Agenda Item 2

Featured Medical Device Start-Up – Harpoon Medical, Inc.

BOARD OF REGENTS

SUMMARY OF ITEM FOR ACTION
INFORMATION OR DISCUSSION

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

HARPOON MEDICAL

University of Maryland Board of Regents Presentation March 27th 2014

Presentation Overview

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

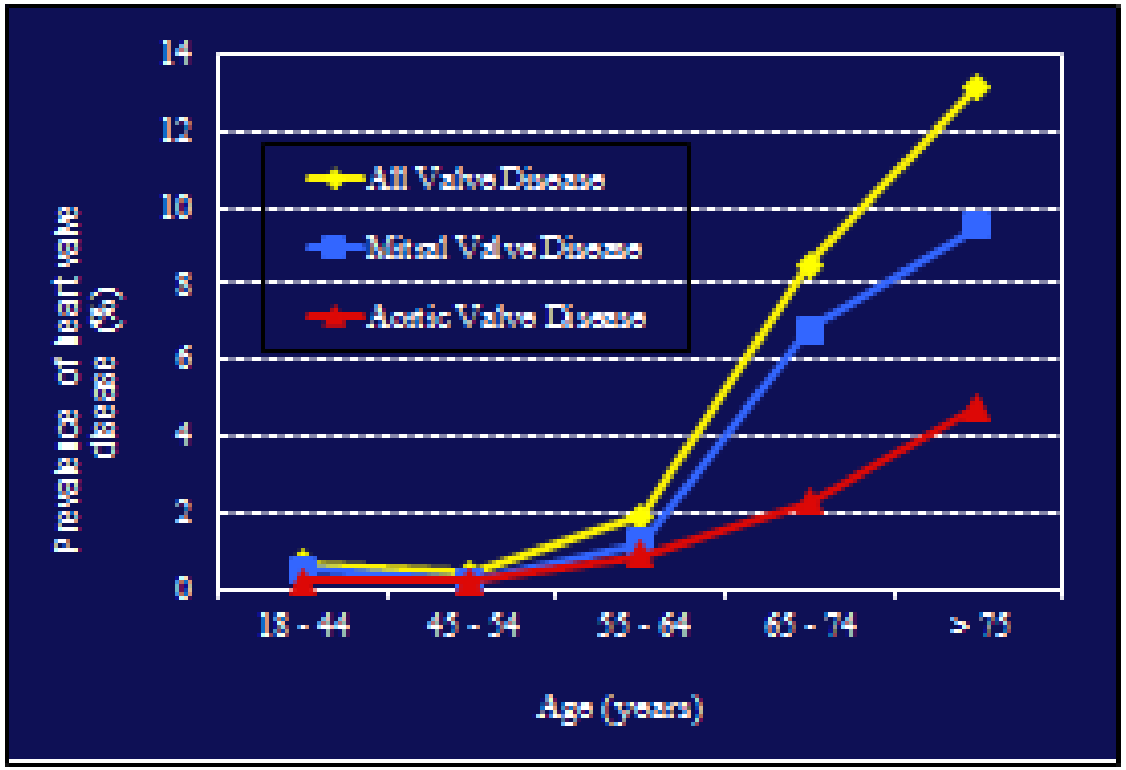
Market Opportunity

- 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

