Industry Insights:

Stem Cells & Regenerative Medicine

Insights from the 2015 faculty ahead of the 10th annual World Stem Cells & Regenerative Medicine Congress 2015

WORLD StemCells Regenerative Medicine Congress 2015

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The World Stem Cells & Regenerative Medicine Congress Story

2005. What a year! London was overjoyed at being elected as host city for the 2012 Olympics, but also devastated by the July 7th terror attacks. The death of Pope John Paul II, that same year, marked the end of an era in the life of the Roman-Catholic Church whilst in Germany, Angela Merkel becomes their first female Chancellor. 2005 also played host to Hurricane Katrina in the United States when it flooded New Orleans, the launch of YouTube and it is where Terrapinn's stem cell story starts.

A decade later and we are delighted to be celebrating the 10th anniversary of an event that was key to the foundations of this medical revolution.

10 years ago when we launched the World Stem Cells Congress, the stem cells sector was one of scientific interest. Focussing on the challenges of how to transform the cells, this conference and exhibition was quite small and the topic area quite niche. Attracting only around 80 people, word of the industry's potential had not yet reached the masses.

2010 witnessed an important transition, not only for the event but the industry as a whole. Key industrial players, such as GE and Lonza, as well as leading pharma companies such as Pfizer, had come to realise the commercial opportunities with stem cells, which would change the sector moving forward.

World Stem Cells Congress would also shift in focus from solely science to incorporate the commercial aspects as well. Both translational medicine and regenerative medicine were added to the conference programme, and an emphasis on achieving market access was enabling successful commercial development within the industry. As industry challenges shifted towards lack of investment and scaling up manufacturing and distribution, discussions moved on to the new business models that were coming into practice as the stem cell sector developed and moved away from traditional pharma models, which would inevitably catapult the industry to where we are now.

What is now the World Stem Cells & Regenerative Medicine Congress is proud to be welcoming an audience of around 600 attendees to London in 2015. As with anything, the event alone has continued develop and this year we will be introducing additional content on tissue engineering and organ regeneration as well as the collocated Investor Forum and Cord Blood World Europe. Delegates will be able to hear and learn from over 60 speakers across the 3 days as well as partake in hundreds of meetings on-site as collaborations become key to commercial success of the industry.

As we reach our 10th anniversary, we asked some of the speakers to give us their thoughts on the biggest achievements over the past 12 months as well as their expectations for the year ahead. This e-book contains just a handful of those answers to give you a taste of what to expect in May.

I hope to see you in London this spring.

All the best,

Hannah Yates
Conference Manager
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PROFILE:
Name: Dr. Brian Dickie
Job title: Director of Research Development
Company: Motor Neurone Disease Association
Role at World Stem Cells & Regenerative Medicine Congress 2015:
Keynote panellist: Panel: Disease foundations' role in promoting healthcare's uptake of regenerative medicine

1. What do you think has been the biggest achievement within the stem cells sector in the last 12 months?

In Amyotrophic Lateral Sclerosis (ALS) I'd say progress in generating and characterising induced pluripotent stem cell lines. These should provide us with a greater understanding of human disease pathogenesis, shed light on new therapeutic strategies and serve as the basis for high throughput compound screening. They will also provide insight into the toxic intercellular environment that exists within the degenerating CNS, which needs to be addressed if cell-based therapy approaches are to be effective.

2. When do you think we will start to see a number of cell therapies in mainstream healthcare systems? What is key to them achieving market access?

Cell therapies for age-related, progressive CNS conditions will prove challenging, as they have proved with more mainstream pharmacological approaches. No surprises, but efficacy, cost and patient acceptance/compliance (especially if a CNS treatment is invasive) will be the crucial factors.

3. Which disease area do you think offers the biggest opportunity for stem cells moving forward?

Sticking with the CNS, I'd view conditions where the damage is more focal, such as stroke or Parkinson's disease, as the best bets, or possibly conditions with a significant neuroinflammatory component.

4. Who (person or company) do you think will be the 'next big thing' within the stem cells sector? And why?

I don't know about the 'next big thing' but within the ALS world I like to keep an eye on Steve Finkbeiner's lab at UCSF to see whether his 'clinical trials in a dish' approaches are delivering.

5. What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?

I just hope it's not 'Regulatory Barriers...'

