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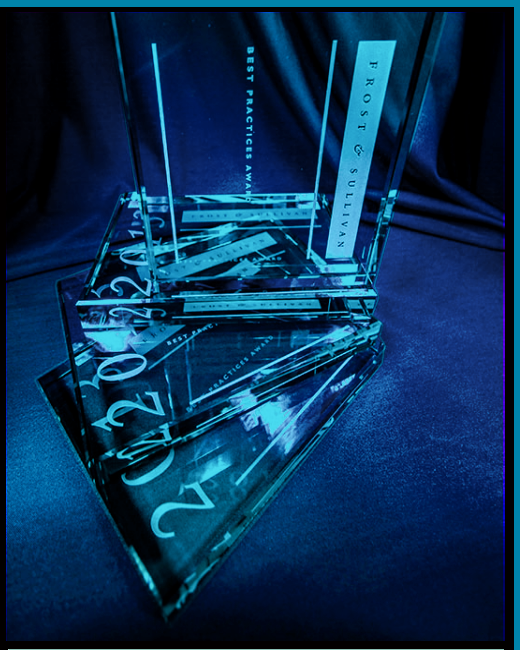
admera health

2016 North American NGS Molecular Diagnostics Panel Technology Innovation Award



FROST & SULLIVAN

2016 BEST PRACTICES AWARD

NORTH AMERICAN
NGS MOLECULAR DIAGNOSTIC PANEL
TECHNOLOGY INNOVATION AWARD

2016
BEST PRACTICES
AWARDS

Contents

Background and Company Performance

Industry Challenges

With the advent of next-generation sequencing (NGS)-based technologies and the substantial reduction in sequencing costs, the promise of personalized medicine is becoming more and more evident. Frost & Sullivan monitors the many companies that have sprung up across the molecular diagnostics space, especially for the development of genomic-based solutions. However, Frost & Sullivan independent analysis reveals that market participants face significant challenges.

Although traditional NGS-based tests are available, there is a critical need for genetic tests that detect multiple gene markers at once by inputting a smaller amount of nucleic acids.

Molecular diagnostics based on NGS must be to detect a range of variants - known as variant calling. These variants could be small or large insertions, deletions, gene copy number variants (CNVs), or even gene fusions. The detection of complicated variants will enable improved understanding of a patient's genetic makeup. These capabilities in pharmacogenomics and cancer molecular tests would enable physicians to improve their treatment regimes.

At times, however, clinicians do not require a comprehensive test, instead preferring more specific tests that cater to one type of cancer or disease.

Frost & Sullivan notes that properly managing the high volumes of data is another major challenge for molecular diagnostic participants that provide clinical laboratory services. They require specific algorithms and specialized infrastructure to manage and maintain data.

A major hurdle that typically occurs during marketing and commercialization is the lack of reimbursements and regulatory approvals. It is vital that the tests developed have the required certification from regulatory bodies.

Frost & Sullivan agrees that companies in the molecular diagnostics space should capitalize on convergence opportunities by developing strategic partnerships to enable further expansion in research and development as well as commercialization and marketing.

Although many companies are developing molecular diagnostics using NGS as the foundation, Frost & Sullivan firmly believes that Admera Health stands out with its innovative pipeline as well as its robust molecular diagnostics panels. The company is forging a path towards providing physicians and patients with precision solutions.

Technology Attributes and Future Business Value

Industry Impact

Advances in genomic sequencing offer great potential for the growth of personalized medicine. However, fragmentation in the current healthcare delivery systems is hindering a balance between patient-centered care and targeted treatments. Numerous companies are focused on bringing about this revolutionary change with precision treatment options.

Admera Health, a next generation molecular diagnostics company, is using its expertise to extend this continuum of care by looking beyond conventional diagnostics methodologies to provide a series of diagnostic tests that give patients and physicians the relevant resources and information to make more informed treatment decisions. Admera's molecular diagnostic panels have been founded on the rapidly evolving area of NGS platforms.

