

# R&D OPEN INNOVATION AND PORTFOLIO OPTIMIZATION

Lean Resource Allocation, Next-Generation Partnership Models and Investment Decision Strategies for High Return R&D

APRIL 8-9, 2014 • DOUBLETREE BY HILTON • PHILADELPHIA, PA

## OPEN INNOVATION

Early-Stage Sourcing

Crowdsourcing R&D

DIGITAL TOOLS

ACADEMIC PARTNERSHIPS

Industry Collaboration Models

Asset and Molecule Repurposing

Investment Decision-Making

Mobile Health

ROI

PORTFOLIO ROI METRICS

New Indications

## Renowned Industry Experts Unveil New Models and Strategies for Portfolio ROI



Simon Bateman,  
Executive Director,  
Global Strategic  
Alliance Management,  
**Novartis**



Cameron Durrant,  
President and  
Chief Executive Officer,  
**ECR Pharmaceuticals**



Standish Fleming,  
Managing Member,  
**Forward Ventures**



Annlouise Goodermuth,  
Director, Alliance  
Management Strategy,  
External Innovation  
and Science Policy,  
**Sanofi-Aventis**



Kenneth I. Kaitin, Ph.D.,  
Director,  
**The Tufts Center  
for the Study of  
Drug Development**



Troy Norris,  
Managing Director,  
**Valamont Advisors, LLC**



Tomasz Sablinski, M.D., Ph.D.,  
Co-Founder, Chief Executive Officer,  
**Transparency Life Sciences;**  
Managing Director, Head  
of Clinical Development,  
**Auven Therapeutics**



Bing Yuan,  
Executive Director,  
Life Cycle Strategy,  
**Novartis**

### PLUS! PERSPECTIVES FROM:

Aisling Capital • FTI Consulting • Booz & Company • Cerulean Pharma, Inc.  
Denovo Biomarkers • Eisai Inc. • Johnson & Johnson Innovation Center • Kowa Pharmaceuticals  
America, Inc. • SmartPharma • University of Pennsylvania • Value Creation Associates



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TUESDAY, APRIL 8, 2014

IN-CONFERENCE WORKSHOP

## FINANCIAL PROJECTIONS AND FORECASTS TO MAXIMIZE ROI

7:30 *Workshop Registration and  
Continental Breakfast*

8:30 *Workshop Leader's Welcome and  
Opening Remarks*

**Workshop Objective:**

Pharmaceutical executives seek greater transparency in R&D decision-making against the back drop of the US fiscal cliff, changing patterns of demand, slashed budgets and the effects of the Affordable Care Act. This workshop equips executives with models for success.

**Key Questions to Be Addressed:**

- How to validate unmet needs?
- What early stage decisions can be made to drive future ROI?
- Should ROI be used to drive R&D decision-making?
- How should financial projections be used for financing and deal-making?
- When is partnering the right decision for biotech or pharma pipeline?

**Workshop Outline:**

I. **Incorporating ROI into R&D Prioritization and Decision-Making**

- Learn elements of ROI analysis — Market-sizing, net present value and probability of success
- Discuss risks and potential pitfalls of using early ROI calculations in R&D decision-making
- Test the market — Generating viable assumptions for ROI analysis

II. **Models for Success**

- Case studies on past performance
- Lean and mean — How to improve ROI
- Thinking outside the box

III. **Analyzing the Numbers**

- Measuring the returns — Is innovation improving R&D bottom line?
- Does collaboration improve ROI?
- Future forecasts

12:00 *Close of Workshop*

*There will be a 30-minute networking and refreshment break at 10:00 a.m.*

**Workshop Leaders:**

Katie MacFarlane serves as Chief Commercial Officer at **Agile Therapeutics**, where she has headed commercial operations since 2010. She is also Managing Partner of **SmartPharma LLC**. Before joining Agile Therapeutics, Ms. MacFarlane served as President and Chief Executive Officer at **Xinria Pharmaceutical Corporation**, a start-up company in the development of berberine for treatment of dyslipidemia and Type II diabetes from 2006 to 2008. Prior to that, Ms. MacFarlane served as Vice President of Women's Health and New Product Planning at **Warner Chilcott**, an international pharmaceutical company focused on women's healthcare, dermatology and urology from 2001 to 2006. Ms. MacFarlane received her Bachelor of Science degree in Pharmacy and Doctor of Pharmacy degree from Purdue University. She completed a Postdoctoral Fellowship in Industrial Pharmacy Practice with Rutgers University and Hoffmann-LaRoche.

