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BioRegio STERN

StartUp Stories – Dr. Severino Urban and Dr. Stefan Frey, founders of Oralgenix GmbH

In everyone's mouth: Early identification of a widespread disease –periodontitis

(Stuttgart/Reutlingen) – Dr. Severino Urban and Dr. Stefan Frey founded Oralgenix GmbH in Reutlingen Technology Park in 2025. Using molecular biological analyses of the mouth microbiome as a basis, the two scientists are developing personalised preventive diagnostics for periodontitis – also known as gum disease. This condition is caused by plaque on the gumline, which interacts with numerous bacteria and their metabolic products to trigger inflammatory processes and, in serious cases, leads to tooth loss. It affects just under 35 million people in Germany alone, so early diagnosis plays a huge part in preventive healthcare. Furthermore, the excessive multiplication of bacteria in the mouth is also suspected to cause other illnesses. The Oralgenix test could ensure that appropriate treatments can be offered in good time.
The story of Dr. Severino Urban and Dr. Stefan Frey is just one of many successful StartUp stories in the STERN BioRegion.

Everyone has bacteria in their mouth. The microbiome of the oral cavity – that is to say, all the bacteria in this part of the body – is unique, and is determined by a number of factors. Genetics, individual lifestyle, nutrition, smoking, and conditions such as diabetes can all play a role. A healthy microbiome can change, lurching from a "peaceful" symbiosis of the various bacteria into an unhealthy state, known as dysbiosis. Using specific genetic markers, Oralgenix can identify bacterial composition and detect changes to a healthy microbiome at an early stage so that countermeasures can be taken. Patients are then spared the unpleasant treatment that can become necessary if the periodontitis becomes more advanced. This involves using a probe to remove the biofilm of bacteria from the pockets around the tooth neck, often in conjunction with antibiotics. Approximately ten percent of all antibiotics are prescribed in the dental sector. Efficient early diagnosis would significantly reduce the use of antibiotics, and therefore also contain the risk of antibiotic resistance.

The idea – how did the start-up come about?

Dr. Severino Urban is a cell biologist. After studying in Zittau and completing his doctorate in Heidelberg, he decided his future did not lie in academia, so he switched to the industrial sector. GMP – good manufacturing practice – became his speciality, and he started working in a biotech company in the STERN BioRegion. “I worked in quality control, then became self-employed. For four-and-a-half years now, I have been a freelance consultant for quality control and quality assurance,” says Dr. Urban. In Tübingen, he met Dr. Stefan Frey, who had studied microbiology and genetics in Göttingen, before also finding his way from the university sector to the business world. Among other things, Dr. Frey headed up a microbiological laboratory specialising in dental analysis. He subsequently moved to the same biotech company as Dr. Urban to become head of their quality control department. “Severino and I shared the position there. It was the perfect way to get to know each other under a lot of stress and still have a respectful relationship,” says Dr. Frey. “The Oralgenix idea and the subject of oral microbiology had been on my mind for quite a while, but I needed the right associate for the project.” Now he had found the right person. Dr. Urban and Dr. Frey quickly discovered that they made a good team, and were prepared to take the risk of founding their own company – albeit not without a safety net. “Alongside setting up this company, we are still pursuing our freelance careers to ensure we have a stable source of income. In addition, we are providing one third of the financing for the start-up ourselves.” The other two thirds are being funded by the Bürgschaftsbank and the L-Bank. As managing partners, the two founders do not (yet) pay themselves any salaries. “As soon as this really takes off, we will give up our other self-employed jobs,” Frey explains. He currently still works as a quality consultant for pharmaceutical and biotech companies.

The need – who benefits from the idea?

The two company founders are aiming to play a part in improving oral health. After all, gum disease is an extremely widespread condition that affects a significant proportion of the population. “Just under 35 million people suffer from it in Germany,” Frey explains. Periodontitis, also known as gum disease, is a chronic inflammation of the periodontium, which ultimately destroys the tissue and bones responsible for holding the tooth. The number one cause of gum disease is plaque that builds up on the gumline and between the teeth. This plaque is made up of numerous bacteria whose

metabolic products trigger inflammation and contribute to changes in the bacterial composition. Initially at least, this process is painless. Patients therefore don't notice what is happening until their gums start to recede, the bone structure breaks down, and their teeth ultimately fall out. "Early diagnosis is vital if the teeth are to survive," says Frey.

