Audrey's Life Science Meeting Picks for Nov. 26, 2017 through April 2018
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Bio2Device Group, Tuesday Morning, Nov. 28, 2017

Topic: "A new S curve in PCI: Devices that Actively Adapt to Vascular Physiology"
Speaker: Vinayak D Bhat, PhD., President & Chief Operating Officer, Elixir Medical
Date and Time: Tuesday morning, Nov. 28, 2017
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
There are no fees or registration required for morning meetings.

Topic Description
The talk will provide an overview of device development in percutaneous coronary intervention, from coronary angioplasty to fully bioresorbable scaffolds. The presentation will focus on a new generation of innovative devices developed by Elixir Medical, that are designed to actively adapt to the changing needs of vascular physiological and work in harmony with the artery to heal the diseased artery. These devices return the pulsatile motion of a beating coronary artery and demonstrate adaptive vascular remodeling that is observed in normal physiologic state. The devices have potential to provide clinical benefits in range of indications from cardiovascular to peripheral vascular diseases.

Speaker Bio
Dr. Vinayak Bhat serves as the President & Chief Operating Officer of Elixir Medical. Dr. Bhat previously served as the Vice President & General Manager of DES Division of Avantec Vascular Corporation, a subsidiary of Goodman Co. Ltd., a Nagoya, Japan based medical product company. Dr. Bhat joined Avantec as Director of R&D, and was part of the management group which secured the sale of the company to Goodman Co. Ltd. in 2002. He also held several research and management positions within the Stent Business Unit of Guidant Corporation (currently Abbott Vascular).
Dr. Bhat is an inventor or co-inventor on 40 US and EU patents and has over 25 pending applications. He also has 15 peer-reviewed publications and book chapters. Dr. Bhat holds a Bachelor's degree in Chemical Engineering from University of Bombay, India, Masters in Biochemical Engineering and Ph.D. in Biomedical Engineering from Duke University, North Carolina.

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WIB-San Francisco Bay Area, Thursday Evening, Nov. 28, 2017

Event: Get Involved with WIB-San Francisco Bay Area: Volunteer Information Session on November 28, 2017
Date and Time: Thursday, November 28, 2017,6:00 p.m. – 8:00 p.m. PST
6:00 p.m. - 6:30 p.m. Check-in and light refreshments
6:30 p.m. - 7:15 p.m. WIB committee overview
7:15 p.m. - 8:00 p.m. Networking time with committee chairs/members
Location: Mission Bay Housing Conference Room, 1560 3rd Street, San Francisco, CA 94158
Pricing: Free
Register at https://womeninbio.site-ym.com/events/EventDetails.aspx?id=1032848&group=

Event Description
Want to learn more about Women In Bio? Already a member and want to take your involvement to the next level? Come volunteer with us! By volunteering, you will have the opportunity to engage with life science companies around the Bay Area, meet inspiring women leaders, and build meaningful relationships with committee chairs and fellow volunteers. Come learn about our volunteer-based organization and how to get involved in 2018!

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Palo Alto AWIS, Thursday Evening, Nov. 30, 2017

Event: Mini Workshop
Topic: "Speaking Up without Freaking Out"
Speaker: Matt Abrahams
Date and Time: Thursday, November 30, 2017, 7- 9 PM
7:00 - 7:25: Networking dinner
7:25 - 7:30: Announcements
7:30 - 9:00: Workshop
Location: Stanford University MSOB X303, 1265 Welch Road, 3rd Floor
Stanford, CA 94305
Fees:
Palo Alto AWIS Members: $5
Pre-registered Non-Members: $15
Fee at Door: $20
Register at https://www.brownpapertickets.com/event/3118379

Do you feel uneasy and nervous when speaking in public?
Learn proven concepts that help reduce your anxiety and communicate with your audience boldly and authentically.

Join us for this mini-workshop by Matt Abrahams

Speaker Bio
Matt Abrahams is a passionate, collaborative and innovative educator and coach. He teaches Effective Virtual Communication and Essentials of Strategic Communication at Stanford Graduate School of Business. Matt is Co-Founder and Principal at Bold Echo Communications Solutions, a presentation and communication skills coaching company. He is also the author of Speaking Up Without Freaking Out, a book written to help people to present in a more confident and compelling way.

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AWIS and Boehringer Ingelheim, Thursday Evening, Nov. 30, 2017

Topic: Women in the Sciences Industry: Executive Company Leaders, Experts, and Decision Makers—An Inspiring Panel Discussion and Networking Eveny
Date and Time: Thursday, November 30th 2017, 5:00 p.m. - 9:00 p.m.
5:00 pm Arrivals/Registrations/Networking
6:00 pm Dinner
7:00 pm AWIS Announcements
7:15 pm Panel Discussion
8:15 pm Q&A, Close
Location: Boehringer Ingelheim Fremont, Inc., 6701 Kaiser Drive, Fremont, CA 94555

This is a free event sponsored by Boehringer Ingelheim

Topic Description

Focus on inspiring bold leadership, innovative insights, learn more about getting into industry, building careers, hear about how the panelists overcame challenges, what challenges women (and others) can expect, and general advice to build careers in the Pharma and Biotech industry.

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Bio2Device Group, Tuesday Morning, Dec. 5, 2017

Topic: "From Condoms to Brain Implants: Protecting Patient Safety Across the Device Spectrum Through Biological Assessment"
Date and Time: Tuesday Morning, Dec. 5, 2017, 8:30 am
Location: Sunnyvale City Council Chambers- 456 West Olive Ave., Sunnyvale
There is no registration or fee for morning meetings.

