2015 European Ventricular Assist Devices Technology Innovation Award
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Background and Company Performance

Industry Challenges

Ventricular Assist Devices (VADs) offer life-saving therapy to patients suffering with end stage heart failure, and for whom a donor organ is not readily available; these patients can be sustained on bridge-to-transplant therapies until a donor organ becomes available. A number of VADs are currently available, however, challenges affecting the adoption of these devices are still prevalent even after a decade of commercially available products.

Blood damage is an inherent problem with VADs and it continues to challenge VAD manufacturers. An assist device essentially consists of an electrically powered pump, using either a centrifugal or axial impeller to pump blood, received from the left atrium into and around the circulatory system, effectively replacing the pumping action of the left ventricle. When blood comes in contact with the impeller, red cells, white cells and blood proteins are subject to shear stresses, cell streaming and physical damage, which over time can lead to a range of unwanted side effects. This is particularly problematic in advanced heart failure patient, the normal recipients of VADs because they have multiple other metabolic deficiencies resulting from their underlying diseases and are almost always receiving anticoagulants to compensate for the pro-thrombotic effect of the implanted VAD.

The design specifications of a VAD hold the key to the success of the product. An ideal assist device must be light, roughly half to one-third the weight of the heart, must have a high blood flow rate, must not consume high levels of power and, most importantly, must not damage blood. Furthermore the hydraulic characteristics of the VAD must be supportive of the heart regaining some degree of normal function. A number of devices have been developed that are large and equivalent to the weight of the heart, making it extremely difficult to place these devices in the pericardial space. Moreover, they have been reported to cause immense discomfort to the patients.

While VAD manufacturers claim to have addressed these problems by developing smaller VADs, the decrease in size usually compromises other aspects of design and utility.

Technology Attributes and Future Business Value

Industry Impact

Calon Cardio-Technology Ltd. has developed MiniVAD™, a device that can be implanted directly into a patient's failing heart. In short, Calon Cardio offers a high quality, optimally designed Ventricular Assist Device. With a design smaller than that of existing VADs, Calon Cardio’s next generation device is superior to pump technology used by competitors. Conventional VADs combine the motor and impeller functions. The impeller rotates either axially, eg Thortec's HeartMate 2 or centrifugally such as HeartWare's HVAD. The optimum flow, power and performance points for the motor and impeller may not be the same, leading to design compromise. Cardio has developed a T shaped design
wherein the impeller is in separated from the motor to permit the optimisation of the motor and the impeller functions separately. Greatly impressed with this innovation, Frost & Sullivan firmly believes that Calon Cardio’s technology will advance and improve the entire VAD industry.

**Product Impact**

The design and pump technology used in MiniVAD has been shown in the laboratory to minimise the damage done to multiple blood constituents. Specifically the impeller layout and internal channels have been optimised to reduce damage to red cells, reduce physical damage to white cells, reduce platelet activation and also minimise degradation of von-Willebrand Factor, a blood protein implicated in the control of capillary bleeding. The pump has optimal hydraulic characteristics, allowing any native pulse to pass through the device, unlike existing systems, especially axial flow devices. Since the pump operates in near silence and is vibration-free, the technology dramatically improves the efficiency. The device will be able to pump blood at a flow rate of between 2 and 10 litres per minute, which is a broader range than the flow rates offered by existing competitors’ VADs. Designed to incorporate a novel pump technology, the device has the potential to reduce driveline infections and changes to systemic perfusion that arise with the use of other VADs. It is also much lighter, making it suitable for both children and adults.

**Scalability**

To provide an efficient partial cardiac support to patients suffering with early-stage heart disease, Calon Cardio has developed a further miniaturized version of the MiniVAD device using the same technology platform. Called the MicroVAD™ the device is suitable for left and right ventricle implantation and can be configured to be implanted in a subclavian chest pocket. It may also be suitable for pediatric use.

Calon Cardio is developing short-term ventricular support device called CathVAD™, which will provide temporary support to patients who have recently undergone a heart surgery and require ventricular assistance for a maximum of 3 days.

**Visionary Innovation**

Calon Cardio has brought together expertise in mechanical engineering, electrical engineering, computational fluid dynamics and biomedical engineering to deliver their novel pump technology used in the development of MiniVAD. With the aim of developing a smaller and low cost heart assist pump that will cause less blood damage, Calon Cardio has designed a fresh product whose design and process is not based on previously existing Ventricular Assist Devices.

The company’s strategy to separate the motor from the impeller in the MiniVAD has drastically brought down the power consumption of the device and has improved the hydraulic characteristics of the pump. By avoiding active magnetic levitation for the bearing system Calon has been able to dramatically reduce the computational
requirements and power consumption of the device. At 0.8 W/Litre/minute the MiniVAD device is amongst the lowest in the industry and this level of performance will certainly make this product a benchmark for new VADs.

