

**Audrey's Life Science Meeting Picks for Dec. 10, 2017 through April 2018  
Complimentary Service of AudreysNetwork.com**

\*\*\*\*\*

**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/asp/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](http://www.pbss.org) before it is closed (it may close BEFORE the deadline if the seating capacity is reached early).

\*\*\*\*\*

**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](http://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.

\*\*\*\*\*

**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](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.

\*\*\*\*\*

### **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.

\*\*\*\*\*

#### **Women in Leadership Initiative, BL Fremont, AWIS, Thursday Afternoon, Dec. 14, 2017**

Event: Holiday Happy Hour

Date and Time: Thursday, Dec. 14, 4-6 pm

Location: WXYZ Lounge, Aloft Hotel, 8200 Gateway Blvd., Fremont, CA

See details at [http://www.ebawis.org/main\\_web/2017/12/03/women-in-leadership-initiative-december-14th/](http://www.ebawis.org/main_web/2017/12/03/women-in-leadership-initiative-december-14th/)

Register at <https://docs.google.com/forms/d/e/1FAIpQLScHm8f33PjxhcRX0hWK-7YzjnWoAb6fnuJQPMGPPYTaxZzD1A/viewform>

\*\*\*\*\*

**Palo Alto AWIS, Thursday Evening, Dec. 14, 2017**

Event: AWIS Palo Alto Holiday Extravaganza, SIP-SMILE-SHARE –Cocktail Party  
Date and Time: Thursday, Dec. 14, 2017, 6:30 pm  
Location: Cafe Venetia, 419 University Ave., Palo Alto, CA 94301  
Fees: Members \$15 (click here to become one);  
Non-members \$30  
Register at <https://www.brownpapertickets.com/event/3193003>

Event Description

Come one, Come All  
in Fancy Dress for a Cozy Cocktail Party  
to Mingle with Silicon Valley STEM Professionals in the Holiday Spirit

About AWIS: Association for Women in Science (AWIS) is a global non-profit organization that inspires bold leadership, research, and solutions that advance women in STEM and drive systemic change. AWIS Palo Alto is the local chapter of AWIS, providing career support and building community among women in STEM in the Peninsula.

\*\*\*\*\*

**Golden Gate Polymer Forum, Wednesday Evening, Dec. 20, 2017**

Topic: " From Fundamental Polymer Synthesis to Applications - Polythioaminals from the Stabilization of Reactive Intermediates for Tailorable Surfaces, speaker, Rudy J. Wojtecki.  
IBM Almaden Research Center, San Jose

Event Date: Wednesday, Dec. 20

6:00 PM social hour

7:00 PM dinner

8:00 PM presentation

Location: Michael's at Shoreline, 2960 N Shoreline Blvd., Mountain View

Cost:

Employed/postdocs: \$30 early registration, \$35 regular registration

Unemployed/retired/students: \$15 early registration, \$20 regular registration

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

After deadline:

Registration not guaranteed, so contact us

Late fee applies if space available -- \$40 regular/employed, \$25

unemployed/student/retired

Deadlines for registration:

End of discounted advance registration Friday, Dec, 15, 11:59 PM

End of regular (full-price) registration Tuesday, Dec. 19, 5:00 PM

Because we must pay the restaurant for the ordered meal, we must ask no-shows to pay for their reservation.

However, penalty-free cancellations are allowed up until the deadline for reservations (Tuesday, Dec. 19, 5:00 PM).

PLEASE NOTE:

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

You may pay at the door.