Topic Description
Using a risk-based approach to address biocompatibility has become mainstream, and actively encouraged by the FDA. This strategy allows manufacturers to leverage previous testing knowledge of device materials and chemistry to reduce their testing burden while improving patient safety. The caveat? Manufacturers have to better understand their materials and how they interact with the body. This presentation will cover assessment of biocompatibility through case studies focusing on real medical devices (including condoms).
Bullet Points (what will be covered):
- Updates to guidance documents that emphasize using a risk-based approach to biocompatibility
- Options and strategies to address biocompatibility with an emphasis on different classes of devices
- Examples of where material assessment has dramatically reduced testing burden

Speaker Bio:
Audrey Turley has 20 years of experience working in research, laboratory, and test design functions in the medical device industry. She is a biocompatibility expert having performed all the in vitro tests offered at Nelson Laboratories, which include cytotoxicity (MEM and agar overlay), hemolysis (PTT, PT, complement activation, blood circulation, ASTM and NIH methods), and genotoxicity (Ames and chromosome aberration). Audrey also has experience performing, consulting and training on bioburden, microbial IDs, sterility and bacteristasis/fungistasis testing. She trains staff within the biocompatibility department and works on a company- wide level to trouble shoot problems.
Audrey was responsible for the development of the in vitro mammalian chromosomal aberration assay at Nelson Laboratories. This included connecting with industry experts who developed the assay under OECD. She is also on the team at Nelson Laboratories for developing the in vitro skin irritation assay for medical devices. Audrey is collaborating with ISO members around the world to approve a procedure for round robin testing in order for this assay to gain acceptance by regulatory bodies in Europe and then in the United States. Audrey is an active committee member of many working groups with the Association for the Advancement of Medical Instrumentation (AAMI).

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WIB, Tuesday Evening, Dec. 5, 2017

Event: WIB-San Francisco Bay Area's Holiday Party: Recapping a Successful Year!
Date and Time: Tuesday, December 5, 2017,6:00 p.m. – 9:00 p.m. PST
Location: Devil's Canyon Brewing Company, 935 Washington Street, San Carlos, CA 94070
Contact: WIB-San Francisco Bay Area
SanFrancisco@WomenInBio.org
Online registration is available until: 12/4/2017
Pricing
Members: $10
Non-Members: $25
Details and registration at
http://www.womeninbio.org/events/EventDetails.aspx?id=1030332&group=

Event Description
Join WIB-San Francisco Bay Area chapter members at Devil's Canyon Brewing Company on December 5th to celebrate another phenomenally successful year. Our events in 2017 would not have been possible without the tireless support of our amazing volunteers and sponsors. Let us say, "Thank You," to them and wish WIB continued success!

Walk-Ins Accepted?
Walk-ins are not accepted – be sure to register early!

Parking Information
- parking lot located next to Devil's Canyon
- plenty of street parking available

Public Transit Information
Devil's Canyon Brewing Company is located between the San Carlos and Redwood City Caltrain stations.

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Biopharma Consortium with DLA Piper, Tuesday Evening, Dec. 5, 2017

Topic: "Beyond the Hype: Big Data at Work in Healthcare & Biotech)
Speakers: Gini Deshpande, Ph.D. (Panelist) Founder and CEO of NuMedii, Tara English, MBA (Panelist) Technology Strategy & Partnerships at Kaiser Permanente National IT; Ivana Schnur, M.D., Ph.D. (Panelist) Co-Founder and Chief Medical Officer of Sensely; Mary Wheeler, Ph.D., MBA (Panelist) Chief Business Officer of SirenasMD; Erica Pascal, Ph.D. Esq. (Moderator) Founder of Ingensity IP
Date and Time: December 5, 2017, 5:00 pm
Agenda:
5:00pm | Registration & Networking
6:00pm | Panel event – Q&A
7:15pm | Networking
8pm | Close
Location: DLA Piper | 2000 University Ave, Palo Alto, CA 94303
Pricing
$25 for early registration thru Friday Nov 17
$30 for pre-registration thru Mon Dec 4
$40 for walk-ins

Registration: http://www.biopharmaconsortium.com/bay-area-events/
*ID required at check-in

Topic Description
We hear a lot of hype about what big data and analytic tools such as AI, machine learning, deep learning and neural networks can bring to healthcare. But let's talk about what's happening right now. Where are these tools being used? Where are they having the most significant impact and what areas face greater challenges and may lag behind?

Join BPC for a panel discussion of real-world examples of big data analysis and applications. We will examine how these new tools are being applied to drug discovery, in clinical trials, in the clinical setting and by healthcare providers. The panelists will examine the variety of data sources and the different challenges each bring when applied to different sectors of the healthcare and biotechnology ecosystem. For areas that to date have presented greater challenges, the panel will discuss applicable solutions they have enlisted to help move these areas along.

REGISTRATION: http://www.biopharmaconsortium.com/bay-area-events/
*ID required at check-in
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Rosenman Institute and QB3, Tuesday Evening, Dec. 5, 2017

Topic: "How to Build a Commercially Valuable, Unassailable Patent Portfolio"
Speaker: IP attorney Adam Schoen, Brown Rudnick
Date and Time: Tuesday, December 5, 5:00 to 6:30 pm
5:00 - 5:30 pm: Networking
5:30 - 6:30 pm: Talk and Q&A
Location: UCSF Mission Bay, Byers Hall, Room 212
Space is limited.
Fee: $10
Register at https://www.eventbrite.com/e/rosenman-d-series-adam-schoen-how-to-build-a-patent-portfolio-tickets-39406814844?mc_cid=539140223a&mc_eid=cb4c38a44a

Topic Description
The D-Series is our forum on medical device development in the Bay Area. Join us to learn about the latest technology and meet leaders in the field.
A secure IP position is absolutely essential for a bioscience startup. It's a key factor in helping you win investment. But how exactly do you build commercial barriers to prevent competitors from entering your space? Join us to get the whole picture from IP attorney Adam Schoen of Brown Rudnick. Adam will cover what investors and strategics are looking for in IP diligence; how that frames portfolio development; classic pitfalls to avoid; and much more.

