

## Carbiotix provides an update on recent developments

**Carbiotix continues to make good progress as the Company enters 2023. This update provides an overview of the progress we have made related to milestones, as well as clarity regarding the direction we are heading with CarbiAXOS, LinkGut and other development activities in the company.**

I am happy to communicate that Carbiotix has made very good progress regarding key milestones and has now an even clearer path to market and profitable growth across all products and services. This has impacted the positioning of our products and services, as well as where we will focus our development activities. Gut health and the microbiome area, in general, are coming of age and Carbiotix is very well positioned to cement the Company's competitive position on the market. Vertical integration, strategic partners and scientific leadership will be key pillars supporting Carbiotix competitive advantage and growth plans going forward.

### **GRAS approval and the production of CarbiAXOS**

The GRAS Self Affirmation (SA) approval process has been both educational and inspirational for the company. The regulatory approval of a company's first product is a very interactive process of feedback between the applicant, consultants and safety experts. While this should ultimately lead to a safe and efficacious product being approved, one does need patience and determination. We have viewed this process as both educational and inspirational, leading to a more valuable and targeted application of our first CarbiAXOS ingredient. Furthermore, we have also needed to get full alignment with our enzyme supplier and build a foundation for a long-term relationship, which I am happy to say is falling into place. Thus, the delays we have experienced in the GRAS SA process should allow us to accelerate regulatory approvals across all markets going forward.

We have also used this time to collect feedback from the market via tradeshows, conferences, and bilateral discussions with many experts. It is thus very clear that Carbiotix should focus its efforts on higher-end nutraceutical and cosmetic ingredients that can be used alone, blended or used in conjunction with medical applications and therapeutics. This means that we will initially target the global prebiotic nutraceutical & cosmetic markets leveraging our LinkGut companion diagnostic to take market share in a combined market worth close to 1 billion Euros (1). The first CarbiAXOS product to be approved will thus be a high-end nutraceutical with multiple applications and this is reflected in the current GRAS SA dossier. While we are doing our best to accelerate the completion of the GRAS SA process, I am of course unable to confirm when this will be given that third parties are involved. In the meantime, we will continue with pre-sales activities by following up on product inquiries and move to ensure that we can provide product and samples for customers.

To secure the production of nutraceutical and cosmetic CarbiAXOS ingredients we need to vertically integrate our production process while working with key partners along the way. While our production facility in Bjuv will initially serve to manufacture cosmetic ingredients as well as nutraceutical samples for safety analysis, formulation work and clinical studies, our first CarbiAXOS product will be manufactured in the US through a contract manufacturing partner for practical reasons. I am happy to say that we have found this partner, as indicated earlier, and will work with them during 2023 to initiate the production of CarbiAXOS to meet market demand. While vertical integration will allow us to accelerate development activities and drive down costs, strategic partners will assist with our growth plans providing key capacity and production knowledge along the way.



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### **Sales and partnering activities**

The last quarter of 2022 marked the beginning of a clear growth trend in LinkGut sales. After transitioning from a B2C to B2B platform, our initial LinkGut partners are now ramping up business activities and partner inquiries have noticeably grown. This is thanks to our competitive position of being the lowest cost, most flexible and reliable B2B consumer microbiome test on the market. The variable and ever-changing nature of the gut microbiome means that testing will always be required regardless of Artificial Intelligence (AI) developments and our ability to vertically integrate the testing service and continually reduce costs means that we will not only take a leadership position in the market but also disrupt the market for consumer microbiome testing. To communicate this and leverage this strategic position, we are now ramping up marketing activities to our extensive potential partner database we have built up over the past four years.

After the launch of CarbiAXOS in November of last year in Boston, USA, and the start of pre-sales, we have also seen a steady growth of customer inquiries. These have mainly come from our initial target customer segment, namely smaller nutraceutical companies. Our goal is to send out samples for safety, formulation, and clinical work as soon as GRAS SA has been achieved for CarbiAXOS, and subsequently ramp up deliveries to establish a solid sales pipeline. Moreover, we will begin shipments of CarbiAXOS to customers, especially those representing smaller nutraceutical and cosmetic companies.

