Induced Pluripotent Stem Cell Market Accelerated by Landmark Events

**The Landscape for Current iPSC Industry Conditions**

Groundbreaking experimentation in 2006 led to the introduction of induced pluripotent stem cells (iPSC). These are adult cells which are isolated and then transformed into embryonic-like stem cells through the manipulation of gene expression, as well as other methods. Research and experimentation using mouse cells at Kyoto University in Japan was the first instance in which there was successful generation of the iPSC. In 2007, a series of follow-up experiments were done at Kyoto University in which human adult cells were transformed into iPSC cells. Nearly simultaneously, a research group led by James Thomson at the University of Wisconsin-Madison accomplished the same feat of deriving iPSC lines from human somatic cells.

While there has been continued excitement at the prospect of what such artificially re-manufactured cells could contribute to medical advances, there have also been issues along the way. By 2010, there were a number of private companies that were ready to capitalize on the breakthrough technology that iPSCs represent. One such company, Advanced Cell Technology in Worcester, Massachusetts, discovered several problematic issues while conducting experiments for the purpose of applying for U.S. Food and Drug Administration approval to use iPSCs in therapeutic applications. Concerns such as premature cell death, mutation into cancer cells, and low proliferation rates were some of the problems that surfaced.

As a result, ACT has since shifted its induced pluripotent stem cell approach to producing iPS cell derived human platelets. One of the benefits of a platelet-based product is that platelets do not contain nuclei, and therefore, cannot divide or carry genetic information. While nothing is completely safe, iPS derived platelets are likely to be substantially safer than other iPSC therapies, in which uncontrolled proliferation is a major concern. However, while ACT’s “Induced Pluripotent Stem Cell-Derived Human Platelet Program” received a great deal of media coverage in late 2012, including being awarded the honor of being named one of the “10 Ideas that Will Shape the Year” by New Scientist Magazine in December 2012, the company did not succeed in moving the concept through to clinical testing during 2013.

Nonetheless, 2013 did represent the first year in which clinical research involving transplant of iPSCs into humans was initiated, with Masayo Takahashi of the RIKEN Center for Developmental Biology in Kobe, Japan investigating the safety of iPSC- derived cell sheets in patients with wet-type age-related macular degeneration. Results from this clinical trial will continue to be collected in 2015 and beyond.

Indeed, within the past twelve months, the iPSC market has been dramatically accelerated by a series of landmark events. In addition to the first ever clinical trial in humans, the iPSC market recently witnessed a major initial public offering (IPO) for a company specializing in the industrial scale production of of iPSCs and differentiated cells derived from iPSCs, a massive grant award that will create the world’s largest human iPSC bank, and a historic patent challenge that could substantially alter the ability of companies to commercialize iPSC products and technologies without paying expensive licensing fees.

**Landmark Events Accelerate iPCS Market Activity**

While the past twelve months have seen many notable achievements related to the commercialization of iPSCs, four landmark events have had a particularly significant impact on the industry:

1. **1st Clinical Trial of iPSCs in Humans:**2013 was the first year in which clinical research involving transplant of iPSCs into humans was initiated, with Masayo Takahashi of the RIKEN Center in Japan investigating the safety of iPSC-derived cell sheets in patients with macular degeneration.
2. **Major IPO within the Industry:**In a landmark event, Cellular Dynamics International (CDI) went public in July 2013 with a offering that raised $43 million dollars for the company, securing the company's position as the global leader in producing high-quality human iPSCs and differentiated cells in industrial quantities.
3. **Major Grant Awards for Production and Biobanking of iPSCs:**In March of 2013, Celullar Dynamics International and the Coriell Institute for Medical Research announced receiving multi-million dollars grants from the California Institute for Regenerative Medicine (CIRM) for the creation of iPSC lines from 3,000 healthy and diseased donors, a result that will create the world’s largest human iPSC bank.

**4. Challenge Issued Against the Historic “Yamanaka Patent” for Derivation of iPSCs:**The famous “Yamanaka Patent” (U.S. Patent No. 8,058,065) for cellular reprogramming of iPSCs is now being challenged in a patent lawsuit by a group called “BioGatekeeper.” If successful, this could spur incredible innovation within the stem cell sector, by allowing for lower cost creation of iPSC products, technologies, and therapies.

In summary, recent months have seen major advances in clinical research applications, production and differentiation technologies, biobanking of iPSCs, and more. It is clear that iPSCs are now a vital research trend within the scientific community.

**Research Advances Fuel Innovation within iPSC Sector**

Continued research and experimentation with iPSCs has also fueled substantial innovation within the iPSC sector. In one example, the University of Michigan announced in “Circulation Research” (2012) that they had developed innovative methods for use of induced pluripotent stem cells derived from skin biopsies to create cardiac muscle cells. This accomplishment quickly fueled other research into the use of iPSCs for the reversal and repair of diseased heart tissue.

Similar advances will continue to be perfected for use of reprogrammed adult cells in the treatment of other diseases and disorders. Original techniques for iPSC production, such as viral induced transcription processes, are quickly being replaced with newer technologies, as private industry joins with the scientific community to develop safer and more efficient methods of iPSC production. With sustained research and experimentation, guidelines for the clinical-grade production of iPSCs will become standardized.

**Research Activity Concerning the Biology, Characteristics,**  **and Applications of iPSCs**

Furthermore, literature concerning the biology, characteristics, and applications of induced pluripotent stem cells has flourished since iPSCs were first produced in 2006 from mouse cells and in 2007 from human cells. Not surprisingly, trend analysis reveals rapid increases in iPSC research activity over the past several years, with substantial increases in iPSC publication rates from 2008 to 2012 and a slowing growth rate for iPSC publications observed during 2013 (12.7% year-over-year increase). Since 2006, induced pluripotent stem cell publications have risen to a total of 4,649 publications. Furthermore, during full-year 2013, induced pluripotent stem cell research publications represented 8.9% of all stem cell research publications, as compared to only 4.0% of stem cell research publications during full-year 2012. As this percent doubled from 2012 to 2013, it suggests that substantially more researchers became involved with the cell type. It is clear that iPSCs are a vital research trend within the scientific community.

Much of this research is being driven by the hope that induced pluripotent stem cells will have cell therapy applications for the treatment of disease, including for purposes of personalized medicine. Interest in therapeutic applications of iPSCs arises from their diverse ability to differentiate into a range of cell types. In addition to basic research, applied iPSC research is focused on pharmaco-toxicological screening, disease modeling, and autologous cell transplantation.

**iPSC Market Metrics**

Taken in aggregate, the forces described above have fueled a growing market for iPSC research products. Indeed, the number of iPSC research products sold worldwide has been growing at an annual rate of 14.7% for the past five years. In addition, 22% of all stem cell researchers now self-report as having used induced pluripotent stem cells within a research project. Furthermore, according to 2014 survey of stem cell researchers conducted by the research firm, BioInformant Worldwide, LLC, the top three providers most often preferred as suppliers of iPSC products are Thermo Fisher Scientific, STEMCELL Technologies, and BD Biosciences, respectively.

In summary, It is clear that recent events have been fueling innovation and progress within the iPSC industry. To learn more about this emerging market area, you can view free product samples for the "[**Complete 2013-14 Induced Pluripotent Stem Cell Industry Report**](http://www.bioinformant.com/iPSC_report.html)" here.