Adam Schoen advises life science and medical device companies regarding implementation of a patent strategy to further business objectives and business goals. Adam's practice encompasses patent preparation and prosecution, portfolio development, product clearance, freedom to operate analysis and intellectual property due diligence. Adam works with public and private companies, investors, and academic institutions.
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ASQ Biomedical, Wednesday Evening, Dec. 6, 2017

Topic: "Modern Approaches To Assessment Of Bio-Compatibility - ASQ Biomedical NCDG December 6, 2017 Roundtable"
Speaker: Audrey Turley, B.S., RM(NRCM), CBA(ASQ), Technical Consultant, Nelson Laboratories, LLC
Moderator: George Marcel, ASQ NCDG
Date and Time: Wednesday, December 6, 2017 from 7:00 PM to 9:00 PM (PST)
Location: Stellartech Research Corporation, 560 Cottonwood Drive, Milpitas, CA 95035
Food: Snacks equivalent to a light meal and beverages are provided at each event at no additional cost.
Email: To be added to or removed from our email list, contact George Marcel (gmarcel@gmail.com)
Registration Link: NCDGDEC2017.eventbrite.com
ONLY Check or Credit Card accepted at door
Questions: For information about this session, contact George Marcel (gmarcel@gmail.com)
Formal discussion and questions will end between 8:30 - 8:45 pm to allow time for networking after the roundtable presentation.
Materials: Handouts provided. Please limit distribution to immediate personal professional use only.
Pricing and registration at https://www.eventbrite.com/e/modern-approaches-to-assessment-of-bio-compatibility-asq-biomedical-ncdg-december-6-2017-roundtable-tickets-39274852140?ref=enivtefor001&invite=MTMyNTA0NzMvYXVkcmV5ZXJiZXNAYW9sLmNvbS8w&utm_source=eb_email&utm_medium=email&utm_campaign=inviteformalv2&ref=enivtefor001&utm_term=attend

Event Description
Topic: This presentation will provide an overview of the most recent updates to the ISO 10993 series, FDA guidance documents touching biocompatibility, and expected changes coming up for EU and CE marks. The overarching strategy for biocompatibility evaluation in light of this rapidly shifting landscape will be outlined, with an emphasis on utilizing a risk-based approach that reduces both cost and testing burden while simultaneously providing enhanced patient safety.

- Updates to guidance documents that emphasize using a risk-based approach to biocompatibility
- Options and strategies to address biocompatibility with an emphasis on different classes of devices
- Examples of where material assessment has dramatically reduced testing burden

Speaker Bio
Audrey Turley has 20 years of experience working in research, laboratory, and test design functions in the medical device industry. She is a biocompatibility expert having performed all the in vitro tests offered at Nelson Laboratories, which include cytotoxicity (MEM and agar overlay), hemolysis (PTT, PT, complement activation, blood circulation, ASTM and NIH methods), and genotoxicity (Ames and chromosome aberration). Audrey is part of a team at Nelson Laboratories that recently completed round robin testing for an in vitro irritation assay in an effort to gain acceptance by regulatory bodies in the United States and Europe.

Audrey is an active committee member of many working groups with the Association for the Advancement of Medical Instrumentation (AAMI):

- BE/WG 06 – Mutagen, carcinogen, reproduction toxicity
- BE/WG 07 – Systemic toxicity
- BE/WG 08 – Irritation and sensitization
- BE/WG 10 – Implantation
- BE/WG 11 – Allowable limits for leachable substances

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PBSS Workshop, Monday, Dec. 11, 2017

Event Name: Clinical Pharmacology & Modeling Strategies for your Drug Development
Program: Fundamentals, Best Practices and Real World Applications
Speakers: David Lau (Foresee Pharmaceuticals), Geoff Banks (Nuventra), Mark Sale (Nuventra), Lauren Lohmer (Nuventra)
Date and Time: Monday, Dec. 11, 2017, 8:45-17:00
Preliminary Agenda
8:45 – 9:00 Welcome and Intro
9:00 – 10:30 – David Lau (Senior Vice President, NCE Preclinical and Clinical Development, Foresee Pharmaceuticals)
Purpose of Clin Pharm Studies in Drug Development
Type of Clin Pharm studies (SAD, MAD, BA/BE, DDI, Disease population, QT, etc)

- What are these studies
- When to do the studies
- Typical study design
- Examples

10:30 – 11:00 – Break and Vendor Presentation
11:00 – 12:30 – Geoff Banks (CEO, Nuventra)
How to Form a Clin Pharm Strategy for your NDA / BLA

- What studies you do & don't need
- "Gap analysis" in your program
- Real world examples

12:30 – 1:30 – Lunch
1:30 – 3:00 – Mark Sale (Senior Vice President, Pharmacometrics, Nuventra)
Modeling & Simulation / Population PK Fundamentals

- What is it?
- How do you do it?
- Allometric scaling
- How do you use it for safety and efficacy?

3:00 – 3:30 Break and vendor presentation
3:30 – 5:00 – Mark Sale and Lauren Lohmer (Manager, Clinical Pharmacology, Nuventra)
Using Modeling & Simulation to Avoid Clinical Trials

- Overview and case studies:
    - CQT
    - Exposure response
    - Additional DDI studies
    - Special population studies
    - Renal impairment

Location: SF Bay Area: Foster City Crowne Plaza
Registration fee (US$): Academic: $125; Regular: $195; For unemployed or students: $30; For major-sponsor rep (incl lunch): $0; For vendor-show rep: $35;

Details and registration at http://www.pbss.org/aspx/eventInfo.aspx?eID=557
Registration deadline:12/8/2017 (it will close sooner if the seating cap is reached)
This is a friendly reminder that you have not registered for the following Workshop . If you plan to attend, please register at www.pbss.org before it is closed (it may close BEFORE the deadline if the seating capacity is reached early).
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Bio2Device Group, Tuesday Evening, Dec. 12, 2017

