Agenda Item 2

Featured Medical Device Start-Up – Harpoon Medical, Inc.
TOPIC: Featured Medical Device Start-Up – Harpoon Medical, Inc. (information item)

COMMITTEE: Economic Development and Technology Commercialization

DATE OF COMMITTEE MEETING: March 27, 2014

SUMMARY: At the request of Committee members, we are continuing to feature successful start-ups facilitated by USM institutions. Harpoon Medical, Inc. is a development stage medical device company commercializing a minimally invasive, image guided surgical tool for beating heart mitral valve repair. With the Harpoon device, surgeons can access and repair the mitral valve in a beating heart via a small incision between the ribs without the need for cardiac arrest or cardiopulmonary bypass.

When introduced to the market, the Harpoon device should transform the traditional open heart mitral valve surgical procedure from a complex 3-6 hour operation to a 60-minute procedure and reduce the recovery period from weeks to days. The technology was developed in the division of Cardiac Surgery at The University of Maryland School of Medicine and licensed by Harpoon Medical.

ALTERNATIVE(S): This item is for information purposes.

FISCAL IMPACT: This item is for information purposes.

CHANCELLOR’S RECOMMENDATION: This item is for information purposes.

COMMITTEE RECOMMENDATION: DATE:

BOARD ACTION: DATE:

SUBMITTED BY: Joseph F. Vivona (301) 445-2783
Presentation Overview

- Degenerative MR market opportunity
- Evolution of neochordal repair
- Economic analysis
- Competitive overview
- Company overview
- Financials
- M&A opportunity
Market Opportunity

• 250,000 new patients diagnosed every year in the US
• Over 50,000 open heart, on pump mitral valve operations in US every year
• Over 75,000 open heart, on pump mitral valve operations OUS every year
• There are over 6M patients worldwide with moderate to severe MR
• Only 20% of patients who could benefit get open heart surgery
Clinical Problem & Solution

Mitral Valve Regurgitation (MR)
The valve does not close properly so blood flows back into the atrium when the heart contracts. Without treatment, MR leads to a number of additional health problems and can eventually cause death.

Large and Growing Problem
- 6.8M people suffer from MR in the US alone
- Standard of Care = open heart surgery on CPB
- Invasive procedure with long recovery period
- Many patients are not candidates for open heart surgery due to age and other morbidities

Harpoon Medical – Changing the Standard of Care
- Minimally invasive, beating heart solution
- No bypass or cardiac arrest
- Short hospital stay
- Quick recovery

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US Market Segmentation

Mitral Valve Regurgitation
6.8M People

Moderate & Severe Regurgitation
4M People

Degenerative Regurgitation
2M People

All Open Cases/Year
~50k

Degenerative Cases per Year
~37k

~$450M / Year Market

~$600M / Year Market

~$4B / Year Market
(Assumes 15%-20% Market Penetration)

~$8B / Year Market
(Assumes 15%-20% Market Penetration)

Harpoon Target Market Development
Valve Repair Operations at UMD

Evolution of Mitral Valve Repair Techniques at Univ of MD

- Leaflet resection
- Neochordal Replacement


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Mitral Valve Regurgitation

The Parachute Analogy

Normal Leaflet

Ruptured Chordae
# Procedural Evolution

<table>
<thead>
<tr>
<th>Open Heart Operation</th>
<th>Harpoon Procedure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large 6-8” incision</td>
<td>Small 1-2” incision</td>
</tr>
<tr>
<td>Sternotomy</td>
<td>No sternotomy</td>
</tr>
<tr>
<td>Cardiopulmonary bypass</td>
<td>No cardiopulmonary bypass</td>
</tr>
<tr>
<td>Arrested heart</td>
<td>Beating heart</td>
</tr>
<tr>
<td>Aortic manipulation</td>
<td>No aortic cross clamp</td>
</tr>
<tr>
<td>Difficult to properly size the neochords</td>
<td>Real-time, echo-guided neochordal adjustment</td>
</tr>
<tr>
<td>1-2% stroke risk</td>
<td>Negligible stroke risk</td>
</tr>
<tr>
<td>3-6 hour procedure</td>
<td>45-60 minute procedure</td>
</tr>
<tr>
<td>4 -7 day hospital recovery</td>
<td>1-2 day hospital recovery</td>
</tr>
<tr>
<td>Return to work time &gt; 1 month</td>
<td>Return to work time 5-7 days</td>
</tr>
</tbody>
</table>
Evolution of Valve Repair
The “Bulky Knot”