Want to hear more from Brian?
Meet him and many more disease foundations at World Stem Cells & Regenerative Medicine Congress 2015 – click here for more information

PROFILE:
Name: Dr. David Pan
Job title: Programme Manager
Company: UK Regenerative Medicine Platform
Role at World Stem Cells & Regenerative Medicine Congress 2015:
Day 1 speaker on: Enabling innovation through the use of national research hubs in the UK

1. What do you think has been the biggest achievement within the stem cells sector in the last 12 months?

Over the last year several complex solid organs have been generated in vitro, for example a functional thymus from reprogrammed fibroblasts, skin cells from hESC and iPSCs and a beating heart. There is a long way to go for full organ replacement as a therapy but this provides excellent proof of concept and will be useful for studying development and disease and testing potential treatments.

2. When do you think we will start to see a number of cell therapies in mainstream healthcare systems? What is key to them achieving market access?

I think we are still several years off from that yet, as despite the tremendous scientific advances being made, there are still steep technological and strategic barriers that must be overcome before the potential of mainstream therapy can be realised. Strategic initiatives, such as the UKRMP, which aim to ensure that research addressing regenerative medicine connects seamlessly from discovery science through to clinical and commercial application are key in achieving success. To do this, interdisciplinary research Hubs with the critical mass and expertise to address the key knowledge-gaps in the translation of stem cell and regenerative biology towards application are being used. These Hubs will provide the novel tools, platform technologies and engineering solutions needed for therapeutic development.

3. Which disease area do you think offers the biggest opportunity for stem cells moving forward?

Debilitating neurological diseases such as Parkinson's and Alzheimer's which have been devoid of appropriate treatment.

4. Who (person or company) do you think will be the 'next big thing' within the stem cells sector? And why?

The Cell Therapy Catapult is already demonstrating its unique position and central role in driving research towards commercial propositions. As we move forward this role is only likely to increase exponentially to the benefit of commercially viable and investable therapies – the companies that may be associated with this and UK plc overall.

5. What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?

Outside of the recent scientific advances, the decision by the ECJ decision to lift the ban on patenting embryonic stem cells made from unfertilised eggs. This MAY speed up development of cell based therapies.

Want to hear more from David?

Meet him and many more cell therapy professionals at World Stem Cells & Regenerative Medicine Congress 2015 – click here for more information

PROFILE:
Name: Dr. Fred Miesowicz
Job title: Chief Operating Officer
Company: Argos Therapeutics

Role at World Stem Cells & Regenerative Medicine Congress 2015:
Roundtable Host: "Personalised" cell therapy

1. What do you think has been the biggest achievement within the stem cells sector in the last 12 months?

Harvard stem cell researchers (Dr. Douglas Melton) announced last year, with human embryonic stem cells as a starting point, that they were able to produce, in large quantities needed for cell transplantation and pharmaceutical purposes, human insulin-producing beta cells equivalent in most ways to normally functioning beta cells. Type 1 diabetes is a condition that affects an estimated 3 million Americans at a cost of about $15 billion annually.

2. When do you think we will start to see a number of cell therapies in mainstream healthcare systems? What is key to them achieving market access?

One of the keys for market success for stem cells and cell-based therapeutic approaches to be economically feasible, particularly within prevailing reimbursement philosophies, is that the manufacturing process must be optimised for cost efficiency and scalable to large patient populations.

The processing of stem cell and autologous cell therapies requires scale-out or throughput instead of traditional scale-up. Issues such as cross contamination and changeover of equipment are exacerbated when manufacturing these therapies. Batch testing and release become major factors as one large disease indication could mean up to 50,000 batches to be manufactured and released per year.

An automated platform would address these limitations by enabling the required traceability and robust processing of these products with electronic batch records streamlining release. Manual processing for the scale-out has limitations that are difficult to overcome such as manpower, facility requirements and maintenance of consistent quality of every product produced. This all translates into a high cost of goods for the product and a much slower timing for increasing capacity to meet the market demands.

The timing of commercializing these therapies is difficult to predict but given the number of companies in Phase 2 and 3 studies, the next 3-5 years will be the timeframe when a number of cell and stem cell therapies are approved and will enter the mainstream of the healthcare systems.

3. Which area do you think offers the biggest opportunity for stem cells and cell therapy moving forward?

The use of stem cells for regenerative medical indications such as heart and neurological repair (for example spinal injury) would address a huge medical need and offer a large market opportunity for companies that could address these indications. In cell therapy, cancer would be the main opportunity especially with the positive clinical results using CAR-T cells (Novartis, Juno, Kite Pharma) and antigen or RNA loaded dendritic cells to treat advanced cancers (Dendreon, Argos). These approaches specifically target tumour antigens and have shown great promise in clinical studies. Dendreon was the first cell therapy approved by the FDA for a cancer indication (prostate cancer) in 2011.