Topic: "How did OptiScan become the only company to gain US approval?"
Speaker: Peter Rule, Consultant to OptiScan (CEO from 2/06 to 10/17), PRI Date and Time: Tuesday, Dec. 12, 2017, 6:00 pm
Location: Wilson Sonsini Goodrich & Rosati - 650 Page Mill Road, Palo Alto
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
At one time, approximately 25 companies totaling well in excess of $1B in funding, attempted to create or modify an existing product to achieve US approval for an ICU continuous glucose monitor. Only one company succeeded. There are 3 reasons for this: first, fitting the end product to the needs of the customer. These included the need to invent a fluidics system to extract a tiny amount of blood, heparinize the blood away from the patient, but not deliver heparin to the patient, centrifuge the sample to create plasma, and invent a new means to measure glucose, which does not require calibration.
The second reason was the commitment to clinical research, where the company learned in 2 EU single-center trials and one final US multi-center trial, about its product, and needed improvements. As well, the company obtained reliability data by launching in a single country in the EU. Prior to submission, the company called an independent Clinical Advisory Board to review the trial's aggregate and patient by patient data to create a Benefit v. Risk assessment.
Finally, the amount of money raised to date was over $150M.

Speaker Bio
Peter is a serial entrepreneur who has led five medical device startups (OptiScan BioMedical, PercuSurge, TheraSense, Ekos, MiniMed, etc.) financed by venture capital. Four of the five are profitable, thriving entities today. These four have been purchased. Most recently, BTG purchased Ekos Corporation for an announced valuation of approximately $220M (in July of 2013). The fifth company, OptiScan, is in "the mold" of the previous four: state of the art, large unmet medical need, cost-effective. Peter has been a part of all these companies from Series A, and driven them as late as profitability and cash flow positive. Characteristics of the companies Peter has been associated with are that they are excellent at clinical research, continuous product improvement, and have cohesive management teams. All have been state-of-the-art in terms of technology. All have, at times, required extensive efforts to finance, with a diverse set of investor groups and financial structures.

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QB3, Wednesday Afternoon, Dec. 13, 2017

Topic: "Synbio from Chemistry to Couture"
Speaker: Dan Widmaier, Co-Founder and CEO, Bolt Threads

Date and Time: Wednesday, December 13, noon to 1:00 pm
Location: Byers Auditorium, Genentech Hall, UCSF Mission Bay
Fees: $10 General Admission
Details and registration at https://www.eventbrite.com/e/qb3-seminar-dan-widmaier-ceo-bolt-threads-synbio-from-chemistry-to-couture-tickets-38414463695?mc_cid=2acb16b329&mc_eid=cb4c38a44a

Topic Description
How did Dan Widmaier, CEO of synbio company Bolt Threads, end up backstage in Paris at Stella McCartney's Spring 2018 Ready-to-Wear runway show?

Bolt has had the most remarkable trajectory of any company in the QB3 network. Widmaier (CEO), David Breslauer, and Ethan Mirsky launched Bolt in 2010 at the QB3 Garage@UCSF to develop synthetic spider silk based on their graduate research. Initially they aimed at military applications, but soon pivoted to the fashion industry.

Under Widmaier's leadership, Bolt has raised multiple rounds of funding, acquired NYC's Best Made, and partnered with Patagonia. Bolt is now front and center of the green fabric fashion movement. Wednesday, December 13 at UCSF Mission Bay, Widmaier will tell the inside story of Bolt's founding and growth, and answer your questions. Join us for what is sure to be a terrific event.

Speaker Bio
Dan is fascinated by finding the right conditions to grow things, whether he’s cultivating the broccoli in his vegetable garden, yeast in his microbrews or the people at Bolt Threads. He’s carefully tended our growth since 2009, using his passion and expertise to lead the company through technology development, expansion, and financing. He earned his Ph.D. in Chemistry and Chemical Biology from UC San Francisco, where his graduate research involved designing genetic circuits to control microbial organelles. He’s also passionate about the growth of something over which he has less control: the progress of the Seattle Seahawks.

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BioScience Forum, Wednesday Evening, Dec. 13, 2017

Topic: "Driving Immunosuppression in the Tumor Microenvironment"
Speaker: Tim Sullivan, Ph.D., Vice President, Business Development, Arcus Biosciences
Date and Time: Wednesday, Dec. 13, 2017, 6:00 pm
6:00 PM - networking
7:00 PM - dinner
8:00 PM - presentation
Location: The Holiday Inn, 275 S Airport Blvd, South San Francisco, CA 94080
Price:
$50 before 9PM, Monday, December 11th
$60 on-site
$40 full-time students pre-registration
$50 full-time students on-site
$3 service fee will be added to the pre-registration price
Register at https://www.cvent.com/events/bioscience-forum-tim-sullivan-arcus-biosciences/registration-6788748e85264f03b4a6c259e35a0cad.aspx?fqp=true

Topic Description

Adenosine receptor antagonists and inhibitors of adenosine production are expected to be highly synergistic with other immuno-oncology mechanisms, as well as with chemotherapy. Because of the promise of the adenosine pathway, several adenosine receptor antagonists discovered years ago and initially developed for other indications have been repurposed for oncology. Arcus Biosciences has generated novel small molecule dual antagonists of the key adenosine receptors A2aR and A2bR, and is also developing a monoclonal antibody to target TIGIT (T cell immunoreceptor with Ig and ITIM domains) and other novel entities.

Adenosine is a powerful immunosuppressive agent produced inside tumors as a result of rapid cancer cell turnover and, in some cases, in connection with certain anti-tumor interventions such as chemotherapy and radiation. The A2aR and A2bR receptors are expressed on the surface of immune cells (such as T cells, NK cells, dendritic cells and macrophages) and mediate the immunosuppressive effects of adenosine. AB928, a small-molecule drug in preclinical development, is able to block both of these adenosine receptors.

