



STATUS REPORT

CARBIOTIX

IMPROVING GUT HEALTH



INTRODUCTION

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Evolving from a promising and award-winning startup company, Carbiotix was listed on the Spotlight Stock Market in October 2019. The IPO subscription price was set to SEK 4,45 per share, bringing the total capital raised to approximately SEK 12 million. At the time of this analysis, the company had a market cap of SEK 23 million.

Since the fall of 2019, Carbiotix has maintained a rapid development pace and by February the CEO **Kristofer Cook** announced that the company would be ready to launch a prebiotic modulator therapy roughly three years earlier than originally anticipated, with several additional milestones expected to be achieved during the year. But before we dig into the details, let us zoom out and take a closer look at the big picture.

A macro trend in the making

The microbiome is an eco system comprising of all the bacteria, virus, fungi and other micro organisms which co-exist in a certain biological environment, i.e. in the skin or mouth.

The specific microbiome of the gut is called the microbiota, and its importance for our health and wellbeing has been firmly established. In science, the condition of the gut is well known to be a key factor for the immune system of the body.

Scientists have long pointed to the important connection between a lack of good bacteria in the gut and various chronic diseases, such as e.g. inflammatory bowel disease (IBD), neurological condicitions, type II diabetes and a number of cancer types.

The increasing demand for products and drugs for improving gut health has also gained strong interest from the life science industry, as well as from major food producers. As an example, the American company **Archer Daniels Midland** (ADM) which currently has a market cap of approximately 18Bn USD, in its annual report singled out the impact of microbiota as one out of seven major global trends that will drive the future growth of the company.

Swiss food producer **Nestlé** also has tapped into the evolving trend, announcing a sponsorship for the **Center for Microbiome Innovation at the University of California San Diego**.

Prebiotics – part of the trend

Probiotics and prebiotics are two common terms when talking about gut health.

Probiotics are live bacteria which have a positive impact on gut health. A typical example of this is using lactose acid bacteria as ingredients in food and food supplements.

Prebiotics provide nutrition for the good bacteria already present in the gut. The prebiotic fibers are not dissolved too early in the food digestion process but stay intact until they reach the gut. Once there, the fibers are fermented, creating metabolites or Short Chain Fatty Acids (SCFAs), which improve the gut environment and benefit the good intestinal bacteria.

Carbiotix niche within the global microbiota trend is specifically focused on prebiotics and gut health tests.

Second-generation prebiotics

With it's second-generation prebiotic fibers, Carbiotix ambition is to play an important part in evaluating the intestinal flora and make it produce the proper amount of metabolites, thus aiming to prevent and treat medical conditions related to gastro-intestinal health.

INTRODUCTION

Carbiotix strives to improve gut health in four complementary business areas:

Diagnostics platform

- **Testing and tracking the gut environment to evaluate and achieve an optimised and individualised therapy for each patient.**

The company is developing the next generation of diagnostics technology for tracking gut health. The test is marketed in a number of channels and formats:

- *OneGut – sold via homepage directly to consumers*
- *LinkGut – white label-marketing via health organisations, healthcare institutions and food producers*
- *StudyGut – a service for research and gut health related clinical studies*

Engineered microbiome modulators

- **Production of the proprietary prebiotic fiber Carbiotix AXOS as an ingredient for food, drinks and in food supplements.**
- **Medical food – Carbiotix AXOS prebiotic fiber as ingredient in medical foods.**
- **Therapeutics – currently the company is developing two drug candidates approaching phase I clinical studies.**
 - CBX 111 for treating inflammatory bowel disease (IBD)
 - CBX 121 for treating hyper ammonemia

These four business areas together offer scalable opportunities for Carbiotix to target a very large number of clients. The demand for services, products and treatments within gut health has increased rapidly in the wake of significant scientific breakthroughs, thus creating a huge market which generates billions of dollars in revenue on an annual basis. As an example, the global market for prebiotic fibers generates an annual turnover of 5.5 billion EUR, according to an analysis from research firm **Global Market Insights**. The report also indicates there will be a strong continued growth in the upcoming years. Below, we take a closer look at the business model and market potential of Carbiotix.



