Press release

April 10, 2024
PI 11808 RB DW/af

Growth through medical technology: Bosch and Randox invest heavily in the Vivalytic analysis platform

Novel Bosch BioMEMS technology helps save lives

- New partnership for Vivalytic analysis platform: Bosch and Randox Laboratories Ltd. to invest 150 million euros in research, development, and distribution.
- Strategic growth field: point-of-care molecular diagnostics expected to become a future market worth billions.
- Growth with fully automated laboratory diagnostics: the two companies aim to achieve sales in the nine-figure range by 2030.
- Smartphone-sized laboratory: sepsis IVD grade test based on cutting-edge BioMEMS technology is a joint development objective.

Crumlin, Northern Ireland / Gerlingen and Waiblingen, Germany – With many diseases, every minute counts, and determining whether a patient is presenting the symptoms of a simple cold, the flu, or something as severe as life-threatening meningitis is usually only possible after time-consuming and expensive laboratory diagnostics. With its Vivalytic analysis platform, Bosch has set itself the goal of making fast and highly precise diagnostics accessible at the point of care – and aims to use molecular diagnostics to become a leading provider in the market by 2030. To achieve this, Bosch has now agreed on a strategic partnership with Randox Laboratories Ltd., a leading diagnostic and medical technology company. The two companies will invest around 150 million euros in joint research, development, and sales activities for new tests for the Vivalytic analysis platform provided by Bosch Healthcare. One goal is the development of a sepsis IVD[1] grade test that will be the first to feature highly innovative and novel BioMEMS technology.

[1] In in vitro diagnostic tests, samples such as blood or saliva are taken from the human body to be analyzed.

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Bosch has defined medical technology as a strategic growth field. Point-of-care molecular diagnostics is expected to become a future market worth billions. And with its Vivalytic analysis platform, Bosch aims to achieve a leading position in this market. “With cutting-edge technology from our own labs and our own production lines, we want to grow long-term together with partners in the field of precision diagnostics,” says Stefan Hartung, chairman of the Bosch board of management. “Here, our medical technology can draw considerable benefit from our diversification, from our expertise, from the groundwork we have done in automation, miniaturization, molecular diagnostics, and from our experience in microchip development and manufacturing,” Hartung adds. “We are investing long-term in an exciting high-tech growth field and continuously developing it together with partners. With technology ‘Invented for life’, we can relieve the burden on medical professionals and help make the diagnose and treatment of disease faster”.

Shared growth: decentralized diagnostics at the point of care

Bosch Healthcare Solutions and Randox are now joining forces in an attempt to accelerate the development and market launch of new tests and to make distribution channels more efficient. The partnership is set to run for more than ten years. With Vivalytic, the two companies aim to achieve sales in the medium nine-figure range by 2030. “Globally, healthcare is moving toward decentralized and personalized diagnostics, that enable rapid interventions and individual treatment plans,” says Marc Meier, managing director of Bosch Healthcare Solutions GmbH. “With our partner Randox, we want to further expand the test portfolio of our Vivalytic analysis device. Our fully automated molecular-diagnostic PCR tests provide clarity directly at the site of sample collection, shorten waiting times, and take the strain off the healthcare system,” Meier adds.

The two partners are a good fit: Bosch can contribute its technology and manufacturing expertise across the fields of molecular diagnostics, microchip development and manufacturing, and miniaturization. The universal Vivalytic platform for molecular diagnostics was developed in over ten years by Bosch researchers and brought to market maturity by Bosch Healthcare Solutions. Randox has 40 years of experience in the design and development of highly sensitive IVD tests performed on a variety of technologies, including microfluidic platforms. In combination with the company’s extensive market knowledge and global sales and distribution network, this adds up to considerable opportunities for growth. “Randox has always been committed to improving health worldwide and sees the need to invest in research and development initiatives that will support clinical decision making across a variety of disease areas. Diagnostics has always been an indispensable component of healthcare, and the alignment of both science and technology makes for the perfect fit in an area for high

potential impact, especially in pressure-driven environments," says Dr. Peter Fitzgerald, Managing Director of Randox Laboratories Ltd.

Bosch Healthcare Solutions and Randox already collaborated during the Covid-19 pandemic. In spring 2020, Bosch launched one of the world's first fully automated PCR tests for the SARS-CoV-2 coronavirus. Together with Randox, the rapid test for use in doctor's offices, nursing homes, testing stations, and hospitals was made ready for the Vivalytic analysis device within the space of just a few weeks.