Admera provides a range of tests that can be used across the entire continuum of patient care (i.e., screening, diagnosis, treatment, monitoring, and patient management), including the seasoned PGxOne™Plus, CardioGxOne™, and oncology tests. PGxOne™ Plus is a pharmacogenomics test that predicts how patients will respond to drug therapy related to pain management, cardiovascular disease, psychiatry, cancer, and other indications. The CardioGxOne™ panel tests for inherited cardiovascular diseases providing clear genetic interpretation for risk assessment and disease diagnosis. Admera's cancer testing offerings include the OncoGxOne™ and OncoGxSelect™. The former is a comprehensive cancer panel that accounts for a range of genomic variations related to targeted therapies and chemotherapeutic response, while the latter is focused on well-established and medically actionable mutations found in lung cancer. The company is also developing multiple products with high potential commercial values. Its liquid biopsy technology reaches industry-leading sensitivity and specificity in circulating tumor DNA (ctDNA) mutation detection for cancer treatment guidance and monitoring, and its aptamer-based technology has several potential applications, such as lung cancer and acute diseases. Finally, the company is currently developing a portfolio of digital health tools associated with various genetic diseases and health management.

With this wide product range and growing pipeline, Admera Health is on the correct trajectory to assist the healthcare system by reducing the overall cost burden through the development of well-informed treatment programs.

Product Impact

The PGxOne™ Plus pharmacogenomics test can screen a patient's genetic makeup to determine reactions to a specific drug based on absorption and metabolism or whether a drug can be used with other prescribed drugs. Physicians can use the PGxOne™ Plus test to gain a comprehensive understanding of a patient in the process of developing an

appropriate treatment regime. Integrating pharmacogenomics results in the design of therapeutic regimes could prevent adverse drug interactions and other side effects related to a patient's inability to handle a specific drug or drug component.

The cost-effective PGxOne™ Plus test can comprehensively assess 25 genes. Its report provides drug recommendations, such as whether a dosage should be altered - or whether a completely different therapy should be prescribed.

The PGxOne™ Plus test can detect CNVs in the CYP2D6 gene, which encodes a liver enzyme that is responsible for 25% of the drug metabolism. CNVs are difficult to detect structural variations, but account for approximately 13% of human genomic DNA. Using proprietary algorithms, Admera is able to detect and provide detailed information on the CNV of CYP2D6. PGxOne™ Plus has displayed a positive detection rate (sensitivity) and a negative detection rate (specificity) of 100%.

Once a patient's buccal swabs are received in the laboratory and the quality of DNA is ascertained, the PGxOne™ Plus amplicon libraries are created and sequenced on the Illumina™ platforms. These are analyzed, and comprehensive information on a patient's genotype and phenotype, along with clinical recommendations, are provided. The PGxOne™ Plus test can give physicians information about more than 150 commercial drugs related to 25 pharmacogenomic genes. The genes tested by the PGxOne™ Plus have been recommended in having clinical implications by the FDA, EMA, and CPIC.

Research posted by the American College of Cardiology shows that close to 30% of patients who are receiving warfarin therapy could be weaned off of it; this could save billions of dollars in healthcare costs.

Visionary Innovation

Frost & Sullivan tracks how the convergence of technologies can truly disrupt industries in need of change. Admera Health is clearly demonstrating its own technological integration as part of its vision to provide better molecular diagnostics. It is tapping into the genomic data space to provide the PGxOne™ Plus using NGS technology. The company has transitioned from conventional microarray assay-based tests, largely due to explosive NGS growth and its scientific superiority and specificity. Using NGS, the company's pharmacogenomics test can detect nucleotide substitutions, insertions and deletions, and CNVs. The company is well aware of the huge data output that takes place using NGS and has strived to find an appropriate solution for data management. Its bioinformatics team actively analyzes and interprets PGxOne™ Plus test data and provides an easy-to-understand, clinically relevant report that a physician will use to develop an appropriate treatment regime.

