

Stuttgart start-up Variolytics: analysis platform accelerates drug development

## Smart manufacturing for biotechnology

**(Stuttgart) – Variolytics GmbH is developing measurement technology that makes the invisible visible. Among other things, this Stuttgart-based start-up’s analysis platform, whose technology has been developed at the Fraunhofer Institute for Interfacial Engineering and Biotechnology (IGB), enables operators of sewage treatment plants to save energy and reduce environmentally harmful gas emissions. However, its patented real-time analysis can also speed up processes in bioreactors, for example for the production of antibody drugs.**

The idea of “making the invisible visible” was the impetus for Dr. Matthias Stier to start his research. In particular, he wanted to know exactly what hazardous substances find their way into the environment. In 2015, the process engineer therefore started his research work at the Fraunhofer Institute for Interfacial Engineering and Biotechnology (IGB) in Stuttgart. Together with his team, he developed an innovative measuring technology for mass spectrometers. Mass spectrometers are used in industry to determine the composition of a substance and monitor how it changes – so far only for gases, however. Stier had the idea for an innovative and patented intake system that would make it possible to analyse up to 30 different substances or components in the gas and liquid phases simultaneously and in real time. “Environmental protection was a very clear motivation for me in this development,” Stier explains. Yet being able to identify pollution in watercourses or the escape of environmentally harmful gases is only attractive for companies if the new technology ultimately helps them make a profit. Consequently, in 2020 he founded the company Variolytics, with assistance from the Fraunhofer Venture programme High-Tech Pioneers and the EXIST support programme from the German Federal Ministry for Economic Affairs and Energy.

Now employing nine staff, the company has established itself on the Fraunhofer campus in Stuttgart-Vaihingen, directly at the IGB in its cell and tissue technologies innovation field. “The method developed by Variolytics at the IGB opens up new possibilities for automated monitoring and control of chemical reactions and biotechnological

processes, both in biotechnology and the pharmaceutical sector,” explains Dr. Markus Wolperdinger, Director of the Fraunhofer IGB. “We’re delighted we’re able to offer Variolytics the opportunity to develop the technology while also helping the company move closer to market launch.” In Stier’s view, the location is perfect: “We’re relatively small as a start-up, but we enjoy the advantages of a first-class infrastructure here. After all, the STERN BioRegion doesn’t just have biotech expertise but also offers a great deal of automation and mechanical engineering know-how.”

The start-up’s first customers are the operators of sewage treatment plants where impurities are biodegraded using microorganisms, for example. The bacteria need oxygen if they are to thrive and do their job. If too little oxygen is added to the tank, the bacteria dies. If too much is added, the energy costs increase without bringing any improvement in yield. In addition, gases that are harmful to the climate – such as methane or nitrous oxide, known as laughing gas – can occur in sewage treatment plants. For Stier, a man of conviction, this is the ideal site for using his analysis platform: “It monitors climate-damaging gases in the aeration tank in the sewage treatment plant and helps reduce them. The operators can expect energy savings of up to 25 per cent, as they can use the measurements and special control strategies to continuously optimise the application of gases during the microbial decomposition of organic matter in the waste water.” Variolytics is collaborating on this project with aquatune GmbH, based in Hahnstätten in Germany’s Rhineland-Palatinate region. Its general manager, Dipl.-Phys. Dr. Jörg Gebhardt, specialises in the intelligent optimisation of water and wastewater processes. As a machine learning pioneer, he was so impressed by how the Stuttgart team succeeded in optimising predictive gas supply in aeration tanks, he decided to support the start-up as a business angel.

Nonetheless, Variolytics is a long way from taking it easy when it comes to sewage treatment plants. Based on identical hardware used with varying software, the company is planning nothing less than to offer a key technology for bioreactors as soon as possible. In particular, this can benefit pharmaceutical companies that cultivate cells or microorganisms in bioreactors to produce active ingredients. To manufacture drugs or vaccines that are effective against COVID-19, for instance, mammalian cell cultures are cultivated in fermenters that require constantly ideal conditions. Unlike sewage

treatment plants, many different process parameters need to be continuously monitored in bioreactors used to develop pharmaceutical active ingredients under conditions in the relevant guidelines for Good Manufacturing Practice (GMP). This means, for example, that none of the required sensors must be allowed to present a contamination risk. For the manufacture of, for instance, drugs with antibodies, modern precision medicine now needs smaller reactors, often with single-use systems. This makes the use of individual sensors uneconomical in some cases. Variolytics calculates that it is for this reason that 40 per cent of the necessary key parameters are not captured at all, thus creating yield losses of up to 50 per cent. “In such cases, it isn’t possible to apply consistent control strategies for countermeasures,” explains Stier. “Inadequate sensor data means bioreactors are ultimately operated with low cell densities and high death rates. We replace five sensors and provide six new process parameters, while companies receive more data and save money.” After all, the aim is not just to speed up costly antibody production but make it more cost-effective, too, so that newly developed drugs – such as those given to former U.S. president Donald Trump during his coronavirus infection – do not remain a luxury for the few, but are instead affordable for all patients in the public health system.

Variolytics has developed the analytical equipment in a handy format for use in bioreactors. The heart of the cube-like box, which measures around half a metre along its edges, is the intake for the analyser unit, which – in a first for mass spectrometry – can also be used to analyse components from the liquid phase. Attached to this intake is a microporous membrane, via which – drawn by a vacuum – volatile substances from the liquid sample evaporate and pass through the membrane. Besides the innovative hardware of the analytical device, Variolytics has also designed the combination of sensors as a complete platform technology modelled on the smartphone. “There are various sensors, but it takes the apps to determine the functions,” Stier says. “We combine life sciences with data science, as the huge volumes of sensor data we are generating can’t be put to use without the right data modelling using artificial intelligence. The aim is smart manufacturing for biotechnology!”

The current pandemic has graphically shown how important it is to speed up drug development and production. Dr. Klaus Eichenberg, Managing Director of BioRegio STERN Management GmbH, emphatically welcomes this successful new start-up:

“Until now, the assumption in the biotech sector has been that it takes a significant number of years to develop new medicines or vaccines. Vaccine development times have now shortened dramatically. If a platform system such as Variolytics is reliably monitoring all the parameters, this can also further accelerate the approval of drugs.”

**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 engineering.

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