

2009 North American Product Innovation Award**Magellan Biosciences**

The 2009 Frost & Sullivan Product Innovation Award in the field of point of care heavy metal toxicity testing goes to Magellan Biosciences. The company has been recognized for its lead toxicity testing product known as the LeadCare® II. This second-generation device uses electrochemical detection to perform rapid testing for lead concentration in blood. A CLIA-waived version of its original LeadCare® system, LeadCare II is portable and easy to use by any healthcare professional without specialized training or certification. By contrast, traditional laboratory-based blood-lead testing employs large-scale, highly complex instrumentation that require significant skill and expertise to operate.

Company Background

Magellan Biosciences is a privately held, medical and laboratory analytical equipment developer headquartered in Massachusetts. The company is majority-owned by Massachusetts based Ampersand Ventures. Other investors include Abingworth Management, Boston Community Venture Fund, Hambrecht & Quist Capital Management, KBL Healthcare Ventures, New England Partners Capital LP, and Nexus Medical Partners II SICAR.

The company began operations in October 2004 and it emerged as a combination of two prominent and dynamic companies in the medical diagnostics domain, namely ESA Biosciences and Dynex Technologies. The latest acquisition by the company was in November 2006, when TREK Diagnostic Systems, a global provider of products for microbiology labs, joined the flagship company Magellan Biosciences. The company develops and delivers a wide array of analytical technologies to the market which varies from stand-alone instruments and reagent consumables, to fully integrated systems for complex sample analyses. These products have applications not only in the industrial R&D sectors but also in the academic markets.

Relevance in the Market Place

Numerous patients worldwide become sick each year owing to toxic metal poisoning. US Census Bureau data published in 2007 states that there are approximately 20 million children below five in the US who are most susceptible to the harmful affects of lead poisoning.

Lead tests on whole blood samples are federally mandated for all children enrolled under Medicaid insurance at one and two years of age. However, data gathered from surveys in US estimate that fewer than 25 percent of these children are being tested. Public health experts believe a primary reason that compliance for lead testing is so low is that most at-risk children are sent off site from the clinic where they receive their healthcare to an outside lab, where a sample is drawn. Few children make it to the off-site lab. Or, if the sample is drawn at the clinic, it is typically sent off-site to a reference lab for analysis. In either case, the child goes home without a result; results can take days or weeks to get back to the child's healthcare provider, and the clinician risks losing track of the child when treatment is needed.

Experts agree that the best way to ensure that children receive mandated testing is to bring the test to the child, not the child to the test. Hence, government agencies have been funding the development of portable devices designed to enable the children suffering from lead toxicity or poisoning to be tested.

How the Technology Works

LeadCare II[®] employs electrochemistry to measure a patient's blood lead level from just two drops of blood using a portable analyzer and disposable sensors, similar to glucose test systems. The underlying method is called Anodic Stripping Voltammetry (ASV). It is a highly precise and almost interference free method, where the blood sample is directly added to the reagent solution. This reacts with the sample and any lead present is released from the blood components. Lead present in the reagent solution is concentrated and plated onto a thin film electrode during the electroplating step of the sample analysis cycle. This plated lead is then removed from the electrode by applying stripping current and thereby the amount of lead is measured by integration of the electrical current released during this rapid electrochemical step. The current used or released during the stripping step is directly proportional to the amount of lead present in the sample.

LeadCare II[®] is unique in that it is the world's only CLIA-waived blood lead test. In addition to improved patient care, doctors are motivated to perform the test by a favorable reimbursement / cost per test ratio.

The LeadCare II[®] system removes all the complications such as waiting days for lab results, spending precious staff time and resources trying to contact patients for critical follow-up care, or tracking down lab results for record-keeping, reporting, or compliance purposes, which were formerly associated with blood-lead testing. Its CLIA-waived status enables a evolutionary transition in lead testing enabling practitioners to test, educate, and initiate follow-up actions on the spot, and all in one visit during the routine well-child check-up. This approach is convenient and easy for the child, parent, and healthcare provider, and thus, it is the most-effective way to ensure those at greatest risk for lead poisoning actually receives mandated lead tests.

