mesoblast
the adult stem cell company

Commercialisation Of Stem Cell Technology

Lodge Partners
June 2009

Mesoblast Company Overview

- **listed Dec. ‘04, raised $21m**
- **strong board and management**
- **major milestones accomplished >6 months ahead of schedule**

- **further capital raised**
  $17m July ’06
  $13m Dec ’07
  $11m March ’09
- **sufficient cash to accomplish major milestones next 12 months**

- **current market cap circa $100m**

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Major Value Inflexion Points Since 2005

Technical

1. Demonstrated **scale-up** of manufacturing process
2. Demonstrated **safety** of manufacturing and cells in patients
3. Shown that **allogeneic** ("off-the-shelf") stem cells are **effective**

Clinical

4. **IND submissions** for four Phase 2a trials cleared by FDA < 30 days
5. **Patient enrolment** for Spinal Fusion, CHF, AMI, BMT Phase 2a trials

Commercial

6. Issued two **US patents:** composition-of-matter & manufacturing
7. **Strategic alliance** with global Cardiovascular Pharma/Device Co.

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Achieving Institutional Shareholder Support

1. transparent corporate structure and governance

2. identifying value inflexion points as corporate drivers
   - (a) commercial
   - (b) technical
   - (c) clinical

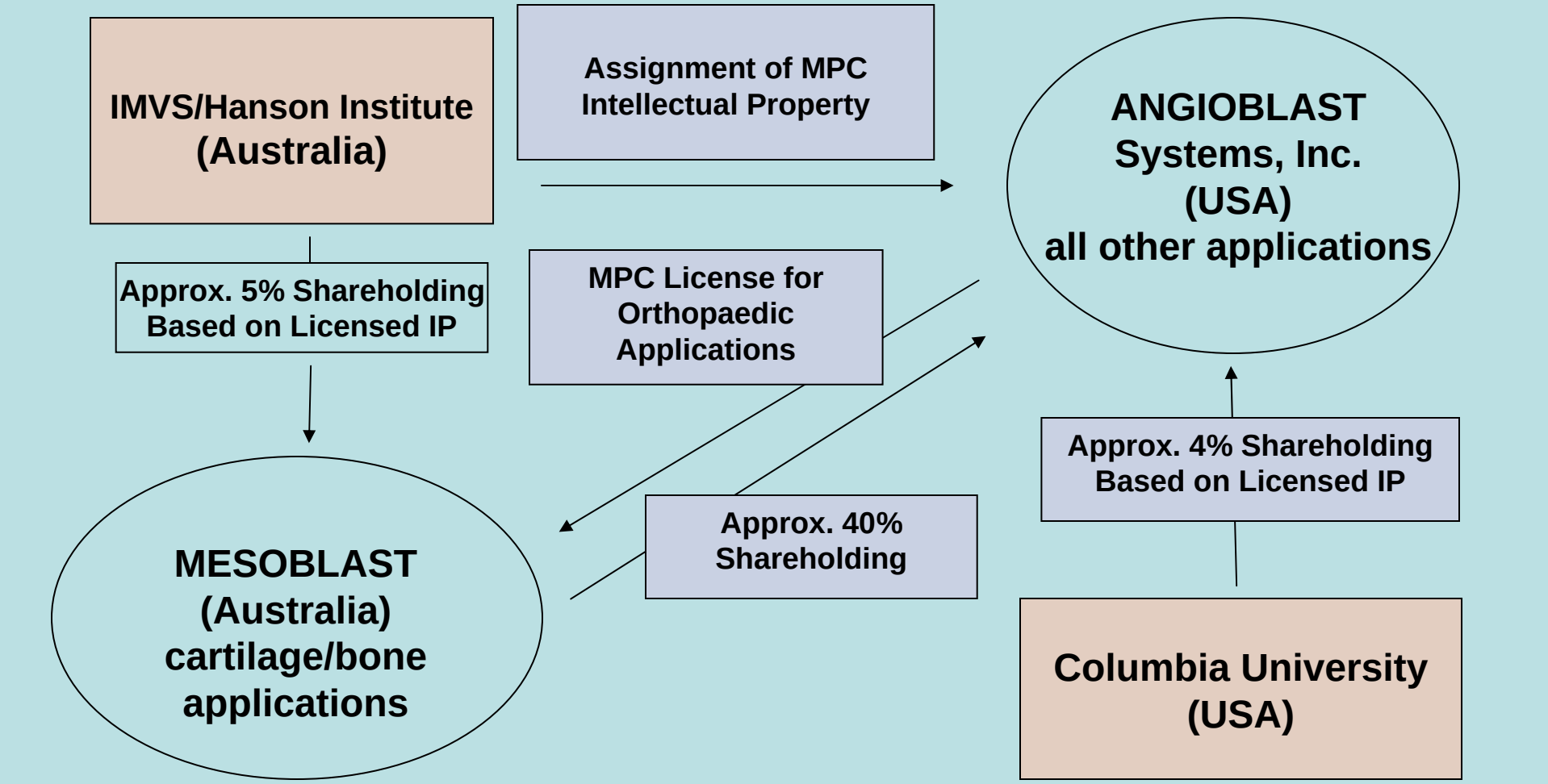
3. risk mitigation strategies
   - (a) seasoned management
   - (b) multiple programs
   - (c) early engagement of partners