UPCOMING TRIGGERS

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- *GRAS self affirmation regarding corn extract in the USA (Q4 2020)*
- **Market launch of medical food in the USA (H2 2021)**

In addition to the above communicated timeline triggers for Carbiotix, we also believe that updates concerning the following events will impact the company's share price:

- **Additional LinkGut partners and follow-up regarding the launch of the diagnostics platform**
- **Partner news and updates concerning up-scaling and production of Carbiotix AXOS**
- **Partnerships within new therapeutic areas pertaining to the launch of prebiotic modulators**

THE COMPANY IN BRIEF

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Carbiotix was established in 2014 based on research at the Department of Biotechnology at Lunds University and the Antidiabetic Food Centre (AFC) in Lund, Sweden.

Board of Directors	Management	Advisory Board	Owners (Largest owners per 2020-03-31)	Vote/Capital
Peter Falck, Chairman	Kristofer Cook, CEO	Prof Eva Nordberg Karlsson, PhD	Peter Falck (Chairman)	25,10%
Kristofer Cook	Peter Falck, CSO	Prof Patrick Adlercreutz, PhD	Kristofer Cook (CEO)	23,30%
John Moll	Stephen Bromley, CTO	Michael Cook, PhD	Sustainability Support Services	5,19%
Gustav Wendel	Henrik Ljung, CFO	Richard A RosenBloom, PhD	Avanza Pension	4,73%
Martin Linde	Martin Erlandsson, CIO	Jan Marsal, MD, PhD	John Moll (board member)	3,12%
			Nordnet Pension Insurance	2,89%
Marketplace	Spotlight Stock Market		Peter Nilsson	2,36%
IPO share price	4,45 kr/share		Eva Nordberg Karlsson (Advisory Board)	2,25%
Number of shares	8 583 000		Patrik Adlercreutz (Advisory Board)	2,25%
Ticker	CRBX		Aksonium	1,65%
ISIN-code	SE0013016128		<i>Kristofer Cook increased his holdings to 2 million shares in March 2020.</i>	
Pre-money valuation	25,78 MSEK			
Current market cap	23 MSEK per 2020-05-25			

BUSINESS MODEL

BUSINESS MODEL

Carbiotix business is focused within four core areas; the diagnostics platform, Carbiotix AXOS, medical foods and drug development



The diagnostics platform

In the last decade, more powerful, easily available and increasingly cost efficient DNA sequencing technology has opened up the field of novel diagnostic methods within gastrointestinal health. Today, a number of companies offer a variety of gut health tests using the new technology.

Carbiotix has developed a proprietary platform for gut health testing based on DNA sequencing (NGS) and PCR technology. Unlike competitors Carbiotix offers a triplicate test as a standard, at merely one-third of the price for current NGS tests on the market. The result derived from using a higher number of measuring points, is more complete than the standard "snapshots", providing data which can be used as a basis for informed decisions and recommendations on treatments as well as dietary advice.

Development through collaboration

Testing and tracking your gut health is key to identifying appropriate preventive measures or treatments for an existing health condition. Thus, the technology platform plays an important role in Carbiotix strategy to provide a leading and cost efficient method to secure relevant information about the gut health.

In order to evaluate, validate and develop its test platform, Carbiotix has entered several collaborations with external stakeholders.

In October 2019, an agreement was signed with **FoodMarble**, a consumer focused company which specializes in monitoring digestive health. Through its service *FoodMarble AIRE*, digestive health can be measured by testing the air that you exhale. The two companies conducted an 8 week-long joint study with positive results, which will be useful for real-time dosing of e.g. prebiotics.

Last year, Swiss pharmaceutical company **Gebro Pharma** started an internal pilot study in which Carbiotix test platform is being utilized by the company's users. The results from this study will contribute to Carbiotix own development and subsequent launch of the platform.

In April 2020, Carbiotix announced that **Lund University** was granted funding for a 4-month clinical study of type-2 diabetes patients using Carbiotix AXOS medical food as a co-treatment to the diabetes drug metformin, one of the most prescribed diabetes drugs in the world. The study will be conducted with **Skåne University Hospital** during the second quarter of 2021, with results expected to provide key clinical data to support regulatory approvals in the US and Europe and a potential commercial launch of a metformin medical food co-treatment product targeting diabetes patients by early 2022.

During 2020, Carbiotix will also launch its new test using PCR technology at a considerably lower price than the closest competitor, thus entering a global market valued at a total of 800 MEUR by analyst firm **Industry Research**.

BUSINESS MODEL

OneGut

OneGut is sold directly to consumers via the Carbiotix web page. Currently, the company is offering a triplicate test (with three measuring points) at a cost of one-third of the price charged by the closest competitor using similar technology. The market for consumer tests including LinkGut has been estimated to an annual value of approximately 100 MEUR.

