



# New Development in Tissue Allografts

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## **AlloSource Vision**

AlloSource will be the trusted and preferred provider of safe, quality allograft tissue for the communities we serve.

## **AlloSource Mission**

Honoring the gift of donation, AlloSource responsibly develops, processes and distributes life-saving and life-enhancing human tissue for our communities.



**We believe in responsibility.** We consider it our duty to maximize the possibilities for each and every gift. When we live up to this obligation, we fulfill our promise and honor the wishes of human tissue donors and their families.

## *Our Guiding Principles*

**We believe in longevity.** The allografts we process are transplanted into recipients forever and, for this reason, we must be continually diligent and attentive in our individual tasks and never waver in our dedication to safety and quality.

**We believe in our communities.** Because our donor communities and recovery partners further the cause of organ and tissue donation they are entitled to preferential treatment and should share in our success. By supporting and giving back to our recovery partners we help strengthen the communities that they serve.

**We believe in showing gratitude.** We are grateful for the life saving and life-enhancing opportunities presented by the gift of donation and for the medical professionals who play an essential role in honoring those gifts with positive patient outcomes. We hold the medical professionals with whom we work in the highest regard and are committed to providing them with responsive, courteous, and unparalleled customer service and tissue allograft availability.

**We believe in our people.** When we support and empower each other, we drive the success of our organization and promote the fulfillment of our mission. For this reason, every individual in our organization has the right to a rewarding career path, professional improvement through training and coaching, a fair wage, and a healthy balance between work and family.

**Finally, we believe in growth and possibility.** We are in awe of the discoveries that allow us to fully utilize donated tissue today. The thought of what may be possible in the future motivates us to continue to grow and change. By continually perfecting and pursuing innovations in our products and processes we expand our capability to deliver life-saving and life-enhancing allografts to more individuals in need.



# Agenda

- Historical Perspective
- Bone Morphogenic Proteins (BMPs)
- Advanced tissue grafts
- Stem cell grafts and sources
- Stem cell development
- Impact on tissue donation
- AlloSource Role in Stem Cells
- Summary



# Historical Perspective



- Hospital Bone Banks
- Late 1980's to early 1990's tissue banks formed; Red Cross, MTF, LifeNet, etc.
- Wild Wild West, over 50 bone and tissue banks, little or no regulation
- Mid 1990's, regulations developed and enforced, consolidation of banks
- Traditional allograft usage flat or down slightly in 2008 and beyond

# Bone Morphogenic Proteins



- Stryker OP-1 (BMP 7)
- Infuse by Medtronic (BMP 2)
  - 700 million in revenues in 2008
  - Severely impacted allografts
- “Spin down techniques”
- Bone Marrow Aspirate (BMA)
- Move to replace autograft bone
- Allograft bone grafts did not contain osteogenesis cells

# Advanced Allograft Forms

- Need to contain viable bone forming stem cells
- Cryopreserved
- Need “surgeon friendly” forms and surgeon applications
- New applications for allograft stem cell grafts



# Stem Cell Sources

- Embryonic Stem Cells
  - Ethical and legal issues
  - Only a “handful of companies” involved
- Umbilical Cords
  - Rich supply of stem cells
  - FDA issues with carriers
- Bone Marrow
  - OK supply of stem cells,
  - No FDA issues with allograft bone as carrier
- Adipose Tissue
  - “Middle aged fat guys”
  - Very rich supply of stem cells



# Stem Cell Development

*“We estimate that there are up to 300 firms worldwide engaged in some aspect of stem cell research and commercialization. Of that number perhaps 75 – 100 are creating stem cell therapies and of those a mere handful are toiling in the garden of embryonic stem cell research, with only one in clinical trials. The vast majority of stem cell companies are focused on adult stem cells—allogeneic, autologous or cultured. And it is becoming increasingly clear that these stem cells can address up to 70 different clinical indications.”*

Source: 4<sup>th</sup> Annual Stem Cell Summit, New York, NY, Feb 17<sup>th</sup>, 2009



