

Stem Cell Culture: Opportunities in an Emerging Market

Biocompare Surveys and Reports

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Report Introduction

The 2006 Stem Cell Culture Report is composed of a market overview and an introduction to the 2006 Stem Cell Culture Survey. The survey itself contained questions about the types of stem cells being used, the methods performed, the types of products purchased as well as information about the purchasing trends in this research area. The report also includes a discussion of the survey results and conclusions and recommendations drawn from both the market analysis of stem cell research and the survey data.

The market overview describes the use of stem cell technology in providing novel approaches to the treatment of disease and provides a comprehensive discussion of the overall cell culture market and the funding challenges for stem cell research specifically. This section also includes a focused look at vendors who support reagents and supplies for this market.

Over the past year, stem cell research has accounted for \$820 million in expenditures, with 10% allocated for consumables such as media and tissue culture dishes. Spending on stem cell investigations is expected to top \$1.26 billion by 2010 and nearly \$2 billion by 2015, increasing consumable expenditures to approximately 20%. A combination of diabetes- and cardiovascular-related research is expected to comprise approximately 75% of future research funding over the next several years. These diseases have been predicted to be highly amenable for stem cell intervention regarding future therapeutic treatment options. The stem cell research area, therefore, is anticipated to only gain in importance and applications to novel therapeutics in the very near future.

Survey Introduction & Methodology

The 2006 Stem Cell Culture Survey is designed to provide life science vendors of stem cell reagents and supplies with information about what products researchers are using and their plans for future purchases. Data were gathered from questions regarding the goals of stem cell research, the types and species of cells used, the differentiation tests applied, the future purchasing plans for specific products, which product areas require the most improvement in quality, the preferred suppliers of stem cell products or cell lines, where researchers obtain their information about relevant stem cell-related products, and the most important characteristics that researchers look for in a stem cell reagents vendor. With this information, suppliers will be better able to focus product development in areas of particular interest to current stem cell researchers and target marketing in areas that are destined to be of future interest to those not yet involved in stem cell research. Vendors will be able to focus specific product lines on new applications and direct customer attention to their specific stem cell product materials. A more complete understanding of the stem cell market, including its vast potential for growth in addition to the challenges and hurdles that need to be overcome, will permit companies to plan realistic goals for orchestrating growth in this research area and forecast plans for increasing stem cell market share more accurately.

The 2006 Stem Cell Culture Survey consisted of 10 questions. Of these, 9 included "other" as an answer choice. One question was used for demographic information. The survey was administered on-line from January 9th – 13th, 2006, and the data gathered, tabulated, and presented here.

Market Overview

Stem cell research has gained a foothold in both privately- and publicly-funded labs. While beleaguered by ethical debates, stem cell research is still being pushed forward because of its potential to provide novel approaches to treating illnesses. Patients dealing with many of these conditions, currently have few therapeutic options. The promise of effectively addressing a long list of diseases has researchers and companies eagerly stepping up their stem cell programs in both basic research, therapeutics and other applications.

“Emerging stem cell research has led to development of novel biodrugs,” said A.N. Aditya, a research analyst at Frost & Sullivan, in a statement. “Applications include gene therapy, tissue engineering, neurological therapies, bone and cartilage repair, cancer, cardiovascular disease, diabetes and other autoimmune disorders, wound healing and cell replacement for failing organs.”

While the field exudes a palpable momentum, few applications for stem cells will materialize until researchers first solidify their basic understanding of stem cell biology and learn to harness their differentiating capabilities. “Some of those target applications will benefit from expansion of stem cells (for example, hematopoietic stem cell transplantation), whereas others will require the production of a specific differentiated cell type with defined characteristics either by controlling the differentiation in a very specific path or by elimination of undesirable cell types that could arise during the production (differentiation) process,”¹ wrote authors of a review on culturing stem cells published in a 2005 issue of the *Journal of Bioscience and Bioengineering*.

Arriving at that point will involve not only persistence, but also the development of new experimental protocols and new instruments and reagents designed for the specific and unique needs of stem cells. For instance, many stem cell culture techniques currently depend upon mouse cells and animal-derived serum, both of which preclude clinical applications, most of which require reliable and ready sources of stem cells and/or differentiated lineages. Thus, developing other culturing protocols and technologies is among the most crucial of goals.

Such pursuits will be a major factor in the growth of the overall cell culture market, which includes media, serum and reagents. In 2005, the worldwide market generated revenues of \$1.02 billion², according to Navigant Consulting. With a compound annual growth rate of 12.7%, revenues should reach \$1.86 billion by 2010. The U.S. market alone brought in revenues of \$587 million in 2005³. By 2010, revenues should reach \$1.2 billion with a CAGR of 15.6%. Analysts at the Business Communications Company, however, estimate that the cell culture market could generate revenues of \$1.7 billion by 2008⁴.

Navigant analysts report that the U.S. and Europe dominate the cell culture market, accounting for 58% and 24% of 2005 revenues, respectively⁵. Growth in the US market is closely linked with increased funding for stem cell research growth, in addition to the expanding set of biologic drugs, the number of which will grow by 20% every year⁶, according to research on the mammalian cell culture market published by Drug & Market Development. The estimated growth of 10 products annually will also mean an increase in biomanufacturing, which depend heavily on cell culture products and mammalian cell cultures.

