

# The 7th Annual BioExec Institute Retreat

Wednesday, 30th March – Saturday, 2nd April 2011, The Ritz-Carlton Palm Beach Resort, FL

## PROGRAM INTRODUCTION & BACKGROUND

### “New Realities”

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When we left the BioExec Institute Retreat 2010 no doubt all participants expected 2010 to be another tough year in our industry. A year ago we started to talk about the search for a new equilibrium among the stakeholders in our industrial ecosystem (pharma – VC – biotech) would intensify. Today - after what was indeed a difficult year with only a handful of highlights on the M&A side, extremely few IPOs, dramatically reduced fundraisings by VCs – there is no doubt that the key questions have not gone away.

While the need for innovation in this industry persists and will persist unabatedly, the biggest question mark is the current “classical” business model of taking science and IP out of academia, establish it within early stage biotech companies, refine it, progress it through the development pipeline financed by venture capital, and then either take it public or sell it to the pharmaceutical majors. Add in the mounting issues of regulatory strategy and implementation and the predictability and consistency of FDA interactions encountered by both biotechs and big pharma, and you arrive at the conclusion that this industry has to fundamentally...

- *Change the way its participants balance their commercial interests in order to sustain the flow of capital into innovative projects, as well as*
- *Adjust the commercial strategies to create value through innovation to the “New Realities” in today’s markets*
- *Proactively utilize development and commercialization opportunities presented by Emerging Markets*

The “classical” path of value creation has worked in the formative years of biotechnology, when it was a new and exciting industry. It seems to work no more. The IPO markets have all but vanished and public offering activity is expected to be focused on revenue stage companies or companies with products in registration.

With the pharmaceutical industry the only practical taker for early stage biotech assets, the balance of power has markedly shifted towards big pharma. While big pharma strategists are realizing the need to find ways to reward success in discovery and development earlier than today to support the companies and people who have made it their business to provide early stage innovation, the business development departments do the best job they possibly can to keep the payoffs small and late, by pushing out payments for licensing or acquisition transactions until risk has been reduced in the underlying development projects in a big way thus squeezing both founders, innovators and the financing venture capitalists.

If the VCs do what most of them truly love to do, namely, put money in the most exciting and fundamentally ground breaking science they find, they will “go broke”. If we do not find a new balance in our ecosystem, there is little doubt that the key financial source of all this innovation, the venture capital industry as we know it today, will vanish, as it will not receive more money from its limited partners to invest in biotech innovation.

Against this backdrop of an industry in search of new models, the Retreat will search for:

- *Ways of dealing with the mounting issues of FDA interaction and regulatory environment in the US*
- *Emerging issues of commercialization in the US market, and alternative regulatory and commercial strategies involving Europe and Emerging Markets*
- *New collaborative and highly networked models for value creation through the discovery and development of novel drugs*

We believe that as innovation will continue, any vacuum in the market created by a weakening classical funding model for companies or a decreasing number of financial backers will be filled by either new models of doing business or new players in the industry, including in Emerging Markets. The participants will all use their best efforts and look into the future to see how the new world order in our industry could look like.

# The 7<sup>th</sup> Annual BioExec Institute Retreat

Wednesday, 30th March – Saturday, 2nd April 2011

The Ritz-Carlton, Palm, FL

## Wednesday 30<sup>th</sup> March

19.00

**The Opening Retreat Cocktail Reception** (The Breeze Bar, The Ritz-Carlton)

## Thursday 31<sup>st</sup> March

08.00

**Registration & Breakfast** (The Ocean Ballroom & Terrace)

### Group Discussion Sessions (Ocean Ballroom)

08.55

**WELCOME:** Hoda Abou-Jamra, CEO, The BioExec Institute

09.00

#### **PANEL: PHARMA BD: SECURING INNOVATION**

The panellists will be asked their views on the following questions:

- *How can BD contribute to making the ecosystem a generator of successful innovation?*
- *What is the relative importance of early vs. late-stage licensing for a pharma company's existing development portfolio?*
- *How do companies make trade-off decisions between investing in internal vs. external innovation?*
- *Are there new risk and value sharing models on the horizon?*

#### Panellists:

Chair: Helmut Schühsler, Managing Partner, TVM Capital

- Demetrios Kydonieus, Executive Director, Strategic Transactions Group, BMS
- Kristin Peck, EVP, Worldwide Business Development & Innovation, Pfizer
- Robert Wills, VP, Alliance Management, Johnson & Johnson
- Barbara Yanni, VP & Chief Licensing Officer, Merck

