12th Annual US-Japan Health Sciences Dialogue
November 27-28, 2012
Union League of Philadelphia

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Risk Management: A 360° View

Risk and risk management in drug development affects every stage of development for drug makers and their investors. Among other issues, perceived risk determines which assets will advance to the clinic, which assets in the clinic are discontinued, the terms of a collaboration agreement, whether or not an innovator company will attract investment. Risk permeates every aspect of drug discovery and development and, considering the overall lackluster performance of the biopharma industry, it leads us to speculate that "risk management", as practiced today, may actually hinder the growth of this sector.

The 12th annual US-Japan Health Sciences Dialogue will examine risk and how it is managed on both sides of the Pacific from 360 degrees.

Welcome you to the 12th Annual US-Japan Health Sciences Dialogue. In addition to plenary sessions, this year's program also features workshops, company presentations and partnering. We hope that you find the content informative and the networking opportunities plentiful.

With best regards,

Sara Jane Demy
James Foley
Peter Sears
Co-Chairs, US-Japan Health Sciences Dialogue

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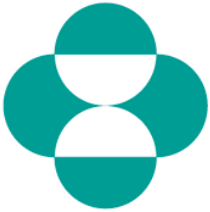

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TIBEREND
STRATEGIC ADVISORS, INC.

Tuesday, November 27

9:00 – 10:15 Opening Plenary

"Risk Management: A 360° View"

10:15 – 11:15 ***"Risk Reduction in Drug Development and Commercialization: Does Size Matter?"***

Company Presentations:

11:15 MAB Discovery
11:30 Ezose Sciences Inc.
11:45 TetraLogic Pharmaceuticals

12:00 – 2:00 Luncheon Plenary

"The Campbell Alliance Dealmakers' Intentions Survey: A Japanese Perspective"

Company Presentations:

2:00 BioBehavioral Diagnostics Company
2:15 TeraDiscoveries, Inc.
2:30 Melior

2:45 – 3:45 ***"How Do You Manage a Biotech Company to a Value-added Exit?"***

3:45 – 5:00 Closing Plenary:

"The Harrington Project: Drug Discovery and Early Development- A New University-Initiated Business Model That Assumes Early R&D Risk"

5:30 – 7:00 Reception

Wednesday, November 28

9:00 – 10:15 ***Pan-Pacific Expansion: Mitigating Risk***

10:15 – 11:15 **"*Thinking Outside of the Box: Lessons Learned*"**

Company Presentations:

11:15	REGiMMUNE
11:30	D. Western Therapeutics Institute, Inc. (DWTI)
11:45	LivTech Inc.

12:00 – 2:00 Luncheon Plenary:

"The Brave New World of Commercialization: The Last Frontier in Value Creation"

Company Presentations:

2:00	NanoCarrier
2:15	Epitek, Inc.

2:45 – 3:45 ***"A Look at Japanese Bioventure: Where is the Money?"***

3:45 – 4:45 Closing Plenary:

A Closing Look at Risk in the Biopharma World: What are the Take Home Messages from Both Sides of the Pacific?

Plenary & Workshop Topics

Opening Plenary Session:

Risk Management: A 360° View

Tuesday, November 27, 2012, 9:00 – 10:15 AM

This panel will focus on "risk management" as practiced by the pharmaceutical industry today and whether it hinders innovation by morphing into "risk aversion". Risk management has many different implications in the world of drug discovery, development and commercialization. Indeed, risk management is a factor with every decision at every stage of development which by necessity, the pharma industry manages very well. However, considering ongoing pipeline challenges, some contend that risk management has actually hindered drug development. This panel will have a broad discussion about risk management, its impact on innovation, and what industry is doing today to address the inherent conflict between risk aversion and innovation.