4. laying out achievable milestones

5. keeping to rigorous timelines

6. communicating effectively both strategy and results

Mesenchymal Precursor Cell Technology Platform



Commercialising Stem Cells:

What is the Right Business Model?

Embryonic Stem Cells — ***NO*** **near-term clinical products (ethics, cancer risk)**

Adult Stem Cells

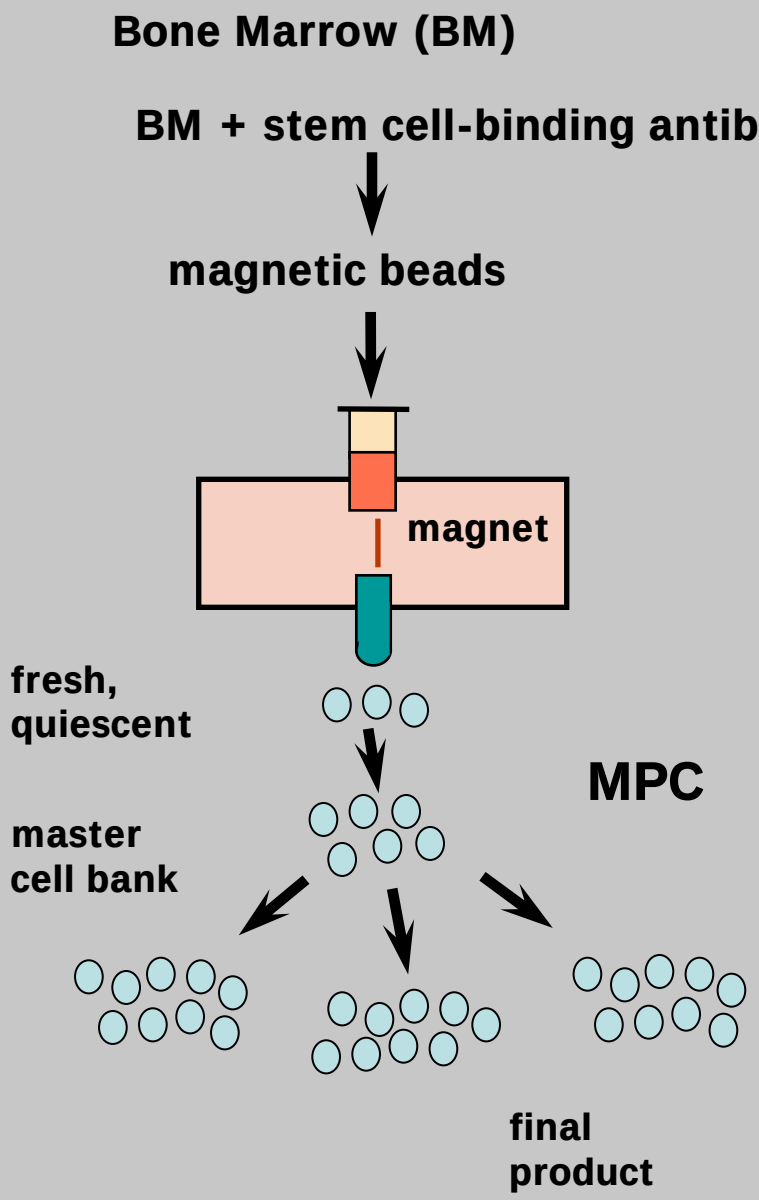
Autologous: **low margin, high cost**
variability of source material
not applicable for emergency use

cord blood (e.g. banking)
hematopoietic or unfractionated cells (devices), e.g. Baxte