Development goal: sepsis test based on BioMEMS technology

One focus of the development partnership with Randox is the implementation of a highly sensitive multiplex[2] test for sepsis on the Vivalytic analysis platform. Sepsis, also known as "blood poisoning," is a potentially life-threatening complication[3] that can occur in conjunction with various infectious diseases. A medical emergency that can lead to multiple organ failure, it requires immediate medical treatment. The planned IVD grade sepsis test is to be based for the first time on the highly innovative and novel BioMEMS technology developed by teams from Bosch corporate research in Renningen and Bosch Healthcare Solutions in Waiblingen. "We have set ourselves the ambitious goal of adding the functions of a high-performance silicon chip based on microsystems technology to our test cartridges for the Vivalytic platform. In doing so, we will combine Bosch's unique expertise in the areas of MEMS chips, molecular diagnostics, and microfluidics," Marc Meier says.

"Clinical outcomes in sepsis depend on timely diagnosis and appropriate early therapeutic intervention. Current methods of sepsis diagnosis are insufficient and time-consuming. With over 10 years of experience in the field of infectious diseases diagnostics, we aim to develop a state-of-the-art sepsis test using the highly multiplexing BioMEMS technology. Such a test could revolutionize sepsis diagnosis, ultimately leading to improved treatment outcomes and lower mortality rates from this life-threatening condition," says Dr. Peter Fitzgerald.

Smaller and faster: from microfluidics to nanofluidics – thanks to BioMEMS

The powerful BioMEMS chip adds a further innovative analysis method to the Vivalytic test cartridge, enabling it to test simultaneously and significantly faster for a large number of different pathogens. It is called BioMEMS because it combines microelectromechanical systems (MEMS) with microfluidics for

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[2] High-multiplex test means that a PCR test can test for a large number of pathogens simultaneously. In comparison, a multiplex test can detect up to 50 pathogens and a lowplex / single test up to 10 pathogens.

[3] With around 50 million cases of sepsis and 11 million fatalities per year, sepsis is responsible for around 20 percent of all fatalities worldwide. [https://pubmed.ncbi.nlm.nih.gov/31954465/].

applications in the field of medical technology. In microfluidics, very small amounts of fluid in the microliter range are moved in a very small space. Miniaturization allows qualitative biochemical polymerase chain reactions (PCR) to run in parallel in real-time on a single BioMEMS chip. “Compared to previous PCR reactions, the volumes of liquids are reduced by a factor of 1,000 to the nanoliter range. The analysis of liquids is left to a small microchip,” Marc Meier explains. With the new BioMEMS technology, fully automatic testing up to 250 genetic characteristics[4] (e.g. pathogens) in one cartridge is possible in less than 15 minutes. The test cartridge is a highly complex laboratory the size of a smartphone, so to speak. Another future advantage of BioMEMS will be simpler and faster adaptation of new tests or existing tests on the chip itself. For example, existing tests can easily be expanded to include additional features. “The BioMEMS technology paves the way for us to move into nanofluidics, where each pathogen will be examined in a reaction vessel the thickness of a hair,” Meier says. To achieve this, Bosch wants to create more capacity on a MEMS chip and expand it what are known as “nanocavities”. Thanks to these very small cavities, even more biochemical processes will be able to run in parallel on a chip. With increasing miniaturization, the technology has potential to be used in oncology as well over the long term. The BioMEMS chips are to be manufactured at the Bosch semiconductor plant in Reutlingen, with bio-integration and cartridge assembly to be carried out at Bosch Healthcare Solutions in Waiblingen.

Vivalytic platform: easy application at the point of sample collection

The advantages of carrying out PCR tests on the Bosch Vivalytic platform lie not only in speedy analysis, but also in the ease of use: Once the sample has been taken, it is placed in the test cartridge. The cartridge, which contains all the necessary reagents for the respective test, is then inserted into the Vivalytic analyser for automated evaluation. Medical staff require only brief training on how to operate it. This enables fast and targeted diagnostics directly at the point of sample collection – either at the doctor’s office or in the hospital – without the often long and time-consuming detour via a central laboratory.

Bosch Healthcare Solutions already distributes various tests for diseases of the upper and lower respiratory tract, such as SARS-CoV-2 – also as a pooling variant and as a saliva test – or a test to differentiate between SARS-CoV-2, RSV virus and influenza. There are also tests for pathogens that cause sexually transmitted infections (STI) and MRSA / SA (“hospital germ”). Starting in summer, it is planned to expand the portfolio with tests for whooping cough (*Bordetella holmesii, Bordetella parapertussis*, and *Bordetella bronchiseptica*), urinary tract infections (UTI), bacterial meningitis, the two most common sexually

[4] Genetic characteristics can be used to detect pathogens such as viruses, bacteria, fungi and parasites, as well as their resistance to drugs, or to identify genetic mutations in tumors.

transmitted diseases (*Chlamydia trachomatis;* CT and *Neisseria gonorrhoeae;* NG), fungal infections (*Candida auris*), and three tests for diarrheal diseases (norovirus, *Clostridioides difficile*, HSP).

