# Audrey's Life Science Meeting Picks for Aug. 16, 2015 – Dec., 2015 Complimentary Service of AudreysNetwork.com Aug.16, 2015

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# Bio2Device Group, Tuesday Morning, Aug. 18, 2015

Topic: "Targeted Brain Cooling For Stroke Prevention and Treatment"

Date and Time: Tuesday, August 18, 2015, 8:30 am

Location: Sunnyvale City Council Chambers, 456 West Olive Ave., Sunnyvale, CA

Speaker: Seth Rodgers, CEO, NeuroSave Inc.

No fee or registration required for morning meetings.

## Topic Description

Temporary reduction of brain temperature soon after ischemic brain injury can have a large and permanent effect on neurological outcome. Many attempts have been made to engineer devices for this purpose but generally speaking they have been too slow or associated with too many complications to be widely accepted. NeuroSave has developed a minimally invasive technology that targets cooling to the brain for a rapid and selective effect without breaking the skin. A recent clinical trial demonstrated cooling rates of up to 16C per hour and a sustained brain-body temperature differential of 3.5C. Applications of the technology to reduce both focal and global ischemic injury associated with cardiac surgery will be illustrated.

# Speaker Bio

Seth Rodgers currently serves as CEO of NeuroSave, inc. A clinical stage medical device company founded to address ischemic brain injury with targeted brain cooling. He was CTO of BioProcessors Corp from 2002 until its acquisition by Seahorse Bioscience in 2009. Prior to that he was a consultant with McKinsey and Company. He holds a Ph.D in Chemical Engineering from MIT.

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#### HBA, Wednesday Evening, Aug. 19, 2015

Event: "Empowering Women to Change the Status Quo Date and Time: Wed, Aug 19, 2015, 6:00 PM - 8:30 PM

Agenda

5:30 PM - 6:00 PM Arrivals and registration

6:00 PM - 6:30 PM Welcome remarks and networking

6:30 PM - 7:30 PM Screening of PBS "Makers: Women in Business" documentary

7:30 PM - 7:45 PM Documentary Q&A session 7:45 PM - 8:00 PM Networking and wrap up

Location: Cooley LLP, 3175 Hanover St, Palo Alto, CA 94304, (650) 843-5000

**Registration information** 

Event is open to: HBA members and nonmembers Online registration deadline: August 14, 2015 Onsite (walk-in) registration: Is allowed

#### Member rate:

\$20 until August 14, 2015 \$25 after August 14, 2015

#### Nonmember rate:

\$30 until August 14, 2015 \$35 after August 14, 2015

Details and registration at

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# **Event description**

Join the HBA San Francisco chapter and Cooley LLP for a summer evening of networking and participating in a discussion on "empowering women to change the status quo" in Palo Alto. This year's event brings together HBA members and non-members for a networking happy hour with a special screening of the insightful one-hour PBS documentary "Makers: Women in Business".

We will start off with some formal networking activities and great food and drinks outside on Cooley's patio. Fred Dorey, special counsel in the life sciences practice group at Cooley, and HBA San Francisco chapter advisory board member, will share opening remarks to kickoff the event. We will then transition to screening the PBS documentary "Makers: Women in Business" indoors in Cooley's event room with a brief discussion afterwards, followed by additional networking over dessert.

This is a great opportunity to visit with old friends, make new ones and sharpen your networking skills in a relaxed and friendly environment. Don't forget to bring your business cards to take full advantage of the networking opportunities.

Pricing includes: heavy appetizers, non-alcoholic and alcoholic drinks (wine/beer), movie screening, networking and prizes.

## Learning objectives

- 1. Sharpen networking skills and cultivate new connections within the growing HBA chapter
- 2. Gain an informative view of this history of women in business and participate in an active discussion with HBA San Francisco chapter leaders

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## NCC AWIS, Saturday Afternoon, August 22, 2015

Event: "NCC AWIS Family Picnic"

Date and Time: Saturday, August 22, 2015, 12:00 pm to 3:00 pm

COST: FREE! RSVP by August 18th via Eventbrite

Location: Beresford Park & Community Center 2720 Alameda de las Pulgas San Mateo, CA

94403.

Parking is available.

All professionals and students in the sciences are welcome.

See details and register at

https://drive.google.com/file/d/0B5xVHaWdV1eEN1d6TEhRRmp1cTA/view Please RSVP by August18th :hKp://ncc-awis2015picnic.eventbrite.com

#### **Event Description**

AWIS is pleased to invite you to our 9th ANNUAL NCC picnic with Palo Alto AWIS, San Francisco AWIS, East Bay AWIS, and Sacramento Valley AWIS! The picnic will be held at Beresford Park in San Mateo which has paths for walking, grassy and picnic areas, several playgrounds for kids, skate park, bocce, tennis and basketball courts are nearby.

<u>About AWIS:</u> The Association for Women in Science is today's premiere leadership organization advocating the interests of women in science and technology. For 40 years, the Association for Women in Science has fought for equity and career advancement for women

- from the bench to the board room. We unite women through our nationwide network of chapters and partnerships with aligned professional organizations. Our success is dependent upon the diversity of our members, our corporate and institutional partners and our sponsors -- all of whom are committed to the advancement of women's leadership in STEM. TIP: Did you know that AWIS members can contact other AWIS members through the AWIS web portal? Next time you need to find an AWIS contact logon to the AWIS website.

