Audrey's Life Science Meeting Picks for Aug. 30, 2015 – Dec., 2015
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Aug. 30, 2015

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Bio2Device Group, Tuesday Morning, Sept. 1, 2015

Topic: End of Summer Open Forum and Networking
Speakesr: Facilitator, Harry Wachob, President and Founder, Biio2Device Group and All Attendees
Date and Time: Tuesday, Sept. 1, 2015, 8:30 am
Location: Sunnyvale City Council Chambers, 456 West Olive Ave., Sunnyvale, CA
No fee or registration required for morning meetings.

Event Description
We have been unable to fill the slot with an invited speaker. Instead we will provide an Open Forum for discussions of issues that affect our members and the life science industries.
Bring your thoughts, questions and lots of answers to the Forum!!!

Facilitator Bio
Harry Wachob, Ph.D., is the Founder and President of the Bio2Device Group. He is an experienced engineering leader in materials science, biomedical device engineering and R&D. He has directed and mentored multidisciplinary teams in solving complex technical issues in order to improve the safety, reliability, and performance of medical devices. He is currently the Managing Materials Scientist at Xoft, Inc. Previously, he was Director of Engineering for Aerogen, Inc., a biopharmaceutical company specializing in novel aerosol drug delivery. Prior to that, Harry was Managing Engineer at Exponent/Failure Analysis Associates where he guided research and development, and product failure investigations covering a broad range of medical and industrial applications. He received his engineering degrees in Materials Science & Engineering from Cornell University.
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FierceLive Webinars, Wednesday Morning, Sept. 2, 2015

Topic:"Precision Medicine: Opportunities and Challenges for Clinical Trials"
Speaker: Franklin O. Smith, III, MD — Vice President Medical Affairs, Hematology and Oncology, Medpace
Date and Time: Wednesday, Sept. 2, 2015, 8:30 am PT (11:30 am ET)
Fee: Free
Details and registration at
https://event.on24.com/eventRegistration/EventLobbyServlet?target=registration.jsp&eventid=1023963&sessionid=1&key=D25DF49385539919B961E06614FB8046&sourcepage=register

Topic Discussion
The momentum and muscle behind "finding the right drug for the right patient at the right dose" has further escalated with President Barack Obama's announcement of a $215 million dollar Precision Medicine Initiative earlier this year. In this webinar, Dr. Frank Smith will explore advances in precision medicine and how it is affecting clinical research. As a pediatric hematologist/oncologist, he will use his extensive clinical and research background

as a backdrop for the discussion.

Topics will include:

- The evolution of "personalized medicine" to "precision medicine"
- How state-of-the-art molecular biology is creating new diagnostic and prognostic strategies
- How these new strategies are helping inform the design of clinical trials
- Case study: How precision medicine is improving clinical trials in hematology and oncology

Speaker Bio
Dr. Smith is an industry leader in hematologic malignancies, stem cell transplantation, bone marrow failure syndromes, and childhood cancers. In addition to being a pioneer in hematologic oncology and cord blood transplantation, he is highly-regarded author, speaker, and industry participant.

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WIB Webinar, Wednesday Morning, Sept. 2, 2015

Topic: "Best Practices for Sharing IP Rights in the Life Sciences"
Speakers: Julie Watson, Special Counsel at Marshall Gerstein & Borun, LLP; Kate Murashige, Senior Of Counsel at Morrison & Foerster and Dawn Matthews, co-founder of Abiant, Inc., a 50% parent of ADMdx
Date and Time: Wednesday, Sept. 2, 2015, 11:00 AM TO 12:15 PM
Wednesday, September 2, 2015 (times listed below for each time zone)
11:00 a. m. - 12:15 p.m. PST
1:00 p.m. – 2:15 p.m. CST
2:00 p.m. - 3:15 p.m. EST
Fee: Free to members and nonmembers
Register at http://www.womeninbio.org/eventdetails.aspx?EventId=26074