The Oralgenix test is suitable for every phase of treatment at the dentist. It could be that the doctor has already established that the patient has periodontitis and now wants to improve treatment by getting precise knowledge of the microbiome. This is especially true for cases of advanced periodontitis, where knowing which bacteria are triggering the inflammation will help dentists intervene quickly and decide on the correct antibiotic. Alternatively, it could be the patient is already suffering from very advanced periodontitis and no antibiotic has been effective thus far. In this case, the test can be used to check whether bacteria are actually to blame, or whether there could be a genetic cause, and antibiotics would be no help at all. Then, of course, there are also patients who have no symptoms but go for regular checkups – in these cases, preventive diagnostics help identify changes in the microbiome that could lead to gum disease in the near future. If the diagnosis is made early enough, periodontitis can be cured in most cases – the condition is only chronic in around ten percent of patients.

In actual fact, periodontitis is not a disease that is limited to the oral cavity. It has now been established that many other diseases can be associated with bacterial inflammation or the mouth microbiome. "There are numerous studies that seem to indicate a direct correlation between bacteria in the oral microbiome and arteriosclerosis. Some of these bacteria can also take hold in parts of the heart. Likewise, there is data that points to a link with the initial development and progression of Alzheimer's disease," Frey explains. The presumption could therefore be wrong that people who have Alzheimer's – and are less careful with their oral hygiene as a result – go on to suffer from periodontitis. It could well be that patients who have periodontitis are more likely to develop Alzheimer's.

The USP – what is the innovation?

"Our test is preventive. It is effective before the periodontitis is present – unlike most other tests, which are only effective once the disease presents," says Frey, explaining

the unique selling point of his product. It is important to the company founders that they are not providing a diagnosis with their method – that remains a task for the dentist. “We provide the medical professionals with information about the microbiome that correlates with periodontitis, enabling them to make their diagnosis earlier.”

The two scientists have succeeded in doing more than just interpret data. “We can identify the changes in full, and we complement our analysis with many customised parameters,” Frey explains. “We can detect resistance genes that would rule out the use of certain antibiotics. What’s more, there are some special cases where the periodontitis has genetic causes. This probably amounts to less than five percent of cases, but five percent is not nothing when there are 35 million patients.” Oralgenix can provide data to these patients, too, enabling the dentist to begin appropriate treatment. “Our preventive screening considers all the changes in the microbiome. This enables us to make individual assessments for each patient,” says Urban. Since so many parameters have to be taken into account, the algorithm used is extremely complex. The company founders view the interpretation of the data as their intellectual property, and they are certain that this is their unique selling point. Not only could the Oralgenix idea revolutionise preventive dental care for the better, it could also lead to a huge reduction in healthcare costs. “Every euro invested in preventing periodontitis achieves a more than 80-euro return,” Frey calculates. “It is a brilliant investment for private individuals and for the entire healthcare system.”

However, the idea the company founders had goes far beyond preventive care at the dentist. They would like to develop another test that will be readily available in chemist’s shops. This test would be able to investigate the causes of bad breath, white tongue, or a predisposition to cavities. Ultimately, they hope to make it as easy to use as a COVID test. Getting a periodontitis diagnosis at the dentist and determining the pathogen involved, on the other hand, is a much more complicated procedure. “It’s not just a cheek swab,” Urban explains. “Several small paper points must be introduced directly into the neck of the teeth to ensure samples are taken correctly.” The samples are then processed at Oralgenix, and the DNA is isolated and analysed.

Milestones – what happens next?

It goes without saying that the regulations here pose a huge challenge for the start-up. “That’s why we’re not just targeting German-speaking countries, but also the United

States and Canada.” Their commitment to Germany as a location remains unchanged, however. “We feel comfortable here, and we intend to stay in the STERN BioRegion with its strong biotech scene. We get a lot of support here, not least from Tübingen and Reutlingen business development. On top of that, ‘Made in Germany’ still commands a lot of respect around the world.” The next step for the two scientists is to complete the test analytics and relevant validation. Currently, the company is still being supported in this by an external laboratory, but it has already rented rooms in the Reutlingen technology building to create space for its own laboratory equipment.

Link to the technology transfer page
https://www.bioregio-stern.de/en/projects/technology-transfer

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About BioRegio STERN Management GmbH:
BioRegio STERN Management GmbH promotes economic development in the life sciences industry, helping to strengthen the region as a business location by supporting innovations and start-up companies in the public interest. It is the main point of contact for company founders and entrepreneurs in the Stuttgart and Neckar-Alb regions, including the cities of Tübingen and Reutlingen.
The STERN BioRegion is one of the largest and most successful bioregions in Germany. Its unique selling points include a mix of biotech and medtech companies that is outstanding in Germany and regional clusters in the fields of automation technology and mechanical and plant engineering.

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