

**2009 Global Immune Health Excellence in Research of the Year Award****Biothera**

The 2009 Frost & Sullivan Excellence in Research of the Year Award in the world immune health market is presented to Biothera. The award recognizes the company's outstanding endeavor in conducting several research projects since 1997 that resulted in immunity enhancing ingredient, Wellmune WGP®. This fruitful outcome was further validated for its positive health benefits through numerous clinical tests. The multidimensional and progressive research accomplishments of Biothera have helped establish Wellmune WGP®'s functionality, across several industries, such as functional foods and beverages and dietary supplements. Apparently, Wellmune WGP® is now considered a benchmark in the market for immune health ingredients. With exhaustive intellectual property patents over Wellmune WGP® and competent research staff, Biothera is set to continue its dominance in the field of scientific research on Wellmune WGP®.

**Consistent Research Expertise**

Biothera is a world renowned manufacturer of Wellmune WGP® and other food-grade ingredients that provide healthy immune function to the functional food and beverage, nutritional supplement, cosmetic, and animal nutrition products. Biothera's Wellmune WGP® is acclaimed to be one of the most evidence-based natural food and beverage ingredients in the industry that activates key immune cells including macrophages and neutrophils and protects against stress-induced health challenges. This has been validated by numerous scientific/clinical studies conducted at some of the world's leading universities and research institutions, and has been widely published in peer-reviewed medical journals.

Two recent clinical studies involving marathoners, individuals with high level of stress lifestyles, and the general population confirms the effectiveness of Wellmune WGP® among a dozen peer-reviewed studies.

- In 2007, a clinical study confirmed Wellmune WGP®'s potential to increase vigor and mental clarity, while reducing fatigue and upper respiratory tract infection symptoms in marathon runners. The double-blind, placebo-controlled study included 75 marathon runners who consumed 250 mg Wellmune WGP® or placebo for four weeks. Marathoners who took 250 mg of Wellmune WGP® daily reported a 22 percent increase in vigor, 48 percent

reduction in fatigue, 38 percent reduction in tension, 38 percent reduction in stress-related confusion, and 66 percent fewer upper respiratory tract infection symptoms, compared with runners treated with a placebo.

- In 2008, another clinical study corroborated Wellmune WGP®'s ability to decrease the amount of upper respiratory tract infections, compared to a similar group of firefighters taking a placebo. The single-blind, randomized, cross-over study included 54 wildland firefighters who consumed Wellmune WGP® or placebo for 14 days. Of the wildland firefighters who took placebo, 48 percent experienced upper respiratory tract infection, while it was only 37 percent for those on Wellmune WGP®.

These aforementioned researches conducted by Biothera on its Wellmune WGP® indicative of the positive consumer group for the product. This product is the company's solution to target consumers who now actively want to protect themselves from mental and physical stress in high-stress real life situations. Therefore, in 2007, the American College of Clinical Nutrition at its annual conference presented the results of both the studies, followed by the publication of the results in a peer-reviewed scientific journal.

### **Clinically Proven Safety and Efficacy of the Product**

Designed for functional foods and beverages and dietary supplements, Wellmune WGP® is a versatile ingredient with a broad range of health benefits, while confirming its safety and efficacy since 1997. Wellmune WGP® is the only specialty ingredient that has been clinically proven to naturally activate the body's innate immune cells to more quickly recognize and kill foreign intruders, resulting in a more complete immune response. For instance, in 2008, the results of a study conducted independently by Miami Research Associates (for Biothera) established that Wellmune WGP® naturally boosts the body's innate immune response, successfully protecting it against and ameliorating the symptoms of common cold. This study has been very recently accepted for publication in *The Journal of Applied Research in Clinical and Experimental Therapeutics*.

Wellmune WGP® has been demonstrated as the most safe and effective immune health ingredient in numerous peer-reviewed clinical (human) and preclinical studies. The immune health ingredient has received the 'generally recognized as safe' (GRAS) status, approved under the provisions of the U.S. Food and Drug Administration 21CFR170.35, and, in 2009, it received non-novel foods status in Canada. Wellmune WGP® stands as a gold standard for the depth and breadth of its research, which other GRAS immune health ingredients are striving to match in today's competitive market scenario. Additionally, Wellmune WGP® is also Kosher-certified, is non-

allergenic, and is free of genetically modified organisms (GMO). The supplement is available as a soluble and insoluble powder for formulation in foods and beverages, including clear liquids, and thus is easy for daily consumption. Its sensory attributes are characterized as being pleasant, lending versatility to formulation.