Invitrogen led the overall cell culture market, generating 34% of revenues⁷. Fisher-Scientific, JRH Biosciences, Serologicals, Cambrex and Sigma-Aldrich follow, generating 20%, 14%, 9%, 7% and 6% of the general cell culture market, respectively. As with the general cell culture market in 2005⁸, Invitrogen is also the biggest supplier of stem cell research products⁹. Stem Cell Technologies and Specialty Media, both of which offer specialty niche products, are chief competitors. Other companies are also tapping into the lucrative potential of the stem cell culture market by completing a series of recent acquisitions¹⁰. In January 2005, Sigma-Aldrich acquired the cell culture business of JRH Biosciences for about \$342.5 million, based on the exchange rate on January 12, 2005 for 283 million Euros. In February 2005, Chemicon's Serologicals acquired Specialty Media for \$6.5 million.

“The Specialty Media acquisition represents another milestone achievement in the execution of our strategic plan to continue to be the premier provider of tools for stem cell research,” said Jeffrey Linton, Chemicon's president, in a statement. He estimated that Specialty Media's products could generate \$4 million in 2005.

Market Overview (cont'd.)

Invitrogen has also responded to the prevalence of stem cell research. The company has more than 1200 products for all stages of stem cell research, isolation, characterization, expansion and differentiation, said Joydeep Goswami, Ph.D., MSc., director of Invitrogen's stem cell business. "We are seeing a good uptake for most products in our portfolio, but media, cytokines, antibodies, qPCR products, RNAi products and beads are seeing strong growth," he said.

According to Goswami, while the revenues from these products have shown "strong" growth, the health of revenues has faced challenges due to the fact that "the growth of human embryonic stem cells in the U.S. has been hampered by patent and NIH funding issues".

The financials of most other companies are also subject to governmental generosity, in addition to the resources of the private sector. "In the U.S., the driving force of stem cell research will come from individual states instead of the federal government. California set the standard with \$3 billion in funding over the next 10 years, while other states are following suit to prevent California from holding a geographic monopoly on the stem cell industry," according to a report published by Navigant¹¹. Other states include Illinois, New Jersey and Wisconsin.

In 2005, stem cell research accounted for \$820 million in expenditures, 10% of which went toward purchasing media and other consumable supplies¹². While 35% was spent on equipment and facilities, 55% went toward labor costs. With an estimated CAGR of 8.97%, spending on stem cell research should reach \$1.26 billion in 2010 and \$1.95 billion in 2015, when 20% of the budget will be spent on media and consumable supplies. About 48% of research funding¹³ will be spent on diabetes research, which includes efforts to differentiate stem cells into insulin-secreting β cells. The investigation of cardiomyocytes and treatments for cardiovascular disease will account for 27% of research funding.

Federal funding will depend upon the outcome of policies ensconced between groups that oppose the "willful creation and destruction of living embryonic stem cells"¹⁴, and proponents who uphold the life-saving potential of stem cells, wrote Debora L. Spar, Ph.D., Spangler Family Professor of business administration at Harvard Business School, in an editorial published in a 2004 issue of the New England Journal of Medicine.

In what could be a glimpse of hope, in December 2005, President George W. Bush signed into law the Stem Cell Therapeutic and Research Act of 2005, which appropriates \$79 million to increase the inventory of umbilical cord blood at blood banks. According to a U.S. Newswire story published on December 20, 2005, "The national program will also promote stem cell research by requiring participating cord blood banks to donate units not suitable for transplant to researchers and scientists."

Whether or not the federal government ever fully embraces stem cell research, Spar wrote, "the future of stem cell research is likely to be driven as much by markets as by science, by the demand that emerges for the products of these cells and the firms that rise to supply them. If we ignore these commercial prospects now, we risk undermining both the business and the science."¹⁵

1. Ulloa-Montoya F. et al., "Culture Systems for Pluripotent Stem Cells", Journal of Bioscience and Bioengineering, 100(1):12-27, July 2005.

2. "Cell Culture: Media, Sera and Reagents", Navigant Consulting, January 2005.

3. Ibid.

4. "US Sales of Media, Sera and Reagents in Cell Culture, 2001-2003 and 2008", Business Communications Company, September 2003.

5. "Cell Culture: Media, Sera and Reagents", Navigant Consulting, January 2005.

6. "Large Scale Mammalian Cell Culture", Drug & Market Development, September 2005.

7. "Cell Culture: Media, Sera and Reagents", Navigant Consulting, January 2005.

8. Ibid.

9. "Stem Cells", Navigant Consulting, January 2005.

10. "Mammalian Cell Culture: Production Technologies and Market Overview", Research and Markets, September 2005.

11. "Stem Cells", Navigant Consulting, January 2005.