# Biodesign Innovation Fellowship, Application Due August 31, 2015

Features of the Fellowship Program Timeline Frequently Asked Questions Application Instructions

#### Webinar Date:

- Aug 19 at 6pm (PDT) register
- Recording of July 30 webinar

The Biodesign Innovation Fellowship teaches a proven, hands-on, project-based approach to identifying important unmet medical needs, developing innovative diagnostic, device, or other medical technology (medtech) interventions to address them, and preparing to bring those products into patient care through start-up, corporate, or other implementation channels. [PLEASE NOTE: This is not the Stanford-India Biodesign fellowship, which is no longer offered.]

The fellowship is a launch pad for initiating, redirecting, or turbo-charging a career in medical technology. Graduates from the program apply their talents to:

- Catalyzing innovation inside major medtech corporations
- Building their own medtech start-up companies
- Teaching and/or leading translational research projects for world-class universities
- Driving innovation initiatives within academic or private medical centers
- Becoming specialists in design, investing, or other aspects of the medtech innovation ecosystem

Individuals with a background in medicine, biosciences, engineering, computer science, product design, or business are encouraged to apply. Masters, medical, or doctorate degrees preferred. Candidate will be selected based on their experience, as well as their potential to become leaders in the medtech field. We encourage persons from all countries to apply.

Fellows become a member of the Stanford Biodesign team at the James H Clark Center on the Stanford University campus. Clinical Immersion is held at Stanford Hospital as well as nearby healthcare venues.

The fellowship is a full-time, intensive experience that runs from the beginning of August through early June each year. Fellows receive a monthly stipend and health benefits during the fellowship period.

Applications for 2016-17 are due on August 31, 2015. To be considered, please complete our online application. For those selected, interviews will be held on the Stanford campus November November 12 and 13. More information about the application process and timing is provided with our application instructions and FAQS.

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# Golden Gate Polymer Forum, Monday Evening, August 24, 2015

Topic: "Computationally Inexpensive Simulation and Modeling for Future Lithography Processes"

Speaker: Prof. Hayden Taylor, Dept. of Mechanical Engineering, U.C. Berkeley

Date and Time: Monday, August 24, 2015, 6:00 pm

6:00 PM social hour 7:00 PM dinner 8:00 PM presentation

Location: Michael's at Shoreline, 2960 N Shoreline Blvd, Mountain View Cost:Employed/postdocs: \$30 early registration, \$35 regular registration Unemployed/retired/students: \$15 early registration, \$20 regular registration

Free if you attend just the lectures at 8:00 PM (but please let us know for headcount)

After deadline:

Registration not guaranteed, so contact us Late fee applies if space available -- \$40 regular/employed, \$25 unemployed/student/retired

#### Deadlines for registration:

End of discounted advance (full-price) registration Monday, Aug. 17, 11:59 PM End of regular (full-price) registration Friday, Aug. 21, 5:00 PM Register at <a href="http://www.GGPF.org">www.GGPF.org</a> http://www.GGPF.org>

#### PLEASE NOTE:

We accept cash or checks at the door, but are unable to accept payment by credit card at the event. You may pay at the door.

Checks may be made to "GGPF"

Please register on the web page

Or, if necessary, contact:

**Eveleen Tang** 

etang@amaranthmedical.com<mailto:etang@amaranthmedical.com> 650-965-3831 ext 228

You should receive confirmation of your registration; if not, please contact us again.

# **Topic Description**

Nanoimprint lithography (NIL) - in which a thermoplastic film or ultraviolet-curing resin is mechanically nanopatterned in contact with a solid template - offers sub-10 nm patterning resolution with lower capital costs than competing technologies such as extreme ultraviolet lithography (EUV). To be adopted widely in data storage and semiconductor manufacturing, NIL's throughput needs to increase and its defect rate needs to fall. One way of improving NIL's throughput and yield is to develop comprehensive models of the process that can guide its optimization.

Over the last six years we have developed a computationally inexpensive simulation technique for NIL. The technique captures the deformation behavior of an imprinted polymeric film or droplet pattern using its mechanical impulse response, and describes elastic deformations of the patterned imprinting mask/template via a point-load response. We have developed the technique to simulate the imprinting of chip-scale patterns containing many millions of features, and to model the imprinting of both thermoplastic resists and ultraviolet-curing resins. I will describe the simulation technique and how we have applied it to: (i) optimize process parameters; (ii) select materials for the template; and (iii) guide the design of the imprinted pattern itself.

We have also applied the model to the manufacturing of polymeric microfluidic devices, and have extended the model for roller-based imprinting on continuous substrates, capturing substrate-speed and roller-load dependencies. By considering viscoelasticity of the imprinted material, we argue that there is an optimal substrate speed that maximizes the fidelity of imprinted patterns. Finally, we introduce recent work to model efficiently the directional spreading and coalescence of tens of thousands of picoliter-

volume droplets of resist beneath a patterned imprint template.