### **Update on evaluation project and current patient study**

As previously mentioned, Carbiotix LinkGut evaluation project with a global lab service provider demonstrated that our LinkGut service is the lowest cost, most flexible and most reliable microbiome test on the market. Thanks to our vertical integration, we will become even more cost competitive over time. We thus will not pursue working with this partner for the time being but are open to re-evaluating a partnership at a later date. During the last six months, Carbiotix has implemented additional changes to LinkGut that have significantly reduced costs, and improved flexibility as well as the reliability of the service, making the service even more competitive.

With regards to our current CarbiAXOS metformin T2D study, roughly 50 patients are currently using the intervention and with planned marketing activities in January we hope to sign up an additional 50 patients. As previously communicated, the intervention phase of the study should be completed by the end of Q2 of 2023. This is our first patient study using CarbiAXOS in conjunction with an established at-market therapeutic targeting a global disease impacting millions of people. We are in the process of submitting an application for financing to extend this study to several hundred patients. This study will serve as a blueprint for future co-intervention studies across multiple disease areas targeting the use of a refined CarbiAXOS nutraceutical in conjunction with other pro-drugs to increase the pharmacokinetics and reduce the negative side effects of therapeutics.

### **Development progress**

Our current focus on developing and launching refined or high-end CarbiAXOS products to be used alone, blended, or used in conjunction with other medical applications or therapeutics has meant that we will continue to upgrade our production site in Bjuv during 2023. These upgrades will allow us to produce customer nutraceutical samples as well as scale up the manufacturing of cosmetic ingredients for a global market. We will continue to explore different substrates to produce CarbiAXOS, however initially focus our efforts on bringing to market products based on corn, oat and pea fiber, the latter two providing an opportunity to upcycle local side-stream products. Reacting to global macroeconomic



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developments, we will also introduce cost savings measures in certain areas while scaling up activities in other areas. For example, we will be expanding our CarbiAXOS development team to accelerate the launch of new CarbiAXOS products.

### **Status on our IP portfolio**

We will continue to review our IP portfolio through the lens of our strategic focus and desire to utilise resources as effectively as possible. In addition to abandoning two legacy B2C-focused pending patents as previously communicated, we will also review our modulator patents to eliminate redundancy and allow resources to be freed up for patents targeting co-intervention applications of CarbiAXOS with other pharmaceuticals. By doing so, we will over time build up a patent portfolio mirroring our strategic focus of targeting the use of prebiotics to increase the efficacy of pharmaceuticals treating a range of leading metabolic and chronic diseases rather than commodity prebiotics used in food & beverage applications for their functional properties.

### **Organisation and investment case for Carbiotix**

As recently communicated, Carbiotix organisation will undergo some changes in conjunction with the AGM on the 21<sup>st</sup> of April. Chairman of the Board Jonas Danielsson and co-founder Peter Falck will step down from their Board duties. I will also step down as CEO and am proposed to become Chairman of the Board and will be replaced by Erik Deaner our COO. I will continue to support Erik and the Company with sales and business development. We will announce two new Board members in conjunction with the invitation to the AGM at the end of March. The motivation for this organisational change is a greater focus on the commercialisation and ramp up of CarbiAXOS production and sales.

Overall, I am very happy with the developments as we enter 2023. We have used the delays in our GRAS SA process with CarbiAXOS to improve the product and focus of the Company. In parallel with this, we have improved the cost competitiveness, flexibility, and reliability of our LinkGut service which is now showing results with regards to increased sales and should become a significant part of our top-line growth and solidify our strategic position in the market. We have a clear plan to upgrade our site in Bjuv to produce the samples and products we want, in addition to having a partner in the USA to scale up production as sales grow. We will soon have an organisation that is even more focused on accelerating product development and sales and have an IP strategy reflecting where we are heading rather than where we have been. I believe 2023 will be a key year for Carbiotix and year that I have been waiting for many years, a transition from a development stage company to a commercial company.

### **Kristofer Cook, CEO of Carbiotix**

#### **Forward-looking statements**

This communication contains forward-looking statements, consisting of subjective assumptions and forecasts for future scenarios. Predictions for the future only apply as of the date they are made and are, by their nature, as is research and development work in the biotechnology segment, associated with risk and uncertainty. With this in mind, the actual outcome may deviate significantly from the scenarios as described in this press release.

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**Carbiotix AB** (CRBX) ([www.carbiotix.com](http://www.carbiotix.com)) is an award-winning biotechnology company pioneering microbiome healthcare through a portfolio of prebiotic modulators and diagnostic testing services.