12. Ibid.

13. Ibid.

14. Spar DL, "The Business of Stem Cells," New England Journal of Medicine 351(3):211-213, July 15, 2004.

15. Ibid.

Conclusions and Recommendations

The data gathered from the 2006 Stem Cell Culture Survey indicate that life science researchers are focusing on basic science applications using primarily neural and mesenchymal adult human and mouse embryonic stem cells in their research. Immunohistochemistry (IHC), RT-PCR, and flow cytometry are the differentiation test methods of choice and, therefore, companies that supply related reagents and equipment would do well to focus on stem cell applications of these basic technologies. Vendors should also take note that stem cell isolation and characterization tools require improvement and, given the expected growth in the stem cell market, investment in such improvements would provide a tremendous growth opportunity for the company as well. Purchases of consumables will also grow, as the use of growth supplements and antibodies is high on the list of stem cell researchers. Both Invitrogen and BD Biosciences share the bulk of stem cell market share presently, but there is plenty of competition, so both companies are well advised to focus on the important vendor characteristics of quality, reliability, and value. A balanced advertising campaign for the distribution of stem cell-related information should be approached as well, as the majority of polled researchers uses both websites and catalogs in order to make decisions about product purchases and to gather useful stem cell-related product information.

Invitrogen has led the overall cell culture market of late, generating 34% of revenue in this area, followed closely by some of the same companies that are competing for limited stem cell funds (i.e., Chemicon, Cambrex, and Sigma). As Sigma acquired the cell culture business of JRH Biosciences a year ago, it is poised to devote a more focused effort in the stem cell consumables market. Chemicon also acquired Specialty Media (cornering a niche market in the stem cell area) nearly a year ago as well, and are also vying for a growing presence in the stem cell marketplace.

The most striking challenge for U.S.-based stem cell research involves the use of federal funds to continue work in this area. These limitations have driven stem cell research by and large into the private sector and to countries with fewer restrictions, and as recent news events have indicated¹⁶, this trend has not met with positive results. In a research area that is predicted to gather more than 75% of future disease-related research funding over the next several years, direct and thoughtful oversight is clearly needed.

16. Normile D. et al., "South Korean Team's Remaining Human Stem Cell Claim Demolished", *Science*, 311(5758): 156-157, January 2006.

Appendix I: Questionnaire

Please characterize your stem cell research.

- I currently use stem cells in my research.
- I do not use stem cells in my research. (exit from survey)

In what type of institution do you work?

- Private Research
- Government
- Biotech
- Pharmaceutical
- Clinical Diagnostic Testing
- Academic
- Other

What is the goal of your stem cell research?

- Basic research
- Cell-based therapies
- Drug screening toxicity
- Other (please specify)

Which of the following are you currently using in your research? (check all that apply)

- Human – embryonic stem cells
- Human – adult stem cells
- Rat – embryonic stem cells
- Rat – adult stem cells
- Mouse – embryonic stem cells
- Mouse – adult stem cells
- Other (please specify)

Which of the following cell types is your research focused on? (check all that apply)

- Neural cells
- Cardiomyocytes (heart muscle)
- Pancreatic cells
- Hepatocytes (liver)
- Osteogenic cells (bone)
- Chondrocytes (cartilage)
- Dendritic cells
- Endothelial cells
- Epithelial cells (please specify tissue)
- Hematopoietic cells (please specify source)
- Mesenchymal cells
- Adult stem cell plasticity
- Other (please specify)

What tests do you typically use to identify differentiated cell types? (check all that apply)

- Colony forming cell assays
- In vivo transplantation assays
- Immunohistochemistry (IHC)
- FACS / flow cytometry
- Activity/enzymatic assays
- Functional assays
- RT-PCR
- Microarray analysis
- Other (please specify)

Which stem cell product area(s) do you think need the most improvement in product quality? (check all that apply)

- Isolation and characterization tools (i.e. antibodies, cell separation tools)
- Cell expansion reagents (i.e. media, supplements)
- Tools for cell differentiation (i.e. media, cytokines, growth factors)
- Other product area (Please specify)

Which of the following do you currently use or plan to use within the next 12 months? (check all that apply)

- Starter kits
- Differentiation kits
- Expansion Kits
- Expansion Media
- Cytokine Panels
- Growth Supplements
- Differentiation Supplements
- Stem Cell Antibody Panels
- Identification/Characterization Kits

Please rank the characteristics you look for in a supplier from 1 to 7 in order of importance (1 = Most important, 7 = Least important). Consider these characteristics as factors which influence your purchasing decision.

- Quality
- Value
- Reliability
- Technical Support
- Variety of Products
- Local Representatives
- Website

From which of the following suppliers do you purchase stem cell culture products or cell lines? (check all that apply)

- BD Biosciences
- Cambrex
- CellGenix
- Chemicon
- Invitrogen
- Miltenyi
- R&D Systems
- ScienCell Research Labs
- Sigma
- Stem Cell Technologies
- Other (please specify)

Where do you obtain your information about new/relevant research products? (check all that apply)

- Website
- Print journal ads
- Online journal ads
- Publications
- Conferences
- Catalog
- Sales Representatives
- Email alerts
- Mailings
- Other (please specify)