**Financial Performance**

The Ventricular Assist Devices market is expected to grow at a compounded annual growth rate (CAGR) of 12.5% from 2015 to 2020, and reach a global market of $1 billion by 2017. To capitalize on the growing demand for Ventricular Assist Devices Calon Cardio’s MiniVAD is expected to receive the CE mark by early 2019 following completion of human trials. As a result of its manufacturing expertise and optimal design, the company expects its cost of goods to be significantly lower than current and future devices, providing increased flexibility in pricing and its overall commercial model. This has relevance not only in the established VAD markets of Europe and the US, but is likely to boost the adoption of MiniVAD in parts of Asia-Pacific, and Middle East as this eases the burden of reimbursement.

**Conclusion**

With superior pump technology and a VAD design that has clear advantages over existing approaches, Calon Cardio-Technology Ltd. has developed a potentially lower cost and more compelling device - the MiniVAD. By separating the motor and impeller functions to optimise both components, this innovative pump technology has the potential to reduce blood damage and thrombus formation while preventing unlikely cardiac events after the device has been implanted. Moreover, with a wider range of blood flow rates, improved hydraulic characteristics and reduced power consumption, Calon Cardio-Technology Ltd. has demonstrated that it is extremely proficient in mechanical pump designs. Because of its strong overall performance, Calon Cardio-Technology Ltd. is recognized with Frost & Sullivan’s 2015 Technology Innovation Award.
Significance of Technology Innovation

Ultimately, growth in any organization depends upon finding new ways to excite the market, and upon maintaining a long-term commitment to innovation. At its core, technology innovation or any other type of innovation can only be sustained with leadership in three key areas: understanding demand, nurturing the brand, and differentiating from the competition.

Understanding Technology Innovation

Technology innovation begins with a spark of creativity that is systematically pursued, developed, and commercialized. That spark can result from a successful partnership, a productive in-house innovation group, or the mind of a singular individual. Regardless of the source, the success of any new technology is ultimately determined by its innovativeness and its impact on the business as a whole.
Key Benchmarking Criteria

For the Technology Innovation Award, Frost & Sullivan analysts independently evaluated two key factors—Technology Attributes and Future Business Value—according to the criteria identified below.

Technology Attributes
  Criterion 1: Industry Impact
  Criterion 2: Product Impact
  Criterion 3: Scalability
  Criterion 4: Visionary Innovation
  Criterion 5: Application Diversity

Future Business Value
  Criterion 1: Financial Performance
  Criterion 2: Customer Acquisition
  Criterion 3: Technology Licensing
  Criterion 4: Brand Loyalty
  Criterion 5: Human Capital

Best Practice Award Analysis for Calon Cardio-Technology Ltd.

Decision Support Scorecard

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Scorecard. This tool allows our research and consulting teams to objectively analyze performance, according to the key benchmarking criteria listed in the previous section, and to assign ratings on that basis. The tool follows a 10-point scale that allows for nuances in performance evaluation; ratings guidelines are illustrated below.

RATINGS GUIDELINES

The Decision Support Scorecard is organized by Technology Attributes and Future Business Value (i.e., the overarching categories for all 10 benchmarking criteria; the definitions for each criteria are provided beneath the scorecard). The research team confirms the veracity of this weighted scorecard through sensitivity analysis, which
confirms that small changes to the ratings for a specific criterion do not lead to a
significant change in the overall relative rankings of the companies.

The results of this analysis are shown below. To remain unbiased and to protect the
interests of all organizations reviewed, we have chosen to refer to the other key players
as Competitor 2 and Competitor 3.

<table>
<thead>
<tr>
<th>Technology Innovation</th>
<th>Technology Attributes</th>
<th>Future Business Value</th>
<th>Average Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>Calon Cardio-Technology Ltd.</td>
<td>9.5</td>
<td>9.0</td>
<td>9.2</td>
</tr>
<tr>
<td>Competitor 2</td>
<td>8.5</td>
<td>8.5</td>
<td>8.5</td>
</tr>
<tr>
<td>Competitor 3</td>
<td>8.0</td>
<td>7.0</td>
<td>7.5</td>
</tr>
</tbody>
</table>

**Technology Attributes**

**Criterion 1: Industry Impact**
Requirement: Technology enables the pursuit of groundbreaking new ideas, contributing
to the betterment of the entire industry

**Criterion 2: Product Impact**
Requirement: Specific technology helps enhance features and functionality of the entire
product line for the company

**Criterion 3: Scalability**
Requirement: Technology is scalable, enabling new generations of products over time,
with increasing levels of quality and functionality

**Criterion 4: Visionary Innovation**
Requirement: Specific new technology represents true innovation based on a deep
understanding of future needs and applications

**Criterion 5: Application Diversity**
Requirement: New technology serves multiple products, multiple applications, and
multiple user environments

**Future Business Value**

**Criterion 1: Financial Performance**
Requirement: High potential for strong financial performance in terms of revenues,
operating margins and other relevant financial metrics