In July 2007, Wellmune WGP® was honored with the prestigious 2007 Institute of Food Technologists (IFT) Food Expo Innovation Award at the IFT annual meeting in Chicago. This proves that Wellmune WGP® has set a new benchmark for all functional food, beverage, and dietary supplement ingredients, in terms of its proven immune-health benefits, efficacy, strong safety profile, long-term stability, ease of formulation, and research portfolio, and stands the highest probability of becoming an undisputed immune support ingredient in the near future.

### **Keen Focus on Research and Development**

Biothera's determined research and development (R&D) efforts toward scientific Wellmune WGP® studies are highly commendable in the market. It has outperformed its competitors for conducting continuous research on Wellmune WGP® and its health effects on humans over the last 12 years. The company along with its research collaborators has invested more than \$250 million on R&D, which is at least 50 percent of the company's annual revenues. The company collaborates with most leading medical and government institutions, including the Brown Cancer Center at the University of Louisville, the National Institute of Health, The Mayo Clinic, and the U.S. and Canadian Departments of Defense, in order to advance the science of immune therapy. The eminent researchers of these institutions, experienced scientists, and competent staff have contributed immensely to Biothera's 12 year-long and successful commitment toward research on Wellmune WGP®.

The research that the company undertakes on the pharmaceutical side benefits its health care (HC) business directly. Its HC business includes the portfolio of immune health ingredients for use in food, beverages, cosmetics, supplements, and animal nutrition. For instance, the company is well versed with how its ingredients impact various immune bio-masses, that is, elements in the immune system, such as the cells, chemicals messengers (cytokines and protein masses). Thus, the fact that the company can leverage its pharmaceutical business for applying research to enhance the immune system benefits the company's HC business.

### **Wide Breadth of Intellectual Property Ownership**

Wellmune WGP®, an evidence-based proprietary strain of yeast, is protected by Biothera's intellectual property portfolio that includes more than 40 U.S. patents and

patents pending, and has additional filings in more than 20 countries. Biothera states that its patents effectively protect the composition, manufacturing process and application of its ingredients. Moreover, Biothera can protect the end-users' supply chain with the only ingredient available in the market - Wellmune WGP®, containing beta 1,3/1,6 gluco polysaccharide that is patented for use in dietary supplements and functional foods and beverages.

### **Successful Global Market Penetration and Acceptance**

Wellmune WGP® has a huge demand from food manufacturers and is widely accepted among health-conscious consumers. Some of the key food applications in which the ingredient has already been incorporated or is fully compatible for fortification include nutritional bars, yogurts, muffins, chews, truffles, breads, cheeses, soups, crackers, cereals, cookies, snacks, juices, dairy-based beverages, waters, sports and energy drinks, coffees, teas, powdered beverages, and dietary supplements. Currently, a number of major food and beverage companies in the United States and other parts of the world have already expressed significant interest in its technology and Wellmune WGP® as a true functional element in food and beverages. The only factor attributing to the growing interest in Wellmune WGP® is that the company's food-grade ingredients are scientifically proven to enhance immune health in humans and animals.

Besides providing immune health ingredients for products worldwide, Biothera also markets its own line of finished retail products including its proprietary brands such as Immune Health Basics and Life Source Basics. Customers can avail these brands containing Wellmune WGP® in various nutrition and health food stores and on the Internet, in a variety of dose sizes for adults, as children's chewables and as skin renewal creams. In total, there are about 75 products worldwide spanning the nutritional supplement, functional food, cosmetic, and animal nutrition markets that contain Biothera's branded ingredients. With 12 years of credible research and safety data backing the ingredient, Wellmune WGP® is expected to continue dominating the health ingredients market in the future as well.

The company has been forming alliances with an extensive network of distribution channels throughout Europe, Australia, Malaysia, Thailand, the Philippines, and other Asian countries. This has enabled the company to efficiently serve its customer base, offering the best conditions and unlimited possibilities for customers to work optimally in their local markets. The company has also started making inroads into the growing Latin American market after entering into a partnership in Mexico. Besides partnering with distributors, the company has also signed joint venture contracts with some of the best local participants, for instance, Nippon Biothera Co., Ltd. and Sino-Biothera Inc. in China and Japan respectively. These partnerships

benefit the company by offering a possibility to reach out to customers across all the food markets, where the company currently does not have direct access.

