Collaborations as part of a Regenerative Medicine Business Model
A Medical Device Company

with a focus on minimally invasive technologies and products

Cook established in 1963 offers three products
An estimated 5 million patients treated using a Cook product.

Global representation interacting with over 40 medical specialties focused on development of minimally-invasive and converging medical technologies (Devices, Biotechnology, Biopharma and Cell Therapy)

22.9 Million units shipped in 2010

Approximately 60% of Cook's revenue is related to vascular products.

that grew and grew
Global Presence, Patient Focus

Cook Medical products and technologies used in 135 countries throughout the world

- 15,000+ SKUs
- 12,000+ employees
- Largest private device manufacturer
- Focus on patients & disease

Cook Medical Companies
Cook Medical Global Coverage
**Cook Pharmica**
Contract development and manufacturing for the biopharma industry
- drug substance
- drug product

**Cook MyoSite**
Autologous cell therapies
- proprietary (phase 3)
- cell lines (myocytes) for drug screening

**Cook Biotech**
Advanced tissue repair
- animal derived
- human derived

**Cook Regentec**
Regenerative Medicine
- tools
- services
- therapeutics
Biopharmaceutical manufacturing (CMO)

- **Cook Pharmica, Bloomington**
  - FDA approved for commercial manufacturing antibodies, vaccines, etc
  - 900,000 sq feet facility, state-of-the-art
Cook Pharmica - Campus

B = 450,000 square feet

A = 450,000 square feet

Bloomington, Indiana

Specific types of collaboration
Human Adult Autologous Stem Cell

Clinical Programs

- SUI, (Stress Urinary Incontinence), female, Phase 3
- 3 other programs not publically disclosed

Products

- Purified human muscle derived
- Myotonic Culture Media

Collaboration: IP acquisition from academic university
Cook Biotech - Overview

- Founded 1995
- Biologic tissue grafts utilizing extracellular matrix (ECM) technology
- > 100 approved clinical uses, used in > 1.5 million patients
Co-op or intern positions
- Full-time students pursuing a B.S., M.S., or Ph.D. degrees
- Gain real-world experience
- Opportunities available
  - Scientific Research and Testing
  - Quality Assurance
  - International and U.S. Regulatory Affairs
  - Product Development
Regenerative Medicine

Cook Regentec, Indianapolis

- established Dec 2014, ca. 100 employees
- FDA registered, AABB accredited, CLIA certified
- licensed Blood Center/Tissue Bank

How to build a Regenerative Medicine company w/o VC style risks?
Regenerative Medicine: A Model

Tools

- Stemulate (HPL)
- CellSeal (cryovial)
# Regenerative Medicine: A Model

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<tr>
<th><strong>Tools</strong></th>
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### Regulatory Burden
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<tr>
<th>Indication</th>
<th>Severe Ischemic Cardiac Failure (chronic)</th>
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<tr>
<td>Design</td>
<td>Safety study 10 patients, open label</td>
</tr>
<tr>
<td></td>
<td>Final study double blind, placebo controlled</td>
</tr>
<tr>
<td></td>
<td>138 patients, 2:1 randomization</td>
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<tr>
<td>Application</td>
<td>Allogeneic ASCs (100 x 10^6 / dose), Intramyocardial injection</td>
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<tr>
<td>SCIENCE study – Consortium Example</td>
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<tr>
<td><strong>PI</strong></td>
<td></td>
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<tr>
<td>Prof J Kastrup MD, Copenhagen, Denmark</td>
<td></td>
</tr>
<tr>
<td><strong>Other clinics</strong></td>
<td></td>
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<tr>
<td>S Chamuleau MD, Utrecht, The Netherlands</td>
<td></td>
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<tr>
<td>D Bergmann MD, Berlin, Germany</td>
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<tr>
<td>W Wojakowski MD, Katowich, Poland</td>
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<tr>
<td>M Gyongyosi MD, Vienna, Austria</td>
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<td>B Vrtovek MD, Ljubljana, Slovenia</td>
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### Collaboration: Laboratory Product

#### SCIENCE study - Consortium Example

| EMA and Danish Health Authority approved |
| Production | central GMP lab at Rigshospitalet, Copenhagen validated reference standards for ASC manufacturing transition from FBS to HPL (Stemulate), 2D to 3D culture cryopreserved in 5 ml CellSeal vials cells thawed and injected directly from vial, no washing |
| Status | Ongoing, 1<sup>st</sup> 10 patients enrolled, treated |
Collaboration: Cell Therapy Device

ND® Infusion Catheter - Licensing of Technology

Multi-channel balloon catheter isolate a specific vascular treatment region from blood flow while allowing infusion into the target region

IP protection important
Collaborations an integral part

Does not have to be ‘one size fits all’

IP remains important foundation

Regulatory environment key part of risk spectrum
Thank You