Admera has partnered with WaferGen Biosystems, a company that focuses mainly on the development of innovative NGS solutions. Through this partnership, Admera has

implemented WaferGen's target enrichment technology, which enables Admera's NGS PGxOne™ Plus panel to attain complete coverage of required genes. To further its growth and provide a more scalable platform, the company has also partnered with hc1 Healthcare Relationship Cloud® as its CRM partner to systemize relationships.

Frost & Sullivan already recognizes hc1 as a leader in the healthcare technology space, especially in providing healthcare relationship management services. This partnership will certainly foster the personalized approach that Admera desires for its patients and physicians.

Application Diversity

Admera is working across a wide range of molecular diagnostics. Its OncoGxOne™ test assays 64 genes, of which 56 genes are related to targeted cancer therapies, and 8 are related to chemotherapeutic response. The comprehensive test assesses all exons, select introns that could represent gene translocation breakpoints, and 5' and 3' UTRs across the target genes. The test sample is the standard format of formalin fixed paraffin embedded (FFPE) tissue, which makes it easier for physicians accustomed to using standard formats that have historically worked well. Admera's OncoGxSelect™ panel is more specific to lung cancer by focusing on 5 specific genes: KRAS, BRAF, EGFR, ROS1, and ALK. It also detects a range of point mutations, indels, and gene fusions, which provide physicians with information to guide better treatment regimes. Admera markets the OncoGxOne™, OncoGxSelect™, and PGxOne™ Plus through Rosetta Genomics and multiple other sales distribution channels throughout the US and abroad.

The CardioGxOne™ panel is a test developed in concert with Health In Code, a European molecular diagnostics company focused on inherited cardiovascular diseases. This panel tests 213 genes involved in cardiovascular disease etiology; with target inclusion based on a proprietary, and arguably largest, clinical knowledgebase. This knowledge base includes nearly 30,000 publications, 25,000 family genetic histories, and 300,000 genetic variants.

Admera's ambitious pipeline includes its innovative liquid biopsy BEST™ technology, which will be clinically validated in a prospective multi-site, academic medical center–based clinical study to demonstrate concordance between invasive tissue biopsy and the blood samples. Internal validation results demonstrate analytic sensitivity of<0.01% mutant allele fraction.

To support its NGS portfolio, Admera has developed a fully automated genomic interpretation system AGIS™ to enable its digital health portfolio. Of importance, this bio-informatics technology platform allows for the company to participate in the rapidly growing whole exome sequencing market.

Admera has ventured into the microbiome testing space with FloraCheck™ tests that can quantify the amount of beneficial and harmful bacteria in a patient. This is important for patients who require prescription of probiotics. FloraCheck™ allows physicians to identify the pathogen causing a disease, as well as characteristic traits (such as phenotype, strain, and rate of growth). The test targets the V3, V4, and V5 hypervariable regions across the 16S gene. Unlike other microbiome tests, this will not require a spike in DNA, resulting in more efficient, faster, and more sensitive information.

Technology Licensing

The FDA has identified a range of in vitro diagnostics tests (known as laboratory developed tests) that can be used to detect and measure a range of analytes. Admera and many other molecular diagnostics participants work in this space, as it is an efficient way to reach consumers who need companion diagnostics. PGxOne™ Plus, CardioGxOne™, OncoGxOne™, and OncoGxSelect™ have been approved for clinical use by the New Jersey Department of Health. Admera, upon physician request, delivers the PGxOne™ Plus specimen collection supplies containing the test requisition and sample collection materials. A patient's two buccal swabs specimen are collected and returned for processing, with a report delivered within 7 to 10 business days. The test results are provided in a clinical report format, and all data are analyzed and interpreted by Admera's internal bioinformatics team using proprietary algorithms. While insurance coverage is a prominent problem in molecular diagnostics, PGxOne™ Plus is covered by a number of insurance providers.

