

Carbiotix provides an update on recent developments

Following a flurry of news in the second quarter of 2022, Carbiotix has been fully focused on making progress across multiple key milestones. This update provides an overview of the progress we have made, status of the milestones, and clarity regarding the direction we are heading with CarbiAXOS, LinkGut and other development activities in the company.

I am happy to say that the completion of our production site in Bjuv and three separate laboratories in Lund have provided key elements to accelerate product development activities. This has allowed us to ramp up development work of CarbiAXOS based on other substrates besides corn bran, potentially leading to a suite of products with different properties. We have also received key learnings from operating our own full-scale production site over the past several months related to product output, composition, and scalability that have allowed us to improve product quality and the CarbiAXOS production process.

GRAS approval and the production of CarbiAXOS

During this period, we have also been waiting for the GRAS approval of our third-party production enzyme (a prerequisite for the approval of our own GRAS dossier), and while delayed, I am happy to communicate that we received confirmation of this in September. Consequently, we now see that this delay, along with related development work and scheduled process upgrades, will also delay the planned approval of our own GRAS dossier (a process that originally should have been completed by the end of October 2022). While regretful, we have used this time to improve CarbiAXOS and make it more appealing from a business and customer perspective, an activity we will continue to do going forward across all modulator classes. This delay will however not impact the planned launch of CarbiAXOS in November 2022 given the high level of confidence by all parties involved in the GRAS Self Affirmation dossier of its upcoming approval.

During the past several months we have also made significant progress with regards to moving closer to a decision on the best means to scale up the production of CarbiAXOS. Given recent economic headwinds, we are even more sensitive to avoiding short-term costs and thus have explored different options to meet our production needs while protecting shareholder value. One option currently being explored is the use of contract manufacturers, with ongoing due diligence in the US expected to be completed in Q4 2022. Contract manufacturers would provide several advantages, for example: more flexible and quicker capacity expansion, lower capex and leasing requirements in a high interest rate environment, provide a bridge to joint venture opportunities, serve as a back-up and buffer to our own capacity expansion, provide a more sustainable transport option with regards to local sourcing and sales, and ensure stronger regulatory alignment leveraging local producer knowledge. Having a contract manufacturer in the US would be suitable for near-term nutraceutical products with higher margins and allow Carbiotix to utilise the Bjuv production site for product and process development activities (taking learnings from our partners), producing samples for customer testing and formulation activities, and exploring the scaled production of non-food applications of CarbiAXOS (for example skincare) with less demanding regulatory requirements. A decision to work with a contract manufacturer in the US will of course push into the future Carbiotix planned capacity expansion at the Bjuv production site reducing short term financing demands.

Sales and partnering activities

With regards to sales activities, I am happy to see a growing interest in both our LinkGut service and CarbiAXOS. Thus, I expect the company to satisfy its goal of signing on new LinkGut partners for 2022 and the foreseeable future. Consequently, revenues from LinkGut should see steady growth from Q4 going forward as our partners begin to launch their services. Given that we are highly confident regarding the GRAS SA approval of CarbiAXOS in the near term and can manufacture CarbiAXOS at an industrial scale, we are also now beginning to align with potential customers regarding samples for efficacy and formulation testing activities. The current GRAS status and further product development activities have also naturally delayed the planned launch of CarbiAXOS with FibreHigh in the US and a new launch plan is under review reflecting market conditions and will be communicated in due course. Given the right of first refusal structure of the agreement with FiberHigh, we foresee that this delay will not impact Carbiotix's ability to ramp up sales activities to other nutraceutical customers in the US.

Update on evaluation project and current patient study

Carbiotix LinkGut evaluation project with a global lab service provider is still ongoing and should be completed by the end of 2022 as planned. Results thus far from this project have indicated that the LinkGut service in its current form offered exclusively by Carbiotix is highly competitive with regards to price, flexibility and reliability. This is testimony to the great work of the team at Carbiotix to develop a white-label B2B gut health testing service that is world-class. We will however complete the current project as planned before drawing any final conclusions on the potential to collaborate (regarding sales and sample analysis) with the current project partner and others going forward.

With regards to our current CarbiAXOS metformin T2D study, we experienced some delays in the recruitment of patients, impacting the CarbiAXOS intervention start-date. I am happy to say that patient recruitment has ramped up in the past two months and thus the intervention phase should start in Q4 of 2022 with a planned completion and presentation of results by 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.

Development progress

As previously mentioned, the completion of the Bjuv production facility and laboratory facilities in Lund have allowed us to ramp up development activities of CarbiAXOS products based on different substrates and across different modulator classes ie. food and non-food ingredients, medical foods and therapeutic co-interventions. We are also focusing on upcycling opportunities to further hedge against increasing supply chain costs, secure raw materials, improve the sustainability profile of our product portfolio, and develop partnerships to accelerate market expansion activities.

The upcoming launch of CarbiAXOS has also triggered a ramp-up of collaboration discussions with potential strategic partners across the LinkGut and CarbiAXOS supply chain, as well as potential customers across modulator classes. As a general structure, collaboration discussions revolve around the development of new products, synergies with existing products, accelerating sales and strategic investments. We of course encourage companies interested in our Smart Prebiotic concept based on CarbiAXOS and LinkGut to contact us. To further reinforce this idea of collaboration and partnering in the prebiotics industry, we are dedicated to positioning our product and service portfolio as a complement to other offerings on the market rather than a replacement, thus increasing our general appeal to the widest possible customer base.

Status on our IP portfolio

We have also comprehensively reviewed our IP portfolio and planned IP to ensure consistency and alignment with our current strategy and B2B focus. Consequently, we are moving closer towards a decision to fully abandon two legacy B2C-focused pending patents (PCT/SE2019/051145 Method for determining fibre intake and PCT/SE2020/050412 Method for measuring and improving gut health). By abandoning these two patents, we will be able to eliminate duplication across patents and save money, allowing for the reallocation of resources to new high value modulator patents in the pipeline.

Strengthening investment case for Carbiotix

With regards to the Carbiotix organisation, we decided to stream-line the IT development team given the CarbiAXOS ramp up focus, and thus have one less person. I am happy to say that while we are always prepared to adjust the organisation to capitalise on market opportunities or face macroeconomic headwinds, we have a solid team in place to execute on the current strategy going forward. COO Erik Deaner, CTO/CSO Stephen Bromley, and CIO Martin Erlandsson today provide key leadership in their respective areas, in turn providing the necessary competencies as we enter this new phase in the company's development.

Overall, I am very happy with the developments during 2022, despite some minor delays. We have however capitalised on these delays to improve our product and service portfolio with regards to quality and cost, further build the infrastructure needed to accelerate product development activities, fully assess the best means to scale-up CarbiAXOS production and our business, streamline the core organisation and IP portfolio, and build out our prospective customer and strategic partner base. This should allow us to bring to market more competitive products and services, quicker and at a lower cost. This in turn will allow us to capitalise on market opportunities going forward and strategically position the company to accelerate sales activities as current macroeconomic headwinds subside, thus allowing Carbiotix to capture market share in target markets and providing a compelling investment case going forward.

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) is an award-winning biotechnology company pioneering microbiome healthcare through a portfolio of microbiome modulators covering prebiotic ingredients, medical foods, and therapeutics, along with cost-effective gut health testing services.