4. Who (person or company) do you think will be the 'next big thing' within the stem cells and cell therapy sectors? And why?

In the cell therapy sector, I believe that targeted cell-based immunotherapies such as CAR-T cells and tumour antigen-loaded dendritic cells will become important cellular therapies for treating advanced cancers. Argos' dendritic cell therapy is in a Phase 3 pivotal study for advanced kidney cancer with final results expected in 2016 and several CAR-T companies (Juno, Kite Pharma, Novartis) are making good progress in Phase 2 clinical studies. These cell-based immunotherapies target specific disease antigens and have demonstrated complete tumour responses and improved survival in advanced cancer indications. Their mechanism of action is understood and the technology can be applied to a variety of tumour types.

5. What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?

A major topic would be the commercial manufacturing of cell-based therapies. Many cell-based therapies are in clinical development and progressing through clinical studies and the regulatory review process. Robust, reproducible, and well-defined automated methods for producing cell-based treatments derived from patient samples will be essential if these therapies are to be manufactured efficiently and cost effectively at commercial scale. Computer-controlled devices capable of performing and integrating sample and cell processing in parallel in a closed system can achieve these goals. Automation holds the key to making a process cost efficient and reproducible from patient to patient, sample to sample, and product to product.

Want to hear more from Fred?

Meet him and many more biotechs at World Stem Cells & Regenerative Medicine Congress 2015 – click here for more information

PROFILE:
Name: Dr. Michael Helmrath
Job title: Surgical Director, Intestinal Rehabilitation Program
Company: Cincinnati Children's Hospital Medical Center

Role at World Stem Cells & Regenerative Medicine Congress 2015:
Tissue engineering speaker: Functional human intestine tissue grown in lab

1. What do you think has been the biggest achievement within the tissue engineering sector in the last 12 months?

The development of an in vivo model to study the intestine.

2. When do you think we will start to see tissue engineering therapies in mainstream healthcare systems? What is key to them achieving market access?

I believe within the next five to ten years we will start to see tissue engineering therapies in mainstream healthcare systems. The market access will require improved health care to patients without other medical options.

3. Which area do you think offers the biggest opportunity for tissue engineering moving forward?

In my area of research understanding the genetic contribution to intestinal disease model to study infectious disease with the greatest opportunity.

4. Who (person or company) do you think will be the 'next big thing' within the tissue engineering sectors? And why?

With respect to the intestine, Dr. James Wells and Dr. Jason Spence.

Want to hear more from Michael?
Meet him and many more tissue engineering professionals at World Stem Cells & Regenerative Medicine Congress 2015 – click here for more information

PROFILE:
Name: Pedro Lichtinger
Job title: President & CEO
Company: Asterias Biotherapeutics

Role at World Stem Cells & Regenerative Medicine Congress 2015:
Roundtable Host: Human clinical development updates on hESC-derived

1. What do you think has been the biggest achievement within the stem cells sector in the last 12 months?

General advancement of the field in the clinic, to the point where for the first time there are numerous companies developing functional tissue cells (as opposed to MSCs or adipose derived cells) with the potential for efficacy readouts in the next 18-24 months.

We are one example of this, having now moved our OPC1 product in spinal cord injury from a first in man study designed to look at safety into a dose escalation study where, on the basis of the strong safety data generated in that initial study, we have now received FDA clearance to move into a study where we can test the doses and the patient population where we think we have the greatest chance of efficacy. In addition to us, other companies such as ACT, Viacyte, CellCure, Stem Cells Inc, Neuralstem, SanBio and others have also now advanced their programs to the point where I expect we will have some really exciting data coming out of the broader stem cell sector over the next two years.

2. When do you think we will start to see a number of cell therapies in mainstream healthcare systems? What is key to them achieving market access?