Like some first-generation immune checkpoints (e.g., PD-1 and CTLA-4), TIGIT is expressed on exhausted T cells, which may reside inside tumors but are unable to mount an effective attack against the cancer cells. It is also expressed on a wide range of other tumor-infiltrating immune cells, such as NK cells and regulatory T cells. By producing proteins that bind to TIGIT, cancer cells and other cell types can interfere with the ability of tumor-infiltrating immune cells to mount an effective anti-tumor response. AB154 is a monoclonal antibody under development which is expected to result in an anti-tumor effect by potently and selectively blocking this interaction.

The research and development of these small molecule and antibody based drug candidates will be discussed, along with the challenges met as they approach clinical testing.

Speaker Bio
Tim has been involved in multiple aspects of drug discovery and development in pharmaceutical and biotechnology companies in the U.S. for more than 15 years, leading discovery and pharmacology teams in a variety of therapeutic areas (e.g., oncology, autoimmune, inflammatory, metabolic and CNS diseases) as well as being involved in groups focused on the external identification of novel technologies and assets suitable for in-licensing and/or acquisition. Prior to joining Arcus, Tim was a Senior Director in the External R&D Innovation (ERDI) group at Pfizer where he focused on identifying new Immuno-Oncology opportunities across all therapeutic modalities, as well as managing the global alliances with Servier and Cellectis focused on the discovery and development of allogeneic CAR-T cell products. Before Pfizer, Tim was a Director in the New Frontier Science group at Takeda, where he primarily focused on identifying and funding very early-stage technologies being developed in academic settings to determine utility in accelerating drug discovery and development.

Prior to Takeda, Tim held various scientific management roles, first at Tularik/Amgen and then as Director of Biology at ChemoCentryx. Tim holds a B.A. degree from the University of Notre Dame and a Ph.D. degree in Cellular and Molecular Biology from the University of California, Berkeley where he trained in the laboratory of Dr. James Allison.
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PBSS, Monday, Jan. 22, 2017

Event: Workshop: Preclinical development & IND/CTA Filing
Speakers: Tracy Chen, Jim Zhang, Peter Staehr, Anne Bonneville, Xingrong Liu
Date and Time: 1/22/2018, 8:30-17:00

Location: SF Bay Area: Foster City Crowne Plaza
Registration fee (USD): Regular: $195; Academic: $125; For unemployed or students: $30;
Registration: http://www.PBSS.org
Registration deadline:1/22/2018 (it will close sooner if the seating cap is reached)
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JLABS, Thursday Morning, Jan. 25, 2017

Topic: "Who's Who in 2018: A Strong Finish to 2017 Healthcare Investing?"
Speaker: Jonathan Norris | Managing Director, Silicon Valley Bank
Date and Time: Thursday, January 25, 2018 from 8:00 AM to 10:00 AM (PST)
Agenda:
8:00 AM | Registration, Breakfast & Networking
8:30 AM | Presentation - Q&A
9:30 AM | Networking
10:00 AM | Program Close
Location:
JLABS @ SSF
329 Oyster Point Blvd - 3rd Floor
South San Francisco, CA
Fees:
$12 | General Public
$8 | Student/Academic
$25 | At the door
Details and registration at https://www.eventbrite.com/e/whos-who-in-2018-a-strong-finish-to-2017-healthcare-investing-tickets-36706212269?aff=weekly

Event Details
2017 saw a banner first half, driven in part by advancements in artificial intelligence and machine learning for healthcare applications and a surge in Series A investments. With 2017 in the review mirror, Jon Norris takes a look at – and makes sense of – the past trends to provide an informed look into 2018.

As the 2018 investment market takes shape, what can we expect for the IPO and M&A markets? Jon will share his expertise and provide insight into:
How the 2017 healthcare landscape compares to previous years
Current and total healthcare and sector investments
Which Biopharma indications attracted the most funds
Which venture firms are most active
Changes in the past crossover phenomenon
Exits: the trends in IPOs and M&A's

At the end of this talk you should be informed as to who is investing, and the type of deals and exits that are likely to be executed in 2018.

Presenter's Biography:
Jonathan Norris | Managing Director, Silicon Valley Bank
Jon Norris is a managing director for SVB's Healthcare practice. Norris oversees business development efforts for banking and lending opportunities as well as spearheading strategic relationships with many healthcare venture capital firms. He also helps SVB Capital through sourcing and advising on direct equity co-investment and limited partnership allocations.

In addition, he has authored numerous thought leadership pieces examining the flow of capital into healthcare, including detailed analysis of venture-backed M&A and IPOs. Norris has more than thirteen years of banking experience working with life science companies and venture capital firms.
Norris earned a bachelor's degree in business administration from the University of California, Riverside and a juris doctorate from Santa Clara University.
About Jon Norris spends most of his non-banking time with his family in Los Altos, attending and coaching many youth sports. An avid baseball fan, he still plays baseball in a men's baseball league in San Jose.

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JLABS, Thursday Morning, Feb. 2, 2018

Event: "Meet With...Versant Ventures"
Speakers: Graham G. Walmsley | Investment Professional, Versant Ventures and Lev Osherovich | Director of Innovation Sourcing, Versant Ventures
Date and Time: Thursday, February 1, 2018 from 10:30 AM to 1:00 PM (PST)
Agenda:
10:30AM | Registration and Networking
11:00 AM | Presentation and Q&A
12:00 PM | Networking Lunch
1:00-5:15 PM | One-on-One Meeting* (30 - minute meetings)

*Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due January 4, 2018. Apply Here.
Location: Johnson & Johnson Innovation, JLABS, 329 Oyster Point Blvd, 3rd Floor South San Francisco, CA
Fees:
Presentation
$25 | General Public
$35 | Onsite
Details and registration at https://www.eventbrite.com/e/meet-withversant-ventures-tickets-36705327623?aff=weekly

One-on-One Meeting
FREE | Application
FREE | Accepted Companies
Apply to meet one-on-one with Graham Walmsley of Versant Ventures. Your application will be reviewed and you will be notified of acceptance on Wednesday, January 18th, 2018. Acceptance of a one-on-one meeting is not guaranteed as all applications must be approved.

