Technology Innovation Leadership Award
Kidney Transplantation
North America, 2013

Frost & Sullivan's Global Research Platform

Frost & Sullivan is in its 50th year in business with a global research organization of 1,800 analysts and consultants who monitor more than 300 industries and 250,000 companies. The company's research philosophy originates with the CEO's 360-Degree Perspective™, which serves as the foundation of its TEAM Research™ methodology. This unique approach enables us to determine how best-in-class companies worldwide manage growth, innovation and leadership. Based on the findings of this Best Practices research, Frost & Sullivan is proud to present the 2013 North American Technology Innovation Leadership Award in Kidney Transplantation Technology to Breonics, Inc.

Key Industry Challenges

Nearly 600,000 people in the US are afflicted with end stage renal disease. Transplantation is the only choice of therapy for people with end stage organ failure. Before transplant, static storage utilizes a cooler filled with ice for the kidneys so that metabolism is suspended. However, they cannot be procured later than 20 minutes of cardiac death as the kidneys are not considered healthy enough beyond this time period. The patients who are considered for organ donation are primarily heart-beating cadaver donors or patients with head trauma maintained on a respirator in an intensive care unit. The use of respirators prevents any sort of warm ischemic damage. Recently, the organ donor pool for transplantation by using marginal organs, such as those procured from elderly donors or those that have been hypothermically preserved for more than 24 hours has been attempted with limited success. Frost & Sullivan firmly believes that these challenges necessitate the need for a technology system to recover cadaveric kidneys from a much larger donor pool to solve the shortage of transplantable kidneys.

Technology Innovation Leadership

The Technology Innovation Leadership Award is a prestigious recognition of Breonics' accomplishments in the Kidney Transplantation Technology sector. As an unbiased, third-party, Frost & Sullivan recognizes Breonics for delivering excellence and best practices in their respective endeavors. The Technology Innovation Leadership Award is backed by extensive analysis. Companies are independently identified, and the uniqueness, impact and relevance of their technology is monitored and evaluated through primary analyst research. This stringent methodology positions Breonics as a superior market participant.

Key Benchmarking Criteria for Technology Innovation Leadership Award

For the Technology Innovation Leadership Award, the following criteria were used to benchmark Breonics's performance against key competitors:

- Uniqueness of Technology
- Impact on New Products/Applications
- Impact on Functionality
- Impact on Customer Value
- Relevance of Innovation to Industry

Decision Support Matrix and Measurement Criteria

To support its evaluation of best practices across multiple business performance categories, Frost & Sullivan employs a customized Decision Support Matrix (DSM). The DSM is an analytical tool that compares companies' performance relative to each other with an integration of quantitative and qualitative metrics. The DSM features criteria unique to each Award category and ranks importance by assigning weights to each criterion. The relative weighting reflects current market conditions and illustrates the associated importance of each criterion according to Frost & Sullivan. Fundamentally, each DSM is distinct for each market and Award category. The DSM allows our research and consulting teams to objectively analyze each company's performance on each criterion relative to its top competitors and assign performance ratings on that basis. The DSM follows a 10-point scale that allows for nuances in performance evaluation; ratings guidelines are shown in Chart 1.

Chart 1: Performance-Based Ratings for Decision Support Matrix

This exercise encompasses all criteria, leading to a weighted average ranking of each company. Researchers can then easily identify the company with the highest ranking. As a final step, the research team confirms the veracity of the model by ensuring 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.

Chart 2: Frost & Sullivan's 10-Step Process for Identifying Award Recipients

Best Practice Award Analysis for Breonics Inc.

The Decision Support Matrix, shown in Chart 3, illustrates the relative importance of each criterion for the Technology Innovation Leadership Award and the ratings for each company under evaluation. To remain unbiased while also protecting the interests of the other organizations reviewed, we have chosen to refer to the other key players as Competitor 1 and Competitor 2.

