

The 15th Annual BioExec Institute Retreat

Wednesday, 27th March - Saturday, 30th March 2019, Eau Palm Beach Resort & Spa, FL

Co-Sponsors:



Supporting Organizations:

Wednesday, 27 March 2019

19.00 – 22.00 **The Welcome Buffet Reception** with wine-tasting and live music (The Breeze Bar)

Thursday, 28 March 2019

08.00 – 09.00 **Registration** (The Ocean Ballroom Foyer) & **Group Breakfast** (The Ocean Ballroom Terrace)

THURSDAY MORNING GROUP DISCUSSIONS (The Ocean Ballroom)

09.00 – 09.05 **Welcome from The BioExec Institute CEO:** Hoda Abou-Jamra

09.05 – 09.10 **Introducing Newcomers:** Helmut Schuehler, Chairman & CEO, TVM Capital Healthcare
New attendees will be welcomed and invited to introduce themselves to the group.

SESSION 1 – BUSINESS TOPIC: ONCOLOGY

09.10 – 09.30
(20 mins) **GUEST SPEAKER:** (Virtual Talk) Mark McClellan, MD, PhD, Professor of Business, Medicine and Policy, and Founding Director of the Duke-Margolis Center for Health Policy, Duke University
The Impact of Recent and Coming Changes at the FDA

- Changes at the FDA and an outlook on how this may impact the development of oncology therapies
- Drug pricing and payment reform – implications for access and costs of cancer treatments, and for reforms in cancer care

09.30 – 09.35
(5 mins) **Q&A from the Room**

09.35 – 09.55
(20 mins) **GUEST SPEAKER:** Bradford Hirsch, MD, CEO & Co-Founder, SignalPath
Oncology and What are the Next Steps?

- Defining regulatory grade data and its uses today
- Pragmatic, hybrid and virtual trials, the present realities and future promise
- The evolving role of a community oncologist in the research paradigm

09.55 – 10.00
(5 mins) **Q&A from the Room**

10.00 – 10.15
(15 mins) **Social & Refreshment Break**

10.15 – 10.35 (20 mins)	<p>GUEST SPEAKER: Jeffrey Hodge, Vice President, Development Solutions, Oncology Center of Excellence, IQVIA</p> <p>How Real World Data Can Impact Drug Development in Oncology Today</p> <ul style="list-style-type: none"> • External comparators bring value through innovation with RWE adding context to single arm data and to clinical development • Favorable conditions for expanded use of external comparators – increasing access to clinically rich data; regulators and payors have high demand for RWE data • Industry is using external comparators for submissions to regulators and payers • Challenges and solutions to delivering studies with external comparators
10.35 – 11.30 (55 mins)	<p>INDUSTRY RESPONSE PANEL</p> <p>An opportunity for an industry led panel to respond to the previous talks and to expand on what they consider to be the key issues as they relate to their sector.</p> <p>Chair: Doug Giordano, SVP, Worldwide Business Development, Pfizer Inc.</p> <ul style="list-style-type: none"> • Zoe Barry, Founder & CEO, ZappRx • Jim Greenwood, President & CEO, BIO • Sanjeev Luther, President & CEO, Rafael Pharmaceuticals • Lloyd Segal, President & CEO, Repare Therapeutics & Entrepreneur-in-Residence, Versant Ventures
11.30– 11.45 (15 mins)	<p>Social & Refreshment Break</p>
<p>SESSION 2 – SOCIETAL TOPIC: CANNIBIS</p>	
11.45 – 12.00 (15 mins)	<p>CONVERSATION STARTER:</p> <p>Neil Closner, former CEO, MedReleaf & CEO, NQC Investment Corp.</p>
12.00 – 12.30 (30 mins)	<p>OPEN ROUNDTABLE DISCUSSIONS</p> <p>These roundtable sessions are an informal and interactive way to discuss the societal topic of the day. Each table holds approximately 10 people and is facilitated by a Moderator, enabling all attendees to provide feedback and input. The discussions take place simultaneously for 30 minutes and the Moderators then give a brief 5-minute synopsis on their table’s discussion for the benefit of the other tables.</p> <p>Topic Area:</p> <p>In recent years, it has been suggested that cannabis could be the white knight of the opioid epidemic. Indeed, recent state regulations in the United States (e.g., Illinois, New York) have explicitly approved medical cannabis as a treatment for opioid addiction and Canada’s historical legalization of cannabis has also in part been in response to this overdose epidemic. Against this backdrop, this session will debate:</p> <ul style="list-style-type: none"> • Cannabis - A Solution to the Opioid Epidemic • The use of cannabis to treat chronic pain • The potential of cannabis to reduce opioid cravings • Medical marijuana - a potential harm-reduction strategy for prescribers, who are increasingly medicolegally liable for continuing patients on high-dose opioids.
12.30 – 13.00 (30 mins)	<p>OPEN ROUND TABLE SUMMARIES</p> <p>Roundtable Moderators provide a brief 5-minute summary of what their table discussed.</p>
<p>THURSDAY AFTERNOON LEISURE ACTIVITIES</p>	
13.00 – 14.30 (1 hr 30 mins)	<p>Lunch (The Ocean Ballroom Terrace)</p>
15.00 – 17.00 (2 hrs)	<p>Group Activities</p> <ul style="list-style-type: none"> • Option 1 (15.00 – 16.30): Strictly Ballroom (Ocean Ballroom) An opportunity to practice some ballroom dance steps with a professional teacher in preparation for the evening Black Tie Dinner & Dance Reception in the Circle Ballroom at The Breakers. • Option 2 (15.00 – 17.00): By the Ocean Weather permitting, a private cabana will be set up for Retreat guests with refreshments, board games and chair massages.