Moderator:

- **Stephen Paul Mahinka**, Partner & Chair, Interdisciplinary Life Sciences Practice, Morgan, Lewis & Bockius LLP

Panelists:

- **Anthony W. Ford-Hutchinson,** Principal, Ford-Hutchinson Consulting Ltd.
- **David Flores**, Co-Founder, President & CEO, BioCentury Publications Inc.
- **John Bathery**, Senior Director, Global Business Development, Takeda Pharmaceuticals International

Workshop:

Risk Reduction in Drug Development and Commercialization: Does Size Matter?

Tuesday, November 27, 2012, 10:15 - 11:15 AM

A recent article in Genetic Engineering News claims just that – size does appear to matter. Furthermore, an analysis of data published by Joseph A. DiMasi, PhD, Director of Economic Analysis at Tufts' Center for the Study of Drug Development shows that 32% of large molecules made it from Phase 1 to approval versus 13% of small molecules. While there are various opinions as to why this is true there is also a further argument to be made to support large molecule development - they may have a longer commercial "shelf life", a significant consideration for drug developers.

Moderator:

- **Michael G. King, Jr**., Managing Director and Senior Biotechnology Analyst, Dawson James Securities, Inc.

Panelists:

- **Jack Geltosky,** Adivisor, Business Development, MAB Discovery
- **Brad Guild**, Ph.D., Senior Director, Technology Development, External Science & Technology Research, Shire Human Genetic Therapies
- **Gerri Hennwith**, President/Founder, Malvern Consulting Group, Inc.

Luncheon Plenary Session:

The Campbell Alliance Dealmakers' Intentions Survey: A Japanese Perspective

Tuesday, November 27, 2012, 12:00 – 2:00 PM

Campbell Alliance is pleased to present the results of its fourth annual Dealmakers' Intentions Survey, the only forward-looking measure of deal-making activity in the pharmaceutical and biotech industries. While there are many quality sources of information that look historically at past deal trends, this survey offers a prospective view of the partnering and licensing landscape for the year ahead. In 2012, in-licensers are pushing risk down the food chain to out-licensers. Supply and demand is skewed heavily toward in-licensers demanding de-risked, late-stage assets in the most established therapeutic areas. The bottom line: safety will be expensive in 2012 and into 2013. While all pharma companies worldwide are concerned with pipeline expansion, what are the drivers and issues that are unique to Japanese biopharmas, and how will they affect your strategy, and what issues are common? This panel of seasoned dealmakers will discuss their experiences in getting deals done with their Japanese counterparts. In particular, they will discuss their win-win strategies.

Presenter:

- **Jeffrey Stewart,** Senior Engagement Manager, Campbell Alliance

Workshop:

How Do You Manage a Biotech Company to a Value-Added Exit?

Tuesday, November 27, 2012, 2:45 - 3:45 PM

Building a biotech company, whether it is taken to an exit through acquisition or, in today's market, the rare IPO is not for the faint of heart. In addition to advancing assets through development, the one thing a CEO needs to think about every day is how s/he is going to get money back for investors, managing the board, and spending limited resources wisely and efficiently. This panel of seasoned executives and investors will share their observations and advice.

Moderator:

- **Joan Lau**, CEO, Azelon Pharmaceuticals

Panelists:

- **David C. U'Prichard**, PhD, Chief Scientific Officer, BioMotiv – The Harrington Project for Discovery & Development
- **John M. Gill**, President and Chief Executive Officer, TetraLogic Pharmaceuticals
- **Elaine V. Jones**, PhD, Executive Director, Venture Capital, Pfizer Inc.