Moreover, achieving GRAS status in the United States was an important milestone for the company that helped it immensely in the commercialization of its ingredients in the functional food and nutrition marketplace. With expansion in distribution network, the company is consistently penetrating new markets and products, over the years.

### **Competitive Edge**

One of Biothera's collaborative research partners, Brown Cancer Center at the University of Louisville, conducted a study comparing the immune-enhancing properties of the Wellmune WGP® to that of various other immune-health enhancing ingredients, such as those from mushroom extract and Echinacea. The study concluded that Biothera's Wellmune WGP® has superior efficacy over other competing immune health ingredients in the market.

Biothera is, therefore, the leading company in the research of yeast-derived beta glucans. Other beta glucans available in the market are generally derived from sources such as oats, barley, and mushrooms. Mushroom glucans have immune health-enhancement properties and barley glucans have cholesterol-lowering properties. However, years of research confirm that yeast glucans are superior to mushroom glucans, in terms of their ability to boost the immune system. A further analysis conducted by researchers on certain other yeast-derived beta glucan products available in the market confirmed that they are not as pure as Biothera's Wellmune WGP®. In addition, the companies offering those products rely on Biothera's research, in order to support the marketing of their products, and are hence not considered as serious competitors by Biothera.

### **Research Pipeline**

Researchers at Biothera are actively looking out for new synergies, reviewing and researching new ingredients that might work with its existing ingredients or alone to promote the immune system. For instance, Biothera is in the process of looking at ingredients that can work synergistically with its existing ingredients (such as anti-oxidants like Vitamin C, Vitamin E, or berry extracts that have strong anti-oxidant potential) to further strengthen its immune-enhancing potential. The company conducts the litmus test to understand how these ingredients work in order to boost the immune system. Biothera has strong research ethics and delivers only well-researched ingredients/ingredient solutions to the market. Hence, safety validation

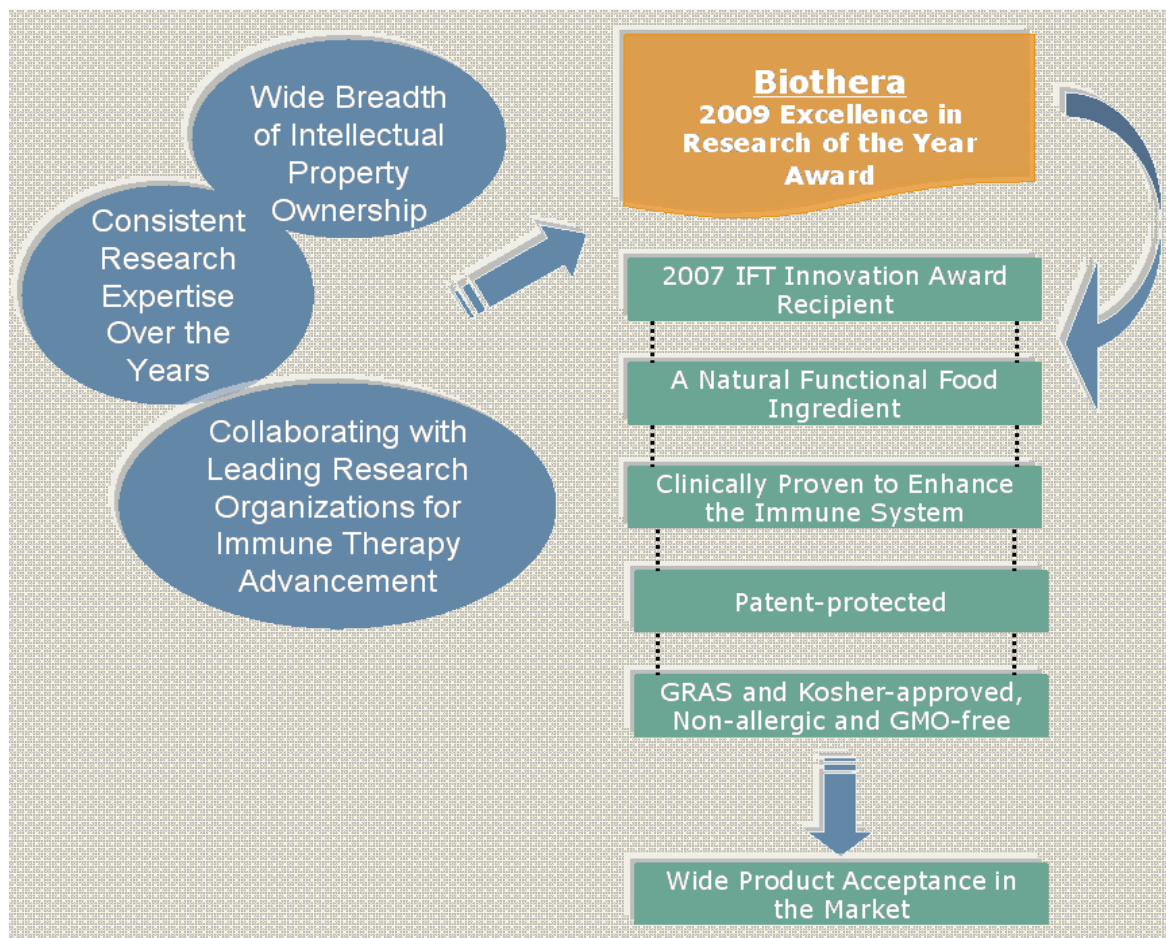
and a deep understanding of mode of action are the key factors that Biothera considers before an ingredient/ingredient solution is rolled out into the market.