Brand Loyalty

Admera Health previously served as the clinical services business unit for GENEWIZ, Inc., a global contract research organization. It became an independent business entity in 2014 and started to provide a range of genomic clinical services, but still benefits from the GENEWIZ brand name. Admera has established itself in the precision medicine field, and completed its Series A financial round with two well-known investing and strategic partners: PVCM and Bioventure. The money raised will be used for expansion plans — especially to increase research and development. A crucial aspect of the molecular diagnostics field is accreditations. Admera Health has a CLIA-certified (Admera Health CLIA ID 31D2038676), CAP-accredited laboratory (CAP Accreditation Number: 8042469) that allows it to deliver laboratory developed tests.

Conclusion

Admera Health is actively transforming the precision medicine field with an impressive set of NGS-based molecular diagnostics. It has developed the PGxOne™ Plus pharmacogenomics test that enables the analysis of specific genes linked to adverse drug reactions. The test can provide detailed and comprehensive report on CNVs that are typically involved in drug metabolism and then recommended actions that can prevent adverse events. Admera has a large pipeline of products in development for utilization across the continuum of care — from screening, diagnosis, and treatment to monitoring and patient management. The company has developed a noninvasive, blood-based liquid biopsy cancer test, and a fully automated bioinformatics platform as its digital health base. Admera has obtained the necessary regulatory laboratory accreditations and is keeping up with compliance of its laboratory-developed tests. Its multiple partnerships enable product marketing and distribution, and the use of healthcare client management experts.

With its strong overall performance, Admera Health has earned the 2016 Frost & Sullivan 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. This spark can result from a successful partnership, a productive in-house innovation group, or the mind of a single 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

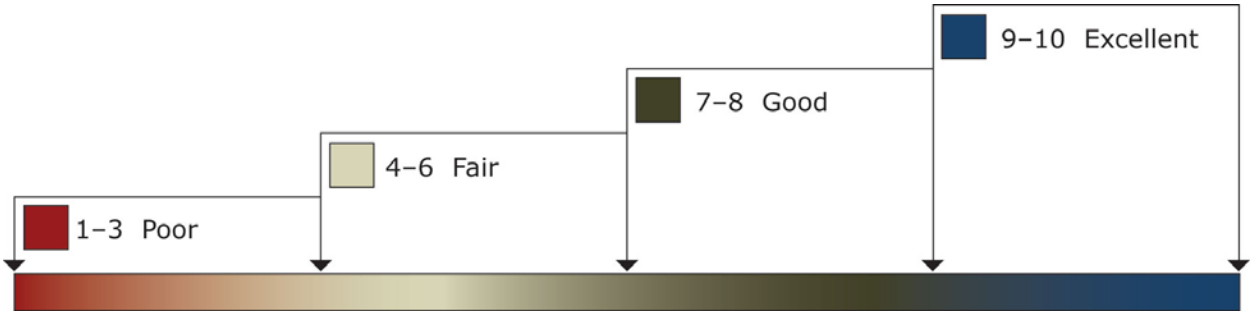
Criterion 1: Financial Performance
Criterion 2: Customer Acquisition
Criterion 3: Technology Licensing
Criterion 4: Brand Loyalty
Criterion 5: Human Capital

Best Practice Award Analysis for Admera Health

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.