Event Details
Committed to transforming the healthcare landscape through innovation, Versant Ventures is eager to help you make an impact in healthcare. Graham Walmsley, MD, Ph.D. and Lev Osherovich, Ph.D. of Versant Ventures will be visiting JLABS @ SSF on February 1, 2018 to provide an overview of Versant's unique investment strategies and meet 1-on-1 with pre-selected companies.

*The one-on-one application process is separate from the event registration process. Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due by January 4th. Apply Here.

Program Overview:
Versant Ventures is a leading healthcare investment firm committed to helping exceptional entrepreneurs who are building the next generation of great healthcare companies. The firm invests across the healthcare sector and at all stages of company development, with an emphasis on the discovery and development of novel therapeutics. With $2.3 billion under management and offices in North America and Europe, Versant has built a team with deep investment, operating, and scientific expertise that enables a hands-on approach to company building. Since the firm's founding in 1999, nearly 70 Versant companies have achieved successful acquisitions or IPOs.
Graham Walmsley, MD, Ph.D. and Lev Osherovich, Ph.D. will be in attendance to provide an overview presentation of their firm's area of interest. They will be on hand to meet with a handful of applicants 1-on-1 after the presentation. To be considered for a 1-on-1 meeting complete the information required here. Applications due by January 4, 2018.

Speakers' Biographies:

Graham G. Walmsley | Investment Professional, Versant Ventures

Graham G. Walmsley, M.D., Ph.D. is an Investment Professional at Versant Ventures focused on biotechnology and healthcare investments. Graham joined Versant after completing his training as a Physician Scientist Fellow at Stanford University School of Medicine. At Versant, Graham helped build and launch BlueRock Therapeutics, a regenerative medicine company formed in collaboration with Bayer through one of the largest series A investments ($225M) in biotech history.

Graham received his M.D. and Ph.D. in Stem Cell Biology and Regenerative Medicine from Stanford University and earned his B.A. in Molecular and Cell Biology with summa cum laude honors from the University of California, Berkeley. He conducted his thesis work in the laboratories of Irving Weissman and Michael Longaker with a focus on regenerative medicine, stem cells, and therapeutic approaches to fibrosis. This work was featured in TIME Magazine and resulted in several patents as well as over 60 peer-reviewed publications in journals such as Science and Cell.

Lev Osherovich | Director of Innovation Sourcing, Versant Ventures

Lev Osherovich, Ph.D. is Director of Innovation Sourcing at Versant Ventures, where he focuses on early stage therapeutic investment. Lev trained in Molecular and Cell Biology at UC Berkeley (undergraduate) and in Biochemistry at UCSF, and completed postdoctoral training at University of Kent at Canterbury and UCSF. After leaving academia, he worked as a biotech industry analyst and science journalist at BioCentury and Nature Publishing Group. Since 2014, Lev has worked at Versant and its discovery engine, Inception Sciences, to evaluate academic research with translational potential and to create new portfolio companies.
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JLABS, Tuesday Morning, Feb. 6, 2018

Topic: “The Art and Science of Productive FDA Meetings”
Speaker: Ron Farkas, MD PhD, Vice President, Technical, PAREXEL Consulting

Tuesday, February 6, 2018 from 10:30 AM to 1:00 PM (PST)
Agenda:
10:30 AM | Registration & Networking
11:00 AM | Presentation
11:40 AM | Q&A
12:00 PM | Networking Lunch
1:00 PM | Program Close
Location: JLABS @ SSF,329 Oyster Point Blvd - 3rd Floor, South San Francisco, CA
Fees:
$25 | General Public
$10 | Student/Academic
$35 | At the door
Details and registration at https://www.eventbrite.com/e/the-art-and-science-of-productive-fda-meetings-tickets-37017978771?aff=weekly

Event Details
Getting solutions to patients can be a long and complicated process. Working with the FDA is a key part of the sequence. Preparing for and understanding the FDA's needs is essential to smooth the way and shorten your time to approval.

Johnson & Johnson Innovation, JLABS is happy to be hosting Ron Farkas, MD PhD, Vice President, Technical, PAREXEL Consulting, to discuss the ins and outs of FDA meetings. Ron will pull from his vast experience which includes a decade plus run at the FDA to help guide us through these vital interactions. Topics will include:
Understanding the FDA's position; not just what it wants but why
What to agree on now and later; What does agreement mean?
The key to proceed
Understanding the dynamics within the FDA
Flexibility and norms and what they mean
Experts, Patients and Advocates at Meetings
Meeting minutes and follow up

Understanding the process will help you better prepare for your meetings and build confidence in and ability to adjust your own plan. Come prepared with your questions!

Speaker Bio
Ron Farkas | Vice President, Technical, PAREXEL Consulting
Dr. Ronald Farkas is a senior regulatory professional with over 15 years of experience in all phases of drug development from preclinical development through marketing application, advisory committee meetings, labeling negotiations, and the post-approval period. Dr. Farkas has in-depth cross-disciplinary expertise in clinical safety and efficacy, clinical pharmacology and pharmacogenomics, preclinical development, statistical analysis, and biomarker/surrogate endpoint development and utilization.

Dr. Farkas uses his extensive scientific, drug development and regulatory experience to assist clients in negotiating with regulatory authorities across the entire product life cycle to achieve their company objectives.

Prior to joining PAREXEL, Dr. Farkas was a Cross-Disciplinary Team Leader at FDA in CDER's Division of Neurology Products, with prior assignments to the Office of New Drugs Guidance and Policy Team and the CDRH Office of Device Evaluation. Prior to

joining the FDA, Dr. Farkas was an assistant professor and attending surgeon at the Johns Hopkins University Wilmer Ophthalmic Institute.