# Stem Cell Sources and Development



***Steadily, consistently, stem cell therapies are being commercialized on three fronts:***

- 1. As allogeneic, viable cells*
- 2. As autologous cells*
- 3. As cultured, off-the-shelf stem cells*

***All three types of stem cells are now firmly in the marketplace. Over the course of the last four years, approximately 30,000 patients have been treated with allogeneic stem cell products in the United States: 2,000 – 3,000 with autologous stem cell products and more than 1,000 with cultured stem cell products.***

Source: 4<sup>th</sup> Annual Stem Cell Summit, New York, NY, Feb 17<sup>th</sup>, 2009

# Stem Cell Indications

- Graft verses host disease
- Orthopedics
- Cardiovascular
- Dental
- Anti-Inflammatory
- Diabetes
- Nerve Repair
- Other



# Stem Cell Therapies



***Stem cells, as commercial products, have demonstrable therapeutic value in the following medical markets:***



- ***Spinal fusion***
  - ***Heart muscle repair***
  - ***Disc nucleus repair***
  - ***Crohn's disease***
  - ***Nerve regeneration***
  - ***Diabetes treatment***
  - ***Non-union fracture repair***
  - ***Acute tissue damage arising from trauma***
  - ***Graft versus host disease***
  - ***Large joint revision***
  - ***Meniscus repair***
  - ***Other chronic and acute inflammatory diseases***
  - ***Cranial maxillofacial repair***
  - ***Articular cartilage repair***
- Source: 4<sup>th</sup> Annual Stem Cell Summit, New York, NY, Feb 17<sup>th</sup>, 2009

# Stem Cell Therapies

- *In 2008 in the United States, there were 35 million patients available for eventual stem cell therapeutic treatment in the 15 markets analyzed in this report. There were:*
- *1 million spinal repair procedures*
- *9 million cardiovascular procedures*
- *3 million nerve treatment procedures*
- *1 million knee repair procedures*
- *20 million diabetes patients*
- *1 million cases of severe inflammatory disease*
- *By 2018, stem cells, we forecast, will be used therapeutically in as many as 2 million annual procedures*



Source: 4<sup>th</sup> Annual Stem Cell Summit, New York, NY, Feb 17<sup>th</sup>, 2009

# What does this mean for us?



- Most stem cell grafts will be adult cadaveric allografts
- OPOs and tissue recovery organizations will be the prime source of adult stem cells
- Increasing recoveries of stem cells will happen from bone marrow, adipose tissue recovery and umbilical cords
- Stem cell tissue sources will be the major tissue recovered and processed for transplantation in the future

# Tissue Banks and Tissue Recovery Organizations



- **Musculoskeletal Transplant Foundation**
  - Will release a stem cell graft for Orthofix in May 2009
  - Cryopreserved cancellous chips
- **AlloSource**
  - Largest current provider of stem cell allografts in the world
  - Processing agreement with Osiris/Nuvasive to make Osteocel, the only adult stem cell product on the market

# Osiris Osteocel



Osteocel ®

multipotential cellular bone matrix



The first biological product to provide all three bone growth properties: osteoconduction, osteoinduction, and osteogenesis

Osiris Therapeutics, Inc. is a leading stem cell therapeutic company focused on developing products to treat medical conditions in the inflammatory, orthopedic and cardiovascular areas. Osiris is a fully integrated company, having developed capabilities in research, development, manufacturing, and distribution of stem cell products.

# AlloSource



- Will continue to be the leading provider of allograft stem cells for transplant
- Will continue to conduct R&D and tissue development for various stem cell allografts
- Adult cadaveric tissue a rich supply of stem cells
- Meets the mission of utilizing all available donor tissues while maximizing the gift of tissue donation
- Stem cell allografts will be increasing focus and the primary tissue processed

# Summary

- Stem cell therapies will be increasing
- Primary source of stem cells will be either autograft or adult cadaveric tissues
- Tissue banks will be leading providers of adult cadaveric stem cells and grafts
- Tissue recovery organizations will be critical partners
- Maximize the gift of tissue donation and maximize patient treatment outcomes