LinkGut

The test is distributed as a white label product via health organisations, healthcare companies and food producers. Carbiotix receives a commission for each test sold and carries no costs for marketing, launch or implementation of the service. It falls upon the distribution partners to attract customers through advisory services and by offering efficient treatment plans.

A strategic strength of this business model is that it relies on the expertise of Carbiotix partners whom, together with their customers/patients, put in place an individual treatment plan for each patient. The LinkGut result is one important piece of the big picture, i.e. the overview of the patient's general health status. Based on this comprehensive evaluation, the healthcare company can suggest the appropriate treatment course. The LinkGut result provides the exact dosing amount of Carbiotix AXOS fibers to achieve the main objective, which is improved gut health.

In addition to providing the customers with a suitable and efficient treatment, Carbiotix has the opportunity – by offering both the diagnostic platform and the prebiotic modulators, to tailor the specific offer to its distribution partners for the benefit of all involved parties.

StudyGut

This service will, by providing a flexible test service at a lower cost, deliver results to organisations and research institutions that conduct clinical trials. The global market for this service has been estimated to generate potential annual sales of 700 MEUR.

BUSINESS MODEL

Microbiome modulators

The microbiota, which produces metabolites – short chain fatty acids essential to our health and well-being – has attracted strong interest from the scientific community over the last 20 years. The growth in academic literature on the subject has also been significant, increasing from around a hundred or so scientific publications in 2004 to more than 3000 articles in 2016. In addition to that, several international research organisations focusing on the area have been established.

Scientists have been able to link insufficient production of metabolites in the gut to a number of common diseases such as Crohn's Disease, Ulcerus Colitis, Type II Diabetes, cardio-vascular diseases, neurological conditions such as Alzheimer's Disease and various forms of cancer.

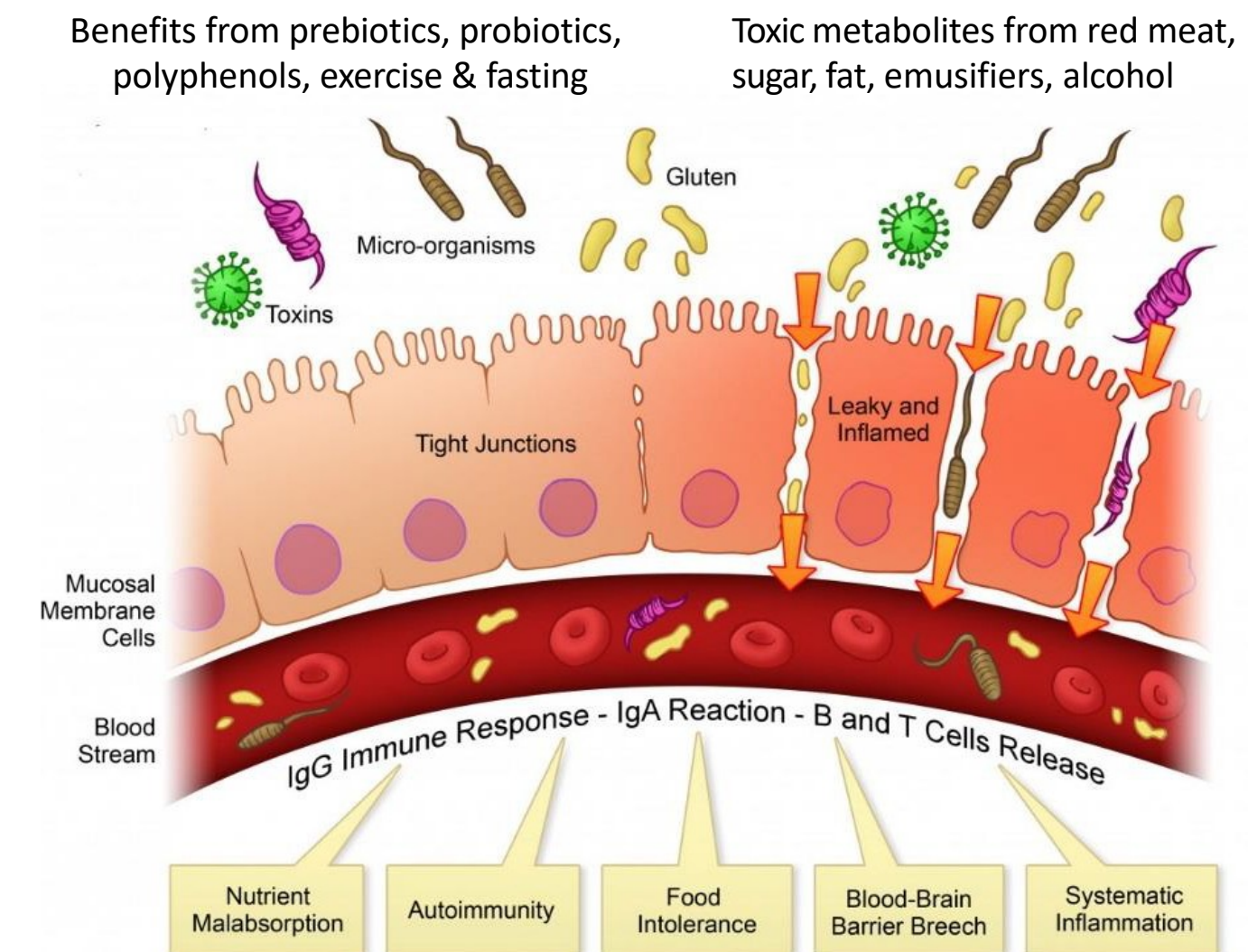
By maintaining optimal balance in the gut mucous membrane, local inflammation can be avoided, while simultaneously lowering the risk of toxic substances and inflammation leaking through the intestine walls and into the rest of the body.