Press photos: #9db61888, #df73841f, #e2588986, #f5326b37, #51d113ea, #c8ffa7a0

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About Bosch:
The Bosch Group is a leading global supplier of technology and services. It employs roughly 428,000 associates worldwide (as of December 31, 2023). According to preliminary figures, the company generated sales of 91.6 billion euros in 2023. Its operations are divided into four business sectors: Mobility, Industrial Technology, Consumer Goods, and Energy and Building Technology. As a leading IoT provider, Bosch offers innovative solutions for smart homes, Industry 4.0, and connected mobility. Bosch is pursuing a vision of mobility that is sustainable, safe, and exciting. It uses its expertise in sensor technology, software, and services, as well as its own IoT cloud, to offer its customers connected, cross-domain solutions from a single source. The Bosch Group's strategic objective is to facilitate connected living with products and solutions that either contain artificial intelligence (AI) or have been developed or manufactured with its help. Bosch improves quality of life worldwide with products and services that are innovative and spark enthusiasm. In short, Bosch creates technology that is "Invented for life." The Bosch Group comprises Robert Bosch GmbH and its roughly 470 subsidiary and regional companies in over 60 countries. Including sales and service partners, Bosch's global manufacturing, engineering, and sales network covers nearly every country in the world. The basis for the company's future growth is its innovative strength. At 136 locations across the globe, Bosch employs some 90,000 associates in research and development, of which roughly 48,000 are software engineers.

The company was set up in Stuttgart in 1886 by Robert Bosch (1861–1942) as "Workshop for Precision Mechanics and Electrical Engineering." The special ownership structure of Robert Bosch GmbH guarantees the entrepreneurial freedom of the Bosch Group, making it possible for the company to plan over the long term and to undertake significant upfront investments in the safeguarding of its future. Ninety-four percent of the share capital of Robert Bosch GmbH is held by Robert Bosch Stiftung GmbH, a charitable foundation. The remaining shares are held by Robert Bosch GmbH and by a corporation owned by the Bosch family. The majority of voting rights are held by Robert Bosch Industrietreuhand KG, an industrial trust. The entrepreneurial ownership functions are carried out by the trust.

Additional information is available online at www.bosch.com, www.iot.bosch.com, www.bosch-press.com.

About Randox Laboratories Ltd.:
Established in 1982, Randox is the largest healthcare diagnostics company from the UK and Ireland. Undertaking research, development, manufacture and distribution of innovative laboratory tests and analysers, Randox has over 3,300 staff, including 650 research scientists and engineers.

In 2020, Randox manufactured 4.2 billion tests and operated in 145 countries. More than 5 % of the world's population (over 370 million people) receive medical diagnosis using Randox products each year.

Randox focuses on the provision of timely and accurate testing to identify risk to health, improve clinical diagnoses and promote preventative healthcare; aiming to achieve better healthcare outcomes whilst reducing the burden on clinical services.

There are four key manufacturing and research and development sites, located in County Antrim, Northern Ireland; Dungloe, County Donegal, Ireland; Bangalore, India; and in the Greater Washington DC area, USA. Our Randox Health Clinics currently located throughout the UK in London, Liverpool, Birmingham, Chichester, Edinburgh, Glasgow, Belfast, Lisburn, Crumlin, Manchester Derry/Londonderry, and Holywood. In Ireland our Randox Health Clinic is newly opened in Dublin.

As well as being available throughout the UK and Ireland via our innovative mobile health clinic. Health checks can also be booked in our health clinic in Los Angeles, California. Randox reinvests up to 25 % of turnover in research and development, and as such has more tests in development than any other diagnostics company. Randox's comprehensive portfolio includes tests for cardiovascular disease, diabetes, cancer, Alzheimer's disease, and stroke.

Randox's proprietary Biochip Technology, the result of a £350 million investment, allows many tests to be run simultaneously, greatly improving the diagnostic power available to clinicians. This innovation enables Randox Health Clinics to provide advanced health screening involving hundreds of diagnostic tests.

In early 2020, Randox recognised the threat from COVID-19 and quickly developed a test to accurately identify the virus. Testing at scale commenced within weeks to support the UK's National Testing Programme and private clients. Randox has processed more than 25 million gold-standard PCR tests for the National Testing Programme and private COVID testing for travel.

Its comprehensive nationwide logistics network for the timely distribution and return of sample collection kits and samples, included more than 200 dropboxes and almost 300 click and collect sites.
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