#### Speaker Bio

Hayden Taylor is an Assistant Professor in the Department of Mechanical Engineering, UC Berkeley. He received his B.A. and M.Eng. degrees in Electrical and Electronic Engineering from Cambridge University in 2004, and a Ph.D. in Electrical Engineering and Computer Science from MIT in 2009. He is a member of the IEEE, the Institution of Engineering and Technology, and the Institute of Physics.

http://www.me.berkeley.edu/faculty/taylor/

# Bio2Device Group, Tuesday Morning, Aug. 25, 2015

Topic: "MALDI TOF MS: An Ongoing Revolution in Microbe Identification and

Characterization"

Speaker: Dr. Gongyi Shi, Director of Scientific Affairs, Bruker Corporation

Date and time: Tuesday, Aug. 25, 2015, 8:30 am

Location: Sunnyvale City Council Chambers, 456 West Olive Ave., Sunnyvale, CA

There is no charge or registration required for morning meetings.

## Topic Description

Microbe identification and classification is widely applicable in many areas including food/consumer product quality control, environmental research, and veterinary and clinical diagnostics. Ideally, accurate microorganism identity should be obtained in an rapid and cost effective manner. Especially in clinical applications, characterization pathogens in a timely manner is the foundation for appropriate antimicrobial therapy and patient management. However, traditional identification methods, which are based on morphological and biochemical traits of microorganisms, could take up to 16 to 24 hours and are with limited in reliability. The introduction of MALDI-TOF MS (matrix assisted laser desorption/ionization mass spectrometry) based whole cell proteomic fingerprinting revolutionized the field by its speed, accuracy and cost effectiveness. Here, fundamentals of this technology platform as well as its applications, impact on patient care will be discussed in the talk.

# Speaker Biio

# BioScience Forum, Wednesday Evening, August 26, 2015

Topic: "Oncology Meets Immunology: Revolution of the Cancer-Immunity Cycle" Speaker: Daniel Chen, M.D., Ph.D., Cancer Immunotherapy Franchise Head, Product Development, Oncology, Genentech

Date ant Time: Wednesday, August 26, 2015 6:00 PM - 9:00 PM

6 pm - 7 pm networking 7 pm - 8 pm dinner

8 pm - 9 pm presentation

Location: The Holiday Inn, 275 S Airport Blvd, South San Francisco, California 94080, USA

Event Registration (\$3 service fee will apply)

Pre-Registration \$50.00
On-Site Registration \$60.00
Pre-Registration ends Monday, August 24th, at 9 pm
Cash or check accepted on the day of the event
\$10 discount for full-time students

Or you can pay with a check made out to "BioScience Forum" and sent to: BioScience Forum
1442A Walnut Street, #308
Berkeley, CA 94709-1405
Please do not mail checks later than Thursday, August 20th
If paying with check, do not complete online registration with Cvent
Register at www.biosf.org

## Topic Description

The genetic and cellular alterations that define cancer provide the immune system with the means to generate T cell responses that recognize and eradicate cancer cells. However, elimination of cancer by T cells is only one step in the Cancer-Immunity Cycle, which manages the delicate balance between the recognition of nonself and the prevention of autoimmunity. Identification of cancer cell T cell inhibitory signals, including PD-L1, has prompted the development of a new class of cancer immunotherapy that specifically hinders immune effector inhibition, reinvigorating and potentially expanding preexisting anticancer immune responses.

The presence of suppressive factors in the tumor microenvironment may explain the limited activity observed with previous immune-based therapies and why these therapies may be more effective in combination with agents that target other steps of the cycle. Emerging nonclinical and clinical data suggesting that cancer immunotherapy is becoming a key part of the clinical management of cancer will be discussed.

## Speaker Biography

Daniel S. Chen, MD, PhD, is the Cancer Immunotherapy Franchise Head in Product Development at Genentech/Roche and Adjunct Faculty in Medical Oncology at Stanford University. He received a BS degree in Biology from the Massachusetts Institute of Technology (1990), a PhD in Microbiology & Immunology (1996) and MD (1998) from the University of Southern California. Daniel completed an Internal Medicine Residency and Medical Oncology Fellowship at Stanford University (2003). He went on to complete a Post-doctoral fellowship with Mark Davis in Immunology, where he was a Howard Hughes Medical Institute Associate. He also ran the metastatic melanoma clinic at the Stanford Cancer Center from 2003-2006, where he continues to care for melanoma patients. In that time, he studied human anti-cancer immune responses pre- and post- cancer vaccination and cytokine administration to determine why anti-tumor immune responses were not more clinically effective. He received a U19 grant to develop better immunologic tools to interrogate human immune responses and ultimately patented the MHC cellular microarray to detect and functionally characterize antigen-specific T cell states.

Since joining Genentech in 2006, Daniel has focused on the clinical development of antiangiogenic and immune modulatory targeted therapies in both early and late development, as well as the diagnostic tools to aid their development. He is a reviewer for Clinical Cancer Research and gave the keynote presentation at the AACR NCI EORTC Annual Meeting 2014. He has continued to publish with academic and Genentech collaborators in the field of cancer immunotherapy.