Prebiotics stimulate gut health

The International Scientific Association for Probiotics and Prebiotics (ISAPP) has defined prebiotics as a substrate which is utilized selectively by microorganisms present in the gut, stimulating a physiologic improvement of the health.

Prebiotics usually exist in the form of fibers, but it is not always the case – and everything that contains fiber does not fill the criteria to be called prebiotics. Prebiotic fibers are usually represented by a group of sugars referred to as oligosaccharides, complex carbohydrates that are not dissolved by enzymes in the digestive process, but rather reach the colon in intact form.

When the gut bacteria ferment prebiotic fibers, short chain fatty acids are formed, which in turn are important for the proper function of the mucous membrane of the intestine. The short chain fatty acids are acetic acid, propionic acid and butyric acid. The fatty acid balance can be disrupted by e.g. antibiotics, a homogenic diet, lack of exercise, stress, alcohol and sugar intake, which all could affect how well the gut functions and its ability to handle and prevent disease.



BUSINESS MODEL

Carbiotix AXOS

Carbiotix develops a novel type of modulators, prebiotic soluble fibers, which are able to restore and optimise the gut environment and function of the mucous membrane in the gut.

An improved metabolic environment can be created using AXOS, which is Carbiotix proprietary fiber, proven to be ten times more efficient than *Inulin*, currently the most commonly used prebiotic fiber. The fact that AXOS has a higher efficacy compared with Inulin, and thus has a greater potential to improve gut health and thereby also lower cholesterol and benefit fat metabolism in the body, has been established in a scientific study.

Completed enzyme development brings scale-up potential

During the spring, Carbiotix announced that the company had completed development of a novel enzyme which is used to hydrolyse corn fiber. This means that the company is now able to produce fibers containing AXOS on a large scale, a key factor in commercialising the innovation.

Carbiotix AXOS can be used as ingredient in food, drinks and food supplements, but also in other applications such as medical food and pharmaceuticals.

Yet another strategic advantage is that Carbiotix AXOS can be produced at a lower cost than any product currently available in the market.

Prebiotic fibers

The global market for prebiotic fibers has been estimated to approximately 5.5 billion EUR annually and is expected to grow to 7 billion EUR in 2024 according to research firm **Global Market Insights**.

In February, Carbiotix communicated that the company expects to receive marketing approval for AXOS in the USA by the end of 2020, two years earlier than previously communicated.

Medical food

The demand for and use of medical food is growing rapidly with an annual market estimated at 15 billion EUR, according to a report from **Grand View Research**.

Carbiotix has engaged Canadian consultant **dicentra** to assist the company in the process of achieving a so called *GRAS self-affirmation* for the American market. Such an approval is mandatory for all substances that are to be added as ingredients in food in the USA. The GRAS-status (*Generally recognized as safe*) can be achieved after the substance being evaluated and deemed safe to use by a panel of experts.

The latest prognosis from the company is that GRAS-status may be achieved as soon as the end of 2020, which means that Carbiotix may have a product ready for launch by the second half of 2021, three years sooner than previously estimated.