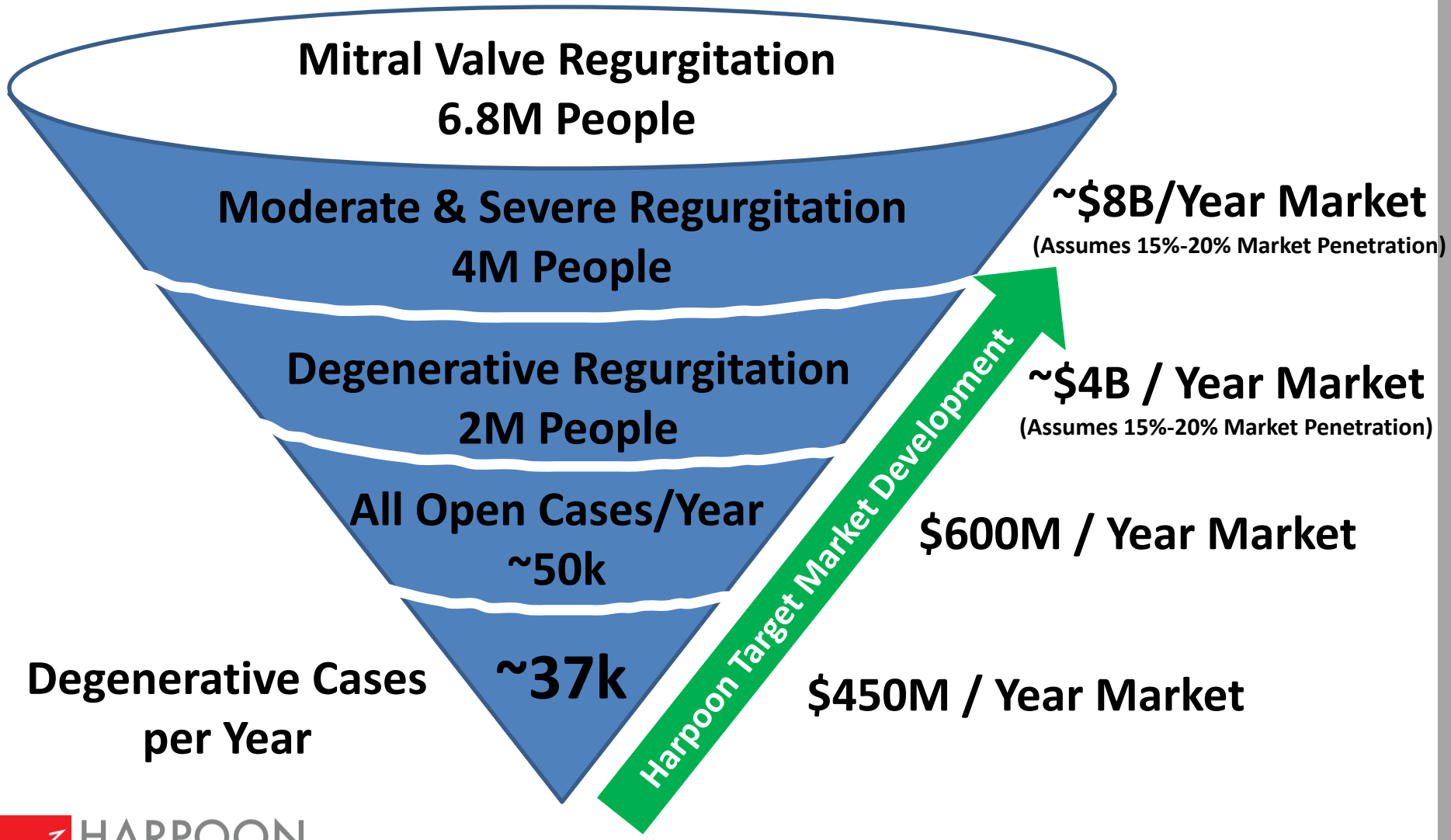
- 6.8M people suffer from MR in the US alone
- Standard of Care = open heart surgery on CPB
- Invasive procedure with long recovery period
- Many patients are not candidates for open heart surgery due to age and other morbidities

Harpoon Medical – Changing the Standard of Care

- Minimally invasive, beating heart solution
- No bypass or cardiac arrest
- Short hospital stay
- Quick recovery

