



BIOPORTO[®]
Diagnostics

2014 European
AKI Diagnostics Market
Product Leadership Award



F R O S T & S U L L I V A N



50 Years of Growth, Innovation & Leadership

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Product Leadership AKI Diagnostics Market Europe, 2014

Letter of Congratulations

We are proud to present you with this year's award for best practices in Product Leadership in the acute kidney injury (AKI) diagnostics market.

Frost & Sullivan has a global team of analysts and consultants continuously researching a wide range of markets across multiple sectors and geographies. As part of this ongoing research, we identify companies that maintain consistently high standards for product or service quality and innovation, allowing them to form deep relationships with their customers. This research involves extensive primary and secondary research across the entire value chain of specific products. Against the backdrop of this research, we are pleased to recognize BioPorto Diagnostics for Product Leadership in the AKI diagnostics market.

To achieve product leadership is never an easy task, but it is one made even more difficult due to today's competitive intensity, customer volatility, and economic uncertainty—not to mention the difficulty of innovating in an environment of escalating challenges to intellectual property. Within this context, your receipt of this award signifies an even greater accomplishment.

Moreover, we recognize that your receipt of this award is the result of many individuals (employees, customers, and investors) making daily choices to believe in the organization and contribute in a meaningful way to its future. We believe that such an achievement should be acknowledged and celebrated.

We hope you use this award as a platform for strengthening your brand, building awareness among new and existing customers, and inspiring your team to even greater levels of performance.

Once again, we congratulate you on your achievements and wish you great success in the future. We are here to support you on any future endeavors.

Sincerely yours,



David Frigstad
Chairman
Frost & Sullivan

Background and Company Performance

Industry Challenges

For patients that have been hospitalised or have life threatening diseases, acute kidney injury (AKI) occurs when the kidneys are unable to effectively filter waste products from the blood. Research data indicates that 13 to 18% of patients admitted to hospitals suffer from AKI, and many do not seek follow-up treatment once released from the hospital.

Unidentified or untreated AKI increases the risk of developing chronic kidney disease, which can lead to renal failure, cardiovascular disease, and other organ failures. At that stage, dialysis and kidney transplant may be warranted; but even with that, mortality rates are high. However, AKI is treatable and reversible, if caught early.

Identifying AKI as early as possible while patients are still in the hospital can help prevent AKI from developing into a more severe form. The current gold-standard test is serum creatinine, which has been used to test kidney function for nearly 100 years. The problem is it can take two or three days for the serum creatinine to show AKI.

To speed up detection, researchers have identified biomarkers that provide early diagnosis of AKI. Early diagnosis benefits patients, physicians and hospitals in these ways:

- Allows for early intervention and appropriate management of condition during hospitalisation
- Provides for risk stratification of AKI
- Offers a way to predict clinical outcomes (dialysis, in-hospital death, length of hospital stay, mortality)
- Allows for monitoring of response to therapy
- Helps lower hospitalisation costs

One of the biomarkers identified by researchers as an early indicator of AKI is neutrophil gelatinase-associated lipocalin (NGAL), which can be found in blood plasma or urine samples. Frost & Sullivan believes the use of these rapid response biomarker tests on hospitalised patients, especially in an aging population, can reduce the progression of kidney injury into chronic kidney disease to save lives while reducing higher treatment costs. This is especially critical for those undergoing cardiovascular procedures and kidney transplantation.

Product Family Attributes and Business Impact of BioPorto Diagnostics

Match to Need

BioPorto Diagnostics A/S, based in Denmark, developed the NGAL Test™ to identify this novel biomarker for quick AKI diagnosis and received the CE mark in 2011 for human diagnostic use in the European Union. The test is available for research purposes in countries outside of the European Union. BioPorto Diagnosis' primary business is antibodies for basic research, but the NGAL Test is the only one that has been pushed to diagnostic use.

The greatest benefits of the diagnostic NGAL Test are that results are available in 10 minutes and show AKI within two hours of injury, compared to the serum creatinine test that requires waiting for two or three days following kidney injury. The NGAL biomarker also shows a proportionate response to kidney injury with specificity and provides a clear indicator. That early intervention is essential to prevent irreversible damage to kidneys for hospitalized patients. This is especially important in ICU settings where patients are tested and monitored daily for AKI injury to prevent permanent kidney damage.

Reliability and Quality

A number of research and clinical trial data indicate NGAL is a reliable and accurate test for AKI. Studies also show the NGAL could be used to identify patients most likely to deteriorate from chronic kidney disease. Specifically, BioPorto's NGAL Test also proves reliable in both plasma and urine analysis.