Allogeneic: **high margin, low cost**
uniform, reproducible source material
ideal for emergency use, e.g. fracture repair, heart attack

mesenchymal lineage cells (Osiris, Mesoblast / Angioblast)

Proprietary MPC Isolation

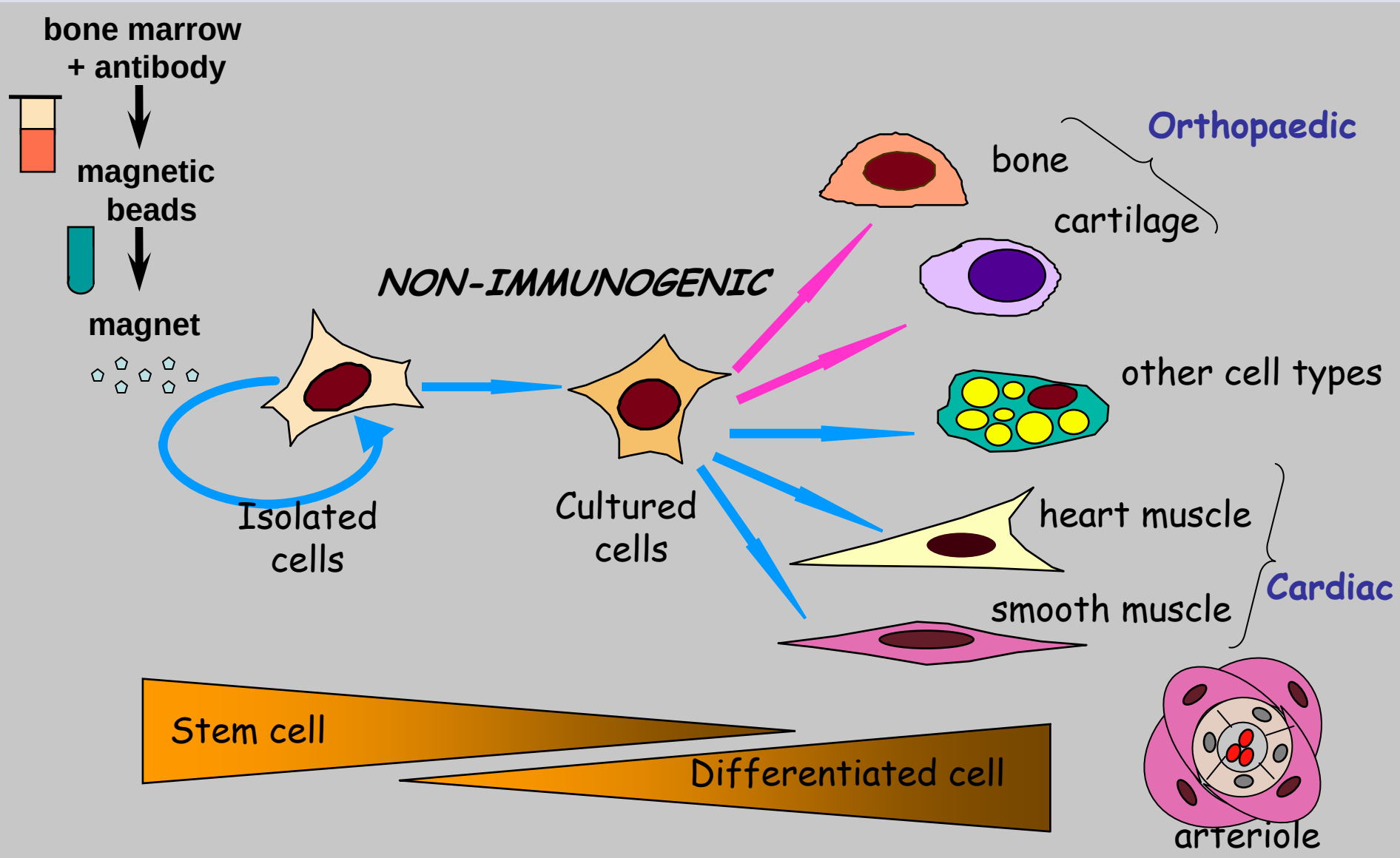


Competitive Advantages:

Precise identification,
ease of isolation and scale-up

- purer initial stem cell pool
- homogeneous population
- efficient large-scale expansion
- lower costs of cell culture process
- batch-to-batch consistency
- stringent release criteria
- greater potency of expanded product