Dr. Farkas completed residency training in ophthalmology at the Harvard University School of Medicine Massachusetts Eye and Ear Infirmary, subsequent to earning dual MD and PhD degrees in neuroanatomy and neuropharmacology from the University of Illinois at Chicago School of Medicine.

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PBSS, Thursday, Feb. 22, 2017

Event: Workshop Metabolite Detection Identification and Qualification for Drug Development
Speakers: S. Cyrus Khojasteh, Bill Fitch, Shichang Miao, Ryan Takahashi, Raju Subramanian, Shuguang Ma
Date and Time: 2/22/2018, 8:30-17:00
Location: SF Bay Area: Foster City Crowne Plaza
Registration fee (USD): Regular: $195; Academic: $125; For unemployed or students: $30; For vendor-show rep: $35; For major-sponsor rep (incl lunch): $0;
Registration deadline:2/22/2018 (it will close sooner if the seating cap is reached)
Register at http://www.pbss.org/aspx/login01.aspx?iURL=

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PBSS Workshop, Monday, March 12, 2017

Topic: "Clinical Trials Essentials: An Intensive One-Week Course (register for the full week or half day sessions)"
Speakers: Edward Rozhon, Mike Huston, Narinder Singh, Gerri O'Riordan, Pete Shabe, Savita Sinha, Clarisa Tate, Frances Ann McKenney
Date and Time: 3/12/2018, 8:30-17:30
Registration fee (USD): One-week full course: $1865; Mon AM: Drug Development Process: $200; Mon PM: Science of Clinical Trials Design: $200; Tue AM: GCP & ICH Investigator & Clinical Research Site: $200; Tue PM: Global Clinical Trials Perspective & Applied Statistics in Clinical Trials: $200; Wed AM: Monitoring Clinical Trials: $200; Wed PM: Medical Devices: $200; Thur AM: Clinical Data Management: $200; Thur PM: Clinical QA/Compliance Audits and the FDA: $200; Fri AM: Good Manufacturing Practices and the Transition to Full Scale Manufacturing: $200; Fri PM: Business of Clinical Research; Study Site Perspective: $200;
Location: SF Bay Area: Foster City Crowne Plaza
Registration: http://www.PBSS.org
Registration deadline:3/9/2018 (it will close sooner if the seating cap is reached)

Topic Description
Clinical Trials Essentials: An Intensive One-Week Course
A joint course between UCSC Extension Silicon Valley and Pharmaceutical and Bio ScienceSociety -- San Francisco

Monday March 12, 2018 – 8:30 am—12:30 pm

Drug Development Process 4 hours – Edward Rozhon

Major players in drug development
Assay development and discovery of new medical entities
Non clinical and clinical development of new drugs
History and regulatory oversight of FDA

Structure of Phase I, II, & III clinical trials
FDA review of New Drug Application.
Monday March 12, 2018 – 1:30 pm—5:30 pm

Science of Clinical Trials Design 4 hours – Mike Huston

Phases of drug development
Objectives of clinical studies
Basic clinical trials designs
Underlying science for clinical trials designs.
Tuesday March 13, 2018 – 8:30 am—12:30 pm

GCP & ICH Investigator & Clinical Research Site 4 hours – Narinder Singh

Historical and legislative roads to Good Clinical Practices (GCP)
Principles of GCP and the research-care conflict
Role of various stakeholders in Clinical Trials
Elements of informed consent.
Tuesday March 13, 2018 – 1:30—3:00 pm

Study Site Perspective 1.5 hours – Gerri O'Riordan

Translational research in an academic center: fundamental strengths and weaknesses
Research Process and Operations management as the success of a trial
Essential conversations between academia, biomedical and pharmaceutical companies, venture capitalists and consultants
Data Integrity and well-supported metrics (Case Studies).
Tuesday March 13, 2018 – 3:15 pm—5:30 pm

Applied Statistics in Clinical Trials 2.25 hours – Pete Shabe

The role statistics plays in clinical research
Basic data summarization techniques
Estimation and Hypothesis Testing Introduction
Estimation and Confidence Intervals
Statistical Hypothesis Testing.
Wednesday March 14, 2018 – 8:30 am—12:30 pm

Monitoring Clinical Trials 4 hours – Savita Sinha

Review the basic regulatory requirements of monitoring a clinical research study
Describe the tasks that should be performed before, during, and after a monitoring visit
Learn how to track all key parameters involved in monitoring a site
Know how to complete visit reports and follow-up on action items after each site visit.
Wednesday March 14, 2018 – 1:30 pm—5:30 pm

Medical Devices, An Overview 4 hours – Clarisa Tate

What is a medical device, a general overview of regulations
Medical devices regulatory pathways: 510(k), PMA, and HDE
Medical device clinical trials: Focus on Investigational Device Exemptions

Post-market surveillance: Focus on 522, complaints, and recalls
Globalization and changing regulatory environment.
Thursday March 15, 2018 – 8:30 am—12:30 pm

Clinical Data Management 4 hours – Instructor TBA

Key data management activities for study startup, conduct, and closeout
Regulations applicable to data management activities
Clinical data management systems and electronic data capture (EDC)
Working with contract research organizations (CROs) for data management.
Thursday March 15, 2018 – 1:30 pm—5:30 pm

Clinical QA/Compliance Audits and the FDA 4 hours – Frances Ann McKenney

Qualifications needed for GXP auditors and FDA Inspectors
Objectives of sponsor audits and regulatory inspections
Similarities and differences between sponsor audits and regulatory inspections
General approach to hosting an audit or inspection
Types of findings that cause concern for auditors or inspectors.
Friday March 16, 2018 – 8:30 am—12:30 pm