Stacey Seltzer serves as a Principal of **Aisling Capital**. Previously, Ms. Seltzer was at **Schering-Plough**, where she held roles in business development, marketing and sales, most recently serving as the US Schering-Plough Brand Lead for Zetia. Prior to Schering-Plough, Ms. Seltzer was the Director of Business Development for **Akceli**, a biotechnology company developing cell-based microarrays. Ms. Seltzer began her career as a management consultant for **McKinsey & Company**. Ms. Seltzer serves as a director of **Miramir Labs**, is the Aisling representative for its investment in Precision Dermatology and serves as a board observer for **Durata Therapeutics** and **Agile Therapeutics**. She was previously a board observer for **Zeltiq Aesthetics** (NASDAQ: ZLTQ). Ms. Seltzer received her M.B.A. from The Wharton School at the University of Pennsylvania, where she was a Palmer Scholar. She received her M.S. and B.S. from Yale University, awarded cum laude in Molecular Biophysics and Biochemistry.

## MAIN CONFERENCE

### DAY ONE TUESDAY, APRIL 8, 2014

12:45 **Chairman's Opening Remarks**  
*Ian Lauf, Associate Director Clinical Alliance Management, Eisai Inc.*

1:00 **R&D at a Crossroads —  
 Choosing the Right Path**

Manage the innovation landscape shifts and changes before they manage you. The time, cost and risk of bringing a drug to market remains a formidable hurdle to clear. Learn how to best move forward without breaking the bank.

- Navigating the evolving innovation landscape
- Identifying and managing sources of portfolio risk
- Evaluating outsourcing and risk-sharing models
- Effectively managing increasingly complex collaboration networks

*Kenneth I. Kaitin, Ph.D., Director,*

**The Tufts Center for the Study of Drug Development**



**Open Innovation Pioneers —  
 Today's Models for Future R&D ROI**

1:45 **KEYNOTE ADDRESS**  
**Open Innovation —  
 The Future of Drug Development**

The Big Pharma financial model is not sustainable. The growth of R&D has outpaced sales growth, yet the output of new medicines has not increased. This Keynote Address brings the future model of drug development directly to you.

- Harness crowdsourcing to deliver promising drugs to market
- Build credibility with diverse stakeholders and produce better results
- Leverage advances in information technology and mobile health
- Lower financial risk and increase financial return

*Tomasz Sablinski, M.D., Ph.D., Co-Founder, Chief Executive Officer, Transparency Life Sciences; Managing Director, Head of Clinical Development, Auken Therapeutics*

*Dr. Sablinski is currently Head of Development and a Managing Director of Auken Therapeutics. He founded Transparency Life Sciences in 2010 stimulated by the opportunities to introduce a new model of drug development afforded by modern computer sciences, technology and new communication and knowledge generation patterns. He has over thirty years of experience in healthcare. This includes fifteen years of pharmaceutical development in a major pharmaceutical company, a CRO and consulting for small biotechnology companies. His experience in these roles include time in*

*the United States, Europe and Japan. In the 1990s, he was a member of Harvard Medical School (Brigham and Women's and Massachusetts General hospitals) teams conducting pioneering work in developing biologic immunosuppressive regimens, induction of transplantation tolerance and xenotransplantation. In parallel, and prior to this, he practiced as a surgeon specializing in renal transplantation and general surgery in his native Poland and in Boston. Transparency Life Sciences' origins lie in a strong belief that the current system of drug development must be completely changed, and in a passion for development of medications at a fraction of current cost. He received his M.D. and Ph.D. from the Academy of Medicine in Warsaw.*

2:30 **Networking and Refreshment Break**

3:00 **How New Research Suggests Better  
 Ways to Manage Risk and Pipeline**

The pharmaceutical industry is in a severe innovation crisis. Learn how to translate the wealth of data we have today to improve the model for tomorrow.

- Rethink the pharmaceutical business model
- Hack through the assumptions, theories and fads that have stunted innovation
- Review key changes that need to be made to assure survival
- Explore the future of open innovation

*Standish Fleming, Managing Member, Forward Ventures*

3:45 **Innovative Approaches to Source the  
 Next, Best Drug Candidate**

With a proliferation of technologies and data at a time when R&D output is slowing, the stakes are high for pharma and biotech portfolio executives to source the next best drug candidate. This session provides the necessary tools to help you access shared knowledge through open innovation, sift through alternative collaboration models, and make smart early stage investment decisions.

- Choose the right collaborative innovation model for your portfolio
- Leverage creative collaboration and transaction models to access early stage assets
- Asset-option, corporate venture, academic partnering and open innovation models
- Identify the highest value programs and partners to extend your R&D portfolio

*Kenneth I. Kaitin, Ph.D., Director,*

**The Tufts Center for the Study of Drug Development**

*Troy Norris, Managing Director, Valamont Advisors, LLC*

5:30 **Close of Day One**

**Networking, Wine and  
 Cheese Reception**

*immediately following the final session on day one*

## DAY TWO WEDNESDAY, APRIL 9, 2014

7:30 *Continental Breakfast*

8:00 *Chairman's Review of Day One*  
*Ian Lauf, Associate Director Clinical Alliance Management,*  
**Eisai Inc.**



### New Models for Partnerships and Collaborations to Minimize Risk and Maximize R&D Returns

8:15 **INDUSTRY DISCUSSION**  
**The Economics of Collaboration — Industry Perspectives on Maximizing the Value of R&D Collaborations**

Bring partnering to the next level by minimizing risk and expense. Learn from industry executives ways to increase efficiency and trim the fat.