Topic Description
A panel of experienced professional women will discuss best practices and potential pitfalls associated with sharing intellectual property (IP) rights. An IP strategy is crucial for a company driven by technological innovation. Our expert panel will share their thoughts on how to effectively share IP, analyze potential collaborations, avoid pitfalls, and maximize an invention's ROI. This is a great opportunity to gain legal perspective and wisdom from industry leaders.
See below for speaker biographies.
Speaker Bios

- About Julie Watson: Julie Watson is Special Counsel at Marshall Gerstein & Borun, LLP, a Chicago-based intellectual property law firm. A licensing professional with over 25 years' experience in structuring and negotiating complex deals, Julie concentrates her practice on intellectual property transactions with a particular emphasis in technology startups and university technology transfer. Julie's prior work includes managing nonprofit intellectual property licensing programs including the Wake Forest Institute for Regenerative Medicine and the American Medical Association. Julie received her law degree from Wake Forest University Law School and is admitted to practice law in Illinois, North Carolina and before the USPTO. She

also holds a master's degree from Johns Hopkins University and is a Certified Licensing Professional.

- About Kate Murashige: Kate is the Senior Of Counsel at Morrison & Foerster and has been doing patent prosecution, opinions, and due diligence for 35 years. She worked as an in-house patent attorney for Syntex and Genentech before going into private practice. Kate has a Ph.D. in organic/biochemistry and did "next case" practice before turning to patents. Additionally, she was awarded Chamber's lifetime achievement recognition and has been consistently listed in Best Lawyers in America.
- About Dawn Matthews: Ms. Matthews has over 25 years of management experience in the life sciences industry, with more than half of those focused on imaging for drug development and disease detection. She is a co-founder of Abiant, Inc., a 50% parent of ADMdx, where she has directed the optimization of quality control, processing, and analysis methods for amyloid and FDG PET image data, the development of novel methods to classify dementias, and the successful implementation of clinical trials. She previously served as CEO of MIICRO, Inc., a medical imaging technology company, and as Director of Business Development for Motorola BioChip Systems. She was a co-founder of Aksys, Ltd., where she served as Vice President and Acting CFO during multiple private financings and the company's Initial Public Offering in 1996, and earlier was a Senior Principal Engineer at Baxter Healthcare.

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Bio2Device Group, Tuesday Evening, Sept. 8, 2015

Topic: "The Dirt on Being Clean"
Speaker: Colleen Cutcliffe, Ph.D., CEO and Co-Founder, Whole Biome
Date and Time: Tuesday, September 8, 2015, 6:00pm
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
Register on website www.Bio2DeviceGroup.org
Payment Options
We use PAYPAL to process your online payment. Print and bring a copy of your online receipt with you. If space permits, walk-ins are welcomed; please be prepared to pay $25 cash or check. There is no refund, exchange, or transfer. Thank you for your cooperation.
To register now, select the appropriate registration level and your meal preference from the pull-down menus below and enter the name and email of the attendee. Then click on the "Pay Now" button to reach the PayPal payment page. Each attendee must be registered separately. Please register a non-member by logging out first.

Make sure you enter the attendee's meal choice, name, and email address.

Event Description
The microbiome is beginning to surface as a potential huge opportunity for medicine and health. For centuries, mankind has believed that the microbes (bacteria, viruses, fungi, etc) that reside in the world around us are having an impact on our health. However, with the advent of next generation DNA sequencing, we now have the ability to survey and explore the microbiome in ways that will allow us to develop diagnostics and new therapeutics. From these surveys, we have already learned that we have 5 to 10-fold more microbial cells on us than human cells and that the microbiome has correlative and potentially curative properties in a wide variety of health issues and diseases, including obesity, Crohn's disease, allergies, depression and autism. In this talk, we'll explore some of the important findings in the microbiome, discuss where the space is headed and learn what we can all do today to drive this science forward.

