

# Immunity ingredient making headway

Biothera, a US-based R&D biotechnology company, is making rapid progress with the commercialisation of its Wellmune WGP, an immunity-boosting ingredient, as food and beverage companies respond to growing consumer interest in products that stave off illness. By RICHARD CLARKE.

Launched in 2007, Wellmune WGP is a beta glucan carbohydrate extracted from the cell walls of yeast. It is said to strengthen and activate 'neutrophils', white blood cells that are the most abundant type of immune cells in the body, allowing them to more quickly find and destroy foreign, invading micro-organisms. According to clinical studies, daily consumption of 2.5 mg of Wellmune WGP per kilogram of body weight has beneficial effects – implying an effective dose of 200mg a day for an 80-kg adult – roughly the amount that can be found in two glasses of Wellmune-fortified juice.

David Walsh, VP communications at Biothera, a biotechnology company founded to develop and commercialise the ingredients, says Wellmune WGP is thriving thanks to consumer enthusiasm for products that offer benefits to the immune system, citing independent research to support this view. "In 2008 the International Food Information Council Foundation interviewed 1,000 American adults about their attitudes to food, nutrition and health," he explains. "One of the findings was that 87% of those surveyed were consuming, or expressed an interest in consuming, foods and beverages that improved immune system function."

A private company, Biothera does not disclose the revenues generated by Wellmune WGP, but Walsh says sales have been growing "extremely well", having more than doubled in 2009 on the previous year, and are now expected to double again this year.

The launch of Wellmune WGP (the WGP stands for 'whole glucan particle') marked a watershed moment for Biothera. The science underpinning the ingredient was originally developed by researchers at the Massachusetts Institute of Technology before being acquired and commercialised by Biothera in 2001. Following this deal, Biothera began supplying bulk beta glucan ingredients primarily to dietary supplement manufacturers. In 2007, however, Biothera launched Wellmune WGP – backed by a recently obtained GRAS approval – in a bid to create a premium brand ingredient that would appeal particularly to manufacturers of added-value functional foods and beverages.

The move appears to have worked. Three years on from its launch and Wellmune WGP is being used more and more frequently in functional food and beverage applications. In fact, Biothera's ingredient sales are now split about 50-50 between food and beverage applications and dietary supplement applications, says Walsh, whereas prior to 2007 they would have been almost exclusively the latter.

Recent launches in the food and beverage market have included a range of functional cookies, called Praeventia, developed by Canadian biscuit manufacturer Leclerc (see pages 17 and 18 of this issue).

Wellmune WGP is also available in two beverage products. One is Oasis Healthbreak Immuniforce, a functional blackcurrant and elderberry juice produced by another Canadian manufacturer, Lassonde. Each 250ml glass provides a 100mg dose of Wellmune WGP.

Launched in June 2009, it was the first juice application for Wellmune WGP. At the time of launch, Solange Doré, VP research and development at Lassonde, said: "This

product represents a very interesting option for those wishing to maintain a healthy immune system and enjoy the benefits provided by Wellmune WGP." Walsh, meanwhile, says: "The launch by Lassonde was important because it is a major refrigerated juice company with distribution throughout Canada and its packaging includes the Wellmune WGP brand logo."

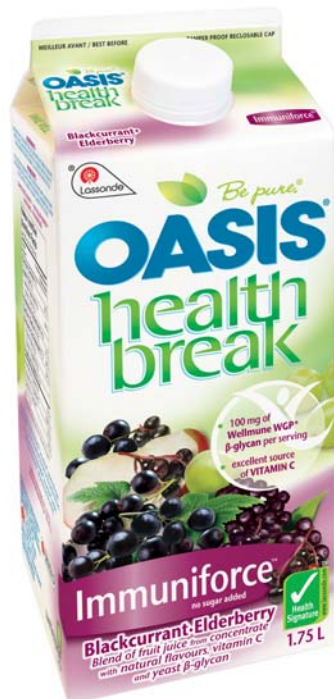
Then in January this year US nutrition and energy beverages supplier MonaVie launched an açai berry-based blend of 19 fruit juices called (M)mūn (which is pronounced 'em-mune'). MonaVie's VP of product management, Jeff Graham, said the product would deliver "a daily immune defence solution to the health-conscious consumer who is on the go".

Food and beverage companies are fast waking up to consumer demand for immune benefits, says Walsh. "We've been selling immunity products for several years. Four or five years ago we'd go into a company and talk to the food scientist there, and they'd say: this technology is great. But then the marketers would say: how do you sell immunity? It doesn't make you feel different – it's like selling insurance.

"But it seems that, for a number of factors over the last several years, consumers have either become more educated or more aware that the immune system is important to their overall health. So there's been more of a demand for immune products and consequently the food and beverage manufacturers are responding and looking at those foods."

Walsh says that Biothera is currently in talks with many more companies wanting to use Wellmune WGP in their food and drink products, but adds that the product development timeline is relatively long – two to three years.

