Regenerated Organs for Transplant

NASDAQ: HART
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This presentation contains forward-looking statements within the meaning of the federal securities laws. You can identify these statements by our use of such words as “will,” “guidance,” “objectives,” “optimistic,” “future,” “expects,” “plans,” “estimates,” “continue,” “drive,” “strategy,” “potential,” “potentially,” “growth,” “long-term,” “projects,” “projected,” “intends,” “believes,” “goals,” “sees,” “seek,” “develop,” “possible,” “new,” “emerging,” “opportunity,” “pursue” and similar expressions that do not relate to historical matters. Forward-looking statements in this presentation may include, but are not limited to, statements or inferences about the Company’s or management’s beliefs or expectations, the outlook for the life sciences industry and the field of regenerative medicine, the Company’s current products or products in development, the Company’s business strategy, the Company’s anticipated regulatory approvals, future revenues and earnings, the strength of the Company’s market position, business model and intellectual property rights, opportunities or potential opportunities in the field of regenerative medicine and related markets, the success of existing treatments utilizing the Company’s products, the market demand and opportunity for the Company’s current products, or the products it is developing or intends to develop and the Company’s plans, objectives and intentions that are not historical facts.

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Investment Highlights

- Regenerated organs for transplant
  - initially for trachea cancer / trauma
- Eight successful transplants so far using our bioreactors
  - last five also used our scaffolds
- $600m per year market in developed world
- Deep pipeline: collaborating with MGH, Mayo and Karolinska on lung, esophagus, heart valves and heart
- Defensible: patents, orphan exclusivity, first-mover
- Capital efficient: small trials, rapid approvals
- Committed to shareholders and patients – CEO owns 5%
Financial Snapshot

• Full NASDAQ listed: HART ticker symbol
• Market cap $34m (Jan 31, 2014)
• $15m cash (November 1, 2013)
• Approximately 2 years of capital at current burn
• Approximately 8m shares outstanding, no debt, no warrants, no preferred stock
• ADTV approximately 50,000 shares per day
• 100% spun off from Harvard Bioscience November 1 2013
• Top institutional holders (Sept. 30): Blackrock, Dimensional Fund Advisors, Foreign and Colonial, Granahan, Hussman, Vanguard, Royce
Clinical Success With Regenerated Tracheas

• Eight patients using our bioreactor technology
  • Most recent five used our scaffolds as well
  • Six of eight are still alive
  • The two that did not survive died of unrelated causes

• Ms. Castillo’s transplant was the world’s first of a regenerated trachea (published in The Lancet).
  • 5-year follow up published – excellent quality of life
  • FEV1 improved from 55% before surgery to 100% at 90 days

• Mr. Beyene’s was the world’s first of a synthetic regenerated trachea (published in The Lancet).
  • Alive at over 2.5 years – prognosis at surgery was 2 weeks

• Hannah Warren’s was the first in the USA (FDA approved under IND)
InBreath Airway Transplant System

- Synthetic porous polymer scaffold
  - No wait for a donor
- Rotating bioreactor seeds patients bone marrow cells onto the scaffold for 2 days
  - No rejection
- Patents issued and pending
Cellularization of the Scaffold

Confocal microscope image of cells seeded on a scaffold

- Blue = cell nuclei (DAPI)
- Green = cell body (phalloidin)
- Red = scaffold fibers (false color)

Cross-section of rat trachea explant

- ★ = regenerated trachea
- + = natural trachea
- = tracheal epithelium (lining)

From: Jungebluth P, et al., Verification of cell viability in bioengineered tissue and organs before clinical transplantation *Biomaterials*; 2013 May; 34(16):4057-67
Trachea Transplant Market

Over 6,500 new patients annually (developed world)

• Trachea Cancer : 2,400 patients
  • Rapidly fatal: 10 month median survival, 15% five-year survival
  • More deadly than breast cancer or prostate cancer

• Tracheal Trauma : 3,900 long-term tracheotomy patients
  • At risk of death from aspiration pneumonia