Speaker Bio
Colleen Cutcliffe is the CEO and Co-Founder of Whole Biome, a venture-backed start up company based in San Francisco that is developing diagnostics and therapeutics that target the microbiome. Prior to starting Whole Biome, Colleen served as the Senior Manager of Biology at Pacific Biosciences and prior to that, served as a Scientist at Elan Pharmaceuticals in the Parkinson's Disease Discovery Group. Colleen received her postdoctoral training at Northwestern University's Children's Memorial Hospital, her Ph.D. in Biochemistry and Molecular Biology from Johns Hopkins University, and her B.A. from Wellesley College.

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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
Companies must have applied for a one-on-one meeting 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 apply online 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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WIB-San Francisco Bay YWIB, Saturday Afternoon, Sept. 12, 2015

Event: WIB-San Francisco Bay Area YWIB Visits the Buck Institute for Research on Aging
Date and Time: Saturday, September 12, 2015 from 12:45 p.m. – 5:00 p.m. PST
12:45 p.m. - 1:00 p.m. Check In
1:00 p.m. - 1:30 p.m. Welcome
1:30 p.m. - 4:30 p.m. Main Program*
4:30 p.m. - 5:00 p.m. Wrap Up and Party
* Includes Lab Tour, Hands-On Activity, and a Career Panel of Buck Scientists.
Location: Buck Institute for Research on Aging, 8001 Redwood Blvd., Novato, CA 94945
YWIB Participant Age Range
Middle school and high school

Walk-Ins Accepted?
Walk-ins and guests are not accepted – be sure to register early!
Pricing Information
Members: Free
Non-Members: Free
Registration Deadline
September 5, 2015
Register at http://www.womeninbio.org/eventdetails.aspx?EventId=25833
Maximum Capacity
100

Please be sure to register your child only once for this event. You will receive a confirmation email that the registration has gone through. If you are unsure if the registration went through please email info@womeninbio.org.

Event Description
The Buck Institute in Novato, California, invites San Francisco Bay area middle and high school girls for a Saturday afternoon of discovering the fun and challenges of a science career. The Buck Institute is the nation's first independent research facility focused solely on understanding the connection between aging and chronic disease, with a mission to increase the healthy years of life.
The main program includes hands-on science activities, lab tours, and a panel discussion with scientists at the Institute. The discussions and activities will be followed by a pizza dinner.
Please read the YWIB permission forms located at http://www.womeninbio.org/ywib
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Bio2Device Group, Tuesday Morning, Sept. 15, 2015

Topic: "How Early-Stage and Growth Companies Can Protect their Intellectual Property"
Speakers: Seth Northrop, Principal & Technology Attorney, Robins Kaplan LLP, and Li Zhu, technology attorney and registered patent agen, Robins Kaplan LLP
Date and Time: Tuesday, Sept. 15, 2015, 8:30 am
Location: Sunnyvale City Council Chambers, 456 West Olive Ave., Sunnyvale, CA
No fee or registration required for morning meetings.

Topic Description
Medtech and biotech companies have sophisticated needs when it comes to intellectual property. The industry is experiencing explosive growth, while IP law has undergone significant changes in recent years, creating unique challenges for early-stage and growth companies. Seth and Li will discuss key pitfalls to avoid when growing your business and securing future investment, and how you can best protect your intellectual property in the current landscape.

Speaker Bios
Seth Northrop is a principal and technology attorney at Robins Kaplan LLP. He is a former entrepreneur who leverages his background in business, technology, and the law to solve his clients' most complicated problems. Prior to attending law school, Seth worked as an engineer and successfully co-founded his own company.
Now as an attorney, Seth focuses his practice on providing strategic advice for large and small companies along with handling large-scale disputes involving a variety of technologies.

Li Zhu is a technology attorney and registered patent agent at Robins Kaplan LLP. Prior to law school, Li worked in a research lab at The Scripps Research Institute. His background provides an intimate understanding of the intersection between technology and science and the process by which technologies travel from the workbench to the courtroom. As an attorney, Li counsels his clients in a broad range of industries, including Medtech, biotech, and life sciences.