Chart 3: Decision Support Matrix for Technology Innovation Leadership Award

Measurement of 1–10 (1 = lowest; 10 = highest)	**Award Criteria**					
	Uniqueness of Technology	Impact on New Products/Applications	Impact on Functionality	Impact on Customer Value	Relevance of Innovation to Industry	**Weighted Rating**
Relative Weight (%)	**20%**	**20%**	**20%**	**20%**	**20%**	**100%**
Breonics Inc.	9.5	9.5	9.5	9.0	9.0	9.3
Competitor 1	9.0	8.5	8.6	8.5	8.5	8.4
Competitor 2	8.5	8.0	8.0	8.0	8.0	8.1

Criterion 1: Uniqueness of Technology

Breonics has developed an exsanguinous metabolic support (EMS) technology that enables continuous oxidative metabolism and functioning of kidneys when isolated from the human body at 32 degrees Celsius. The ability to maintain the organ intact in tissue culture-like conditions is achieved by adequate metabolic support by providing all the necessary nutrients and substrates and also maintaining vascular integrity by preserving the normal barrier function of the blood vessel wall. The pressure controlled perfusion system includes a siliconized membrane oxygenator and a pulsatile pump retrofitted with controllers to maintain arterial oxygen, carbon dioxide, acidity, and temperature initiated with a systolic pressure in an EMS medium of acidic and basic fibroblast growth factor together with hemoglobin. Present day organ preservation involves chilling the organ to temperatures between 4 to 8 degrees C to suspend metabolism and limit the ischemic conditions caused by the lack of oxygen. Without the cold to suspend the metabolism and blood flow to provide oxygen, an organ loses its ability to function. The effect is considered irreversible. While the static storage can keep the organ function for only 30 minutes, measures to extend the lifetime of the organs are considered essential. Competitors' technology utilizes machine perfusion, which is believed to prolong the average cold storage time from the current 18 hours to 35 hours. In Frost & Sullivan's opinion, with EMS technology, kidney transplants may become elective rather than emergency-style procedures.

Criterion 2: Impact on New Products/Applications

The ability to provide continuous oxidative metabolism when the organ is isolated from the rest of the human body, allows EMS technology to provide a number of unique opportunities for medical applications. Breonics's EMS represents the potential of a warm perfusion technology in its early stages. Active metabolism while an organ is maintained ex vivo presents the opportunity for pretransplantation treatment regimens, such as immunomodulation and the development of effective gene transfer technologies with protein expression. With the future of organ preservation moving towards warmer and more physiologic temperatures, Frost & Sullivan expects EMS to impact other organ transplants, such as skin, heart, and tissue engineering applications.

Criterion 3: Impact on Functionality

The transplant outcomes with kidneys from non-heart beating donors with limited warm ischemia causes delayed graft function and primary non-function, thereby hampering effective use of the donor kidney. The kidney can tolerate 2 hours of warm ischemia before the damage becomes irreversible. The added cold ischemia can preserve the kidney during the period of tissue typing, matching, and transport. Frost & Sullivan notes that with the EMS technology, the warm perfusion after warm ischemia can re-establish metabolism, restore vascular integrity, and re-institute cell volume regulation ex vivo sufficiently to render severely damaged kidneys capable of providing life-sustaining functions when reimplanted. Clinical studies by researchers have also proven better performance by

perfused kidneys as compared to statically stored kidneys post-transplant. The devices used by competing technologies pump chemical solutions to minimize the tissue damage.

Criterion 4: Impact on Customer Value

Ex vivo recovery of organs provides the foundation for changing the current time frame for procuring organs from within minutes of death to hours. Frost & Sullivan's research reveals that Breonics's warm perfusion technology enables the recovery of organs after nearly 2 hours after death and offers a potential solution to the persisting organ shortage problem. Frost & Sullivan firmly believes that Beronics' EMS technology will propel the expansion of the donor pool to include several hundreds of thousands of potential deceased donors who were never considered previously. The more elective style of kidney transplant will also reduce the hospital costs and result in improved outcomes. The company has been developing this technology for over the last 15 years and is currently in the clinical trial stage with a grant from the National Institutes of Health (US).

Criterion 5: Relevance of Innovation to Industry

The patient population with end stage renal disease maintained with hemodialysis continues to grow and outnumber the projections by healthcare groups. There has been no substantial progress made in developing a comparable increase in the number of available grafts. There exists a gap between the demand and supply of kidneys for transplantation. Also, there is an ethical dilemma associated with obtaining consent for donation of organs, which complicates the procurement in the current scenario. According to Frost & Sullivan's research, the greatest potential for procuring more organs is in 95% of the trauma patient population, where circulatory arrest has existed for more than half an hour post mortem without intervention.