>$600$ million per year opportunity
Strategy

• Target life-threatening medical conditions
  • Trachea cancer, organ transplant; not skin, bone etc.
  • FIM under compassionate use reduces late stage failure risk
• Fast path to market – small trials, rapid follow up
• Favorable reimbursement profile
• Orphan status likely – 7/10 years exclusivity
• Grant funding, e.g., Russia $5m, EU $5m

• Use trachea as platform to other organs
  • Esophagus
  • Lungs

• Collaborate with leading surgeons and institutions
  • Prof. Macchiarini at The Karolinska Institutet
  • Dr. Ott at Massachusetts General Hospital
Clinical Trial Design Proposal

- 30 patients
- 3 sites: US, EU, Russia, 10 patients per site
- Single arm, open label
- Lung function as primary endpoint (e.g., patency, FEV1)
- Patient as comparator (before and after surgery)
Timeline

• End 2017 approval in USA

• We expect a somewhat shorter timeline in the EU
Favorable Reimbursement Profile

Our products can save lives and reduce medical costs, creating a highly favorable reimbursement profile:

Cancer therapeutics are typically priced at $50k - $100k per patient for 3-4 months of survival benefit
  • Beyene is alive at 2+ years, was given 2 weeks to live prior to transplant

The following major costs are avoided:
  • Organ procurement $40-90k
  • Immune suppression $20-30k per year
  • Chemotherapy $24k per year

$100k - $200k would likely be attractive to payors
Deep Product Pipeline

Development | Pre-Clinical | First-in-human | Clinical Trial

Trachea Transplant (Karolinska/Krasnodar)
Lung Transplant (MGH/KI/Others)
GI Tract Transplant (Confidential)
Heart Valve Transplant (Mayo Clinic)
Heart Transplant (THI/Maragnon/others)
Pre-clinical Success with Solid Organs

The lungs were regenerated in our lung bioreactor and transplanted into a rat
- The lungs showed near-normal function
- The work was published in *Nature Medicine* in July 2010

The regeneration of a human heart in our bioreactor is being developed at the Mayo Clinic
Strong Intellectual Property Position

Bioreactors
• Exclusive license to InBreath technology
• Issued patent (in Germany) on improved InBreath technology
• Additional US and international patents pending (327 claims)

Scaffolds
• Ownership of Macchiarini’s inventions
• Three additional US and international patents pending

Patents + orphan exclusivity + first-mover advantage
= strong, defensible position
Management and Board

• CEO: David Green, BA Physics (Oxford), MBA Harvard Business School. Unilever, Monitor and Harvard Bioscience (founder, president then CEO)
• Owns approx. 5% personally
• CFO: Tom McNaughton, BS Babson, CPA Deloitte, Cabot, Tivoli, Harvard Bioscience
• CEO and CFO left HBIO to run HART
• Board is industry veterans:
  • Tom Robinson (Boston Scientific, Spencer Stuart)
  • Jim McGorry (Genzyme, Champions Oncology)
  • John Canepa (StemGent, Arthur Anderson)
  • John Kennedy (Harvard Bioscience, KPMG)
Expected Near-Term Milestones

2014
✓ Pre-IND meeting with FDA at end of January
• Equivalent in EU likely in Q1
• Orphan designation determination by FDA Feb/Mar
• Further patients treated in Russia
## Public Comparables

<table>
<thead>
<tr>
<th>Company</th>
<th>Ticker</th>
<th>Market Cap</th>
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<tbody>
<tr>
<td>Cytori</td>
<td>CYTX</td>
<td>$178m</td>
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<tr>
<td>InVivo</td>
<td>NVIV</td>
<td>$169m</td>
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<td>Organovo</td>
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<td>$728m</td>
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<td>Athersys</td>
<td>ATHX</td>
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<td>Advanced Cell Tech.</td>
<td>ACTC</td>
<td>$206m</td>
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<td>BioTime</td>
<td>BTX</td>
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<tr>
<td>NeoStem</td>
<td>NBS</td>
<td>$197m</td>
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<td>Pleuristem</td>
<td>PSTI</td>
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Source: Yahoo Finance, Jan 31 2014
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Yulia Tuulik,
Alive at over a year

Andemariam Beyene,
Alive at over two years

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