Biothera, as a research-focused company, is expected to continue its unrelenting efforts aimed at unveiling hidden facts about the immune system, at the same time providing strong science back-up for its immune-health ingredients. These endeavors are expected to be bolstered by uncompromising research investment, studies conducted by independent and collaborative research bodies, scientific publications, and patents.

Chart 1.1 presents the factors contributing to the Frost & Sullivan Excellence in Research of the Year Award for Biothera in the World immune health market in 2009.

Chart 1.1

Immune Health Market: Factors Contributing to the Frost & Sullivan Excellence in Research of the Year Award for Biothera (World), 2009



## Conclusion

Positioned as a natural immune-enhancing ingredient, Wellmune WGP® is the result of extensive and dedicated research conducted by Biothera. The company has successfully yielded verified reports on a host of health benefits of Wellmune WGP® and continues to conduct extensive research on expanding its beneficial health applications. As a result of the rigorous research, Wellmune WGP® has been established as a clinically proven and highly effective ingredient with impressive consumer appeal and a receptive global market of significant size. Moreover, with several advantages over similar extracts and potential to become an industry standard, Wellmune WGP® has gained worldwide acceptance. All the above factors clearly indicate the competitive edge the company has exhibited over other participants in the market; thereby, making Biothera the worthy recipient of the 2009 Frost & Sullivan Excellence in Research of the Year Award in the world immune health market.

## Award Description

Frost & Sullivan's Excellence in Research of the Year Award is bestowed upon a company that has carried out new 'disruptive' research; and has, in general, a strong commitment to research and development. This award recognizes a company's research and development program that has or is expected to bring significant contributions to the industry in terms of adoption, change, and competitive posture. The fruits of this research may already have or will potentially impact certain market sectors. The award also recognizes the company's overall research excellence as well as its commitment toward differentiating itself based on science-backed services or solutions.

## Research Methodology

To choose the award recipient, Frost & Sullivan's analyst team tracks research and innovation in key hi-tech markets. The selection process includes primary participant interviews and extensive primary and secondary research via the bottom-up approach. The analyst team shortlists candidates on the basis of a set of qualitative and quantitative measurements. The analysts also consider the pace of research and technology innovation, and the significance or potential relevance of the research to the overall industry. The ultimate award recipient is chosen after a thorough evaluation of this research.

## Measurement Criteria

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

- Number or type of research projects
- Significance of research in the industry, and across industries (if applicable)
- Absolute R&D expenditures (vis-à-vis industry norm), and % growth (if applicable)
- Caliber/reputation of research staff
- Potential of products of research to become industry standard(s)
- Breadth of intellectual property ownership (patents, scientific publications, papers in peer-reviewed journals, and so on)

### 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.

### About Frost & Sullivan

Frost & Sullivan, the Growth Consulting Company, partners with clients to accelerate their growth. The company's Growth Partnership Services, Growth Consulting and Career Best Practices empower clients to create a growth focused culture that generates, evaluates and implements effective growth strategies. Frost & Sullivan employs over 45 years of experience in partnering with Global 1000 companies, emerging businesses and the investment community from more than 30 offices on six continents. For more information about Frost & Sullivan's Growth Partnerships, visit <http://www.frost.com>.

[www.awards.frost.com](http://www.awards.frost.com)