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# JLABS, Wednesday, Sept. 9, 2015

Topic: "Meet with ... Astellas Venture Management"

AVM Participating Representatives:

Sakae Asanuma MBA, CFA | President & CEO, Astellas Venture Management Takashi Futami | Associate Investment Director, Astellas Venture Management Taro Masunaga, Ph.D. | Senior Investment Director, Astellas Venture Management Hideaki Matsuoka, Ph.D. | Associate Investment Director, Astellas Venture Management

Nobuaki Shindoh, Ph.D. | Associate Investment Director, Astellas Venture Management

Date and Time: Wednesday, Sept. 9, 2015, 10:30 am – 12:30 pm

Agenda:

10:30am | Registration Opens and Networking

11:00am | Presentation and Q&A

12:00pm | Networking Lunch

12:30-5:00pm | One-on-one Meetings\*

\*Companies must have applied for a one-on-one meeting ahead of time and be approved. The application period ends on August 5th.

Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd., 3rd Floor, South San Francisco, CA

Fees:

Presentation & Lunch

\$25 | General Public

\$35 | General Public Onsite

Includes presentation, Q&A, and lunch. All attendees must pay this fee, regardless of one-on-one meeting status. Registration to attend the presentation, Q&A, and lunch will remain open until September 8th (or sold out).

One-on-One Meeting

FREE | Application

FREE | Accepted Companies

<u>Companies must have applied for a one-on-one meeting</u> ahead of time. The one-on-one application period ends on August 5th. Your application will be reviewed and you will be notified of acceptance by August 21, 2015. Acceptance of a one-on-one meeting is not guaranteed as all applications must be approved.

Register at http://www.eventbrite.com/e/meet-with-astellas-venture-management-tickets-17393910655?aff=weekly

#### **Event Description**

Investing in opportunities to improve health through innovation is a key driver of solutions for today's most difficult healthcare problems. Astellas Venture Management (AVM) /Innovation Management ("AIM") are interested in supporting early stage opportunities to advance the creation of human therapeutics. AVM/AIM will be presenting at Johnson and Johnson Innovation, JLABS on September 9th, 2015.

AVM is the venture group within one of Japan's second largest pharmaceutical company, Astellas Pharma Inc. You may be familiar with some of AVM's successful, local portfolio companies including eFFECTOR Therapeutics and Fate Therapeutics.

With hundreds of millions in an evergreen fund, AVM is looking to invest in more private companies in the early stage drug discovery and platform technology across several therapeutic areas, including:

- Immunology and Inflammation, Urology, Oncology, Nephrology and Neuroscience
- Ophthalmology, Hearing Loss, Muscle disorder and Regenerative Medicine.

Also, AVM has another mission by AIM to execute early stage innovative collaborations with Academia and biotech companies. Recent collaboration deals include MD Anderson Cancer Center (oncology drug discovery), Potenza (Immune oncology drug discovery) and Kanyos Therapeutics (Autoimmune drug discovery). AVM/AIM will provide equity and non-dilutive capitals to our portfolios and partners while actively looking for innovative new opportunities.

Representatives from AVM/AIM will be in attendance to give an overview presentation on the company's key areas of interest and best practices when seeking funding. Following the presentation, don't miss this opportunity to network with fellow attendees and the AVM/AIM representatives during lunch. For those companies who <u>apply online</u> and receive approval, one-on-one meetings with AVM will provide a private forum to discuss your company.

# AVM Representatives' Bios

Sakae Asanuma MBA, CFA | President & CEO, Astellas Venture Management Mr. Sakae Asanuma joined AVM in June 2011. Prior to joining AVM, he served as Director at Yasuda Enterprise Development America, Japan's major VC firm with \$800M under management, from 2000 to 2011 and originated Yasuda's biotech investment activities in the US. Based in Bay Area since 2000, he has invested in 30+ US biotech venture companies and deeply involved in the business development discussions with Japanese pharmaceutical companies on behalf of his portfolios. To date, his portfolio companies successfully achieved 9 IPOs and 8 M&As. Prior to Yasuda, he was venture capitalist and buy-side equity analyst from 1988 to 1999, managing \$20B+ equity portfolios for Meiji-Yasuda Life Insurance Company (one of the largest life insurance companies in Japan). He holds Master of Business Administration from Carnegie Mellon University.

Takashi Futami | Associate Investment Director, Astellas Venture Management Mr. Futami joined Astellas Venture Management in Oct 2013. Prior to joining AVM, he worked as a Senior Researcher at Astellas Pharma Inc. He served as a team leader at Oncology Labs of Astellas Pharma, and led a drug discovery research and preclinical development of kinase inhibitor programs in oncology therapeutics area. He also has experiences of collaboration with several institution like The University of Tokyo Hospital, Metabolex Inc. etc.

Taro Masunaga, Ph.D. | Senior Investment Director, Astellas Venture Management Dr. Masunaga joined Astellas Venture Management in Oct 2013. He has more than 25 years experience of drug discovery research from target discovery to development mainly in Immunology area including transplantation and autoimmune. From 2007 to 2012, he served as associate director to start up the Astellas Research Institute of America (ARIA) which is engaging early drug discovery (target identification, Hit/Lead generation and therapeutic strategy) in transplantation. Prior to joining AVM, he worked as a head of Advanced Drug Discovery (ADD) group in Pharmacology Research Laboratories taking a responsibility for early drug discovery of small

molecules for every single focused therapeutic area, Urology, Oncology, Immunology, CNS, Kidney diseases and Frontier diseases.

