

## Occlutech Q2 2022 – Positive revenue growth 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 has issued a quarterly update with start from Q1 2022, which includes revenue development and comments from the CEO.

Sabine Bois, CEO, comments on Q2 2022:

### **8.4 percent revenue growth for H1 despite new increases in Covid-19 cases**

Occlutech's revenue increased by 8.4 percent for H1 2022 and amounted to EUR 15,869 thousand (14,643), with sales in Europe and the Americas showing strong growth compared to H1 2021. Our quarter-to-quarter revenue has been affected by certain seasonality due to tender processes, which mainly explains the fluctuation between 14.2 percent growth in Q1 2022 and 2.9 percent growth in Q2 2022. Furthermore, and across the industry, revenue growth has still been dampened by the Covid-19 pandemic. During the pre-summer congress season in Q2, we had many interactions with physicians and other key stakeholders confirming strong interest in our products. The continued dialogue, particular in the heart failure segment addressed by our Atrial Flow Regulator (AFR) device, remains crucial for us to build this novel therapy. Our EBIT position improved in both Q2 and H1 compared to last year and we continue to aim for profitability within 3 – 5 years.

### **Key milestones achieved in the strategic US market**

Our focus in geographic expansion is the US market, which, due to its market size coupled with an attractive reimbursement system, represents significant growth potential for Occlutech. Over the past year, we have worked intensively on growing the US organization with the main purpose of conducting clinical studies and building the supporting infrastructure to successfully commercialize our products on the market. Our US office is located in Minneapolis, which is one of the largest medtech hubs in the US and enables us to recruit in an area of excellence.

A major stepping-stone for our commercialization in the US was in May when Occlutech signed an exclusive distribution agreement with B. Braun Interventional Systems Inc. (BIS). B. Braun is one of the world's leading medical technology companies with sales of EUR 7.9 billion in 2021, of which almost 25 percent is generated in North America. The agreement, which came into force with immediate effect, means that BIS will start marketing and commercializing activities for Occlutech's ASD Occluder in the US market, where we anticipate the product to be approved by the FDA within 6 months. BIS' excellent reputation and proven sales capabilities will significantly improve our commercial strength and I am convinced that this collaboration will successfully drive our market entry.

During Q2, the first hospitals in Canada and the US also started enrolling patients in our US PFO study OCCLUFLEX with European hospital sites expected to participate and contribute in H2 2022. We expect to keep our timeline for the approval of the PFO device in the US by 2026. Earlier this year a milestone was achieved when Occlutech received full FDA approval for the FROST-HF clinical trial which will allow the company to conduct a pivotal human clinical study of Occlutech's AFR for heart failure. Enrolling patients is expected to begin in H2 2022 and Occlutech anticipates receiving FDA market approval for the US in 2027.

#### **Focus on operational excellence and leadership**

In parallel with our focus on growth, we are gradually working to develop and strengthen the company's operational excellence and leadership. Our work to implement a new ERP system is going according to plan, as is the work on the MDD to MDR transition. It should be mentioned that review times from notified bodies are significantly longer than in previous years due to the new regulations. This has not only put pressure on the whole medical device industry, but also constraints on the availability of small parts of our inventory, which is expected to be sorted out during the summer. As we keep building and strengthening the company, I was glad to welcome three new members to the Executive Management Team in the quarter, all with significant skills and experience.

#### **Creating value for people, society and shareholders**

As the summer period comes to an end, I am very much looking forward to kick-starting the fall with my team and meet our customers, distributors and KOLs at congresses such as the PICS Society Symposium and TCT in the US in September and CSI APAC in late October. All with the aim to improve the quality of life for people, enhance health economics in society and create long-term value for our shareholders.

**For more information, please contact:**

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#### **About Occlutech**

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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](http://www.occlutech.com).

## Attachments

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