The key to achieving market access is demonstrating significant improvements in clinically meaningful endpoints for substantial unmet medical needs with a high cost to the Health Care system. If we, as a field, can significantly improve the ability of spinal cord injury patients to care for themselves, improve the sight of patients with advanced dry AMD, or reduce mortality in lung cancer, insurance companies will reimburse our therapies and patients will adopt them. Cell therapies have substantial potential to deliver these types of transformative results, given their ability to address complex conditions in ways that small molecules and protein therapeutics simply can't. However, to demonstrate this, we need well designed, statistically powered prospective studies. Given that many of the most promising potential stem cell products are currently in early efficacy studies, it is probably 5-7 years until those products can complete pivotal studies and be on the market with the kind of data that would enable broad based market access.

3. Which disease area do you think offers the biggest opportunity for stem cells moving forward?

We firmly believe that the best disease areas in which to apply stem cell therapies are those where the pathology of the disease makes a cellular therapy far more likely to be efficacious than small molecule or protein therapeutic. Additionally, the disease or condition should have a very high level of unmet medical need – essentially, it should be a life threatening or highly debilitating condition. And finally, there should be clear endpoints that enable demonstration of clinically meaningful efficacy in a clinical study of a reasonable size and duration. We are excited about our programs in spinal cord injury (AST-OPC1) and lung cancer (AST-VAC2) because they meet each of these criteria. There are numerous other diseases that meet these criteria as well, including other neurodegenerative diseases such as stroke and multiple sclerosis, diabetes, AMD, and numerous cancer indications.

4. Who (person or company) do you think will be the 'next big thing' within the stem cells sector? And why?

To date, the therapies, that have made it into late stage clinical development, have been predominantly mesenchymal-like cells and autologous cell derived products. I am excited about the fact that we now have a number of pluripotent cell therapies in the clinic, including our AST-OPC1 product, Viacyte's VC-01 for diabetes, and CellCure and ACT in AMD and Stargart's disease. These therapies have great potential to improve on both efficacy and scalability of the previous generation of cell therapies and I am excited to see what kind of data they will generate over the next 18-24 months.

5. What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?

One topic that I think will be of great interest to follow over the next year, and that I hope will be a major topic of conversation at the Congress is changing regulatory paradigms to enable faster development and approval of stem cell based products. With the recently approved new regulatory paradigm in Japan, it will be interesting to see how that is implemented and whether regulators in Europe and the US adopt similar initiatives to accelerate this new class of therapies to patients as well as to how the early clinical experience in Japan will impact regulatory paths in the United States.

Want to hear more from Pedro?

Meet him and many more biotechs at World Stem Cells & Regenerative Medicine Congress 2015 – click here for more information

PROFILE:
Name: Mr. Perry Karsen
Job title: Chief Executive Officer
Company: Celgene Cellular Therapeutics

Role at World Stem Cells & Regenerative Medicine Congress 2015:
Keynote: Translating the science into products that are commercially viable

1. What do you think has been the biggest achievement within the stem cells sector in the last 12 months?

The advance of CAR-T as a viable therapeutic and the accompanying recognition that cells, in this case engineered, can deliver meaningful therapeutic benefits.

2. When do you think we will start to see a number of cell therapies in mainstream healthcare systems? What is key to them achieving market access?

The key to achieving market access is to conduct rigorous clinical trials and delivering definitive safety and efficacy data. As cell therapies begin to enter Phase 3 trials, we should start seeing therapies in the mainstream healthcare system in the early 2020's.

3. Which area do you think offers the biggest opportunity for stem cells and cell therapy moving forward?

Initially cancer offers the biggest opportunity followed by immunological disorders and then vascular disease.

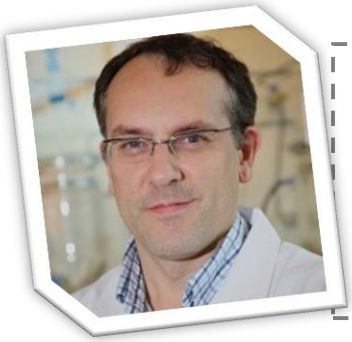
4. What do you think will be the 'next big thing' within the stem cells and cell therapy sectors? And why?

Gene editing will be the next big thing and the ability to harness gene editing for therapeutic purposes thereby directing cells against specific diseases.

5. What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?

The biggest topic will be the advancement of cell therapies to patients with CAR-T, gene therapy, gene editing and unique cell populations demonstrating clinical utility in the coming years.