- Proprietary, preformed, adaptable topology of ePTFE suture.
- Delivered to the valve via a low profile (<.070”, 6 Fr) delivery system
- Implant grade ePTFE suture that will comprise the final neochord or structural repair element
Procedural Animation
## Competitive Comparison

<table>
<thead>
<tr>
<th>Harpoon</th>
<th>MitraClip</th>
<th>NeoChord</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transapical approach</td>
<td>Catheter Based</td>
<td>Transapical approach</td>
</tr>
<tr>
<td>Both Neochordal &amp; Edge-to-Edge repair</td>
<td>Edge-to-Edge repair only</td>
<td>Only Neochordal repair approved</td>
</tr>
<tr>
<td>Easy to deliver &quot;bulky knot“</td>
<td>Difficult to master</td>
<td>Must &quot;capture&quot; leaflet</td>
</tr>
<tr>
<td>Very low profile device</td>
<td>Limited patient population</td>
<td>Large device needed to capture leaflet &amp; deliver suture</td>
</tr>
<tr>
<td>Strong anchoring system</td>
<td>Failure to reduce MR below moderate in ~50% of patients</td>
<td>Concerns about suture ripping out</td>
</tr>
<tr>
<td>No CE Mark</td>
<td>CE Mark March 2008</td>
<td>CE Mark Jan 2013</td>
</tr>
<tr>
<td>Targeting $9k-$12k</td>
<td>Price = €20k (~$27k)</td>
<td>Price = €12k</td>
</tr>
</tbody>
</table>
Management Team

Bill Niland, President & CEO
- 25+ years experience
- Founded Vapotherm, Inc.
- Successfully sold 2 Medtech businesses he started

Peter Boyd, Biz Dev & GC
- Associate at Latham & Watkins, LLP
- Business Dev at Vapotherm
- JD/MBA from UVA

Pete Wilson, VP Engineering
- Device R&D Consultant 10 yrs
- Lead engineer 3 successful medical device startups
- 6 years at Boston Scientific

Mark Collins, CPA, VP of Finance/Operations
- 25+ years experience
- 9+ at Vapotherm HR, IT & accounting

Zita Yurko, VP Regulatory & Quality
- Director Regulatory Affairs
- 30 yrs RA/QA U.S. and global experience
- RAC

***Over 90 combined years of medical device experience***
Milestones to Date

• Formed company (7/2/13) & finalized License with University of Maryland (8/23/13)

• Prototypes successfully tested in multiple acute sheep studies and device freeze for First-in-Man

• Recruited 5 person cross-functional team with extensive medical device experience
Current Financing

- Current $3.5M round of Angel investor financing open
- Successfully Raised $900k with an additional $400k committed
- Secured >$550k in non-dilutive funding
- Series A will begin immediately after First-in-man outcomes (closing projected Q1/Q2-2015)
Next value creation date

• “First-in-Man” pilot protocol (n=5-10) to evaluate Harpoon neochordal repair procedure on degenerative MR patients

• Site selected and agreed with well known and respected clinical center in Europe

• Procedures to begin in Q4 – 2014

• Additional funding to be secured pending procedure safety outcomes (Q2-2015)
Timing of Capital Requirements & Use of Proceeds

- Q1-2014: Design freeze with verification and validation testing
- Q1-2015: Completion of First-in-man study
  Series A financing secured
- Develop tooling and manufacturing processes
- Establish ISO 13485 Quality System
- Expand IP portfolio
Future Financing

• $8M - $12M round of financing from institutional investors

• Fund pivotal clinical study to support CE Mark and European sales

• Ramp up manufacturing & quality departments

• Build out European sales & marketing efforts

• Expand IP portfolio
Structural Heart M&A Activity

Select Structural Heart Exits
(in Millions with Milestone Information)

Milestone Payments
Upfront Payments

CryoCath
$380
7x

Ablation Frontiers*
$10
$225

CoreValve
$700

Ventric
$325

E Valve (MitraClip)
$320
4.5x

ATS Medical
$375

Sandata Medical
$225

Atritech
$275
$100

Rhythmia Medical
$175
$90

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Exit Opportunities

- Potential exit strategy exists for $500M - $750M after initiation of IDE US clinical trial
  
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- In the aortic valve market strategics quickly acquired all the players including Medtronic which bought 2 competitive companies for >$1B