Highly Expandable Commercial Stem Cell Production



Our products combine speed to market with a high margin business model

MPC products are biologic drugs in a bottle

- safer than small molecules
- greater predictability from pre-clinical to human trial end-points
- more rapid regulatory approval
- one donor -- thousands of patient doses
- unrelated (*allogeneic*) recipients
- centralized manufacturing (FDA and GMP compliant)
- frozen product immediately available -- good physician uptake
- low manufacturing costs, high margin
- ideal for large unmet markets

Road To FDA Approvals For An Allogeneic Stem Cell Product

Preclinical

- ✓ characterize stem cell population
- ✓ proof-of-principle small animal studies
- ✓ optimize *ex vivo* culture process in GMP facility
- ✓ safety / dose-ranging studies in large animal models

Clinical

- phase 2 trials to identify safe, effective dose
- phase 3 trials to establish efficacy for product registration

Lead Orthopaedic Programs

1. **Spinal Fusion**
   - ✓ Lumbar fusion: single-center Phase 2a study
   - • Lumbar fusion: multi-center Phase 2 trial (minimally-invasive)
   - • Cervical fusion: multi-center Phase 2 trial commenced

2. **Intervertebral disc repair/regeneration**
   - ✓ preclinical large animal study completed
   - • planned IND submission for Phase 2a clinical trial

3. **Long bone repair**
   - ✓ preclinical large animal models knee osteoarthritis completed
   - ✓ Phase 1b trial long bone non-union completed

4. **Knee Osteoarthritis**
   - ✓ preclinical large animal models knee osteoarthritis completed
   - • Phase 2 clinical trial commenced

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Programs In Partnership With US-Based Angioblast Systems, Inc.

1. **Congestive Heart Failure (CHF)**

   FDA-cleared Phase 2a clinical trial in up to 60 patients
   multicenter, 3 dose-escalation
   20 patients each dose, randomised 3:1 treatment/control
   first dose 11 patients enrolled, no safety concerns to date
   evaluating cardiac functional recovery at 3, 6 and 12 months

2. **Acute Myocardial Infarction (AMI)**

   FDA-cleared Phase 2a clinical trial in up to 25 patients
   multicenter, dose escalation, no cell safety concerns to date
   evaluating cardiac function at 6 and 12 months

3. **Bone Marrow Transplantation, Expansion of Umbilical Cord Blood**

   Orphan Drug Designation
   FDA-cleared Phase 1/2 clinical trial in up to 30 patients
   evaluating safety, bone marrow engraftment, survival

Programs In Partnership With US-Based Angioblast Systems, Inc. (c'td)

4. Age-Related Macular Degeneration (AMD) and Diabetic Retinopathy

efficacy demonstrated in rodent study;
42-animal non-human GLP primate study completed
optimal dose identified for monotherapy
significant synergy in combination with anti-VEGF therapy
IND filing and Phase 2a trial planned for 2009

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United States Market Opportunity For CHF Product

- Class II-IV EF < 35% is 40% of existing 5.5M pool plus 550,000 new-onset annually
- CHF post-AMI...20% of 800,000 new cases/annually
- projected annual growth in cell therapy uptake 45%
- peak penetration Year 8 post-launch, predicted 16% low EF pts.
- expected ASP $15,000/cell dose

Congestive Heart Failure (CHF) Program

Pre-Clinical

- positive results of allogeneic MPC in sheep with ***established*** CHF
  … effects dose-related, independent of mode of delivery
  (similar results with surgical and endoventricular catheter delivery)

- positive results of allogeneic MPC in sheep with ***early*** CHF post-MI
  … effects dose-related, independent of mode of delivery
  (similar results with surgical and endoventricular catheter delivery)

Clinical

- IND for 60-patient, 3-dose, Phase 2 clinical trial class II-IV CHF (EF < 40%) cleared <30 days, actively recruiting

- positive results from first, low-dose, 20-patient CHF cohort

- IND for 25-patient Phase 2 clinical trial CHF post-AMI (EF < 45%) cleared <30 days, actively recruiting