Biothera takes the science behind Wellmune WGP very seriously. Although it is not the only beta glucan product on the market, Walsh says Biothera's processes are protected by more than 40 US patents or pending patents. Additionally, it has patents filed in more than 20 countries outside of America. Biothera fiercely protects its intellectual property and has issued several



Launched in mid-2009, each 250ml glass of Oasis Health Break provides two servings of fruit and 100 mg of Wellmune WGP.

patent infringement lawsuits in recent years.

Biothera has also invested heavily in scientific studies to support Wellmune WGP's claimed benefits. The most recent examples include:

- In a study of 122 healthy volunteers, presented at the Experimental Biology conference in Anaheim in April, participants taking 250mg of Wellmune WGP daily for 12 weeks reported a 58% reduction in upper respiratory tract infection (URTI) symptoms compared with individuals taking a placebo. Using a Profile of Mood States (POMS) psychological survey to assess changes in mental and physical energy levels and overall well-being, the study also demonstrated that the Wellmune WGP group rated their overall well-being and vigour 9.5% and 11% higher, respectively, compared with the placebo group.
- In a double-blinded, placebo-controlled study, published in the journal *Agro Food Industry Hi-Tech* in February, 150 people with moderate to highly stressful lifestyles consumed Wellmune WGP or a placebo each day for four weeks. After two weeks, 32% of the subjects in the placebo group reported URTI symptoms, compared with only 10% in the group taking 250mg of Wellmune WGP. At four weeks, 28% of the placebo group reported URTI symptoms, compared with 8% in the group taking Wellmune WGP. In addition, in comparison with the placebo group the Wellmune WGP group also reported statistically significant increases in vigour, and reductions in fatigue (38%), tension (19%) and confusion (15%).
- In a double-blind placebo-controlled study, published in the December 2009 issue of the *Journal of Sports Science and Medicine*, 75 runners from the 2007 Carlsbad Marathon in California consumed Wellmune WGP during the four-week period following the race. After two weeks, 68% of the placebo group reported URTI symptoms compared with 32% of the Wellmune WGP group. After four weeks, 24% of the placebo group reported URTI symptoms compared with 8% of the Wellmune WGP group. When asked how the supplement regimen was affecting their overall health, participants

consuming 250mg of Wellmune WGP daily reported 38% higher scores compared with the placebo group. In addition, the Wellmune subjects reported significantly better scores on a variety of mood states, including a 22% increase in vigour, a 48% reduction in fatigue, a 38% reduction in tension and a 38% reduction in confusion.

These studies all incorporate a focus on symptoms of stress, which reflects Biothera's belief that this is the root cause of many illnesses. "There's a large body of research demonstrating that physical and mental stress can weaken the immune system and render somebody vulnerable or more susceptible to illness," says Walsh. "Conducting clinical studies with people under high lifestyle stress, such as marathon runners and firefighters, we found that those people consuming Wellmune WGP as part of their diet had fewer incidences of upper-respiratory tract infection."

This plays well in the functional industry, says Walsh. "Some of our customers have found that a claim that says: 'helps you maintain a healthy immune system during stressful times', appeals to consumers. Let's face it, everybody feels under stress. People can relate to that. A lot of people have had that experience themselves, when they're going on vacation and leading up to it they're cranking it up trying to get everything done. And what happens? They get sick when they're away. It happens to kids after finals.

After a period of stress your immune system is weakened. So some manufacturers like to look at the stress angle."

Wellmune WGP is distributed across the world, in North America, Europe, Asia and Australia. Various regional regulatory hurdles present a challenge but Biothera is tackling them head-on. In Europe, for example, Wellmune WGP is approved for use in dietary supplements. But Biothera is currently awaiting news of whether it has obtained novel food approval so that Wellmune WGP can also be used in food and drink products. Walsh says the company expects a verdict from the European Food Safety Authority in 2011.

In the meantime, Biothera, in conjunction with its European distributors, has applied for health claims approval for Wellmune WGP via the Nutrition & Health Claims Regulation's Article 13.1 route. There are two separate applications as follows:

- Substance: Beta-glucan  
Health relationship: Immunity  
Claims examples: *For immunity; strengthens immunity*  
Conditions of use: Food supplement with 125-150mg WGP
- Substance: WGP beta-glucan; (1,3)b-D-glucan from yeast  
Health relationship: Immune system  
Claims examples: *Contributes to the normal function of the immune system; WGP beta-glucan contributes to adequate immune response*  
Conditions of use: 25-500mg/day adults; 125mg/day children

Anyone could be forgiven for finding the regulatory landscape daunting. But Biothera, with its belt and braces approach to science, spies compliance as an opportunity. "We're building Wellmune WGP as a worldwide brand," says Walsh. "If you're dealing with a multi-national manufacturer, they're going to want to distribute their products around the world. If we say: you can't sell your product in Europe, then that would be a major drawback."

Biothera will remain focused on "developing the brand equity of Wellmune WGP", says Walsh, who adds: "It is the ingredient used in all of our clinical research and it is the ingredient of choice of major food and beverage companies. As Wellmune WGP becomes recognised as a branded immune health ingredient, there will be greater benefits to manufacturers to choose it."