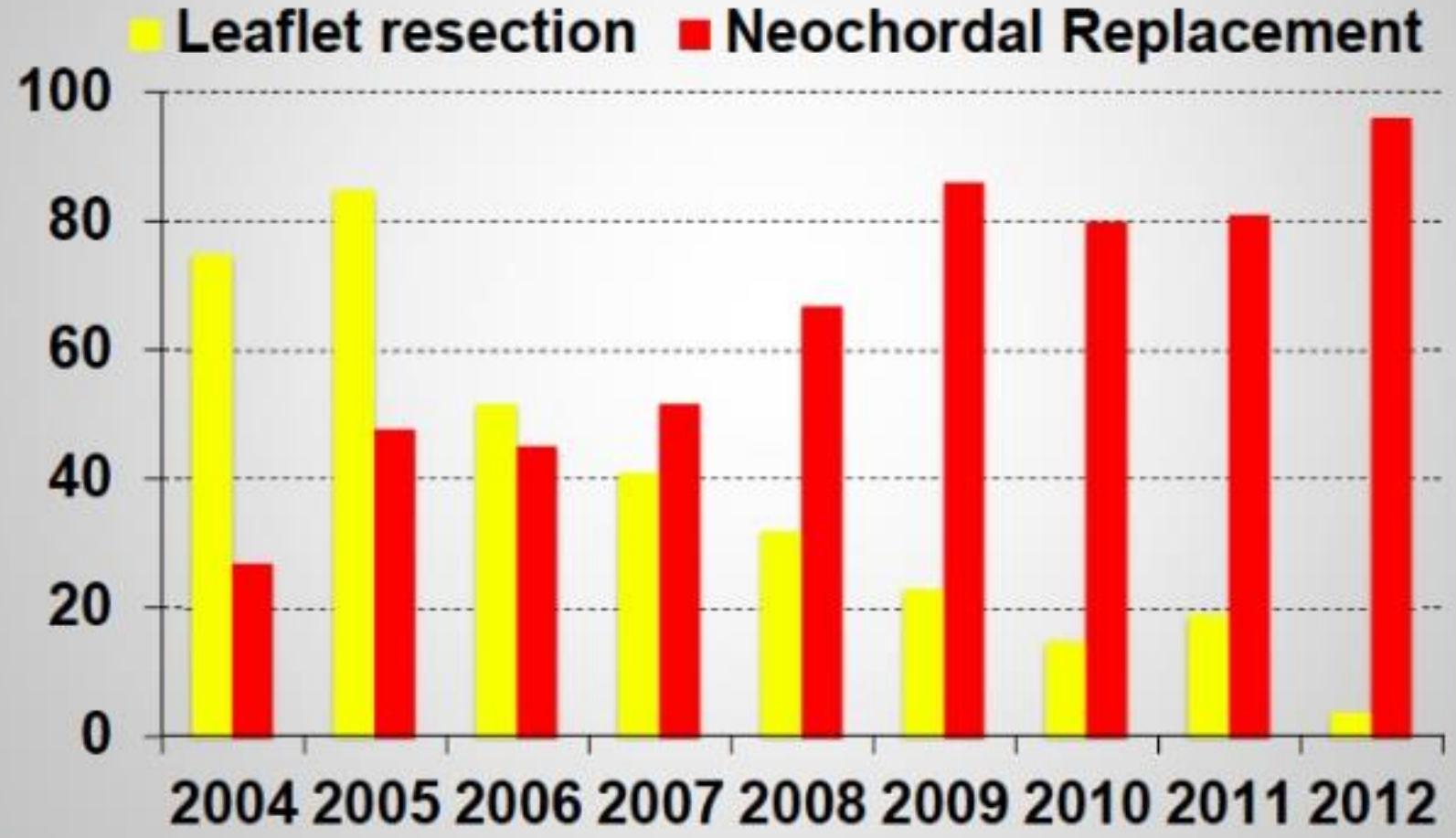
Nkomo VT et al. Burden of valvular heart diseases: a population-based study. Lancet 2006; 368:1005–11