BUSINESS MODEL

Drug development

Using its unique formula of probiotics and prebiotics, Carbiotix ambition is to address various diseases. By studying the link between the gut bacterial flora and the prevalence of certain diseases and conditions, Carbiotix aims to examine the relevance that a lack of specific bacteria may have for the development of those metabolic conditions. The therapeutic approach is to identify and add the exact bacteria found to be missing, in combination with Carbiotix AXOS which amplifies the effect of the added bacteria.

Currently two drug candidates are subject to ongoing pre-clinical development within the areas in which Carbiotix will launch treatments with medical food:

CBX121

Metabolic disorders, hyper ammonemia, i.e. elevated levels of ammonia in the blood.

CBX111

Inflammatory bowel disease (IBD).

The therapeutic projects have been pushed forward in time, since Carbiotix will prioritize the establishment of its medical food. By launching a medical food, the company will accumulate important knowledge and gain experience that will prove useful for the development of the pharmaceutical projects.

The demand for pharmaceuticals targeting the microbiome is also expected to grow in the coming years, according to **Persistent Market Research**, who estimate the market potential at 100 MEUR annually.

COMPETITIVE LANDSCAPE

COMPETITIVE LANDSCAPE

The increasingly strong interest in the microbiome, gut health and good fibers is a global trend that has been gaining force during many years. The major global food producers are well aware of the current trend and have already launched their own products to tap into the growing demand.

As a result of a broad and general health tech trend, a plethora of new companies have been established using new innovative technology, such as e.g. the now more easily available DNA sequencing technology. Carbiotix is one of those companies, providing both diagnostics and modulators in a combination which few, if any, other companies can offer. With several business areas and a flexible business model, Carbiotix is in a position to attract interest from many different potential companies for partnering and license deals.

There are a wide range of companies that are focusing on various aspects of the microbiome. Here we highlight a few examples with obvious common characteristics, whom could also be potential partners. Another important aspect to look at is the valuation of peers, either in the stock market or by professional investors in the field.

Company	Country	Area of business	Market cap/valuation in previous financing rounds (MUSD)	Note
Atlas Biomed	UK	Diagnostics	25	Estimate
DayTwo	Israel	Diagnostics/dietary advice	53 (approx. 100 in total)	Raised in series B
Evelo Biosciences	USA	Pharmaceuticals	145	Market cap
Kaleido Biosciences	USA	Pharmaceuticals	200	Market cap
MS Prebiotics	USA	Prebiotics	25	Estimate
OptiBiotix	UK	Medical food	55	Market cap
Pendulum	USA	Medical food	35 (approx. 60 in total)	Raised in series B
Prenexus Health	USA	Prebiotics	25	Estimate
Seres Therapeutics	USA	Pharmaceuticals	360	Market cap
Viome	USA	Diagnostics	45 (approx. 90 in total)	Raised in series B

Source: Crunchbase, Infront

The table below lists a number of companies currently active in the same business segments as Carbiotix. Valuation estimates were based on information regarding previous financing rounds and/or current market caps. Series B financing refers to the second round of financing of a company.

One example that gained a lot of attention was the American company **uBiome** which was formed in 2012 and offered gut health tests aimed at consumers. The company raised 105 MUSD from investors, reaching a peak valuation of 600 MUSD, but in April of 2019 the **FBI** investigated irregularities within the company, which subsequently led to the company filing for bankruptcy later that same year. However, the financing and valuation that uBiome attracted clearly shows the level of interest and expectation this business segment can create.

As was mentioned in the introduction chapter, global food production giants **ADM**, **Bunge** and **Cargill** with an annual revenue of 40-110 billion USD, already have shown interest in the prebiotics segment. A collaboration with Carbiotix could be seen as a natural step for a leading company, in order to maintain its strong position as a market leader.



IP SITUATION & REGULATORY NOTICES

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Carbiotix has applied for and been granted a number of patents for the company's central technology and methods in key markets.

A preliminary approval notice from the European patent authority for Carbiotix AXOS was received on February 21, 2020.

The GRAS-self affirmation process regarding medical food for the American market is ongoing and expected to be completed by the end of 2020.

Patent number	Title	Status	Application made	Region
PCT/SE2016/050377 US 15570580 EP 16786855.3 ZA-21093097	Preparation comprising Arabinoxyloligosaccharides	In progress in the US Preliminary approval in Europa Approved in ZA	2015-04-30	USA, Europe, ZA
PCT/SE2016/050843 US 15759228 EP 16844807.4	Low molecular weight Arabinoxylans with branched Oligosaccharides	In progress	2015-09-11	USA, Europe
PCT/SE208/051145	Method for determining fibre intake	In progress	2017-11-09	PCT phase
PCT/SE2019/050412	Method for measuring and improving gut health	In progress	2018-05-09	PCT phase
1950255-8	Microbiome modulator	In progress	2019-02-27	Sweden

FINANCIAL STATUS

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In its Q1 2020 report Carbiotix reported a negative operating profit of 1,35 MSEK. Cash at hand was 4,47 MSEK, with a cashflow from operations for the period of -1,26 MSEK.