The administration of the procedure or the protocol is much simpler when compared to the traditional blood-lead tests. The LeadCare II[®] device requires only a finger-stick sample, can be combined with other routine waived blood tests, and saves considerable administrative time spent on paperwork, tracking, and follow-up. Practitioners have even been able to do multiple different tests from a single lancet puncture. These tests include the types of blood lead, hemoglobin, and ZPPH, a test for iron deficiency anemia.

Where it has been implemented, providers serving at-risk children have found that using the point-of-care system provides a significant public health benefit in both the short- and long-term. When children are identified with significantly elevated lead levels, they are taken directly to the hospital for confirmation and follow-up, allowing life-saving treatment to start in a matter of hours, rather than days or weeks, a danger of prescription-based or send-out testing methods. Significantly, educating parents on the hazards of lead at the same time they see their child's lead-levels come up on the LeadCare II[®] screen has a dramatic effect in improving overall compliance with follow-up visits and reducing future lead exposure. Parents get to understand the implications and take action to ensure that they follow physician recommendations and that their child's surroundings remain lead-free. The immediate results from the LeadCare II[®] also bolster lead enforcement programs, which use elevated results tied to a specific address to target lead remediation and enforcement actions.

Best Practices

Magellan Biosciences is an emerging leader in the global clinical-diagnostics market, serving customers with rapid point-of-care analyzers and automated systems for

hospital-based labs and near-patient testing that improves clinical outcomes. The products innovated by the company are also used for life-science research and QA/QC. This company has attained fast organic growth throughout the years with scale, momentum, and ambitions to be an innovator and market leader. The organization is built out of a well seasoned management team and motivated employees who deliver consistent performance ensuring the company's double-digit organic growth. The company has built a good value proposition out of strong platform technologies for point-of-care, hospital-based laboratory markets, and for life science research, as well as compelling, high-quality products and a robust new product pipeline. Going further, in the near future the company is also looking forward to accelerate its growth inorganically, through acquisitions. The LeadCare II[®] product is one of the latest developments from Magellan Biosciences having a unique value proposition in terms of efficiency and speed of testing.

Conclusion

Frost & Sullivan is pleased to present the 2009 North American Product Innovation Award to Magellan Biosciences in recognition of the company's work in developing the LeadCare II[®] system. With strong capabilities and credentials, Magellan Biosciences is presently well-positioned to carve a niche for itself by addressing the present day challenges of bulky instrumentation and complex circuitry through a product that is not complex and is affordable.

Award Description

The Frost & Sullivan Award for Product Innovation is presented each year to the company that has demonstrated excellence in new products and technologies within its industry. The recipient company has shown innovation by launching a broad line of emerging products and technologies.

Research Methodology

To choose a recipient of this Award, the analyst team tracks all new product launches, research and development (R&D) spending, products in development, and new product features and modifications. This is accomplished through interviews with the market participants and extensive secondary and technology research. All new product launches and new products in development in each company are compared and

evaluated based on degree of innovation and customer satisfaction. Companies are then ranked by number of new product launches and new products in development.

Measurement Criteria

In addition to the methodology described above, there are specific criteria used to determine final competitor rankings in this industry. The recipient of this Award has excelled based on one or more of the following criteria:

- Significance of new product(s) in its industry
- Competitive advantage of new product(s) in its industry
- Product innovation in terms of unique or revolutionary technology
- Product acceptance in the marketplace
- New product value-added services provided to customers
- Number of competitors with similar product(s).

About Best Practices

Frost & Sullivan Best Practices Awards recognize companies in a variety of regional and global markets for demonstrating outstanding achievement and superior performance in areas such as leadership, technological innovation, customer service, and strategic product development. Industry analysts compare market participants and measure performance through in-depth interviews, analysis, and extensive secondary research in order to identify best practices in the industry.

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