DECISION SUPPORT SCORECARD FOR TECHNOLOGY INNOVATION AWARD

Measurement of 1–10 (1 = poor; 10 = excellent)			
Technology Innovation	Technology Attributes	Future Business Value	**Average Rating**
Admera Health	**9.0**	**9.5**	**9.3**
Competitor 2	8.0	8.0	8.0
Competitor 3	8.0	7.0	7.5

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

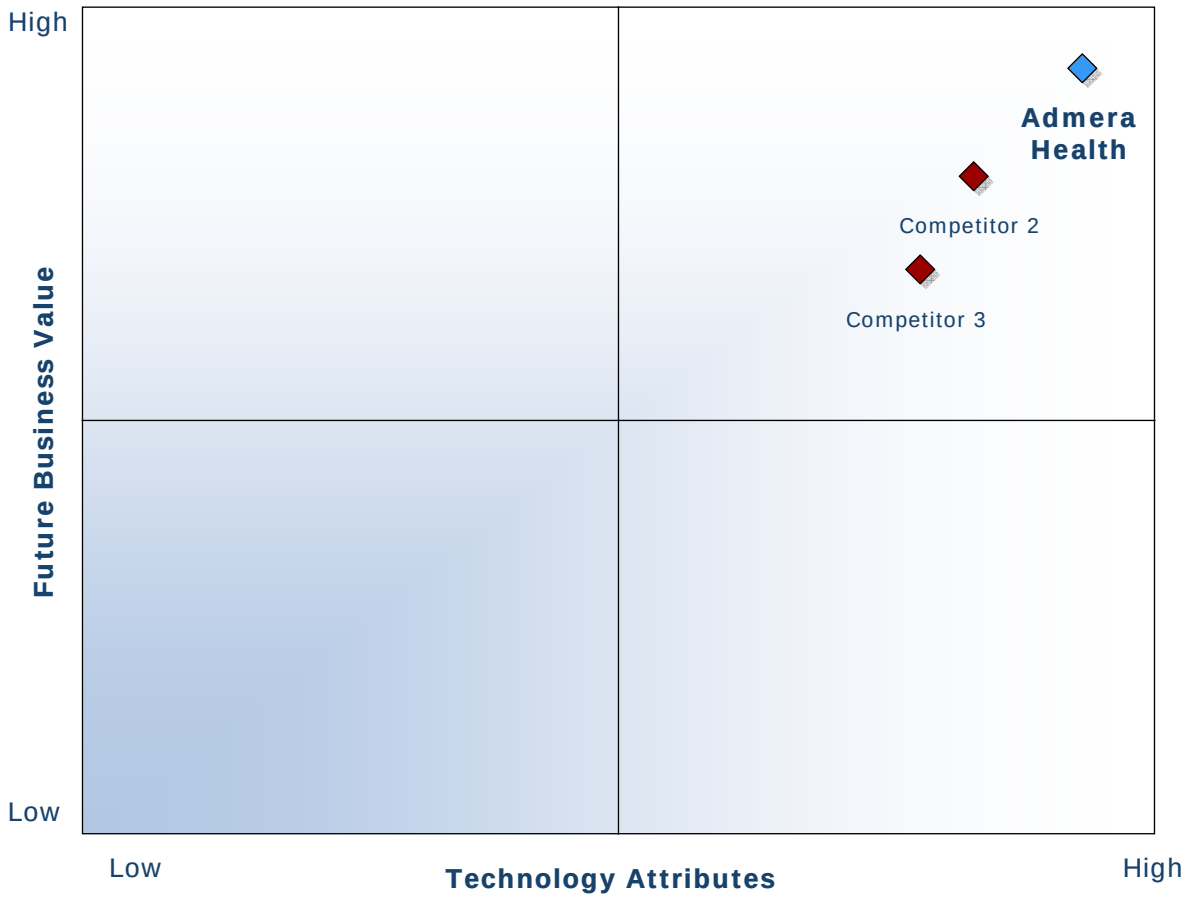
Criterion 5: Human Capital

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 FOR TECHNOLOGY INNOVATION AWARD



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.

360-DEGREE RESEARCH: SEEING ORDER IN THE CHAOS

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.

	STEP	OBJECTIVE	KEY ACTIVITIES	OUTPUT
1	**Monitor, target, and screen**	Identify Award recipient candidates from around the globe	• 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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	• 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, company may share Award news with stakeholders and customers	• 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.