Advanced Bifurcation Systems

Revolutionary Technology
First Platform of Multiple Systems for Treatment of All Bifurcations

Management Presentation
**Company Overview**

**Company Profile**
- Clinical stage medical device company developing innovative stenting platform for the treatment of bifurcation lesions in coronary angioplasties
- Simplify current techniques used in CAD bifurcations by overcoming limitations of stenting systems in today’s market
- Strong management team comprised of executive responsible for multiple M&A and IPO transactions involving healthcare companies, interventional cardiologist, and engineer of world’s first transcatheter heart valve and delivery system

**Product**
- Proprietary bifurcation drug-eluting stenting system
- Mother/Daughter (MD) platform technology for treatment of **ALL** CAD bifurcation cases
- Only stenting solution capable of complete coverage regardless of branch angles, sizes, and plaque locations
- First-in-Human trials with successful 12-month follow up

**Opportunity**
- Capital efficient with only $5 million invested
- 39 patents (33 issued) in the U.S. and globally
- Ease of use increases number of participating physicians and treatable cases
- Standard of best practice in market valued at approximately $2 billion
Device R&D | Practice Leadership | Startup-to-IPO

Charles A. Laverty; Chief Executive officer
- > 30 year career in capital markets and senior management positions including Chairman & CEO of multiple medical device companies
- U.S. Turnaround Entrepreneur of Year as Chairman & CEO of Curaflex Health Services –Morgan Stanley private investment company, Granted by Merrill Lynch & Ernst Young

Mehran J. Khorsandi, MD; Co-Founder, Chairman & Chief Medical Officer
- Interventional cardiologist at Cedars-Sinai Medical Center
- Member of the team that developed the HARTS stent at Cedars-Sinai
- Co-inventor of ABS stent technology with multiple U.S. patents
- Assistant Clinical Professor of Medicine at UCLA

Henry Bourang; Co-Founder, President & Chief Technology Officer
- > 29 years senior management and technical experience in medical device industry including research & development, manufacturing and commercialization of percutaneous valves, stents, catheters, and other angioplasty, neurological and peripheral vascular devices at Biosensors, Edwards Life Sciences, Boston Scientific and Guidant the inventor of the world’s first transcatheter heart valve and delivery system (Edwards Sapien Valve)
- More than 100 U.S. and international issued and pending patents
Key Opinion Leaders | Worldwide Influence

- **Dr. Roxana Mehran** - Mount Sinai Hospital, New York, NY
- **Drs. Alex Abizaid, Ricardo Costa** - Dante Pazzanese Institute, Sao Paulo, Brazil
- **Dr. Thierry Lefevre** - Institut cardiovasculaire Paris Sud, Hospital Prive Paris, France
- **Drs. Raj Makar, Saibal Kar, Neal Eigler** - Cedars-Sinai Medical Center, Los Angeles, CA
- **Dr. Matthew Price** - Scripps Clinic, La Jolla, CA
- **Dr. Jose Condado** - Centro Medico, Caracas, Venezuela
- **Dr. Sameer Dani** - Ahmadabad, Gujrat, India
Agenda

- Market Need
- Advanced Bifurcation Systems Platform
- Competitive Advantage
- First in Man Clinical
- Intellectual Property
- Regulatory Pathway and Reimbursement
- Timeline
- Use of Proceeds
Percutaneous Coronary Intervention (PCI)

• Coronary artery stents are either bare metal stents (BMS) or drug-eluting stents (DES)
  - Average restenosis rate with stents is about 2% with DES, compared to 18% for BMS
  - DES requires longer period of dual anti-platelet (blood thinners) therapy

• Coronary stent global market approximately $10 billion in 2016
  - Estimated to reach $15 billion by 2024

• 25-30% of all coronary disease involves bifurcations

• Restenosis and target vessel revascularization rates at bifurcations are significantly higher
Current PCI Bifurcation Techniques: Provisional T, crush, culotte

- Tedious, lengthy, complex, and cumbersome – experts only
- Unpredictable overall procedure outcomes
- Gap in tissue coverage or excess metal and injury
- Repeated procedures for revascularization, referral to surgery
- Unreliable acute outcomes, high restenosis/recurrence rates
Unmet Need For Effective Bifurcation Stenting

Complex and Ineffective
- Competitors dedicated bifurcating stents have serious issues
- Incomplete or excessive coverage
- Unpredictable outcomes, alignment, angle limitation or post-op restenosis

Limited technical viability and commercial uptake
- Estimated alternatives used in <1% of Global procedures

Significant potential for an effective, dedicated bifurcation system

<table>
<thead>
<tr>
<th>Stent With Dedicated Side Branches</th>
<th>Stent With Fixed Angles</th>
<th>Stent With Side Hole</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="logo.png" alt="Tryton Medical" /></td>
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<td><img src="logo.png" alt="Minvasys" /></td>
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**Advanced Bifurcation Systems Platform**

**Mother/Daughter (MD) Platform**

- Complete coverage for all lesions
  - Branch angles, size, plaque burden and location

- Single system addresses main and side branch

- Self alignment and perfect placement

- Mechanically fail-safe
  - Automatic main vessel aperture and side vessel alignment

- No torqueing or micro alignment

- No gaps and/or overlaps
  - Reduces restenosis and thrombosis
Revolutionary Solution