Plenary Session:

The Harrington Project: Drug Discovery and Early Development- A New University-Initiated Business Model That Assumes Early R&D Risk

Tuesday, November 27, 2012 3:45 - 5:00 PM

To reduce their internal R&D P&L risk, pharmaceutical and biotech companies are increasing their outreach into the academic community for discovery and early development partnerships that deliver novel products with demonstrated clinical proofs of concept. In response to this interest, life science academic research communities have come together proactively to create centers of discovery and development excellence that pharma and biotech companies, as well as investors, can draw on to build their pipelines and companies. The Harrington Project for Discovery and Development, a new $250 million global initiative underway at Cleveland's University Hospitals, includes a new clinical research initiative, University Hospitals Harrington Discovery Institute, and BioMotiv, a new mission-aligned development "therapeutic accelerator' company. Using a novel business model, BioMotiv will assume the risk of early translational-development phase products (in the so-called "valley of death") through licensing agreements, which will be developed in a financially and management efficient manner through to a recognized clinical proof of concept or clinical relevance. At this point, potential partners can acquire rights to complete development, obtain regulatory approval, and commercialize the science. Biomotiv operates as an "evergreen" holding company, managing a portfolio of single-product virtual companies with an experienced team of ex-pharma technical and business professionals in Cleveland and Philadelphia. Biomotiv's outreach is global with respect to both asset sourcing, and academic and CRO relationships, and as such BioMotiv has a strong Asian and European focus.

Presenter:

- **David C. U'Prichard,** PhD, President, Druid Consulting LLC and Chief Scientific Officer, BioMotiv LLC

Plenary Session:

Pan-Pacific Expansion: Mitigating Risk

Wednesday, November 28, 2012, 9:00 – 10:15 AM

Many eastern and Western biopharmaceutical companies have made decisions to expand into the emerging Asian healthcare markets, including China and India. Their strategies have ranged from the establishment of an independent office, to joint ventures with local companies, and collaboration agreements to conduct clinical trials as well as sell products approved in the West. Needless to say, problems have emerged that have caused the "pioneers" to rethink their strategies and adapt to local actualities. This panel will share wisdom gained from engaging in these markets.

Moderator:

- **Martina Molsbergen**, CEO, C14 Consulting Group

Panelists:

- **Gunther Winkler**, PhD, Principal, ASPB Consulting Group
- **Greg Wiederecht**, Vice President, Worldwide Licensing & External Research, Merck
- **Russell L. Gantt**, Vice President, Regional & Corporate Business Development

Workshop:

Thinking Outside of the Box: Lessons Learned

Wednesday, November 28, 2012, 10:15 - 11:15 AM

Establishing a cross-border biopharma operation is a serious strategic undertaking for any management team, whether from a large or small company. This panel will discuss the challenges, inherent risks including the cultural and scientific integration of global operations, employee work ethics and attitudes and scientific approach. The lessons learned range from profound to amusing, often resulting in a stronger company.

Moderator:

- **Kathleen M. Shay**, Partner, Duane Morris LLP

Panelists:

- **Scott Siegel**, PhD, CEO, Ezose Sciences Inc.
- **Taku Nakahara**, Director of Bioinformatics, Ezose Sciences Inc.
- **Tamao Watanabe**, Head, Global Licensing and Business Development, Kyowa Hakko Kirin Co., Ltd. ("KHK")
- **Grady Barnes**, PhD, Chief Scientific Officer, Fujirebio Diagnostics, Inc.

Luncheon Plenary Session:

The Brave New World of Commercialization: The Last Frontier in Value Creation

Wednesday, November 28, 2012, 12:00 - 2:00 PM

In today's world, product approval is merely another milestone on the road to value creation. The panelists will share their opinions and insight about what is needed in a product profile to make it commercially successful in an evolving, global reimbursement environment where payers, clinicians and patients are more and more sensitive to efficacy, safety, quality of life and cost.

Moderator:

- **David Flores**, Co-Founder, President & CEO, BioCentury Publications Inc.

Panelists:

- **Edward Saltzman**, President, Defined Health
- **Roger Longman,** CEO, Real Endpoints LLC

Workshop:

A Look at Japanese Bioventure: Where is the Money?

Wednesday, November 28, 2012, 2:45 – 3:45 PM

Life Science research in Japan is arguably equal too and potentially better than science in other developed countries with robust biotech communities. Therefore, we wonder why Japanese Biotech is lagging behind the rest of the work in biotech company creation. Are Japanese bioventure companies attracting investment they need to grow? If not, why not?