- Get the most return by leveraging investments
- Deliver value for both parties
- Bridge the funding gap at early stages of the partnering spectrum
- Learn best practices on up-front, royalty and milestone payments

*Michael Haller, Ph.D., Chief Operating Officer and Board Director, **Denovo Biomarkers***

*Linda Smibert, Senior Director, Operations and Business Development, **Kowa Pharmaceuticals America, Inc.***

*Michelle Browner, Partnership and Portfolio Management, **Johnson & Johnson Innovation Center, Boston***

9:00 **Best Practices and Strategies for Academia Collaborations and Alliances**

This panel discussion delves into strategies for effectively tapping into innovation within the academic research segment. Learn how to meet expectations and avoid pitfalls when striking a deal with academia.

- Understand the governance of an academic collaboration
- Use academic innovation to bolster pipeline
- Avoid common stumbling blocks
- Learn how transparency and people management equals success
- Learn how to align your goals and incentives

*Moderator: Cameron Durrant, President and Chief Executive Officer, **ECR Pharmaceuticals***

*Panelists: Annlouise Goodermuth, Director, Alliance Management Strategy, External Innovation and Science Policy, **Sanofi-Aventis***

*Simon Bateman, Executive Director, Global Strategic Alliance Management, **Novartis***

*Dana Hammill, Director, Alliance Management, Translational Research Program, **University of Pennsylvania***

9:45 **Improve the Outsourcing Model — Improve Efficiency and Accelerate Cycle Times**

Outsourcing drug research and development is more important than ever. Learn from an expert on best practices to make it work.

- Learn the importance of aligning goals with CRO partners
- Understand the value of incentives and penalties to guarantee a strong ROI
- The art of managing relationships
- Avoid the temporary staff trap

*Ian Lauf, Associate Director Clinical Alliance Management, **Eisai Inc.***

10:30 *Networking and Refreshment Break*



### Decision-Making and Investment Prioritization

11:00 **Wall Street Insights on Investment Decisions in a Crowded Market — Assess and Adjust**

Learn how to read the tea leaves.

Putting today's landscape in context to help navigate the future — this session tracks trends and exposes opportunity.

- How to make investment decisions in a crowded space
- Indication selection — Business vs. analytics
- How to get in on a growing market
- How do biosimilars fit into your portfolio
- What is the future of generics

*Barbara Ryan, Managing Director, **FTI Consulting***

11:45 **Portfolio Management that Drives Value and Balances Risk and Return**

Learn how to streamline your portfolio process and make it work optimally.

- Become an effective portfolio manager
- Create a well-designed, efficient and effective process
- Develop strong portfolio management practices

*Michael Menke, Ph.D., Adjunct Professor, Engineering and Technology Management, **Portland State University**; President,*

***Value Creation Associates***

12:30 *Luncheon*

1:45 **Forward Approaches to Portfolio Metrics, Analytics and Project Prioritization**

The link between strong innovation and portfolio performance is clear. This session presents next-generation approaches and models for leveraging forecasting and key metrics to ensure your portfolio out performs expectations.

- Link portfolio management and other key innovation activities
- Understand how to sharpen portfolio decision making throughout the process
- How to move the needle on ROI with better investment resource decisions
- Discuss investing metrics and tracking tools to measure return on portfolio assets

*Alex Kandybin, Partner, **Booz & Company***

2:30 **Use Technical Innovation to Maximize Molecules and Magnify Markets**

Explore how incremental investments in technical innovation can enhance molecules' clinical profile, enable new clinical indications, increase patient acceptance and adherence and extend the life of brands.

- Use new technologies to optimize products' pharmacological and clinical profile
- Enable new indications and widen therapeutic windows through targeted delivery
- Enhance pills and packaging to drive, differentiate and defend new markets
- Modify molecules to create next generation chemical entities
- Achieve full potential with difficult compounds

*Troy Norris, Managing Director, **Valamont Advisors, LLC***

*Bing Yuan, Ph.D., Executive Director, Life Cycle Strategy, **Novartis***

3:15 *Close of Conference***WHO SHOULD ATTEND**

You will benefit from attending this event if you are an executive or senior-level professional at a pharmaceutical, biotech, medical device or diagnostics company with responsibilities or involvement in the following areas:

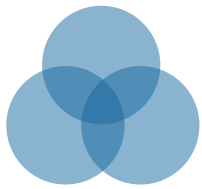
- **Portfolio Management**
- **Pipeline Planning**
- **Resource Planning**
- **Asset Management**
- **Corporate Development**
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- **R&D Management**
- **Risk Management**
- **Business Intelligence**
- **Product Management**

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## R&D Open Innovation and Portfolio Optimization

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