Want to hear more from Perry?
Meet him and other keynote speakers at World Stem Cells & Regenerative Medicine Congress 2015 – click here for more information



PROFILE:
Name: Prof. Stefan Przyborski
Job title: Chief Scientific Officer
Company: Reinnervate
Role at World Stem Cells & Regenerative Medicine Congress 2015:
Tissue engineering speaker: The innovative use of scaffolding structures to support 3D cell growth

1. What do you think has been the biggest achievement within the tissue engineering sector in the last 12 months?

In relation to engineering tissues in vitro for cell-based assays, the most significant development over the past year has been the stabilisation of the sector in terms of the development of advanced technologies for building tissue-like constructs in vitro. Essentially there are three main approaches (aggregate-based technologies; hydrogel techniques, and solid scaffold approaches) and the provision of such products / services from the commercial sources is now beginning to settle.

2. When do you think we will start to see tissue engineering therapies in mainstream healthcare systems? What is key to them achieving market access?

In relation to engineering tissues in vitro for cell-based assays, using advanced technology to build more advanced in vitro models of tissue-like constructs is now becoming well established and is likely to rapidly grow and develop.
Such technology needs to be readily available and transferrable so users can easily adopt it for their specific needs. Supply of off-the-shelf products and demonstration of their application is essential for customer engagement.

3. Which area do you think offers the biggest opportunity for tissue engineering moving forward?

In relation to engineering tissues in vitro for cell-based assays, one of the biggest opportunities is to improve the culture of cells in screening applications and create more physiologically relevant models through engineering tissue-like constructs in vitro. This will enhance the predictive accuracy of the models, providing more valuable data from which researchers can better judge drug performance, which in turn will reduce development costs and animal usage.

4. Who (person or company) do you think will be the 'next big thing' within the tissue engineering sector? And why?

There are several small companies now coming to prominence that market various technologies to help researchers build tissue constructs in vitro. There is no one solution and the user must select the most appropriate model system for their needs.

5. What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?

Control of cell differentiation in a robust and reproducible manner to create tissue-like constructs for use in vitro for research/discovery/screening and in vivo for cellular repair therapies.

Want to hear more from Stefan?

Meet him and many more tissue engineering professionals at World Stem Cells & Regenerative Medicine Congress 2015 – click here for more information

PROFILE:
Name: Dr. Stephen Badylak
Job title: Deputy Director
Company: McGowan Institute for Regenerative Medicine
Role at World Stem Cells & Regenerative Medicine Congress 2015:
Tissue engineering speaker: In-situ influence of cell fate for functional soft tissue reconstruction

1. What do you think has been the biggest achievement within the tissue engineering sector in the last 12 months?

The biggest achievement in tissue engineering has been the advancement in whole organ engineering.

2. When do you think we will start to see a number of tissue engineering therapies in mainstream healthcare systems? What is key to them achieving market access?

Several types of tissue engineering initiatives have already been successfully translated to the clinical arena. For example, more than 10 million patients have been implanted with inductive biologic scaffolds to promote functional tissue remodelling. Cell-based approaches must solve problems both with the basic science and reimbursement areas before becoming widely accepted.
The key to achieving market success relies upon:

- Solving a non-medical need
- Regulatory approval and cost reimbursement
- Education for health care providers

3. Which disease area do you think offers the biggest opportunity for tissue engineering moving forward?

The area that offers the greatest opportunity for tissue engineering is whole organ regeneration, specifically, liver and lung replacement.

4. Who (person or company) do you think will be the 'next big thing' within the tissue engineering sector? And why?

Companies such as Harvard Apparatus, Inc., that can provide user-friendly bioreactors and decellularised 3D biologic scaffolds will be the 'next big thing'.

5. What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?

I think progress in specific stem cell therapies, CNS tissue engineering, and whole organ engineering will be hot topics at this congress.

Want to hear more from Stephen?

Meet him and many more tissue engineering professionals at World Stem Cells & Regenerative Medicine Congress 2015 – click here for more information

PROFILE:
Name: Dr. Thomas Fellner
Job title: Head of Business Development, Cell Therapy Development Services
Company: Lonza
Role at World Stem Cells & Regenerative Medicine Congress 2015:
Speaker on: Bioreactors as adaptable and scalable manufacturing platforms for multiple therapeutic cell types

1. **What do you think has been the biggest achievement within the stem cells sector in the last 12 months?**

In my opinion, the biggest achievement the stem cell field has seen in the last 12 months is related to induced pluripotent stem cells (iPSCs). In October 2014 – only 8 years after Dr. Yamanaka first discovered the generation of iPSCs – the first patient was treated with iPSC-derived Retinal Pigmented Epithelium (RPE) cells in Japan. This is also indicative of the fact that Japan has been taking a leading role in bringing cell therapies to the clinic.