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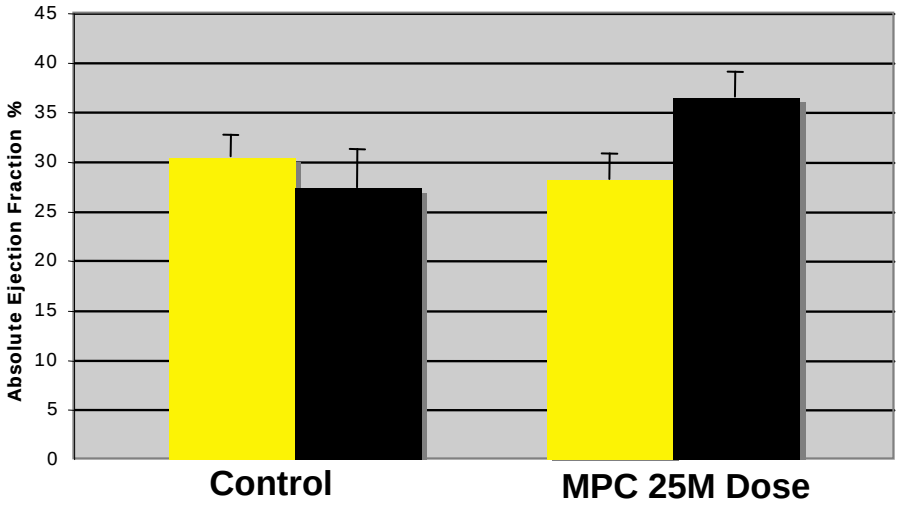
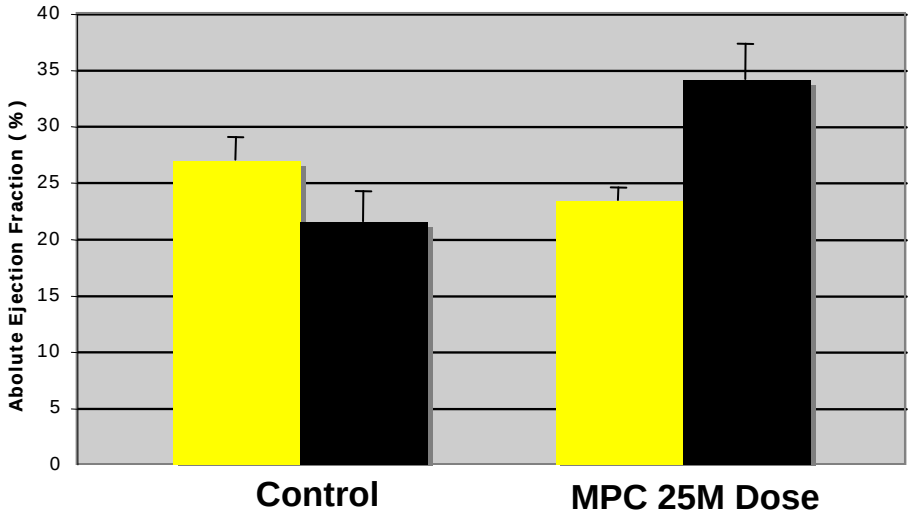
Phase 2a Congestive Heart Failure (CHF) Trial

- 60 patient multi-center, randomized, controlled trial
- class II-IV CHF
- three cohorts of 20 patients, each cohort testing progressively increasing allogeneic cell dose
- cells injected by JNJ NOGA Myostar catheter
- 20 patients first dose cohort enrolled, no adverse events
- evaluating cardiac functional recovery at 3, 6 and 12 months

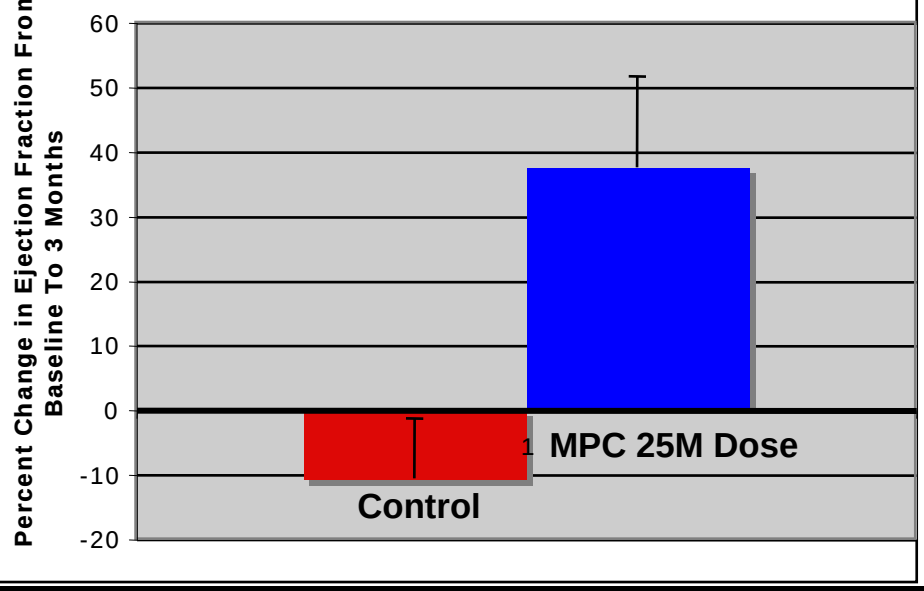
Over 3 Months, Allogeneic MPCs Increase EF In CHF Patients (EF ≤ 40), Whereas Controls Deteriorate