09.45

#### **PANEL: PHARMA – VC – BIOTECH - ACADEMIA: A NEW ECO SYSTEM**

The panellists will be asked their views on the following questions:

- *How will biotech companies react to the financial pressures in the market?*
- *Where will real innovation come from in the next 20 years?*
- *Is classical VC going to make a comeback? Or are other investors stepping in?*
- *What is the changing - and expanding - role of academia in early stage development?*

#### Panellists:

Chair: Jean-François Formela, Senior Partner, Atlas Venture

- Aris Persidis, President, Biovista, Inc.
- Ken Noonan, Partner, LEK Consulting LLP
- Kathleen Williams, Partner, Intellectual Property, EAPD
- Meeta Chatterjee, Head, Global Out-Licensing and Asset Management - Worldwide Licensing, Merck

10.30

**Coffee Break** (Ocean Ballroom Terrace)

11.00

#### **PANEL: THE FDA & THE REGULATION OF PRODUCTS**

The panellists will be asked their views on the following questions:

- *The extreme raising of the bar on safety*
- *The lack of transparency and predictability from end of phase II meetings to approval*
- *The likelihood that single arm trials will not be acceptable and the subsequent effect on approvals for oncology and rare disease products*
- *The dangerous bleeding over of reimbursement issues into the approval path*

#### Panellists:

Chair: Alex Barkas, Managing Director, Prospect Venture Partners

- Nicholas Fleischer, Vice President, Clinical Pharmacology & Biopharmaceutics, The Weinberg Group Inc.
- Ansbert Gadicke, Managing Director, MPM Capital
- Edward Mathers, Partner, New Enterprise Associates
- Art Pappas, Managing Partner, Pappas Ventures
- Robert Schotzinger, CEO, Viamet Pharmaceuticals

11.45 – 12.15	<p><b>OPEN ROUNDTABLE DISCUSSIONS</b></p> <p>These roundtable sessions are a less formal and more interactive way in which to discuss industry issues. Each table, holding approx. 10 persons, is facilitated by a Moderator and allocated a topic for discussion for approx. 30 minutes. The discussions will take place simultaneously and at the end of the session, the Moderators are each invited to give a brief synopsis on their table’s discussion to provide comparison for the benefit of the other tables.</p>
	<p><b><i>Topics for these open roundtable sessions follow on from the Opening Panel Discussions.</i></b></p> <p><b>TABLE 1: <i>How is Big Pharma Innovating Internally?</i></b> Moderator: Doug Giordano, SVP, Worldwide Business Development, Pfizer</p> <p><b>TABLE 2: <i>VC Strategies of the Future: Is It All the Same?</i></b> Moderator: Ansbert Gadicke, Managing Director, MPM Capital</p> <p><b>TABLE 3: <i>Pharma-VC-Biotech-Academia Ecosystem: How to Find the New Balance?</i></b> Moderator: Barbara Yanni, VP &amp; Chief Licensing Officer, Merck</p> <p><b>TABLE 4: <i>Does Product Regulation and the FDA Drive Biotechs Abroad?</i></b> Moderator: Nicholas Fleischer, Vice President, Clinical Pharmacology &amp; Biopharmaceutics, The Weinberg Group Inc.</p> <p><b>TABLE 5: <i>The Changing Role of Academia in the Business of Innovation</i></b> Moderator: Alexandra Goll, General Partner, TVM Capital</p>
12.15 – 13.00	<p><b>OPEN ROUND TABLE SUMMARIES</b></p> <p>Each of the moderators will provide a summary of what their table discussed and the outcomes of these discussions.</p>
13.00	<p><b>Lunch</b> (Ocean Ballroom Terrace)</p>
<b>Group Activities</b>	
14.30 – 16.30	<p><b>Group Beach Activities and The Annual Retreat Soccer Match</b></p> <p>A private area has been set up for Retreat guests on the Beach with refreshments, umbrellas, and loungers. Everyone is invited to either participate in or support the annual Beach Soccer match which will kick off at <u>15.00pm</u> and, as usual, there will be champagne afterwards for the willing participants! Plus sailing, kayaking and a beach masseuse!</p>
19.00	<p><b>Cocktail &amp; Dinner Reception at Mar-a-Lago</b></p> <p>All guests to rendezvous in the hotel foyer for 19.00pm transfer departure. Return transfer at 23.00pm.</p>