US Market Segmentation



Valve Repair Operations at UMD

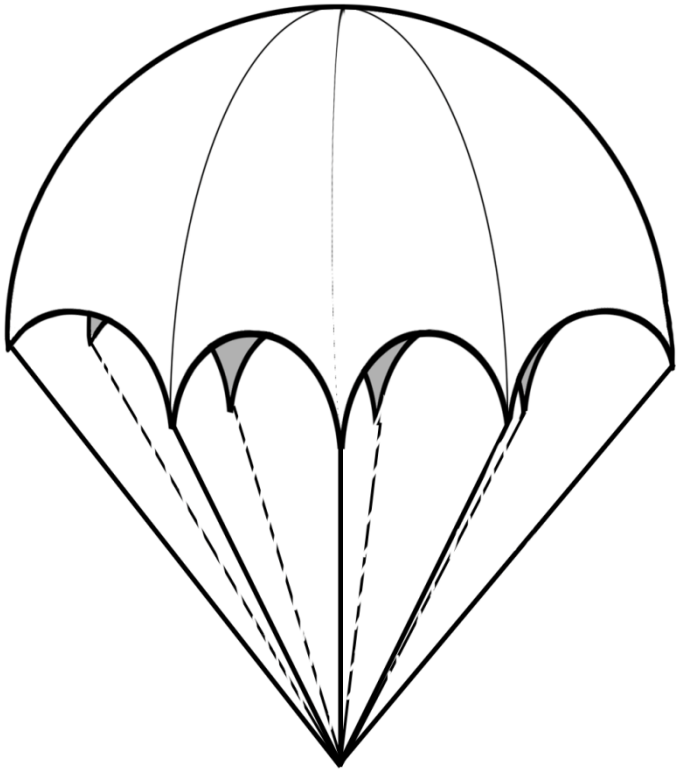
Evolution of Mitral Valve Repair Techniques at Univ of MD