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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

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CABS, Wednesday Afternoon, Sept. 19, 2015

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

Agenda:

1:00 - 1:25 pm	Registration, networking, workshop introduction
1:25 - 1:50 pm	Mike Schwartz, Co-founder and VP of Marketing, Fluxion Biosciences
	Liquid biopsy innovations for oncology using sequencing of circulating tumor cells
1:50 - 2:15 pm	Shengrong Lin and Paul Tang, Co-founders, AccuraGen
	Title tbd
2:15 - 2:40 pm	Mojgan Haddad, former Sr. Director, Bioinformatics and Analytics, Health Tell
	HIV Drug Resistance Diagnostics: Path of Discovery to Clinical Application
2:40 - 3:00 pm	Break
3:00 - 3:25 pm	John Waldeisen, Co-founder and CEO, DiAssess
	My Life as an Entrepreneur
3:25 - 4:50 pm	Nikolay Sergeev, R & D leader, Natera
	Applications of Massively-Multiplexed PCR for Liquid Biopsy
4:50 - 5:00 pm	Wrap-up

* Lunch will be provided.

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

Topic Description
Over the past few years, there have been remarkable advances in DNA detection and sequencing technologies that enabled faster and better diagnostics developed for liquid biopsies. Liquid biopsies have now emerged as promising tools that are safer and cheaper than traditional tissue biopsies to survey health and disease state. For the first time, we are now able to obtain a wealth of information from blood and urine derived circulating DNA fragments that could revolutionize research and patient care. Began with prenatal screening, these technologies now allow physicians to make early disease diagnosis, monitor progression, and predict treatment benefits. This workshop will be led by founders and leaders of many prominent companies which have pioneered the frontiers of peripheral
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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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QB3, Monday Afternoons, Sept. 24, 2015

Workshop: QB3 NIH/NSF SBIR WORKSHOP FALL 2015
Instructors:
Shauna Farr-Jones, PhD, UCSF/QB3 grant writer
Crystal Nyitray, PhD, Entrepreneurship Program Manager
Dates: Sept. 24 – Dec. 17
Schedule
9/24 (Thurs) 1:00-4:30 pmMH-1401
10/22 (Thurs)1:00-4:30 pmBH-212
11/19 (Thurs)1:00-4:30 pmBH-212
12/10 (Thurs)1:00-3:30 pmBH-212
12/17 (Thurs)1:00-4:30 pmBH-212
Location:UCSF Mission Bay
Fee: Standard rate for the entire 14-hour workshop: $750 per company; Discounted rate for UC affiliates, QB3 Startup in a Box Members, and QB3 Accelerator Members: $250 for entire course per company

Workshop Description
Five two-and-a-half hour SBIR classes, with two additional one-hour sessions on Phase 2 submissions and resubmissions, and two additional one hours sessions on NSF submissions. Starting Thursday, Sepember 24th and concluding Thursday, December 17th.
There are a limited number of seats, so please sign up as soon as possible by registering here on Eventbrite and also filling out the online application form (*must be completed by 9/18/2015*).
This five-session workshop will take you through all the steps necessary to successfully file a well-written SBIR/STTR grant application for the January 5th, 2015 NIH SBIR deadline and the December NSF deadline. This course will focus on crafting a well-structured research plan, getting persuasive letters of support, crafting an efficient budget, and helping you anticipate reviewers' comments. We will help you speed through the application instructions, saving you hours of time. The course culminates in a submission clinic that will ensure your application is correctly filed.
One or more team members from the company should be prepared to attend every session. Remember to bring your laptop; these will be working sessions.
Course includes
- Five 2.5-hour working sessions
- One 1-hour resubmission working session
- One 1-hour Phase 2 working session
- Two 1-hour NSF working sessions
- Pre-submission review of specific aims by our course instructors

Topics include
- Understanding the requirements of an SBIR
- Preparing to apply for an SBIR (company formation, registration at all required websites, identifying the best PI)
- Assembling all the necessary parts of the application (letters of support, sub-contract quotes and letters, facilities to execute the grant, and research plan)
- Composing a competitive research plan
- Understanding and assembling a budget and justification
- Documentation required to use human samples, vertebrate animals, select agents, resources
- Composing competitive innovation and significance sections as well as specific aims
- Searching for program announcements and finding opportunities
- Assembling and filing (completing the 424 correctly and filing on time)

