10th Annual

Commercial Translation of Regenerative Medicine

Guarantee Successful Commercialisation of Cell Therapies with Sustainable Production and Business Continuity

London, UK

28th – 30th November 2012

Including Half-Day Interactive Pre-Conference Workshop:

A Guide to Cell Therapy Commercialisation

Led by:
Robert J Sexauer
Executive Vice President
Intellicell Biosciences Inc.

Chris Mason
Professor of Regenerative Medicine Bioprocessing
UCL

Attending this Premier marcus evans Conference Will Enable You to:

• Understand the optimal business models for the future of regenerative medicine
• Explore the new technologies in this fast growing field
• Ensure a well defined risk mitigation plan
• Gain knowledge on funding and reimbursement strategies

Learn from Key Practical Case Studies:

• Pfizer on their risk-based approach to cell therapy manufacturing
• Athersys on a step forward from small to large scale manufacturing
• Intellicell Biosciences Inc. on developing a sustainable business model
• GSK on regen med commercialisation strategies for big pharma
• Pluristem on best platforms and facilities for commercialisation of cell therapy

In the Chair:
Chris Mason
Professor of Regenerative Medicine Bioprocessing
UCL

marcus evans Expert Speaker Panel:

Jim Faulkner
Vice President, CMC & Supply
GSK

Natalie Mount
Executive Director, Acting Head of Clinical Research
Pfizer

Randy Mills
President & Chief Executive Officer
Osiris

Wilfried Dalemans
Chief Technology Officer
Tigenix

John Engels
Vice President, Co-Founder
AxoGen Inc.

Anthony Ting
Director of Regenerative Medicine
Athersys

Michael Schuster
Executive Vice President of Global Therapeutic Programs
Mesoblast

David Haddow
Chief Executive Officer
Altrika Ltd.

Jakub Schurek
Chief Scientific Officer
Primecell

Robert J Sexauer
Executive Vice President
Intellicell Biosciences Inc.

Francis Verhoeye
Manufacturing Director
Cardio3BioSciences S.A.

Christine Guenther
Chief Executive Officer
Apceth

Joanne Miller
Scientific Director
Quy Biosciences Ltd.

Michael May
Chief Executive Officer
Centre for Commercialisation of Regenerative Medicine (CCRM)

Charles Kessler
Principle Scientific Officer
European Commission

Daya Lettvin
Director, Investor Relations
Pluristem

Petter Bjorquist
Head of Regenerative Medicine
Cellectis stem cells

Aidan Courtney
Chief Executive Officer
Roslin Cells Ltd.

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**Half-Day Interactive Pre-Conference Workshop**

**28th November 2012**

13:30 Registration and Coffee

14:00 Workshop Leader Introduction and Opening Remarks
Led By:
Robert J Sexauer
Executive Vice President
Intellicell Biosciences Inc.

Chris Mason
Professor of Regenerative Medicine Bioprocessing
UCL

**A GUIDE TO CELL THERAPY COMMERCIALISATION**

14:05 The Key Considerations for Scale Up
- Securing funding for the scale up process
- Harmonising the interests of all stakeholder groups
- Creating a quality driven manufacturing process

15:45 Coffee and Networking Break

16:15 R&D Through to Market Success
- Preparing your organisation for market entry
- Evaluating optimal market entry strategies
- Understanding logistics and the supply chain

17:30 Workshop Leader’s Closing Remarks and End of Workshop
08:30 Registration and Coffee

09:00 Opening Address from the Chair
Chris Mason
Professor of Regenerative Medicine Bioprocessing
UCL

AN INSIGHT INTO THE GLOBAL MARKET FOR REGENERATIVE MEDICINE

09:10 Opening Address: Global Market Overview of Regenerative Medicines
- Commercial prospects for regenerative medicines in Europe/USA
- Assessing opportunities in different forms of regenerative medicine
- What are the future growth rates and market pockets?
David Haddow
Chief Executive Officer
Altrika Ltd.

09:50 Case Study: Developing a Sustainable Business Model
- How to identify values from technological opportunities
- Where is the value created in regenerative medicinal products?
- How to deliver the end product
Robert J Sexauer
Executive Vice President
Intelllicell Biosciences Inc.

10:30 Morning Coffee and Networking Break

OVERCOMING CHALLENGES – PROCEEDING TOWARDS CLINICAL AND MANUFACTURING DEVELOPMENT

11:00 Case Study: Justifying the Costs of Regen Med Products
- Competing against existing products
- Demonstrating cost effectiveness
- Expenditure to yield an appropriate return
Randy Mills
President & Chief Executive Officer
Osiris

11:40 Case Study: A Step Forward From Small- to Large-Scale Manufacturing
- Third party involvement – saving on resources
- Partnering with larger pharma/biotech companies
- How to maintain consistency of your product
- Realistic timescales for development
- Cost effective cell culturing for manufacturing
Anthony Ting
Director of Regenerative Medicine
Athersys

12:20 Quality By Design For Cell-Therapy Product Development
- Rationale for risk-based approach in clinical innovation
- Individualised platform technologies in regenerative medicine-no contradiction
- Cost-management and sustainable quality
Christine Guenther
Chief Executive Officer
Apceth

13:00 Luncheon

14:00 Coffee and Networking Break

14:30 Case Study: Translation from R&D to Market Access
- Strategies for lowering cost of product
- Enhancing regen med market access capabilities
- Which are the best markets for your products?
Wilfried Dalemans
Chief Technology Officer
Tigenix

15:10 Case Study: Effective Supply Chain Management in the Regenerative Healthcare Industry
- Development considerations for regenerative medicine supply chain
- Meeting delivery and quality requirements
- Establishing strategic, operational and contractual relationships
Francis Verhoeve
Manufacturing Director
Cardio3Biosciences S.A.