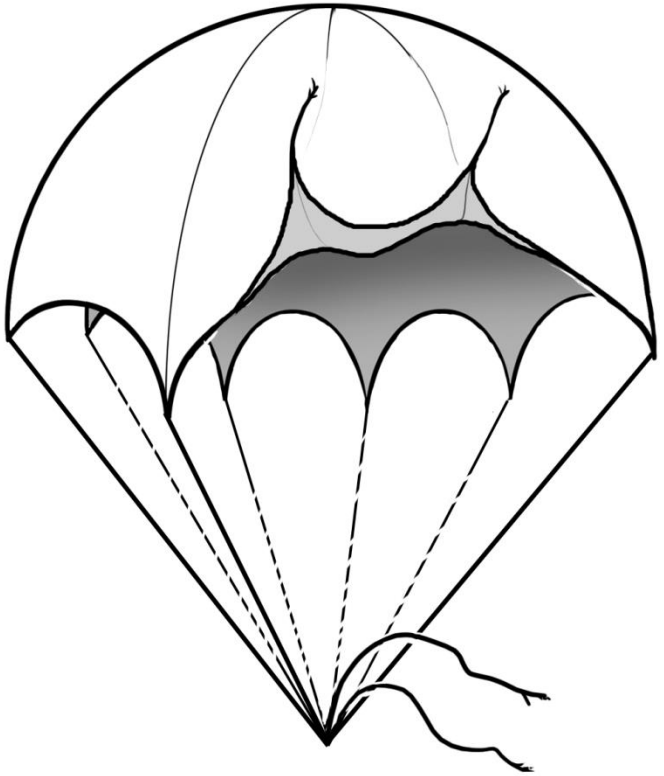
Mitral Valve Regurgitation

The Parachute Analogy

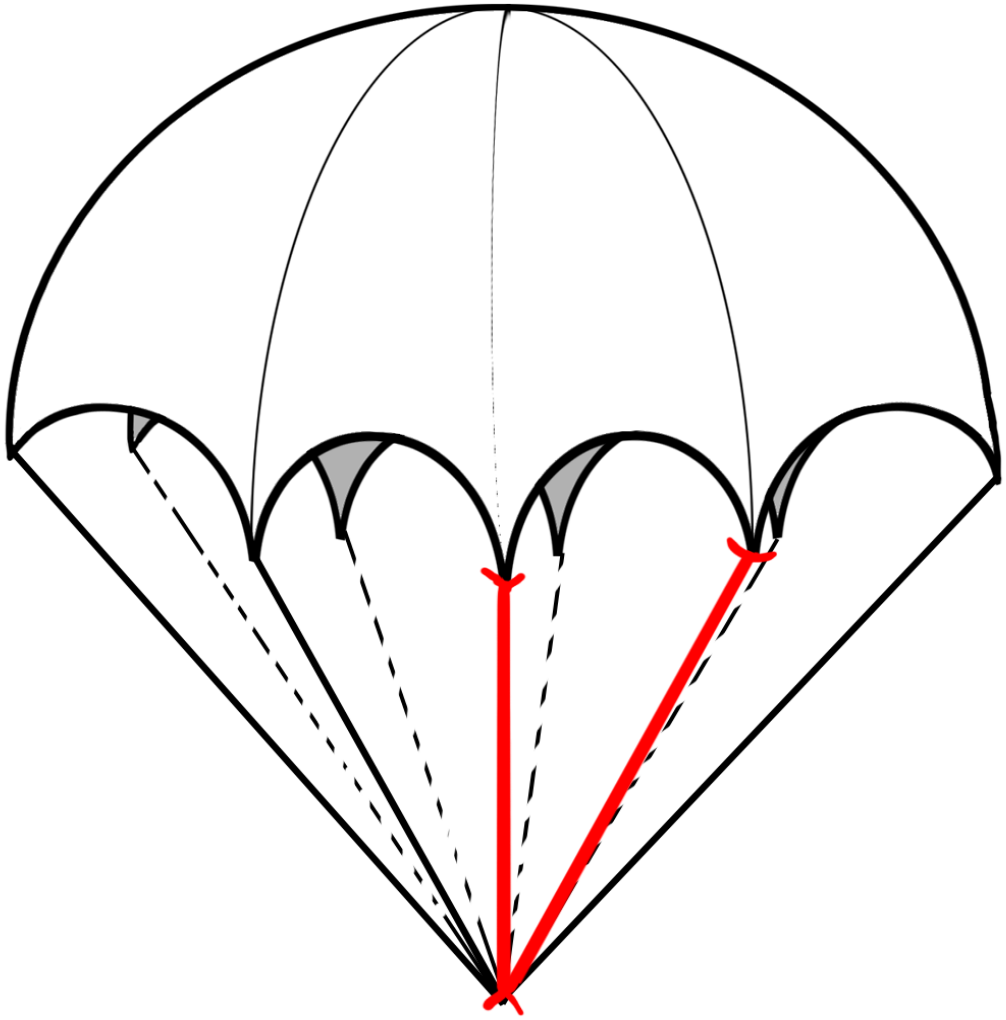
Normal Leaflet



Ruptured Chordae



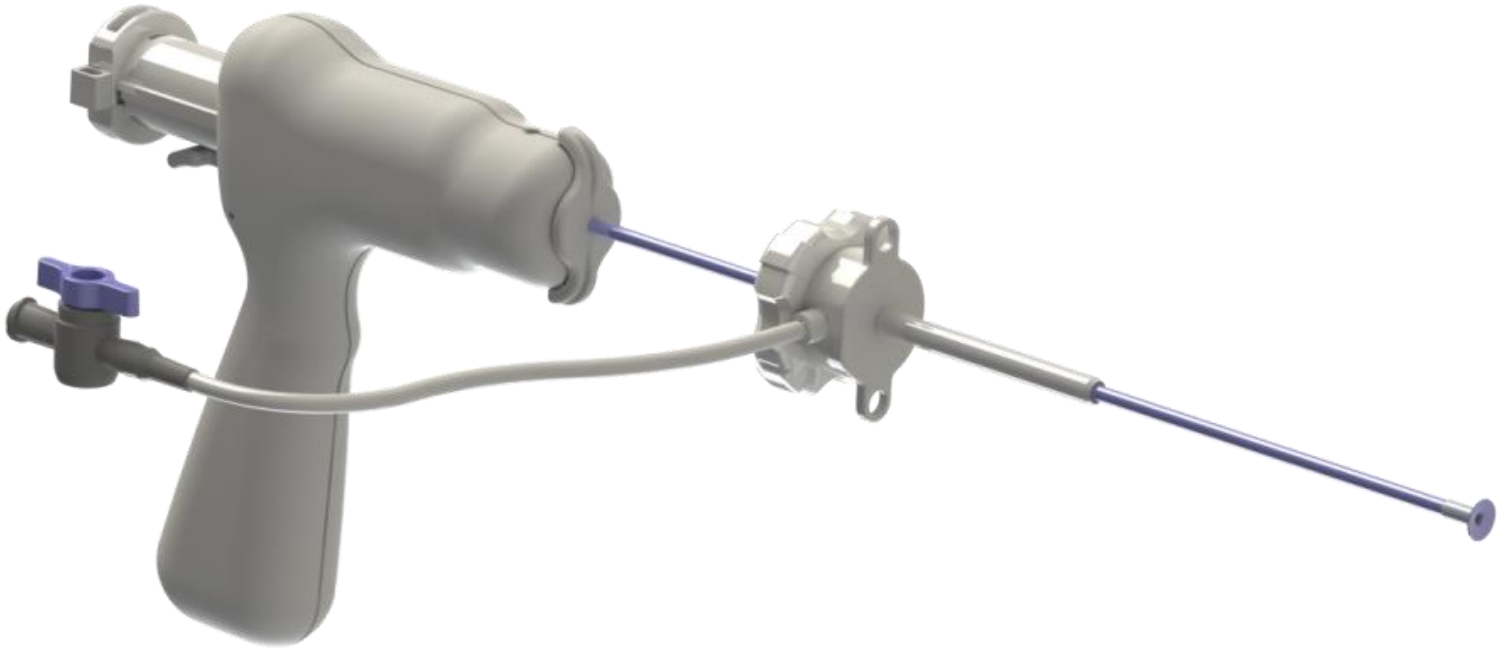
Cord Replacement



Procedural Evolution

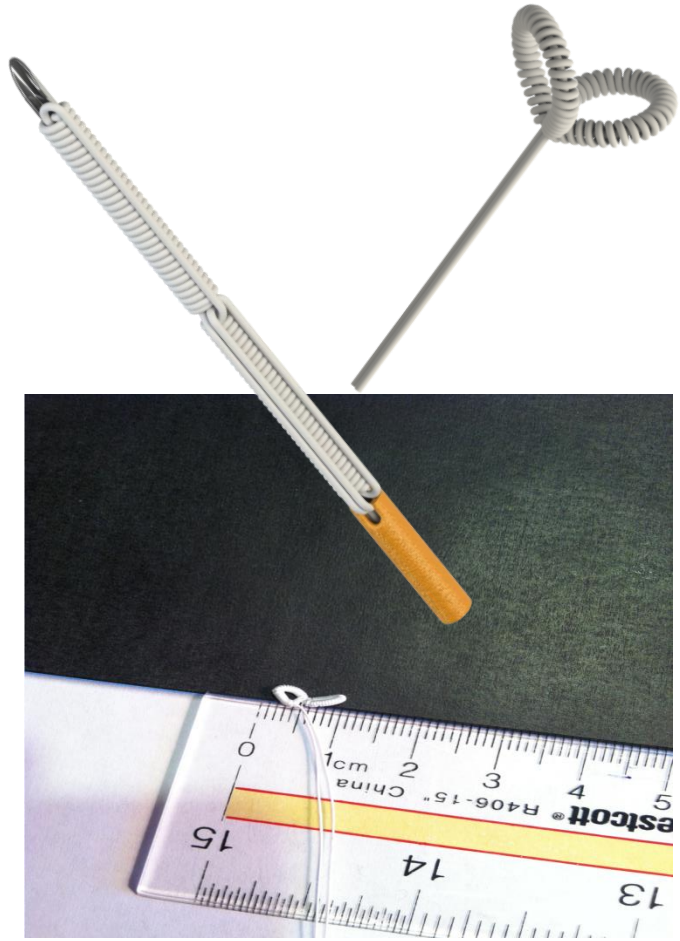
Open Heart Operation	Harpoon Procedure
Large 6-8” incision	Small 1-2” incision
Sternotomy	No sternotomy
Cardiopulmonary bypass	No cardiopulmonary bypass
Arrested heart	Beating heart
Aortic manipulation	No aortic cross clamp
Difficult to properly size the neochords	Real-time, echo-guided neochordal adjustment
1-2% stroke risk	Negligible stroke risk
3-6 hour procedure	45-60 minute procedure
4 -7 day hospital recovery Return to work time > 1 month	1-2 day hospital recovery Return to work time 5-7 days

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

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

Management Team

Bill Niland, President & CEO

- 25+ years experience
- Founded Vapotherm, Inc.
- Successfully sold 2 Medtech businesses he started