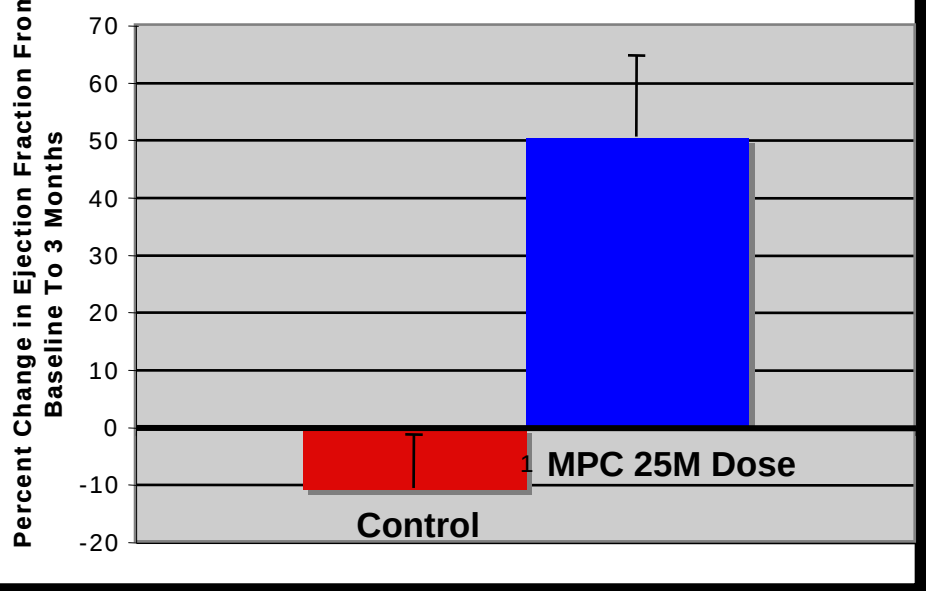
Allogeneic MPCs Increase EF Most Effectively In CHF Patients With Worst Baseline Function (EF <30%)



CHF Patients With EF ≤ 40



CHF Patients With EF < 30



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Bone Marrow Transplantation By Expanding Cord Blood HSC

- **Pre-clinical data shows >20-fold expansion of Hematopoietic Stem Cells (HSC) by MPC co-culture**
- **Orphan Drug designation received for increasing HSC in cancer patients needing allogeneic BMT**
- **Investigator-led IND program for up to 30 patients to be transplanted with MPC-expanded cord blood HSC**
- **Pilot trial to show earlier bone marrow engraftment, reduce in-hospital stay, reduce GVHD**
- **Plan for pivotal trial to obtain early FDA approval**

Clinical Trial Results

- First 5 patients transplanted have all engrafted successfully, no safety issues
- All have demonstrated >20-fold expansion of HSC by MPC co-culture with allogeneic cord
- Median time to neutrophil engraftment 15 days (historic controls approx. 4 weeks)
- Support for accelerated Phase 3 program

Eye Program For AMD and/or Diabetic Retinopathy

- positive results of MPC in rodent model of AMD
- positive results in primate study for IND submission
- synergistic efficacy with Lucentis
- IND submission for Phase 2a clinical trial in patients with AMD and/or diabetic retinopathy
- one-off therapy to treat underlying disease

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Commercial Strategies For Our Biologicals

1. **Taking Individual Applications to Market On Own**
   - highest capital and execution risk
   - greatest shareholder return

2. **Partnering Specific Applications**
   - share the risk, share the reward
   - reduces risk of execution failure

   e.g. Genetics Institute-Sofamor Danek/Medtronic
   BMP-2 for bone growth (spine/trauma/other)

3. **Broad-Based Partnering Of Platform Technology**
   - simultaneous development of multiple applications
   - extensive resources applied to programs

   e.g. Osiris-Genzyme
   allogeneic adult stem cells