Hideaki Matsuoka, Ph.D. | Associate Investment Director, Astellas Venture Management

Dr. Matsuoka joined AVM in October 2014. He has more than 14 years experiences of drug discovery research in the field of immunology, cell biology, and molecular biology at Astellas Pharma Inc., and served as a principal scientist at Astellas Research Institute of America (ARIA) from 2007 to 2010 specifically focusing on early drug discovery (target identification, Hit/Lead generation and therapeutic strategy development) in transplantation. Prior to joining AVM, he served as a senior manager in charge of scientific evaluation at Astellas Innovation Management (AIM) and has a significant track record of leading several partnering deals.

Nobuaki Shindoh, Ph.D. | Associate Investment Director, Astellas Venture Management

Dr. Shindoh joined AVM in November 2014. He has 18 years experiences of drug discovery research in the field of Oncology, Urology and renal disease at Astellas Pharma Inc. and covers broad range of drug discovery from target identification to clinical development with successful experience in oncology. From 2011-2012, he worked at the Dana-Farber Cancer Institute as a visiting scientist to identify novel drug targets. Since Oct 2013, he served as associate director of Astellas Innovation Management (AIM) in charge of scientific evaluation in the oncology disease area and led the partnering with CRUK.

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#### **PBSS, Friday, Sept. 18, 2015**

Topic of Workshop: "Conducting a Successful End-of-Phase2 Meeting with the FDA:

Overview, Strategies, and Perspectives from the FDA and Industry"

Speakers: Azin Shahzamani, Yaning Wang, Mike Eldon, Terry Sweeney, Ramani Raghavan, Detlef Albrecht

Date and Time: Friday, September 18, 2015; 8:45-17:00

Location: SF Bay Area: Foster City Crowne Plaza

Registration fee (US\$): Regular: \$195; For major-sponsor rep (incl lunch): \$0; For vendor-show rep: \$35; For unemployed & students: \$30; Webcast: \$350; For others, details available upon online login.

Registration deadline: 9/17/2015 (it will close sooner if the seating cap is reached) Topic Description

An End-of-Phase 2 (EOP2) meetings is a meeting between the US FDA and the sponsor of a clinical development program after the completion of the Phase 2 study and prior to the start of the Phase 3 study. It is most useful to the sponsor and should be held before major efforts and resources are committed to specific Phase 3 studies. The purpose of an EOP2 meeting is to determine sufficient safety prior to Phase 3, to evaluate the Phase 3 plan and protocols, the adequacy of current studies and plans to assess pediatric safety and effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation.

This workshop is intended to address the important topics for an effective discussion at an EOP2 meeting and to provide an overview of a successful meeting preparation. Regulatory aspects will be provided from the FDA and the industry perspective. For clinical pharmacology the progress of PK study data and additionally needed studies will be reviewed. The preclinical safety and toxicology as it relates to dose, duration & route of

administration will be discussed. In the CMC area the approach to specifications and test methods as well as the formulation to be used in clinical trials and "to be marketed" formulation will be addressed. In the clinical discussion at an EOP2 meeting, agreement needs to be reached with FDA on pivotal study designs, dose selection, patient population and the safety and efficacy endpoints for Phase 3 studies. Topics:

- Regulatory Overview of End of Phase 2 meeting What to consider? Industry perspective - Azin Shahzamani (Genentech/Roche)
- The FDA perspective of a successful EoP2 meeting, how to avoid the common mistakes; and Phase 3 dose selection aspects - Yaning Wang (FDA)
- Nonclinical safety and toxicology aspects and strategy Terry Sweeney (Nektar)
- CMC aspects and strategy Ramani Raghavan (Genentech/Roche)
- Clinical aspects and strategy Detlef Albrecht

# CABS, Wednesday Afternoon, Sept. 19, 2015

Event: "CABS Science and Technology Workshop: New Frontiers in Peripheal Monitoring"

# Agenda:

Registration, networking, workshop introduction
Mike Schwartz, Co-founder and VP of Marketing, Fluxion Biosciences
Liquid biopsy innovations for oncology using sequencing of circulating tumor cells
Shengrong Lin and Paul Tang, Co-founders, AccuraGen
Title tbd
Mojgan Haddad, former Sr. Director, Bioinformatics and Analytics, Health Tell
HIV Drug Resistance Diagnostics: Path of Discovery to Clinical Application
Break
John Waldeisen, Co-founder and CEO, DiAssess
My Life as an Entrepreneur
My Life as an Entrepreneur  Nikolay Sergeev, R & D leader, Natera

<sup>\*</sup> Lunch will be provided.

Location: Hangi Investment Inc., 1633 Bayshore Highway Suite 280 Burlingame, CA 94010 Registration Requirement:

Online registration is strongly encouraged.