Peter Boyd, Biz Dev & GC

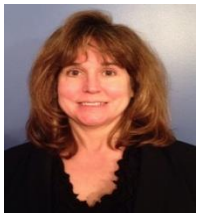
- Associate at Latham & Watkins, LLP
- Business Dev at Vapotherm
- JD/MBA from UVA

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

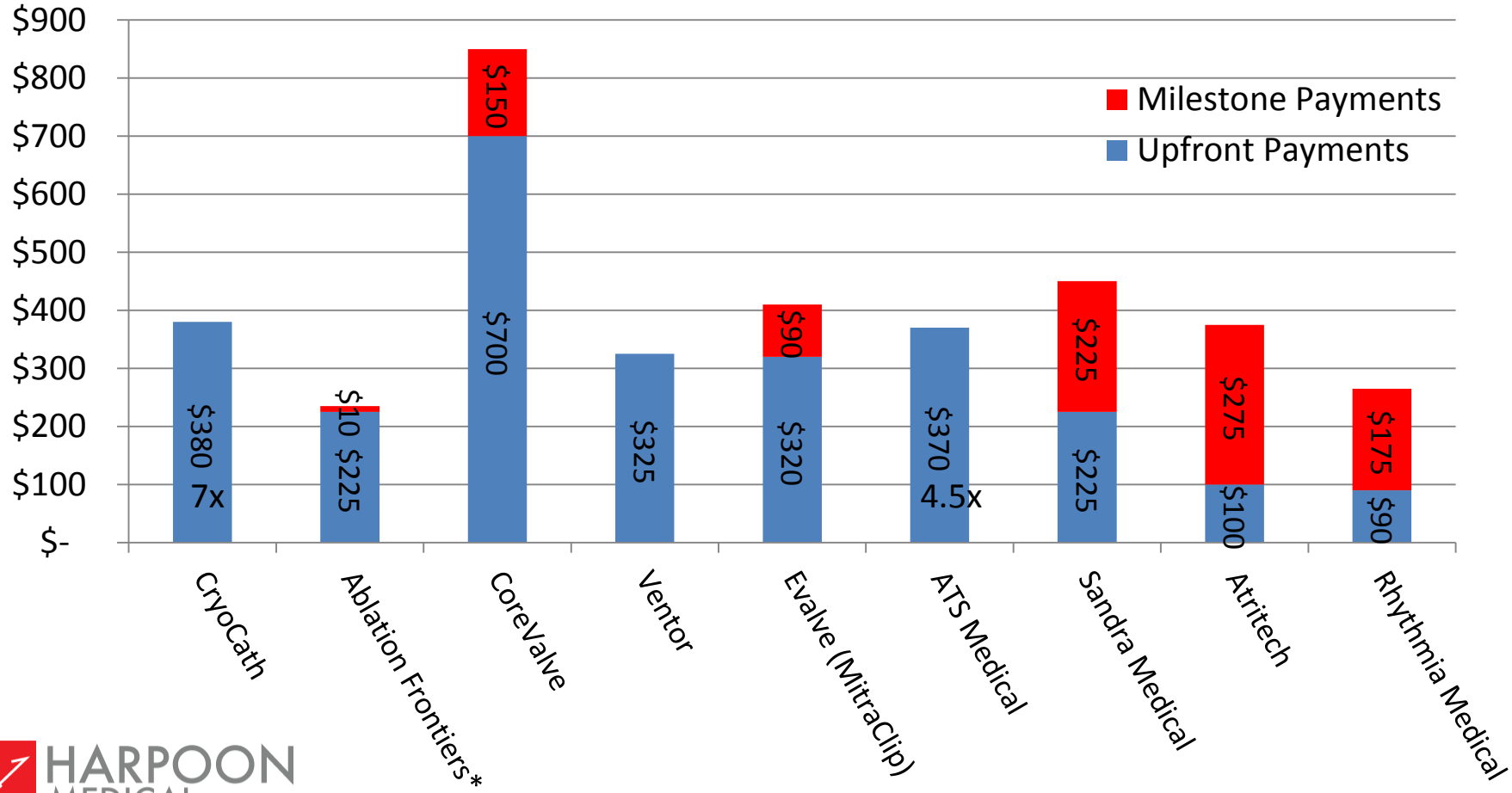
Future Financing

- $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)



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