In addition, BioPorto's manufacturing standards ensure a reliable, quality product. BioPorto provides a wide product portfolio that includes assays for underserved diseases such as NGAL for acute kidney injury. For all its products, BioPorto adheres to the highest quality standards in manufacturing and support. The company follows quality management systems in accordance with the European IVD directive, the Canadian medical device regulations, and ISO 13485 requirements.

Design

The NGAL Test works in a number of automated chemical analysers, which means hospitals and clinics do not have to purchase or change equipment to accommodate this diagnostic test, while similar tests are limited to specific chemical analysers. Also since the test works on either urine or plasma samples, this further expands chemical analyser options. While there are competing NGAL tests, those are limited to either urine or plasma, making BioPorto's NGAL Test the only one that can utilise both sample types. Frost & Sullivan sees that this broad application provides greater opportunity for expanded use in clinical and hospital settings, helping differentiate it from competitors.

Positioning and Growth Potential

BioPorto Diagnostics is seeking licensing partnerships with large distributors in the healthcare marketplace. Some agreements are already in place, and the company anticipates more agreements in the near future.

Initially the company is targeting the NGAL Test in Europe, mainly Germany, Italy, Spain, France, and the United Kingdom. The plan is to use direct sales to reach hospitals to educate staff on the benefits of the test. Once hospitals use BioPorto's NGAL Test, they appreciate the rapid results and that it gives them an opportunity to reduce or reverse kidney injury following surgical procedures.

Human Capital

Currently, BioPorto has 28 employees, but see that number growing, especially in regards to sales. A recent restructure of leadership and implementation of a new strategy produced positive results for the first half of 2014 with continued upside potential for the remainder of the year.

BioPorto established a European scientific advisory board of renowned AKI specialists from cardiac, nephrology, and intensive care unit medical areas to identify clinical practices and approaches to improve AKI diagnostics. This group met in May 2014 with another meeting later in the year to review challenges and opportunities for NGAL for kidney transplantation and cardiopulmonary bypass procedures.

Conclusion

As hospital staff and doctors understand the importance of early detection in acute kidney injury, especially in emergency care and intensive care unit settings, identifying and using NGAL biomarker to obtain a rapid result as soon as kidney injury occurs is critical to reducing advancement of chronic kidney disease. BioPorto Diagnostics' focus on developing and marketing of NGAL biomarker test for human diagnostic use in the European Union and its other products for research in other countries, brings the healthcare community closer to reducing the development of chronic kidney disease in hospitalised patients. With its strong overall performance, BioPorto Diagnostics has earned Frost & Sullivan's 2014 Product Leadership Award in the AKI diagnostics market.

Significance of Technology Innovation Leadership

Ultimately, growth in any organization depends upon customers purchasing from your company, and then making the decision to return time and again. A comprehensive product line, filled with high-quality, value-driven options, is the key to building an engaged customer base. To achieve and maintain product excellence, an organization must strive to be best-in-class in three key areas: understanding demand, nurturing the brand, and differentiating from the competition. This three-fold approach to delivering Product Leadership is explored further below.



Understanding Technology Innovation Leadership

Demand forecasting, branding, and differentiation all play a critical role in finding growth opportunities for your product line. This three-fold focus, however, must be complemented by an equally rigorous focus on pursuing those opportunities to a best-in-class standard. Customer communications, customer feedback, pricing, and competitor actions must all be managed and monitored for ongoing success. If an organization can successfully parlay product excellence into positive business impact, increased market share will inevitably follow over time.

Key Benchmarking Criteria

For the Product Leadership Award, we evaluated two key factors—Product Family Attributes and Business Impact—according to the criteria identified below.

Product Family Attributes

- Criterion 1: Match to Needs
- Criterion 2: Reliability and Quality
- Criterion 3: Product/Service Value
- Criterion 4: Positioning
- Criterion 5: Design

Business Impact

- Criterion 1: Financial Performance
- Criterion 2: Customer Acquisition
- Criterion 3: Operational Efficiency
- Criterion 4: Growth Potential
- Criterion 5: Human Capital

Product Family Attributes

Criterion 1: Match to Needs

Requirement: Customer needs directly influence and inspire the design and positioning of the product family

Criterion 2: Reliability and Quality

Requirement: Products consistently meet or exceed customer expectations for performance and length of service

Criterion 3: Product/Service Value

Requirement: Products or services offer the best value for the price, compared to similar offerings in the market

Criterion 4: Positioning

Requirement: Products or services unique, unmet need that competitors cannot easily replicate or replace

Criterion 5: Design

Requirement: The product features an innovative design, enhancing both visual appeal and ease of use

Business Impact

Criterion 1: Financial Performance

Requirement: Strong overall financial performance in terms of revenues, revenue growth, operating margin and other key financial metrics

Criterion 2: Customer Acquisition

Requirement: Product strength enables acquisition of new customers, even as it enhances retention of current customers