Online: \$10 for CABS members, \$15 for non-members

Onsite: \$20

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Register at http://www.cabsweb.org/CABSweb/feventslist.jsp?id=1120

## Topic Description

# AWIS, Tuesday, Sept. 22, 2015

Event: "2015 National Summit On Innovation And Entrepreneurship: A Roadmap For

Inclusion"

Keynote Speaker: Janet Napolitano

Date and Time: Tuesday, September 22, 2015, 10:00 am – 2:00 pm; networking reception

1 – 3 pm

Location: Oakland Marriott City Center | Oakland, CA

Registration fee: \$50 members, \$125 general registration.

Register at https://awis.site-ym.com/events/register.aspx?id=666640&itemid=07945d5e-

0d68-4ebc-b53f-b357820e9c3c

## **Event Description**

In partnership with the University of California and the California Life Sciences Association, we are pleased to invite you to join us in Oakland, CA on September 22, 2015 for the National Summit on Entrepreneurship and Innovation.

Building upon our inaugural Summit which was held in partnership with The Ohio State University, this meeting will focus on how we, as a society, can develop inclusive, fiscally-responsive systems to drive research excellence, feed long-term economic growth, and fuel innovative solutions to global challenges facing all our citizens. Janet Napolitano, President of the University of California, will serve as the keynote speaker.

# A NATIONAL DIALOGUE ON GENDER AT THE NEXUS OF INNOVATION AND ENTREPRENEURSHIP

A full day of sessions, keynote address from Janet Napolitano, President of the University of California, plus networking reception provide a forum for the exchange of advanced knowledge on gender at the nexus of innovation and entrepreneurship.

Expert speakers: The National Summit engages panelists and participants in evidence-based and thought-provoking discussions.

Networking: Connect with experienced innovation professionals who represent the science, technology, engineering, and mathematics (STEM) community from corporate, academic, and government agencies.

Tickets are going fast. Registration is open to you first as a valued member of AWIS. Reserve your \$50 member-only ticket today before general registration opens on August 11th. This event is expected to sell out.

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# PBSS, Thursday, Oct. 1, 2015

Topic: "Cancer Immunotherapy: A Game Changer for Cancer Treatment - Breakthroughs in Science, Translational Medicine, Clinical Development &

Latest Trends in Oncology Practice and Business Partnerships"

Date and Time: Thursday, Oct. 1, 2015, 8:45 - 5:00

Location: Foster City Crowne Plaza

Register at http://pbss.org/

## Topic Description

An End-of-Phase 2 (EOP2) meetings is a meeting between the US FDA and the sponsor of a clinical development program after the completion of the Phase 2 study and prior to the start of the Phase 3 study. It is most useful to the sponsor and should be held before major efforts and resources are committed to specific Phase 3 studies. The purpose of an EOP2 meeting is to determine sufficient safety prior to Phase 3, to evaluate the Phase 3 plan and protocols, the adequacy of current studies and plans to assess pediatric safety and effectiveness, and to identify any additional information necessary to support a marketing application for the uses under investigation.

This workshop is intended to address the important topics for an effective discussion at an EOP2 meeting and to provide an overview of a successful meeting preparation. Regulatory aspects will be provided from the FDA and the industry perspective. For clinical pharmacology the progress of PK study data and additionally needed studies will be reviewed. The preclinical safety and toxicology as it relates to dose, duration & route of administration will be discussed. In the CMC area the approach to specifications and test methods as well as the formulation to be used in clinical trials and "to be marketed" formulation will be addressed. In the clinical discussion at an EOP2 meeting, agreement needs to be reached with FDA on pivotal study designs, dose selection, patient population and the safety and efficacy endpoints for Phase 3 studies.

#### Topics and Speakers:

- Regulatory Overview of End of Phase 2 meeting What to consider? Industry perspective - Azin Shahzamani (Genentech/Roche)
- The FDA perspective of a successful EoP2 meeting, how to avoid the common mistakes; and Phase 3 dose selection aspects - Yaning Wang (FDA)
- Nonclinical safety and toxicology aspects and strategy Terry Sweeney (Nektar)
- DMPK issues & Clinical pharmacology (Mike Eldon)
- CMC aspects and strategy Ramani Raghavan (Genentech/Roche)
- Clinical aspects and strategy Detlef Albrecht

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# JLABS, Wednesday Mid Day, Oct. 14, 2015

Topic: "Meet with...OrbiMed

Speaker: Peter Thompson, M.D. | Private Equity Partner, OrbiMed

Date and Time: Oct. 14, 2015, 11:00 am - 1:30 pm 11:00 AM | Registration, Lunch, and Networking

11:30 AM | Presentation

12:15 PM | Discussion and Q&A

12:30 PM | Audience Pitches and Critique

1:30 PM | Program Close

\*Companies must have applied for a one-on-one meeting ahead of time and be approved. The application period ends on September 11th.

Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California

Fees:

Presentation & Lunch

Fees:

\$35 | General Public

\$20 | Student/Academic

\$45 | At the door

One-on-One Meeting

FREE | Application

FREE | Accepted Companies

Companies must have applied for a one-on-one meeting ahead of time. The one-on-one application period ends on September 11th. Your application will be reviewed and you will be notified of acceptance by September 25, 2015. Acceptance of a one-on-one meeting is not guaranteed as all applications must be approved.