Conclusion

It's Frost & Sullivan's opinion that Society will be faced with the public healthcare issue of sustaining the costs associated with transplantation when relatively few patients will have the opportunity to be transplanted. Frost & Sullivan's research clearly shows that with the persisting organ shortage problem posing a major obstacle in the field of clinical transplantation, effective utilization of organs from a non-heart beating donor will certainly go a long way in meeting organ shortages. In recognition of the pioneering development of the EMS technology, the 2013 North American Technology Innovation Leadership of the Year Award in Kidney Transplantation Technology to Breonics Inc.

The CEO 360-Degree Perspective™ - Visionary Platform for Growth Strategies

The CEO 360-Degree Perspective™ model provides a clear illustration of the complex business universe in which CEOs and their management teams live today. It represents the foundation of Frost & Sullivan's global research organization and provides the basis on which companies can gain a visionary and strategic understanding of the market. The CEO 360-Degree Perspective™ is also a "must-have" requirement for the identification and analysis of best-practice performance by industry leaders.

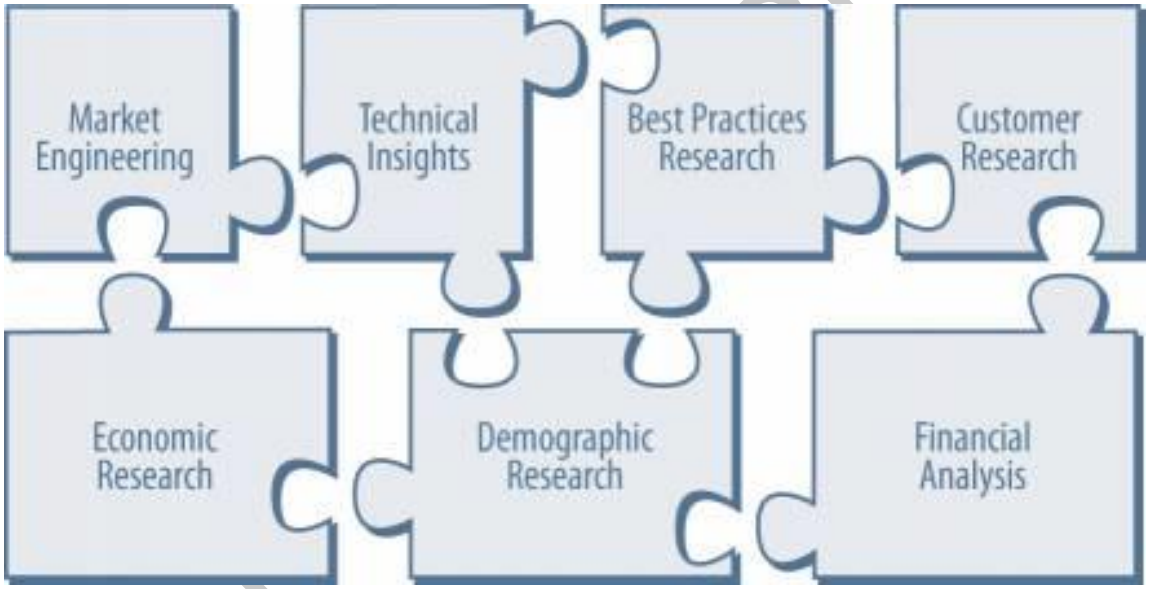
The CEO 360-Degree Perspective™ model enables our clients to gain a comprehensive, action-oriented understanding of market evolution and its implications for their companies' growth strategies. As illustrated in Chart 4 below, the following six-step process outlines how our researchers and consultants embed the CEO 360-Degree Perspective™ into their analyses and recommendations.

Chart 4: The CEO's 360-Degree Perspective™ Model Research

Critical Importance of TEAM Research

Frost & Sullivan's TEAM 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 seven of Frost & Sullivan's research methodologies. Our experience has shown over the years that companies too often make important growth decisions based on a narrow understanding of their environment, leading to errors of both omission and commission. Frost & Sullivan contends that successful growth strategies are founded on a thorough understanding of market, technical, economic, financial, customer, best practices, and demographic analyses. In that vein, the letters T, E, A and M reflect our core technical, economic, applied (financial and best practices) and market analyses. The integration of these research disciplines into the TEAM Research methodology provides an evaluation platform for benchmarking industry players and for creating high-potential growth strategies for our clients.

Chart 5: Benchmarking Performance with TEAM Research



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 50 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from more than 40 offices on six continents. To join our Growth Partnership, please visit http://www.frost.com.