- Significant reduction in risk profile of bifurcation stenting practice
- Simplifies complicated effort into a PCI procedure significantly reducing the procedure time
- Major cost-reduction opportunity for hospitals/insurers
  - Lower procedure time, recovery
- Stent introduction procedure familiar to cardiologists worldwide
  - No new skill set required
  - More treatable cases and participating physicians
- Platform encompassing **ALL** bifurcation scenarios/procedures
  - MD; MD-P; MD-O
- Improve outcomes
ABS Technology Animation

**Dedicated Bifurcating Stent**

https://www.youtube.com/watch?v=1pvOxlALzs4

**Main Branch Bifurcation Stent**

https://www.youtube.com/watch?v=blCFm9v7luQ
The Left Main Opportunity

• Left Main Coronary Artery Disease (LMCAD) is increasingly prevalent with aging population\(^{(1)}\)

• Issues
  - Large bifurcating vessel
  - Majority referred for open chest surgery CABG

• Current solution
  - CABG
  - PCI scarce, high risk and with high rates of recurrence

• Estimated 10%-30% of all CABG procedures are for LMCAD\(^{(2)}\)

• ABS a simple reproducible alternative

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\(^{(1)}\) Rev Esp Cardiol. 2006;59(8):794-800; \(^{(2)}\) Eur Heart J (2011) 32 (11): 1331-1336

\(^{(2)}\) Circulation Cardiovascular Interventions. 2009; 2: 59-68;
### Competitive Advantage

<table>
<thead>
<tr>
<th>Stenting System</th>
<th>ABS Platform technology</th>
<th>Tryton™ Side Branch Stent</th>
<th>Devax AXXESS Pathfinder (Multi-Linlk Frontier™)</th>
<th>Nile®</th>
<th>Taxus Petal</th>
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</thead>
<tbody>
<tr>
<td>Platform Technology</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Stenting Technique</td>
<td>ABS MD System</td>
<td>Culotte</td>
<td>Provisional</td>
<td>Provisional-T</td>
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<tr>
<td>Stent Type</td>
<td>BMS/DES</td>
<td>BMS</td>
<td>DES</td>
<td>DES</td>
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<tr>
<td>Regulatory Clearance</td>
<td>In CE Process</td>
<td>CE-Mark, FDA</td>
<td>CE-Mark</td>
<td>CE-Mark</td>
<td>CE-Mark</td>
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<tr>
<td>Additional Stent Required</td>
<td>NO</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>Stent Gap/Overlap</td>
<td>No/No</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
<td>Yes/Yes</td>
</tr>
<tr>
<td>Self Alignment and Self Orientation</td>
<td>Yes/Yes</td>
<td>No/No</td>
<td>No/No</td>
<td>No/No</td>
<td>No/No</td>
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Multicenter trial completed

- Sao Paulo, Brazil, Ahmadabad, India, Caracas, Venezuela
- 10 patients, ages 45-71
- 7 patients: 100% successful deployment of all two stent bifurcating stent (MD) implantations
- 3 patients: 100% successful deployment of all side branch access provisional systems (MD-P)

Significant reduction in procedure time

Excellent follow-up results

No target vessel revascularization after 12 months
Initial Human Clinical Results

First Human Trial

**Before**
- **Proximal Stenosis**
- **Bifurcation Disease**

**After**
- **Proximal Stent**
- **Bifurcating Stent**

**Final Result**: Bifurcation Stented Directly (no predilatation)
Over 300 Unique Claims | 39 Issued and Pending Patents

- Stent alignment, partial crimping, and placement methodology
- Issued: 11 US, 7 Europe, 15 Japan, China, Australia and Canada
- Additional patents pending
- Long patent life
- Freedom to Operate
Regulatory Pathway and Reimbursement

Regulatory Pathway (Concurrent Programs)

- CE approval of ABS BMS – Animal trial only (2 years)
- CE approval of ABS DES – Human clinical trial (3 years)
- FDA U.S Clinical Trial approval under IDE (2 years)
- FDA approval of DES – PMA (4-5 years)

Reimbursement

- Anticipate coverage under current stent coding
Timeline

BMS GMP Operations & Manufacturing

Drugs Program Licensing & Set-up

File New MD Product Patents

BMS CE-Mark Process (provisional + full MD)

Submit CE-Mark BMS Application

Completion of Animal Studies for BMS CE-Mark

OUS Left-Main First-in-Man Build

DES Manufacturing

OBS FDA Process

2018

Obtain BMS CE-Mark

OUS BMS Clinical Enrollment

Start OUS Left-Main Implants

BMS FDA Process

2019

OUS BMS Clinical Enrollment

U.S. FDA IDE

OUS DES Clinical Enrollment

BMS CE-Mark

Product Launch

OBS BMS
Investment Opportunity

Cardiologist Developed Stent Technology
• Intuitive and effective solution for an unmet clinical need

Only Solutions to Simplify Procedure, Reduce Risk/Cost, and Improve Outcomes

Bifurcation Stenting ≈$2B Market Opportunity
• Bifurcation stenting targets large subset of ~$10.5B annual global coronary stent market

Strong Early Human Trial Data

Extensive IP protection
• To date 33 patents Issued/Granted

Experienced Management Team and Stellar Advisory Board
• Extensive experience with coronary stenting practice, R&D, start-up and commercialization of medical technology