Criterion 3: Operational Efficiency

Requirement: Staff is able to perform assigned tasks productively, quickly, and to a high quality standard

Criterion 4: Growth Potential

Requirements: Product quality strengthens brand, reinforces customer loyalty and enhances growth potential

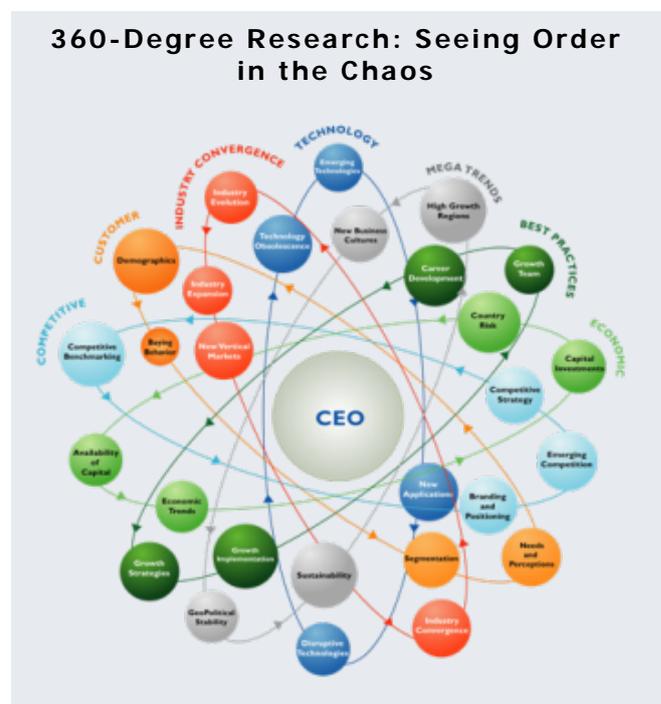
Criterion 5: Human Capital

Requirement: Company culture is characterized by a strong commitment to product quality and customer impact, which in turn enhances employee morale and retention

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

Our awards team follows a 10-step process (illustrated below) to evaluate award candidates and assess their fit with our best practice criteria. The reputation and integrity of our awards process are based on close adherence to this process.

STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1 Monitor, target, and screen	Identify award recipient candidates from around the globe	<ul style="list-style-type: none"> • Conduct in-depth industry research • Identify emerging sectors • Scan multiple geographies 	Pipeline of candidates who potentially meet all best-practice criteria
2 Perform 360-degree research	Perform comprehensive, 360-degree research on all candidates in the pipeline	<ul style="list-style-type: none"> • Interview thought leaders and industry practitioners • Assess candidates' fit with best-practice criteria • Rank all candidates 	Matrix positioning all candidates' performance relative to one another
3 Invite thought leadership in best practices	Perform in-depth examination of all candidates	<ul style="list-style-type: none"> • Confirm best-practice criteria • Examine eligibility of all candidates • Identify any information gaps 	Detailed profiles of all ranked candidates
4 Initiate research director review	Conduct an unbiased evaluation of all candidate profiles	<ul style="list-style-type: none"> • Brainstorm ranking options • Invite multiple perspectives on candidates' performance • Update candidate profiles 	Final prioritization of all eligible candidates and companion best-practice positioning paper
5 Assemble panel of industry experts	Present findings to an expert panel of industry thought leaders	<ul style="list-style-type: none"> • Share findings • Strengthen cases for candidate eligibility • Prioritize candidates 	Refined list of prioritized award candidates
6 Conduct global industry review	Build consensus on award candidates' eligibility	<ul style="list-style-type: none"> • Hold global team meeting to review all candidates • Pressure-test fit with criteria • Confirm inclusion of all eligible candidates 	Final list of eligible award candidates, representing success stories worldwide
7 Perform quality check	Develop official award consideration materials	<ul style="list-style-type: none"> • Perform final performance benchmarking activities • Write nominations • Perform quality review 	High-quality, accurate, and creative presentation of nominees' successes
8 Reconnect with panel of industry experts	Finalize the selection of the best-practice award recipient	<ul style="list-style-type: none"> • Review analysis with panel • Build consensus • Select winner 	Decision on which company performs best against all best-practice criteria
9 Communicate recognition	Inform award recipient of award recognition	<ul style="list-style-type: none"> • Present award to the CEO • Inspire the organization for continued success • Celebrate the recipient's performance 	Announcement of award and plan for how recipient can use the award to enhance the brand
10 Take strategic action	Upon licensing, share award news with stakeholders and customers	<ul style="list-style-type: none"> • Coordinate media outreach • Design a marketing plan • Assess award's role in future strategic planning 	Widespread awareness of recipient's award status among investors, media personnel, and employees

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>.

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