a closed-loop anesthesia monitoring system, the development of data acquisition post-processing techniques for comparison of O2 conserving devices for patients with hypoxemia, and the development of specialized sensors for pulmonary disease molecular markers.

During 2004-2007, Colin was the Director of Clinical Research for non-acute medical products at the Invacare Corporation, specializing in respiratory therapy (primarily oxygen therapy), sleep disorder research, and establishing a new clinical research program strategy. Prior to joining Invacare in 2000, Colin was the Manager of Marketing and Business Development for the Powder Systems Group at the Nordson Corporation, focusing on product development, international high-technology manufacturing coating system start-ups, and eBusiness initiatives. Earlier, Colin spent 8 years at the NASA Lewis Research Center developing programming techniques for complex aircraft system analysis and turbomachinery stability. He holds three product patents and has a fourth pending. Colin is very active in the Cleveland area and serves in a variety of capacities for several non-profit organizations.

Russ Donda

Entrepreneur-in-Residence

Glide, BioEnterprise

With more than 25 years of experience at both executive and entrepreneurial levels, Russ's competencies include very early stage work where technologies existing only in concept, must have their feasibility confirmed through a clear assessment of the time and cost to market, product cost, market size, related intellectual property and competitive issues, regulatory issues, and other factors. He developed the "5 Critical Steps of Technology Innovation," a unique means of assessing innovation feasibility from an investor/commercialization perspective. Russ has helped form a number of companies and is familiar with start-up operations, development related issues, patent law, intellectual property management, and strategic alliance structuring.

Kalyan Handique, Ph.D.

CEO

DeNovo Sciences

Biography: Kalyan Handique is currently the CEO of DeNovo Sciences, a cancer diagnostics start-up that recently won the Grand Prize in 2011 Accelerate Michigan Innovation Competition. Prior to joining DeNovo Sciences, Kalyan co-founded HandyLab, a start-up molecular diagnostic company which was acquired in 2009 by Becton Dickinson (BD) Diagnostic Systems in a landmark deal valued at \$275 Million. He was pivotal in forming the vision, vibrant culture and team and was a key contributor in HandyLab's successful entrepreneurial journey from start-to-exit. Contributions included: technology transfer, raising venture capital and government grants, growing the team, developing intellectual property, strategic collaborations, developing and launching FDA approved molecular diagnostics platforms to the eventual sale of the company. After HandyLab's sale to BD, Kalyan served as the VP of R&D Systems Development for BD Diagnostics from 2009-2011. Kalyan has a Ph.D. in Chemical Engineering from the University of Michigan. Kalyan is active in the entrepreneurial community and serves as an adviser for the Frankel Fund, Augment Ventures, Wireless Integrated Microsystems and the Chairman of 3D Biomatrix.

Daniel Laskowski, B.S.,R.P.F.T.,C.C.R.C.

Director, Advanced Physiology Core

Respiratory Institute & Department of Pathobiology

Cleveland Clinic

Biography: Mr. Laskowski has been a researcher at the Cleveland Clinic for over 20 years. He has collaborated with many outside institutions such as National Jewish, Penn and the NIH. He is a private business owner and has been a consultant for many major pharmaceutical companies. He is the author or co-author of over 100 abstracts, papers and book chapters, including work at High Altitude that lead to a publication in Nature.

At The Cleveland Clinic Mr. Laskowski is the Director of the Advanced Physiology Core which has lead him to significant findings. He was the first to recognize the use of small scale sensors to detect lung cancer. Worked with the Navy to detect respiratory disease in Dolphins and continues to reach outside of the box to find new applications for Memes and micro sensor arrays in the medical field.

He also has significant experience in asthma and physiology research. In addition, he has spent significant time organizing large-scale and well received CME conferences at the Cleveland Clinic for the past fifteen years. These include an Asthma Summit he has been the Co-director of yearly since 2004 and conferences on other topics such as pulmonary hypertension, breath research, critical care medicine, pulmonary fibrosis, and advanced lung disease including lung transplantation. Raising over \$600,000 in grants to support the Lung summit mission of bringing innovation into the health care field.

Grant McGimpsey, Ph.D.

Vice President for Research and Sponsored Programs

Kent State University

Biography: Grant McGimpsey is Vice President for Research at Kent State University. Prior to his current role, he spent 22 years as Professor of Chemistry at Worcester Polytechnic Institute (WPI) in Massachusetts. Throughout his tenure at WPI he also served as Associate Provost for Research and Director of the WPI Bioengineering Institute. In 2009 he was also appointed Professor of Biomedical Engineering. His research interests include surface chemistry and medical sensors. He has published over 80 journal articles and holds 7 patents. In 2005 he founded Active Surface Technologies Inc. (ASTI) to commercialize sensor and surface technologies. In January 2012, ASTI became AT Biosciences Inc.

Raymond Vennare

Co-Founder

ThermalTherapeutic Systems

Biography: Raymond F. Vennare is an accomplished senior executive and venture entrepreneur with more than two decades of hands-on experience creating, launching and building biotechnology and information technology companies across diverse markets. Acting on behalf of investors, boards of directors and senior

executives, Raymond plays a key role in the evaluation, protection and progress of existing or emerging business and investment opportunities. Informed by the technology, guided by the business, Raymond F. Vennare is an accomplished senior executive and venture entrepreneur with more than two decades of hands-on experience creating, launching and building biotechnology and information technology companies across diverse markets.

Venture Capital Panel

Brian Duncan, M.D.

Venture Partner

Arboretum Ventures

Biography: Brian Duncan, M.D., is a Vice President on the medical devices team at BioEnterprise and is also the Ohio Venture Partner for Arboretum Ventures. Duncan is a cardiac surgeon who has more than 20 years of clinical experience. After completing training at Massachusetts General Hospital, he was a staff surgeon at Childrens Hospital in Boston, Seattle Childrens Hospital and Cleveland Clinic. Duncan also has experience developing pediatric ventricular assist devices. Most recently, Duncan was the Medical Director for Cleveland Clinic Emerging Businesses Unit. He has authored more than 100 peer-reviewed manuscripts, 25 book chapters, and the definitive textbook on pediatric circulatory support entitled Mechanical Support for Cardiac and Respiratory Failure in Pediatric Patients. He serves on the boards of BioOhio, American Society for Artificial Internal Organs and Accord Bioscience. Duncan received his B.S. and M.D. degrees from Indiana University and also has an M.B.A. from the University of Michigan.

Michael Lang

Venture Partner

Jumpstart Inc.

Michael brings 30 years of executive experience in the medical devices industry. He played key roles in the development paradigm changing medical technologies including minimally invasive cardiovascular therapies, laparoscopic procedures and implantable biomaterials. He has an extensive background in product development, marketing, general management, strategic business development, and technology assessment. He has worked in venture investing and has started several venture capital funded device companies.

Karen Spilizewski

Vice President

RiverVest Venture Partners

Karen Spilizewski is a leader of BioEnterprise's medical device team and is also a Vice President with RiverVest Ventures. She brings nearly 20 years of experience in new product development and business development in medical and non-medical technologies. Spilizewski worked as a business development manager at Avery Dennison and in product development roles ranging from research manager to associate. She was responsible for conducting marketing, financial, technical, and competitive analyses of new opportunities for microelectronic, biomedical, optical display, and MEMs applications. In product development roles, she has developed and commercialized products for various medical devices, including wound care, diagnostics, surgical, and electromedical applications. Spilizewski received her MBA, M.S. in Macromolecular Science and a B.S. degree in Biomedical Engineering from Case Western Reserve.