Checks may be made to "GGPF"

Please register on the web page, [www.GGPF.org](http://www.GGPF.org)<<http://www.GGPF.org>>

Or, if necessary, contact:

Nayan Ashar

[nayandevyani@gmail.com](mailto:nayandevyani@gmail.com)

408-316-1619

#### Topic Abstract

1,3,5-hexahydro-1,3,5-triazines (HTs) and their thermosetting polymer analogues, PHTs, have attracted recent attention in the materials space as they exhibit a number of attractive properties such as healability, facile preparation of anti-microbial surfaces, and even as detectors for heavy metals.[1] HTs also demonstrate unique reactivity towards sulfur containing compounds. Hydrogen sulfide will, for instance, readily react with HTs at room temperature to form dithioazine, where the six-member HT ring undergoes replacement of two nitrogen atoms with sulfur. Organic thiols will also react with HTs to produce thioaminals, a transformation that was recently exploited to generate a new class of linear step-growth polymers, polythioaminals.[2] The synthesis of polythioaminals are tolerant to a variety of substituents, functional groups, and monomers, and the subsequent polymers enable access to interesting post-polymerization chemistries such as the facile introduction of end-groups to produce functional oligomers. Subsequent studies of the formation of HTs have shown the use of electron withdrawing substituents on aromatic diamines extend the stability of reaction intermediates. In the presence of these intermediates dithiols could be readily reacted to form polythioaminals without the use HTs. The resulting reaction leads to linear polymers that possess monothioaminal linkages, moieties found to be latent crosslinks activated at higher temperatures and leading to the formation of chemically stable network polymers. This reactivity enabled access to a broader substrate diversity of polymers and polymer networks. Furthermore, using the chemically responsive behavior established in linear polythioaminals produced from HTs, end-group functionality could be introduced to these networks to produce tailorable surfaces and the introduction of desired functional groups. These networks possess an attractive characteristic of easy-to-process fluorinated polymers with applications that include hydrophobic coatings and adhesives and lithography.

[1] R. J. Wojtecki, A. Y. Yuen, T. G. Zimmerman, G. O. Jones, H. W. Horn, D. J. Boday, J. L. Hedrick, J. M. García, *The Analyst* 2015, 140, 5184-5189.

[2] R. J. Wojtecki, G. O. Jones, A. Y. Yuen, W. Chin, D. J. Boday, A. Nelson, J. M. García, Y. Y. Yang, J. L. Hedrick, *J. Am. Chem. Soc.* 2015, 137, 14248-14251.

#### Speaker Bio

Dr. Wojtecki graduated from Case Western Reserve University with a Ph.D. in Macromolecular Science & Engineering under the auspices of Stuart J. Rowan, now at the Univ. of Chicago. His research focused on the synthesis of mechanically interlocked polymers composed of catenanes, chemical units that were the subject of the 2016 Nobel prize in chemistry on molecular machines (catenanes & rotaxanes). This work was recently accepted into the journal *Science* in a report titled "Poly[n]catenanes: The Synthesis of Molecular Chains." Rudy joined IBM Almaden Research Center after completion of his graduate work. He is an author/co-author of 19 peer reviewed scientific publications including a *Nature Materials Review* article. In 2017 he was recognized as an IBM Master Inventor for work highlighted in 35 issued patents. Rudy's current research efforts are geared to address ongoing challenges for lithography and patterning materials used in the manufacturing of semiconductors that include selective deposition schemes using atomic layer deposition and extreme ultraviolet lithography.

\*\*\*\*\*

**Simon+Kucher Partners, Friday, Jan. 11, 2018**

Forum: "Redefining Value in the Life Sciences"  
Date and Time: Friday, Jan. 11, 2018, 12:00-5:00 pm  
Location: InterContinental San Francisco  
Panel Description:

This year's panel discussions will focus on addressing pharma innovations, digitalization of healthcare, and emerging value models. Panelists include:

- Durga Bobba, Chief Business Officer, SutroVax Inc.
- Justin Kao, Co-founder & Senior Vice President, Helix
- Marc Schwabish, US Head Pharma Business Development & Licensing, Bayer

During this program, you will have the opportunity to build connections with fellow leading industry professionals and gain new insights into current and evolving trends including novel healthcare delivery initiatives and value-based care models, and how these advancements will impact the life sciences landscape in the near future.

For more details or to RSVP, please go to: <http://www.simon-kucher.com/en-us/events/redefining-value-life-sciences>.

Full speaker list and detailed agenda are forthcoming.