Startup in a box membership fee for new members includes this workshop. If you fall under this category, you may register for free (ask Crystal Nyitray for the code).
A light snack and coffee is included for all sessions.
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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 http://www.eventbrite.com/e/meet-with-orbimed-tickets-17394113261

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 apply online 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 start-ups 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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PBSS, Tuesday, November 10, 2015

Topic: " Effects of Food and pH on Drug Absorption and Pharmacokinetics: Fundamentals, Investigation, Prediction, and Formulation Remedies"
Speakers: Matt Wright, Mark Ratain, Joe Ware, Grazyna Fraczkiewicz, Jan Wahlstrom, Atik Rahman, Charles Yang
Date and Time: Tuesday, Nov. 10, 2015, 8:45 – 17:00
Location: SF Bay Area: Foster City Crowne Plaza
Registration at http://www.pbss.org/aspx/homeSF.aspx
Registration deadline: 11/9/2015 (it will close sooner if the seating cap is reached)
Topic Description

- Review of Human GI Physiology and Responses to Food - Physicochemical and BCS Class Considerations (Matt Wright, Genentech)
- Food effect: Clinical Lesson Learned in Oncology: Where we have been and where we are going (Mark Ratain, University of Chicago)
- pH-dependent drug-drug interactions (Joe Ware, Genentech)
- PBPK modeling to predict and learn from food effect and pH-dependent interactions (bottom-up/top down approaches) Grazyna Fraczkiewicz, Simulations Plus
- Case study and Lessons Learned (Jan Wahlstrom, Amgen)
- FDA speaker on food effect and pH-dependent Drug-Drug Interactions (Atik Rahman, FDA)
- To Eat or Not to Eat? Contemplating a Nobler Formulation to Address Food Effect (Charles Yang, Genentech)

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Chief Medical Officer West, Monday – Tuesday, Nov. 9-10, 2015

Event: 2nd Chief Medical Officer West Conference
Speakers: CMOW is delighted to welcome back members of our distinguished faculty and also welcomes aboard new speakers from Kite Pharma, Kearney Venture Partners, Sorrento Therapeutics, Sunesis Pharmaceuticals, Apricus Biosciences, Skyline Ventures, Tocagen, Roche Venture, NGM Biopharmaceuticals, Relypsa, Nevro, EddingPharm, Bay City Capital and Vivo Capital.
Date and Time: Monday – Tuesday, Nov. 9-10, 2015
Location: Hilton San Francisco Airport Bayfront, Burlingame, CA
Price: Standard 2nd Early Bird, through 9/12—S1,295.00; Academic/Govt 2nd Early Bird Through 9/12--$647.50 through 9/12 **10% Discount with Code TEML**

Register at https://theconferenceforum.org/events/cmo-west-2014-2/

Event Description
The 2015 CMOW program is the only conference of its kind dedicated to addressing the unique challenges faced by CMOs in emerging biotechs. The program is designed with input from CMOs and our lead advisor, Dr. Pamela Palmer, CMO & Co-founder, AcelRX. It is an R&D leadership event unique to the CMO.

New Novel Topic Discussions
New topics including, CMO / Investor Joint Interview; Selling the Buy-side: Interacting with Healthcare Hedge Funds; Think Globally: Gaining EU Approvals & Navigating the EU Market; Separation vs Collaboration of Medical and Commercial Roles in Biotech; Latest Clinical Development Approaches for CMOs; and much more!

Networking & Benchmarking Opportunities
Meet other CMOs facing similar challenges and exchange ideas and best practices. Opportunities to get a comprehensive update on helpful technologies and other services for smaller pharma are in the exhibit area.

See agenda at http://theconferenceforum.org/conferences/cmo-summit-west/agenda/

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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.

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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.
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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 15th 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.