Friday 1 <sup>st</sup> April	
08.00	<b>Breakfast</b> (The Ocean Ballroom & Terrace)
Group Discussion Sessions (Ocean Ballroom)	
09.00	<p><b>PANEL: M&amp;A AND CREATING REAL VALUE AT EXIT</b></p> <p>The panellists will be asked their views on the following questions:</p> <ul style="list-style-type: none"> <li>• <i>A VC perspective on alternatives to going public</i></li> <li>• <i>Can a change in tax policy reinvigorate the Capital Markets?</i></li> <li>• <i>How to create a capital environment where you get rewarded before the revenues come in – who is being creative and what options exist?</i></li> </ul> <p><u>Panellists:</u>  Chair: Stelios Papadopoulos</p> <ul style="list-style-type: none"> <li>➤ James Barrett, Partner, Edwards Angell Palmer &amp; Dodge</li> <li>➤ Fred Frank, Vice Chairman, Peter J. Solomon Co.</li> <li>➤ David Schechner, Managing Director, Canaccord Genuity</li> <li>➤ Helmut Schühsler, Managing Partner, TVM Capital</li> </ul>
09.45	<p><b>PANEL: EMERGING MARKET OPPORTUNITIES</b></p> <p>The panellists will be asked their views on the following questions:</p> <ul style="list-style-type: none"> <li>• <i>What are the different BD&amp;L strategies that are being implemented in emerging markets?</i></li> <li>• <i>What is the right portfolio approach to emerging markets?</i></li> <li>• <i>What are the main risks and experiences seen?</i></li> <li>• <i>How do we define emerging markets? Brazil, Russia, India and China are all very different.</i></li> <li>• <i>Are there in-license opportunities for big pharma from emerging markets?</i></li> </ul> <p><u>Panellists:</u>  Chair: Tony Rosenberg, Head, Partnering &amp; Emerging Businesses, Novartis Pharma</p> <ul style="list-style-type: none"> <li>➤ Darren Carroll, Vice President, Corp. Business Development, Eli Lilly</li> <li>➤ Ayse Kocak, Managing Director, moksha8</li> <li>➤ Sri Mosur, President &amp; CEO, Global Drug Discovery &amp; Development, Jubilant Life Sciences</li> <li>➤ Paul Sekhri, Head, Biotech Ops Group, TPG Biotech</li> </ul>
10.30	<b>Coffee Break</b> (Ocean Ballroom Terrace)
11.00	<p><b>OPEN ROUNDTABLE DISCUSSIONS</b></p> <p>Each table, holding approx. 10 persons, is facilitated by a Moderator and allocated a topic for discussion for approx. 30 minutes. The discussions will take place simultaneously and at the end of the session, the Moderators are each invited to give a brief synopsis on their table's discussion.</p>
	<p><b>Topics for these open roundtable sessions follow on from the Opening Panel Discussions.</b></p> <p><b>TABLE 1: M&amp;A and Creating Real Value at Exit</b>  Moderator: David Schechner, Managing Director, Canaccord Genuity</p> <p><b>TABLE 2: Emerging Market Opportunities</b>  Moderator: Paul Sekhri, Head, Biotech Ops Group, TPG Biotech</p> <p><b>TABLE 3: Pharma Business Development: New Challenges</b>  Moderator: Meeta Chatterjee, Head, Global Out-Licensing and Asset Management - Worldwide Licensing, Merck</p> <p><b>TABLE 4: Pharma Innovation Strategies: New Models and Approaches</b>  Moderator: Lauren Silverman, Managing Director, Novartis Option Fund</p> <p><b>TABLE 5: What Role Can ex-US Markets Play in Commercial Strategies?</b>  Moderator: Mary Tanner, Managing Director, Peter J. Solomon Co.</p> <p><b>TABLE 6: Entrepreneurial Biotech Companies: How to Create Value</b>  Moderator: Jean-Pierre Sommadossi, Founder &amp; Ex-CEO, Idenix</p>
11.30	<p><b>OPEN ROUND TABLE SUMMARIES</b></p> <p>Each of the moderators will provide a summary of what their table discussed.</p>
12.00	Lunch (Ocean Ballroom Terrace)
Group Activities	
13.00	<b>Golf at Bear Lakes Country Club:</b> Transfer departs from the hotel foyer at <u>13.00pm</u> . Return transfer is at 18.00pm.
14.30 – 16.00	<b>Group Beach Activities:</b> Volley ball, sailing, kayaking and a beach masseuse!
19.30	<b>Drinks Reception:</b> (Outside Lawn, Ritz-Carlton)
Saturday 2 <sup>nd</sup> April	
10.00 – 11.00	<b>Farewell Breakfast</b> (Outside Lawn, Ritz-Carlton)