Details and registration at <a href="http://www.eventbrite.com/e/meet-with-orbimed-tickets-17394113261">http://www.eventbrite.com/e/meet-with-orbimed-tickets-17394113261</a>

# Topic Description

Can you provide healthcare innovation that will help humanity live healthier, longer and more productive lives? Then OrbiMed wants to talk to you.

OrbiMed is the world's largest life sciences-dedicated investor with specific interests in biopharma, diagnostics, med tech and healthcare services. They've helped to nurture and commercialize some of today's most successful healthcare companies focused on creating healthier, longer and more productive lives around the globe. OrbiMed is seeking novel healthcare innovations across biopharma, devices, diagnostics and healthcare IT at any stage of development in both public and private companies.

A representative from OrbiMed will be in attendance to give an overview presentation about the company's key areas of interest and best practices when seeking funding. Following the presentation, don't miss this opportunity to introduce yourself to Peter Thompson during the networking lunch. And finally, for those companies who <u>apply online</u> and are approved, one-on-one meetings with OrbiMed will provide a forum to discuss your company.

#### About the Meet with... Series:

The purpose of the Meet with Series events sponsored by JLABS is to help start-up entrepreneurs, as well as the academic community, connect with potential partners, such as big pharma or other investment corporations, through one-on-one meetings. It is also a chance for the featured corporation to outline their specific business development goals and clarify what types of products or research they are interested in and how best to approach them to get the partnering process started. Past participants include the Wellcome Trust, Bill & Melinda Gates Foundation, MedImmune Ventures, NCI, Mercury Fund, DARPA's Biological Technologies Office, Correlation Ventures, Breakout Labs, New Enterprise Associates, Canaan Partners, Thomas McNerney & Partners, NCATS, NINDS, Johnson & Johnson Innovation, Poliwogg, California Institute for Regenerative Medicine, Astellas Venture Management, and OrbiMed.

OrbiMed Participating Representative Bio

Peter Thompson, M.D. | Private Equity Partner, OrbiMed

Peter Thompson is currently a Private Equity Partner with OrbiMed who brings over 20 years of industry experience. He co-founded and was CEO of Trubion Pharmaceuticals, co-founded Cleave BioSciences, serves on the Boards of Cleave, Anthera, Methylgene, Principia Biopharma, and Response Biomedical, and was an executive of Chiron Corporation and Becton Dickinson. Dr. Thompson is an Ernst & Young Entrepreneur of the Year awardee, an Affiliate Professor of Neurosurgery at the University of Washington, an inventor on numerous patents, and a board-certified internist and oncologist. He was on staff at the National Cancer Institute following his internal medicine training at Yale University.

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# JLABS, Tuesday Mid Day, Nov. 3, 2015

Topic: "It Must be Witchcraft"

Speaker: John Bates | Chief Executive Officer, Executive Speaking Success & Business

Coaching

Date and Time: Tuesday, Nov. 3, 2015, 11:00 am - 1:30 pm

Agenda:

11:00 AM | Registration, Lunch, and Networking

11:30 AM | Presentation

12:15 PM | Discussion and Q&A

12:30 PM | Audience Pitches and Critique

1:30 PM | Program Close

Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd, 3rd Floor,

South San Francisco, CA

Fees:

\$35 | General Public

\$20 | Student/Academic

\$45 | At the door

Details and registration at http://www.eventbrite.com/e/it-must-be-pitchcraft-

tickets-17169625813

## Who Should Attend:

Life science industry executives, founders, CEOs, and marketing managers of startups and other private companies.

Details and registration at http://www.eventbrite.com/e/it-must-be-pitchcraft-tickets-17169625813?aff=weekly

#### Program Description

Have you ever wondered why you didn't get the investment? The potential funders loved the idea. They loved the team. They thought the market would be receptive... But, they wanted to think about it a little longer.

In this enlightening session with world renowned Communications & Leadership Expert, John Bates, you will learn the secrets behind pitches that succeed. You will leave ready to apply the secrets of PitchCraft to all of your pitches. From internal presentations to fundraising and client pitches you will learn not only what works, but why it works.

John has trained teams to take pitches from disaster to success that have raised hundreds of millions of dollars. In preparing PitchCraft John enhanced his own

extensive experience by interviewing many top funders in the Healthcare ecosystem. From leading grant reviewers and high stakes venture fund managers to startup founders, John has gathered and distilled the principles, practices and gems no one ever discusses.

Even though you have a great idea, a great product, and a great team, you need to be able to communicate that well or it can languish while an inferior idea, product and team rise to prominence. Make sure your pitch skills are worthy of your idea, product and team. Make sure you are skilled in the art of PitchCraft.

The "How to... Workshop" series is dedicated to giving you the keys to a successful business, from creation to exit. As with all our events, the "How to... Workshop" is interactive and informal so bring your questions with you!