Good Manufacturing Practices and regulatory trends 4 hours – Narinder Singh

Good Manufacturing Practices (GMP) for drugs
GMP for biologics and related products, including Good Tissue Practices
Considerations for Quality Systems.
Friday March 16, 2018 – 1:30 pm—3:00 pm

Global Clinical Trials Perspective 1.5 hour – Narinder Singh

Trends in global clinical trials.
Role of FDA and local regulatory culture.
Friday March 16, 2018 – 3:15 pm—5:30 pm

Business of Clinical Research 2 hours – Mike Huston

The Market Players – Pharma, Biotech, Contract Research Organizations (CROs)
Cost of Doing Business – Cost of conducting clinical research
Outsourcing and CROs – It costs money to make money
Innovative Ways to Reduce Cost – Business Strategies and Process Innovations.
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JLABS, Thursday Mid Day, March 29, 2018

Event: Meet With... Frazier Healthcare Partners
Speakers: James W. Brush, M.D. | Senior Associate, Frazier Healthcare Partners and Patrick Heron, MBA | Managing General Partner, Frazier Healthcare Partners
Date and Time: Thursday, March 29, 2018 from 10:30 AM to 1:00 PM (PDT)
Agenda:
10:30AM | Registration and Networking
11:00 AM | Presentation and Q&A
12:00 PM | Networking Lunch
1:00-5:15 PM | One-on-One Meeting* (30 - minute meetings)

*Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due February 22,, 2018. Apply Here.
Location: JLABS @ SSF, 329 Oyster Point Blvd - 3rd Floor, South San Francisco, California

Fees:
Presentation
$25 | General Public
$35 | Onsite

One-on-One Meeting
FREE | Application
FREE | Accepted Companies
Apply to meet one-on-one with Jamie Brush of Frazier Healthcare Partners. Your application will be reviewed and you will be notified of acceptance on March 13th. Acceptance of a one-on-one meeting is not guaranteed as all applications must be approved.
Details and registration at https://www.eventbrite.com/e/meet-with-frazier-healthcare-partners-tickets-36705859213?aff=weekly

Event Description
With over 26 years of exclusively investing in over 170 healthcare companies, Frazier Healthcare Partners has a great deal of experience building successful life science businesses. On March 29, 2018, Jamie Brush MD, and Patrick Heron, MBA will be visiting JLABS @ SSF to provide an overview of Frazier Healthcare Partners' unique investment strategies and meet 1-on-1 with pre-selected companies.

*The one-on-one application process is separate from the event registration process. Companies must have applied for a one-on-one meeting ahead of time and been approved. Applications are due by February 22nd. Apply Here.

Program Overview:
Frazier Healthcare Partners is committed to helping great healthcare companies who are working hard to make a difference in the future of life sciences. The firm has partnered with exceptional entrepreneurs at all stages and focuses on therapeutic development. With $3 billion under management, investments in over 170 companies and 35 IPOs, Frazier Healthcare Partners has built a team with deep knowledge and scientific expertise that enables company building.
Jamie Brush, MD and Patrick Heron, MBA will be in attendance to provide an overview presentation of the firm's areas of interest. They will be on hand to meet with a handful of applicants 1-on-1 after the presentation. To be considered for a 1-on-1 meeting, please complete the information required here. Applications due by Feb 22, 2018.

Speakers' Biographies:

James W. Brush, M.D. | Senior Associate, Frazier Healthcare Partners
Jamie joined Frazier Healthcare Partners in 2016 and focuses on investment identification, due diligence, and deal closing.

Before joining Frazier, Jamie was a management consultant with the Boston Consulting Group, where he was a core member of the Healthcare Practice. In this

capacity, he led projects involving Biotechnology mergers and acquisitions, R&D, manufacturing and business development strategy.

Jamie received his M.D. from the University of Southern California, where he was inducted into Alpha Omega Alpha honors society, and his B.A. from Middlebury College. He completed his postgraduate training in Internal Medicine at Beth Israel Deaconess Medical Center in Boston. He has co-authored several papers in top-tier journals on genomic instability and its role in cancer, and is a member of the board of directors of Longwood Symphony Orchestra.

Patrick Heron, MBA| Managing General Partner, Frazier Healthcare Partners

Patrick is a Managing General Partner of Frazier's Life Sciences team. He joined the firm in 1999 and opened Frazier's Menlo Park office in 2003. Throughout his 12 years as General Partner, Patrick has led or co-led investments across nearly 20 companies.

Patrick has successfully partnered with entrepreneurs across a range of company types and stages, from early – stage anti-infectives companies to >$100M commercial-stage dermatology companies. Patrick has also been active in company formation around both early – and later – stage assets. He has led and served as director for many successful Frazier Life Sciences investments, including Tobira Therapeutics (acquired by Valeant), MedPointe (acquired by Meda), and Collegium (NASDAQ: COLL). He currently serves on the boards of Imago BioSciences, Iterum Therapeutics, Silvergate Pharmaceuticals, SutroVax and Zavante Therapeutics.

Prior to joining Frazier, Patrick helped develop McKinsey & Company's West Coast biotechnology consulting practices, where he led projects involving mergers and acquisitions, product launches, sales force optimization, corporate partnering, and research prioritization.

Patrick received his M.B.A. from Harvard Business School. He also holds a B.A. from the University of North Carolina at Chapel Hill, where he is a Phi Betta Kappa graduate and Morehead Scholar.
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PBSS Workshop, Tuesday Afternoon, April 24, 2017

Topic: "Regulatory Authority Inspection Preparation and Outcomes"
Speakers: Kim Burson (Achaogen)
Date and Time: Tuesday, 4/24/2018, 12:30-17:00
Location: SF Bay Area: Foster City Crowne Plaza
Registration fee (USD): Regular: $125; Academic: $75; For unemployed or students: $25; For vendor-show reps: $25; For major-sponsor rep (incl lunch): $0;
Registration: http://www.PBSS.org
Registration deadline:4/24/2018 (it will close sooner if the seating cap is reached)