15:50 Afternoon Tea and Networking Break

16:20 Case Study: Comparison of Different Business Strategies for Commercialisation
- Assessment of value of external collaborations
- Different business plans
- Financial forecast layout
- Accurate identification of risks and opportunities
Joanne Miller
Scientific Director
Quy Biosciences Ltd.

17:00 Case Study: Best Platforms and Facilities for the Commercialisation of Cell Therapy
- Robust and scalable production of stem cells
- Challenges for embryonic stem cell processing
- The future of cell therapy bio processing
Daya Lettvin
Director, Investor Relations
Pluristem

17:40 Closing Remarks from the Chairperson and End of Day One

Business Development Opportunities:
Does your company have services, solutions or technologies that the conference delegates would benefit from knowing about? If so, you can find out more about the exhibiting, networking and branding opportunities available by contacting:

Ola Samuelsson, Senior Marketing Manager,
marcus evans, London
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Day Two

30th November 2012

08:30 Registration and Coffee

09:00 Opening Address from the Chair
Chris Mason
Professor of Regenerative Medicine Bioprocessing
UCL

09:10 Opening Address:
Entering Advanced Therapies Market in CEE
• Role of the state and key public institutions
• Joint research, joint development, and joint venture
• What licenses are required?
• Cord blood banking strategies
Jakub Schurek
Chief Scientific Officer
Primecell

09:50 Keynote Address:
Will the Commercialisation of Regenerative Medicine Products be Led by Specialised Biotech or Big Pharma?
• Different models of commercialisation for regenerative medicine products
• What skill sets will be required to be successful?
• Who is best placed to maximise the potential of regenerative medicine products?
Jim Faulkner
Vice President, CMC & Supply
GSK

10:30 Morning Coffee and Networking Break

11:00 Case Study:
A Risk-Based Approach to Cell Therapy Product Development and Manufacturing
• How to identify risks
• Best strategies for risk mitigation
• Implementation of an integrated risk mitigation plan
Natalie Mount
Executive Director, Acting Head of Clinical Research
Pfizer

11:40 Case Study:
Collaborating with Big Pharma
• The acquisition process
• At what stage of development to partner
• Choosing the perfect partner
• Road map for a stem cell treatment for diabetes – the model of partnership
Petter Bjorquist
Head of Regenerative Medicine
Cellectis stem cells

12:20 Interactive Roundtable Discussion
Opportunities and Barriers for Big Pharma in Regenerative Medicine
• Barriers in developing new regen med therapies for diabetes?
• New challenges in commercialisation of these products?
• Is there a lack of regulatory guidance which will affect the product pipeline?
Moderators:
Jakub Schurek
Chief Scientific Officer
Primecell
Jim Faulkner
Vice President, CMC & Supply
GSK

13:00 Luncheon

14:00 Coffee and Networking Break

Booking Line:
Ola Samuelsson
Tel: +44 20 3002 3276
Fax: +44 20 3002 3016
E-Mail: OlaS@marcusevansuk.com

ACHIEVING FUNDING AND REIMBURSEMENT FOR REGENERATIVE MEDICINE PRODUCTS

14:30 Case Study:
A Capital-Efficient, Collaboration Model of Translation in Regenerative Medicine
• Industry-academia collaborations – opportunities and challenges
• Alternative funding sources
• Technology bundling
• International collaborations among translation centres
Michael May
Chief Executive Officer
Centre for Commercialisation of Regenerative Medicine (CCRM)

15:10 Case Study:
Regenerative Medicines – Meeting Global Requirements
• Expanding international commercialisation for a regenerative medicine product
• Reviewing country specific criteria for regen med product launch
• Meeting country specific requirements
John Engels
Vice President, Co-Founder
AxoGen Inc.

15:50 Afternoon Coffee and Networking Break

16:20 EU Support to Regenerative Medicine Research
• Framework and activities supported
• Trends and observations
• Framework and activities supported
Charles Kessler
Principal Scientific Officer
European Commission

17:00 Case Study:
Strategies for Funding the Development of New Cell Therapies
• Defining the whole product
• What do you own and what else do you need
• Defining the regulatory path
• Defining the milestones along the way
• Who will fund what?
Aidan Courtney
Chief Executive Officer
Roslin Cells Ltd.

17:40 Closing Remarks from the Chairperson and End of Conference

Who Should Attend:

VPs, Directors, Heads, Managers, Coordinators of
• CEO
• Chief Scientific Director
• Regenerative Medicine
• Regenerative Medicine Commercial Translation
• Business Development
• Product Development
• Market Access

From:
• Large Biotech
• Small Pharma
• Research Institutions & Universities
10th Annual
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**CONFERENCE:** COMMERCIAL TRANSLATION OF REGENERATIVE MEDICINE

**DATES, VENUE:** 28TH – 30TH NOVEMBER 2012, HILTON LONDON KENSINGTON, UK

**TO REGISTER:** Scan and email or fax bookings directly to Ola Samuelsson
Email: OlaS@marcusevansuk.com
Fax: +44 20 3002 3016

Regenerative medicine has shown phenomenal potential to play a vital role in delivering the next generation of healthcare. It offers treatments and possible cures for life threatening illnesses. Pharmaceutical companies are all eyeing on this new source of revenue with maturing technologies. What business models are regen med companies using? What are the key challenges for scaling up manufacturing production phases? What are the regulatory hurdles? This marcus evans forum will answer these key questions to help delegates learn the best ways to further develop and commercialise their regenerative medicine products.

**Confirmation Details:** After receiving payment a receipt will be issued. If you do not receive a letter outlining joining details two weeks prior to the event, please contact the Conference Coordinator at marcus evans conferences.

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