Moderator:

- **Chizuko Koseki**, Founder, TransB

Panelists:

- **Paul Bolno**, Vice President, Business Development - Asia, GlaxoSmithKline, Shanghai
- **Haru Morita**, Chairman, President and Chief Executive Officer, REGiMMUNE Corporation
- **Tetsuro Iwata**, Senior Manager, MP Healthcare Venture Management (MPH)

Closing Plenary Session:

A Closing Look at Risk in the Biopharma World: What are the Take Home Messages from Both Sides of the Pacific?

Wednesday, November 28, 2012, 3:45 – 4:45 PM

For biotech companies, it is return on investment. For pharma companies, it is products, products, products. In between these two extremes, it is managing risk.

Moderator:

- **James Foley**, Partner, AquaPartners

Panelists:

- **Allen Downs**, Senior Executive Director, Licensing & Business Development, Purdue Pharma L.P.
- **David C. U'Prichard**, PhD, Chief Scientific Officer, BioMotiv – The Harrington Project for Discovery & Development

Speakers & Moderators

Grady Barnes, PhD, Chief Scientific Officer, Fujirebio Diagnostics, Inc.

John Bathery, Senior Director, Global Business Development, Takeda Pharmaceuticals International

Paul Bolno, Vice President, Business Development - Asia, GlaxoSmithKline, Shanghai

Allen Downs, Senior Executive Director, Licensing & Business Development, Purdue Pharma L.P.

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Gunther Winkler, PhD, Principal, ASPB Consulting Group

Greg Wiederecht, Vice President, Worldwide Licensing & External Research, Merck

Presenting Companies

BioBehavioral Diagnostics Company (BioBDx)

manufactures and markets technologies for the diagnosis and management of neurological and psychiatric conditions. Commercially, the company offers the FDA-cleared Quotient ADHD System (portable or modular models), which aids in the objective and accurate assessment of neural control functions related to ADHD. Quotient tests are available for children aged 6 to 14 years, as well as adolescents and adults 15-55 years with comprehensive reports specifically for ADHD that summarize motion, attention, and shifts in attention state. The company's assessment technology sensitively analyzes discrete behaviors that correlate strongly with brain-based inhibitory functions relevant to ADHD and other neurological disorders. BioBDx serves all clinicians and researchers working with ADHD and neurological disorders with particular focus on neurologists, pediatricians, and psychiatrists in the United States. The privately-held company has medical/product development offices in Westford, Massachusetts and executive offices in Plymouth Meeting, Pennsylvania.

Represented by:
Dr. Calvin Sumner, Sr. Vice President & Chief Medical Officer

D.Western Therapcutics Institute,Inc(DWTI) is a drug discovery focused company based in Nagoya, Japan and listed in JASDAQ. Our efforts have been focused on the research and development of the innovative drugs,using science based on protein kinase inhibitors. We have three products in clinical stage. which include anti-glaucoma agent, ,anti-platelet agent, and anti-cancer agent. DWTI have already successfully licensed out worldwide exclusive right to develop and commercialize those three products to Japanese pharmaceutical company. We have been actively working on several discovery projects and pursue patentability of newly discovered potential drug candidates Several small molecules in our portfolio compounds having protein kinase inhibitory effect are currently ready for licensing out.

Represented by:
Yuichi Hidaka, CEO

Epitek, Inc. is a biotechnology company that focuses on (1) drugs and devices for Radiation Protection and Therapy and (2) Regenerative Biology. Epitek is expanding its collaboration with Temple University to examine the feasibility of establishing a binational Center for Radioprotection Research and Education on the Tokyo and Philadelphia campuses.