2. **When do you think we will start to see a number of cell therapies in mainstream healthcare systems? What is key to them achieving market access?**

The cell therapy field is supposed to reach an inflection point in 3 – 5 years when several companies will report the outcome of phase III clinical trials. To be successful in the marketplace, it will be critical to overcome both existing technical as well as commercial challenges, such as the ability to manufacture product at scale and an acceptable cost.

3. **Which area do you think offers the biggest opportunity for stem cells and cell therapy moving forward?**

Based on some very promising data, cell-based immunotherapies seem to provide a huge opportunity for the treatment of some of the most debilitating diseases. However, pluripotent stem cell-based therapies could possibly turn out to be a more effective treatment for certain degenerative diseases, such as Age-related Macular Degeneration (AMD). Specifically for AMD, positive phase I/II data have been reported.

4. **What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?**

I think that one of the hottest topics at the next congress will be Japan, and how the new regulatory framework will impact the overall cell therapy field. In particular, it will be interesting to follow discussions on the EMA's and FDA's position and what their responses would be to these regulatory changes in Japan.

Want to hear more from Thomas?

Meet him and many more cell therapy professionals at **World Stem Cells & Regenerative Medicine Congress 2015** – click here for more information

PROFILE:
Name: Dr. Thomas Gaborski
Job title: Assistant Professor of Biomedical Engineering
Company: Rochester Institute of Technology
Role at World Stem Cells & Regenerative Medicine Congress 2015:
Tissue engineering: Using ultra-thin nano-membranes and adipose stem cells to create the vascular network necessary in engineering tissue, skin and organs

1. **What do you think has been the biggest achievement within the stem cells & tissue engineering sector in the last 12 months?**

One of the most exciting achievements in 2014 was certainly Viacyte's approval by the FDA to initiate clinical trials on its cell replacement therapy for type 1 diabetes.

2. **When do you think we will start to see tissue engineering therapies in mainstream healthcare systems? What is key to them achieving market access?**

I think tissue engineering therapies will start to become mainstream in about 10 years. One of the keys to general market acceptance success will be the availability of multiple products and solutions for a number indication areas.

3. **Which area do you think offers the biggest opportunity for tissue engineering moving forward?**

Cardiovascular is a broad and very large indication area, which could be the lowest hanging fruit. The success of many regenerative medicine products hinges on developing a successful vascular system.

4. **Who (person or company) do you think will be the 'next big thing' within the stem cells & tissue engineering sectors? And why?**

I'm excited about what Viacyte has accomplished and where they are going. They have had significant success in 2014 partnering with pharma (J&J Janssen), receiving additional public funding (CIRM) and also initial approval from the FDA.

5. **What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?**

The field is reaching a point where traditionally trained engineers are meeting with biologists and vice versa. This is critical for technology advancement past the laboratory bench (i.e. product development and manufacturing).

Want to hear more from Thomas?
Meet him and many more tissue engineering professionals at **World Stem Cells & Regenerative Medicine Congress 2015** – click here for more information

PROFILE:
Name: Mr Yaky Yanay
Job title: Chief Operating Officer & President
Company: Pluristem

Role at World Stem Cells & Regenerative Medicine Congress 2015:
Roundtable host: Updates on Phase I/II studies using PLacental eXpanded cells

1. **What do you think has been the biggest achievement within the stem cells sector in the last 12 months?**

Europe and Japan establishing early access regulatory path for early approval.

The Human Placenta Project of the NIH recognizing the importance and the need for understand the contributions of placental development to long term health and disease.

2. **When do you think we will start to see a number of cell therapies in mainstream healthcare systems? What is key to them achieving market access?**

We will see cell therapies products in the market during 2018.
The key to achieve market access are scalable controlled manufacturing process that will allow manufacturing in large quantities with reasonable COGS.

3. **Which area do you think offers the biggest opportunity for stem cells and cell therapy moving forward?**

Longevity therapies.

4. **What do you think will be the 'next big thing' within the stem cells and cell therapy sectors? And why?**

Not a person or company, the EMA adaptive licensing will be the next big thing in the sector.

5. **What do you think will be the biggest topic of discussion at next May's World Stem Cells & Regenerative Medicine Congress?**

Readiness of cell therapy companies to launch products to market and manufacturing challenges.

Want to hear more from Yanay?
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