18.30 – 23.00 (4 hrs)	Black Tie Dinner & Dance Reception in The Circle Ballroom at The Breakers Join in our special 15th annual celebrations with a night of fine-dining and wines, music from a big band, live ballroom dancing entertainment and dancing. Please meet in The Eau Palm Beach Resort lobby by 18.25 for a group bus transfer that will depart promptly at 18.30 . Return bus transfer at 22.30 and 23.00 .
Friday, 29 March 2019	
08.30 – 09.30	Group Breakfast (The Ocean Ballroom Terrace)
FRIDAY MORNING GROUP DISCUSSIONS (The Ocean Ballroom)	
SESSION 3 – BUSINESS TOPIC: FINANCE	
09.00 – 09.50 (50 mins)	FINANCE PANEL DISCUSSION <ul style="list-style-type: none"> • <i>How will the biotech capital market look over the next 6-12 months?</i> • <i>Will the potential changes in the capital markets change the model for building companies?</i> • <i>Independently of whether they can, should companies be going public as quickly as they have been?</i> • <i>Private mega rounds, where do they fit into the picture?</i> • <i>Have public equity investors and high valuations displaced partnerships?</i> • <i>Why isn't big Pharma/biotech buying more companies?</i> Panellists: Chair: Jean-Francois Formela, Partner, Atlas Venture <ul style="list-style-type: none"> • Marina Bozilenko, Managing Director, William Blair • Annette Grimaldi, Managing Director, Life Sciences, BMO Capital Markets • Matthew Perry, Portfolio Manager, BVF Partners LP • Peter Reikes, Vice Chairman, Stifel • Sandy Zweifach, President & CEO, Nuvelution Pharma, Inc.
09.50 – 10.10 (20 mins)	GUEST SPEAKER: Nicholas Simon, Senior Managing Director, Blackstone Life Sciences The Clarus and Blackstone Deal <ul style="list-style-type: none"> • <i>Evolution of a Life Science venture firm focused on emerging companies</i> • <i>Providing funding at scale across the entire spectrum of drug development through commercialization</i>
10.10 – 10.20	Q&A from the room
10.20 – 10.50 (30 mins)	Refreshment Break & Room Checkout: As well as a coffee break, this is also an opportunity for attendees departing today to check out of their rooms in time for the 12pm deadline. We recommend that any luggage be stored safely with the concierge until your departure.
10.50 – 11.45 (55 mins)	INDUSTRY RESPONSE PANEL <i>An opportunity for an industry led panel to respond to the previous talks and to expand on what they consider to be the key issues as they relate to their sector.</i> Chair: Art Pappas, Managing Partner, Pappas Capital <ul style="list-style-type: none"> • Fred Frank, Chairman, Evolution Life Science Partners • Andrew Hindman, Chief Business Officer, Acorda Therapeutics • Bjorn Koch, SVP, Wealth Management, UBS • Rob Wills, Executive Chairman, GTx, Inc.
11.45 – 12.00 (15 mins)	Social & Refreshment Break
SESSION 4 – SOCIETAL TOPIC: CRISPR	
12.00 – 12.20 (20 mins)	OPEN ROUNDTABLE DISCUSSIONS <i>These roundtable sessions are an informal and interactive way for everyone to discuss the societal topic of the day. Each table holds approximately 10 people and is facilitated by a Moderator, enabling all attendees to provide feedback and input. The discussions take place simultaneously for 30 minutes and the Moderators then give a brief 5-minute synopsis on their table's discussion for the benefit of the other tables.</i>

	<p>Topic Area: <i>“Through technology, the health industry is witnessing rapid and novel advancements, such as CRISPR Technology. With these advancements comes an inevitable re-assessment by the industry of their former methods of therapeutic scale building and portfolio optimization to push technology to the forefront – and serious ethical concerns”</i></p> <ul style="list-style-type: none"> • <i>What is CRISPR to humanity?</i> • <i>The issue of ‘Informed Consent’ when edits affect the embryo and future generations.</i> • <i>Designer children: Is there a future of individuals classed by their engineered genome?</i> • <i>Justice and Equity - will genome editing only be accessible to the wealthy?</i> • <i>Products in development, safety and the possibility of off-target effects and mosaicism.</i>
12.20 – 12.30 (10 mins)	<p>OPEN ROUND TABLE SUMMARIES Roundtable Moderators provide a brief summary of what their table discussed.</p>

FRIDAY AFTERNOON LEISURE ACTIVITIES

12.30 – 14.00 (1hr 30 mins)	<p>Lunch (The Ocean Ballroom Terrace)</p>
13.30 – 18.00	<p>Group Activities Option 1 (13.30 – 18.00): Golf at Palm Beach Par 3 Golf Course Golfers to meet in Eau Palm Beach Lobby for a 13.30 transfer to the golf course. A return group transfer will depart the golf course at 18.00.</p> <p>Option 2 (15.00 – 17.00): By the Ocean Some private cabanas will be set up for Retreat guests with refreshments, board games and chair massages.</p>
19.00 – 22.00	<p>Informal Dinner at Eau Palm Beach Resort on the Lawn.</p>

Saturday, 30 March 2019

10.00 – 11.00	<p>Farewell Breakfast (The Ocean Ballroom Terrace)</p>
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