Carbiotix is currently an early-stage growth company and does still not report any significant sales revenue. Thus, at this point creating detailed revenue models and making accurate calculations on future revenue could prove difficult, since the market launches for both medical food and Carbiotix AXOS as an ingredient still lie a few years ahead. Accurate calculations will be possible to make once more variables in the equation become known.

It should be said, however, that the market potential is significant and that demand is rising, which certainly makes for a promising long term development for the segment as a whole.

Moving towards commercialisation, the market will need to see that Carbiotix can deliver on the milestones and objectives they have identified, in order to support future financing.



Peter Falck, Chairman of the Board



Kristofer Cook, CEO

Financial status in brief

(SEK)	Q1 2020	Q1 2019	Helår 2019
Net revenue	18 463	76 069	188 431
Operating profit	-1 349 961	-1 158 938	-5 396 007
Cash flow from ongoing operations	-1 257 454	-1 202 919	-5 184 981
Cash and cash equivalents	4 473 922	2 674 778	6 894 895
Financial solidity	95%	90%	94%

Financial calendar

	Datum
Interim report 2020	2020-08-11
Quarterly report Q3	2020-11-20
Year end report 2020	2021-02-09

BIOSTOCK'S COMMENTS

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Investing in Carbiotix is investing in a niche, which is part of a larger global macro trend. As the subject of gut and intestinal health is attracting increasing interest both from consumers and within the scientific community, strong commercial players in the food and drug industries have also identified the trend and are currently investing heavily to position themselves to meet the increasing demand from the market.

Carbiotix is a small, innovation-driven company positioned somewhere in between a MedTech outfit and a pharmaceutical company. By combining its advanced proprietary diagnostics technology platform with the development of a novel and more efficacious prebiotic fiber, Carbiotix has created an attractive mix of complementary operations that few companies in the segment can match.

The company also aims to further strengthen its position by offering a diagnostic test at a price level significantly lower than the competition, while providing at least the same level of technical sophistication.

The organisation built around the diagnostic test differentiates Carbiotix from its competition. By focusing primarily on LinkGut, Carbiotix and its distribution partners can deliver better value to the customers, through providing a more complete assessment and evaluation of each individual's comprehensive health status.

In addition, this is a distribution model which enables Carbiotix to attract new customers without significantly increasing the costs.

Although the health tech trend in itself currently enjoys a strong momentum, the major commercial potential for Carbiotix lies within medical food and the production of AXOS fibers. The company might be a small player in a big and fiercely competitive market, but according to our assessment it still has a good chance to make a real impact, despite its size.

The strongest arguments in favor would be that Carbiotix AXOS is a novel product with a proven track record of significantly benefiting gut health in comparison with first-generation prebiotic fibers. In addition, it comes with a production process that is highly scalable and less demanding in terms of resources. A more efficient and less expensive product certainly has what it takes to be able to grab its fair share of a competitive and sizeable market.

By implementing a flexible business model with several possibilities to partner up and entering licensing agreements, Carbiotix has the opportunity to capitalize on its innovations in several different ways. A strategic strength is that Carbiotix remains in control of both the test platform as well as the prebiotic fiber supply. A food producer could for example use the LinkGut offer to create or access a loyal customer base with a great demand for Carbiotix AXOS in food, drinks, food supplements and other applications.

In the shorter perspective, the announcement that the launch of a treatment with prebiotic modulators could be executed three years earlier than expected is a significant value driver for the company. The stock market should therefore expect that Carbiotix within shortly will start investing in its production capacity – either by building its own facilities, through partnering, or by other means available. Regardless of which, significant investments and resources will be necessary in order to create the kind of impact on a billion dollar market that the company is planning to do.

*Considering the fact that the company recruited a CFO, **Henrik Ljung**, in March a stronger focus on financing should be anticipated going forward. A need for additional funding will likely arise towards the end of this year, but provided that the company has delivered on its milestones according to plan, a new financing round should be little more than a natural next step for Carbiotix on its continued journey towards commercialisation.*

DISCLAIMER

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