**Criterion 2: Customer Acquisition**
Requirement: Specific technology enables acquisition of new customers, even as it
enhances value to current customers
**Criterion 3: Technology Licensing**
Requirement: New technology displays great potential to be licensed across many sectors and applications, thereby driving incremental revenue streams

**Criterion 4: Brand Loyalty**
Requirement: New technology enhances the company’s brand, creating and/or nurturing brand loyalty

**Criterion 5: Human Capital**
Requirement: Customer impact is enhanced through the leverage of specific technology, translating into positive impact on employee morale and retention

**Decision Support Matrix**
Once all companies have been evaluated according to the Decision Support Scorecard, analysts can then position the candidates on the matrix shown below, enabling them to visualize which companies are truly breakthrough and which ones are not yet operating at best-in-class levels.

![Decision Support Matrix Diagram](image)
The Intersection between 360-Degree Research and Best Practices Awards

Research Methodology

Frost & Sullivan’s 360-degree research methodology represents the analytical rigor of our research process. It offers a 360-degree-view of industry challenges, trends, and issues by integrating all 7 of Frost & Sullivan's research methodologies. Too often, companies make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. The integration of these research disciplines into the 360-degree research methodology provides an evaluation platform for benchmarking industry players and for identifying those performing at best-in-class levels.
# Best Practices Recognition: 10 Steps to Researching, Identifying, and Recognizing Best Practices

Frost & Sullivan Awards follow a 10-step process to evaluate award candidates and assess their fit with select best practice criteria. The reputation and integrity of the Awards are based on close adherence to this process.

<table>
<thead>
<tr>
<th>STEP</th>
<th>OBJECTIVE</th>
<th>KEY ACTIVITIES</th>
<th>OUTPUT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Monitor, target, and screen</td>
<td>Identify award recipient candidates from around the globe</td>
<td>Pipeline of candidates who potentially meet all best-practice criteria</td>
</tr>
</tbody>
</table>
|      |           | • Conduct in-depth industry research  
|      |           | • Identify emerging sectors  
|      |           | • Scan multiple geographies | |
| 2    | Perform 360-degree research | Perform comprehensive, 360-degree research on all candidates in the pipeline | Matrix positioning all candidates’ performance relative to one another |
|      |           | • Interview thought leaders and industry practitioners  
|      |           | • Assess candidates’ fit with best-practice criteria  
|      |           | • Rank all candidates | |
| 3    | Invite thought leadership in best practices | Perform in-depth examination of all candidates | Detailed profiles of all ranked candidates |
|      |           | • Confirm best-practice criteria  
|      |           | • Examine eligibility of all candidates  
|      |           | • Identify any information gaps | |
| 4    | Initiate research director review | Conduct an unbiased evaluation of all candidate profiles | Final prioritization of all eligible candidates and companion best-practice positioning paper |
|      |           | • Brainstorm ranking options  
|      |           | • Invite multiple perspectives on candidates’ performance  
|      |           | • Update candidate profiles | |
| 5    | Assemble panel of industry experts | Present findings to an expert panel of industry thought leaders | Refined list of prioritized award candidates |
|      |           | • Share findings  
|      |           | • Strengthen cases for candidate eligibility  
|      |           | • Prioritize candidates | |
| 6    | Conduct global industry review | Build consensus on award candidates’ eligibility | Final list of eligible award candidates, representing success stories worldwide |
|      |           | • Hold global team meeting to review all candidates  
|      |           | • Pressure-test fit with criteria  
|      |           | • Confirm inclusion of all eligible candidates | |
| 7    | Perform quality check | Develop official award consideration materials | High-quality, accurate, and creative presentation of nominees’ successes |
|      |           | • Perform final performance benchmarking activities  
|      |           | • Write nominations  
|      |           | • Perform quality review | |
| 8    | Reconnect with panel of industry experts | Finalize the selection of the best-practice award recipient | Decision on which company performs best against all best-practice criteria |
|      |           | • Review analysis with panel  
|      |           | • Build consensus  
|      |           | • Select winner | |
| 9    | Communicate recognition | Inform award recipient of award recognition | Announcement of award and plan for how recipient can use the award to enhance the brand |
|      |           | • Present award to the CEO  
|      |           | • Inspire the organization for continued success  
|      |           | • Celebrate the recipient’s performance | |
| 10   | Take strategic action | Upon licensing, company may share award news with stakeholders and customers | Widespread awareness of recipient’s award status among investors, media personnel, and employees |
|      |           | • Coordinate media outreach  
|      |           | • Design a marketing plan  
|      |           | • Assess award’s role in future strategic planning | |
About Frost & Sullivan

Frost & Sullivan, the Growth Partnership Company, enables clients to accelerate growth and achieve best in class positions in growth, innovation and leadership. The company's Growth Partnership Service provides the CEO and the CEO's Growth Team with disciplined research and best practice models to drive the generation, evaluation and implementation of powerful growth strategies. Frost & Sullivan leverages almost 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from 31 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.