Represented by:
Dr. Steven Baranowitz, President

Ezose Sciences Inc. (pronounced ā-zose) is a glycomics-focused company that leverages its unique, high-throughput glycan analysis technology in two ways: As a platform to discover & develop new biomarkers and therapeutic targets and as a glycoform analytical service to support biologic and biosimilar drug development. Ezose Sciences offers a proprietary new high-throughput solution that is compatible with complex biological samples and can deliver both qualitative and quantitative data on glycans of biological and clinical interest. Ezose operates under a flexible business model, with projects ranging from partnership to fee-for-service, all designed to meet the needs of our business partners.

Represented by:
Scott Siegel, PhD, COO

LivTech is a privately owned biotech company based in Kanagawa, Japan. LivTech was founded in 2004 in order to translate cutting-edge stem cell research at a government grant research project (KAST; Kanagawa Academy of Science and Technology) into the antibody drug discovery targeting malignant tumors. Our research focus is on early phase of antibody development. It has developed a unique research platform that generates antibodies against target molecules involved in carcinogenesis. This involves the isolation of organ-specific stem cells and progenitor cells in order to identify genes specifically expressed in these cells. Taking advantage of the similarities between normal tissue stem cells and cancer stem cells / tumor initiating cells, LivTech has selected several stem / progenitor cell-specific genes for the generation of anti-tumor monoclonal antibodies. So far, LivTech has track records of out-licensing its lead antibody to Kyowa Hakko Kirin in 2008 and to Yakult in 2011.

Represented by:
Koji Nakamura, Ph.D, President and CEO

MAB Discovery's approach to creating high quality monoclonal antibodies relies on the natural antibody maturation process following immunization; and the ability to clone and select B cells expressing matured antibodies employing state of the art automation. Rather than relying on conventional single hit optimization techniques of a few selected antibodies, the MAB Discovery approach creates a diverse collection of many hundreds of high affinity antibodies that arise from immunization of different species, including rat and rabbit. By using sophisticated B cell cloning techniques, the MAB Discovery scientists can capture and examine virtually the immunized animal's entire repertoire to a given immunogen.

Represented by:
Dr. Birgit Zech, Head of Business Development

Melior Discovery is a pioneer of *in vivo* phenotypic screening and a leader in the area of drug repositioning. The company has developed a proprietary platform, *thera*TRACE®, that enables rapid and cost-effective identification of new therapeutic potential by systematically screening candidates across an array of validated *in vivo* disease models across a broad range of therapeutic indications.

Represented by:
John Farah, CBO

REGiMMUNE Corporation is a private biopharmaceutical company developing innovative solutions for treating immune disorders caused by nonspecific and/or excessive immune reactions. REGiMMUNE uses its proprietary technology platform, reVax (reverse vaccination), to target immune tolerance against specific disease-causing antigens through induction of regulatory T cells (Treg). This technology has potential applications in a number of immune system disorders and diseases including Graft versus Host Disease (GvHD), type 1 diabetes mellitus (T1DM), rheumatoid arthritis (RA), multiple sclerosis (MS) and systemic lupus erythematosus (SLE).

Represented by:
Haru Morita, President and CEO

TeraDiscoveries' mission is to improve, accelerate and dramatically reduce the cost of discovery and preclinical development of new drugs and diagnostics. We do this by using leading edge computational chemistry and bioinformatics. Our Inverse Design chemoinformatics software was developed at and exclusively licensed from Duke University. TeraDiscoveries discovers, optimizes and develops early stage drugs from target selection through lead discovery and optimization, synthesis, testing and clinical planning.

Represented by:
Ed Addison, CEO

TetraLogic Pharmaceuticals is a leader in the discovery and development of small molecule drugs called Smac mimetics for the treatment of cancers. Smac mimetics are an entirely new class of targeted drugs that specifically induce cancer cell death and inhibit fundamental mechanisms of cancer cell survival and resistance, enabling tumors to die.

Represented by:
Tony Meehan, VP Alliance Management and Operations

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Greg Wiederrecht, PhD
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Peter Sears
Health Sciences Dialogue Committee Chairman, Japan America Society of Greater Philadelphia