\*\*\*\*\*

**PBSS, Monday, Jan. 22, 2018**

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)

\*\*\*\*\*

**Precision Medicine World Conference (PMWC) Silicon Valley 2018, Jan. 22-24, 2018**

Event: Medical Conference  
Date and Time: January 22, 2018, 8:00am to January 24, 2018 5:00pm  
Location: Computer History Museum, 1401 N Shoreline Blvd, Mountain View, California, 94043  
Cost: \$1350 by December 13th, 2017  
Registration: 3-Day Access to Talks, Exhibition & Reception:  
Learn more at: <http://www.pmwintl.com/2018sv-info/>

Event Description:

Precision Medicine World Conference (PMWC) Silicon Valley is organized by Precision Medicine World Conference (PMWC) and will be held during Jan 22 - 24, 2018 at Computer History Museum, Mountain View, California, United States Of America.

The preeminent Precision Medicine World Conference (PMWC) series is recognized as a vital cornerstone for all constituents of the healthcare and biotechnology community and considered an exceptional forum for the exchange of information about the latest advances and topics in technology, clinical implementation, research, and the regulatory and reimbursement sectors. Learn first-hand from the experts in precision medicine: recognized leaders and innovators, top researchers, medical professionals, and more, catalyzing cross-functional fertilization and collaboration.

PMWC 2018 SV, co-hosted by Stanford Health Care, UCSF, Intermountain Healthcare, Duke Health, and Duke University will cover all facets of Precision Medicine including current hot

topics like immunotherapy, the Precision Medicine Initiative (All of US), liquid biopsy, the human microbiome, big data, and cancer & companion diagnostics.

Session Themes :

- Metabolomics Proteomics Applications
- Medical Health Apps
- Cancer Immunology, Immunotherapy
- Patient Recruitment for Clinical Trials
- Cancer Stem Cells
- Infectious Disease Monitoring, Pathogen Identification
- The Economics and Financial Impact of Bringing PM to the Clinic
- Addressing Disparities and Public Health
- Reimbursement - the Payer Perspective
- Liquid Biopsies
- Biobanking
- Telemedicine
- Large-scale integrated genomics, phenotype, and clinical data analysis
- Data Sharing
- Interoperability in Healthcare.

Speakers:

- Sir John Bell, Regius Professor of Medicine, Oxford University
- Dame Sally Davies, Chief Medical Officer, Department of Health, UK Government
- Elizabeth Blackburn, Nobel Laureate, President, Salk Institute for Biological Studies
- George Sledge, Professor, Division Chief, Stanford University Medical Center
- Jeffrey Bluestone, CEO and President, Parker Institute for Cancer Immunotherapy
- Christopher Ianelli, Founder and Chief Executive Officer, iSpecimen
- Kenneth J. Pienta, Director, Brady Urological Institute, Johns Hopkins Medicine
- Roy Beveridge, Senior Vice President & Chief Medical Officer, Humana
- Kimberly Blackwell, Professor of Medicine, Assistant Prof. of Radiation Oncology, Duke Cancer Institute
- Joshua Denny, Professor of Biomedical Informatics & Medicine, Vanderbilt University Medical Center
- Edward S. Kim, Chair, Solid Tumor and Investigational Therapeutics, Levine Cancer Institute
- Howard L. McLeod, Medical Director, Personalized Medicine Institute, Moffitt Cancer Center
- Lee Newcomer, SVP, UnitedHealthcare Oncology and Genetics
- Vinod Khosla, Partner and Founder of Khosla Ventures
- Troy Brennan, Executive VP & CMO, CVS Health
- Ira Mellman, VP, Cancer Immunology, Genentech

\*\*\*\*\*

**JLABS, Thursday Morning, Jan. 25, 2018**

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.

\*\*\*\*\*

#### **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.

\*\*\*\*\*

**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.

\*\*\*\*\*

#### **PBSS, Thursday, Feb. 22, 2018**

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/asp/login01.aspx?iURL=>

\*\*\*\*\*

### **PBSS Workshop, Monday, March 12, 2018**

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 Science Society -- 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.  
\*\*\*\*\*

**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 Beta Kappa graduate and Morehead Scholar.

\*\*\*\*\*

**PBSS Workshop, Tuesday Afternoon, April 24, 2018**

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)