Speaker Bio

John Bates | Chief Executive Officer, Executive Speaking Success & Business Coaching

John fell in love with the Internet the moment it dawned on him what it would do for communication. Since then he has worked with early stage companies as a founder or early employee and has been instrumental in raising hundreds of millions of dollars in Venture Capital. He co-founded BIGWORDS.com, a dotcom darling which ended up going bust in the dotcom bomb of 2000 and he was the first employee and is a part owner of Goldstar.com. John has been asked to speak and teach all over the world at events ranging from Web Attack to the St Gallen B-School World Leaders Symposium, the Leiden Veerstichting conference for Global Leaders, TEDActive twice, and many TEDx's. Most recently he taught groups of entrepreneurs and business owners in Bratislava, Slovakia via the University of Ekonomics, American Chamber of Commerce and the American Embassy. These days John loves bringing the ideas of others to life.

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#### JLABS, Thursday Mid Day, Nov. 12, 2015

Topic: "ABCs of the FDA - How to... Set a Preclinical Roadmap"

Speaker:

Michael Kelley, VMD, Ph.D., DABT | Senior Scientific Director, Janssen Research & Development

Date and Time: Thursday, 11:30 am - 1:00 pm

Agenda:

11:30am | Registration, Networking and Lunch

12:00pm | Presentation

12:30pm | Q&A

1:00pm | Close

Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd, 3rd Floor,

South San Francisco, CA

Fees:

\$35 General Public

\$20 Student/Academic

\$45 At the door

Details and registration at http://www.eventbrite.com/e/abcs-of-the-fda-how-to-set-a-preclinical-roadmap-tickets-17169970845

Topic Description

Moving a program from Discovery through Development is an arduous task. Key among these challenges is designing a safe and druggable molecule that can withstand the rigors of preclinical testing in support of First in Human (FIH) trials, human Proof of Concept (POC), and finally global drug registration. This session will highlight design considerations to optimize drug disposition and safety characteristics in the Discovery phase, to ensure the preclinical road in Development is a smooth one. In addition, you will learn what startups need to know about preclinical requirements and resources to support early clinical trials through Human POC. This workshop is geared towards pharmaceutical and biotech startups.

## Topics will include:

- Key drug metabolism, pharmacokinetic and toxicology characteristics that should be considered in molecule design
  - Preclinical requirements to support FIH trials and POC
  - Evaluating preclinical resources (consultants and CROs) to support your program
  - Hiring your first Preclinical FTE

The workshop will feature Michael Kelley, VMD, PhD, DABT, Senior Scientific Director with Janssen Research & Development. Mike has over 25 years of industry experience and has held leadership positions in both small and large biopharmaceutical companies.

The "How to... Workshop" series is dedicated to giving you the keys to a successful business, from creation to exit. As with all our events, the "How to... Workshop" is interactive and informal so bring your questions with you!

#### Speaker Bio

Michael Kelley, VMD, Ph.D., DABT | Senior Scientific Director, Janssen Research & Development

Mike is currently Senior Scientific Director/Head of Preclinical Projects & Submissions at the Janssen R&D site in Spring House, PA. As part of this role, he is responsible for a portfolio of discovery and development projects in the Oncology, Cardiovascular and Metabolism therapeutic areas. Mike is also the Janssen R&D preclinical scientific liaison to the Johnson & Johnson Boston Innovation Center. Mike has more than 25 years of preclinical experience working for small and large biopharmaceutical companies. He is a full member of the Society of Toxicology, Past-President of the Mid-Atlantic Chapter of the Society of Toxicology, and a Diplomate of the American Board of Toxicology. Mike received his BA and VMD degrees from the University of Pennsylvania, and his PhD in toxicology from Texas A&M University.

#### Bio2Device Group, Tuesday Evening, Dec. 8, 2015

Topic: "Vaccines, Canaries and Coalmines: What lessons for Biopharma from the Oldest Class of Biologics?"

Speaker: Piers Whitehead, Special Advisor to the CEO, Acquisitions, PaxVax

Date and Time: Tuesday, Dec. 8, 2015, 6:00 pm

Location: Wilson Sonsini Goodrich & Rosati, 650 Page Mill Road, Palo Alto CA Cost:

\$6 - Students/In-transition - Members only

\$11 - Early-bird Registration - Members only

\$20 - Late Registration and Non-Members

\$25 - Walk-ins

# Register at www.Bio2DeviceGroup.org

## Topic Description

Since at least the 15<sup>th</sup> Century, people have been vaccinating against infectious disease. As the most "mature" biopharma sector, what can we learn from it about broader biopharma trends, such as industry concentration, the role of developing country producers, achieving global access, industry cycles and more?

# Speaker Bio

Mr. Whitehead joined PaxVax in early 2013 and brings 20 years of experience in the vaccines and biopharmaceutical industries. He previously served as Vice President of Corporate Development for Paris-based Neovacs. Prior to that, he was Vice President of Corporate and Business Development for vaccine company, VaxGen. At VaxGen, he negotiated several important partnerships and led the company's commercial strategy, resulting in the award of a nearly one billion dollar Project Bioshield Act contract. He also spent 10 years at Mercer Management Consulting, where he headed the San Francisco office and led marketing, strategy, and manufacturing projects for clients including the Global Alliance for Vaccines and Immunization (GAVI), UNICEF, and several private-sector pharmaceutical and biopharmaceutical companies. Mr. Whitehead has published extensively on the vaccine industry and related public policy matters and holds an A.B. from Oriel College, Oxford University, England.