

Occlutech Q1 2022 – Strong revenue increase and important milestones achieved in the strategic US market

Occlutech Holding AG (Occlutech) is a leading specialist provider of minimally invasive structural heart implants. The company sells and markets its products in around 85 countries and the global addressable market for congenital and structural heart devices provides a significant growth opportunity. To meet the high interest for Occlutech and its development the company will issue a quarterly release from Q1 2022, which will include revenue development and comments from the CEO.

Sabine Bois, CEO, comments on Q1 2022:

Strong revenue increase and positive sales trends

Occlutech showed a strong revenue increase in Q1 2022, with March approaching an all-time high. All markets performed well with the best result in the company's history from sales in direct markets. The strong performance underlines the rebound in the global healthcare market and confirms the quality and competitiveness of our products. Our revenue increased by 14.2 percent in Q1 2022 compared to corresponding quarter in 2021 and amounted to EUR 8,114 thousand (7,106) and the gross margin was well in line with the company's financial target. We have a profitable base business with our structural heart market and are now investing in the growth areas of geographical expansion as well as the heart failure market, and we aim to be profitable within 3 – 5 years.

Important milestones achieved in the strategic US market

Capturing the significant US market is an important part of Occlutech's growth strategy. A milestone was reached during the quarter when Occlutech met all FDA conditions in the AFR study FROST and can proceed to conduct a pivotal human clinical study of Occlutech's Atrial Flow Regulator (AFR) for heart failure. Enrollment of patients is expected to start in 2022 and Occlutech expects to receive FDA market approval for the US in 2027.

During the quarter, the first hospital site in Canada was activated in our US PFO study OCCLUFLEX, and is thereby ready to enroll patients, and in May 2022 the first patient was enrolled. The study aims to investigate the safety and efficacy of Occlutech's Patent Foramen Ovale (PFO) Occluder and allows Occlutech to collect data to support a Premarket Approval application to the FDA upon completion and we expect FDA approval of the PFO Occluder in the US by 2026.

A major stepping-stone in Occlutech's commercial development in the US was achieved in May 2022, when Occlutech signed an exclusive distribution agreement with B. Braun Interventional Systems Inc. (BIS). The agreement is, in effect, immediate and under this agreement BIS will start the US commercialization activities for Occlutech's FLEX II ASD Occluder where the FDA approval is expected during 2022. Through the collaboration, Occlutech positions itself for success in the largest congenital and structural heart device

market in the world, which is characterized as a premier and commercially attractive healthcare system. I am convinced that this collaboration will successfully drive our market entry.

Creating value for people, society and shareholders

We see a positive impact from the market's gradual recovery, with stronger demand and better access to customers. Strengthened by the share capital we raised at the end of 2021, I am confident that with our proven expertise of innovation and commercialization coupled with our experienced organization, we can improve the quality of life for people, improve health economics in society and at the same time create long-term value for our shareholders.

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About Occlutech

Occlutech is a leading specialist provider of minimally invasive structural heart implants, with a mission to improve the quality of life for people with heart conditions. The vision is to become a leading global specialist in cardiac implants, addressing congenital heart defects, stroke prevention and heart failure. Since 2003, the company has developed, manufactured, and commercialized occluders and interatrial shunt products. Occlutech has a broad and proven portfolio, based on proprietary technology, and over 200 patents with more than 146,000 products sold. The company markets and sells its products in around 85 countries. The company has around 290 employees and is a public limited liability company registered in Switzerland. For more information: www.occlutech.com.

Image Attachments

[Lars Wadell CFO](#)
[Sabine Bois CEO](#)

Attachments

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