Occlutech Q4 2023 - key approval in the US, solid progress in clinical study and continued strong growth

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.

Sabine Bois, CEO, comments on Q4 report 2023:

The final quarter of 2023 has been a momentous one for Occlutech, marked by a key approval in the US, solid progress in our clinical study and continued strong growth. Undoubtedly, Q4 also saw some continued challenges around gross margins and supply chain bottlenecks, where we have taken steps to ensure positive development in the coming year. Together, these results and actions place us on a firm footing that gives us great cause for optimism in 2024.

FDA approval opens door to US market
We have achieved approval from the U.S Food and Drug Administration (FDA) for the ASD Occluder and Pistol Pusher to be used in the treatment of Atrial Septal Defects (ASD). Officially granted on December 29, 2023, the news came earlier than we had foreseen in our past communication, marking a great end to the year. This is a significant moment for the organization, as we can now begin work to commercialize through an exclusive distribution partnership with B. Braun Interventional Systems. To date, we have sold over 90,000 of our ASD devices outside of the US. Now, with the FDA's approval, we are ready to enter the largest congenital and structural heart disease market in the world.

ASD closure already represents a $40 million market in the US, and with solid growth predicted, our move could not be timelier. A lot of hard work has gone into this journey so far, and we extend our deepest gratitude to the patients, partners and all stakeholders who have been involved.

Making progress across other clinical focus areas
Alongside the developments with our ASD and Pistol Pusher, I am pleased to report that the OCCLUFLEX (PFO) trial continues to progress well and is on track, with US approval targeted for 2026. In Q3 I reported that we will be conducting a review of our clinical strategy for our AFR device in H1 2024 as we wait for the competitor results to be published, which will help determine the direction for a potential US path to market. In the meantime, and parallel to our ongoing AFR registry (AFTER), a simulation study has been kicked off to further explore the importance of different shunt sizes. Another important regulatory update is that we remain, overall, on track with our MDR submissions despite

significant delays on the notified body side. In parallel with completing these, we have also successfully prolonged all of our products which are yet to be MDR marked until 2027 under the still accepted MDD (Medical Device Directive), safeguarding their commercialization.

Sales and marketing activities continue to advance
We continue to deliver on major sales targets in key markets, and Q4 once again saw us gain revenue share on our competitors. Direct markets, in particular Europe, have proven to be a solid engine for us through the whole of 2023, and a firm foundation from which we can grow moving forward. Q3 was a busy period for congresses and meetings, and Q4 has continued that momentum with several important events. Among the most significant congresses we attended was CSI APAC, which also gave us the opportunity to hold a productive meeting with our Asia Pacific distribution partners. Another important event to take place in Q4 was the TCT (Transcatheter Cardiovascular Therapeutics) congress in San Francisco and the CSI DHF in Frankfurt on Devices in Heart Failure. These exhibitions are staples in our calendar, providing us opportunities to discuss and present our latest research and innovations, as well as connecting with customers, suppliers and other stakeholders in our sector.

Overcoming pressures on profit margins
It would be amiss of me not to mention that, despite a positive quarter, we have faced challenges in relation to margins and hitting our company target of 75%. There are several factors feeding into this, the first being ongoing inflation and cost pressures. There were also some one-off costs we faced during Q4, including accruals related to announcing the moving of Istanbul production into Jena facilities within 2024, a process which should be finalized over the next 12 to 18 months. Once that is fully completed, we expect this will have a positive impact on gross margins. Additionally, measures like reviewing the price structure and initiating some inflation related price increases have been implemented. Another cost we incurred was due to writing off the FROST HF AFR study in the US. Additionally, the transformative journey we have been on has also involved significant expenditure, especially in relation to revamping our sales and marketing structures to facilitate future growth. Related to this, we have finalized our SAP implementation and are continuing insourcing previously outsourced activities as we put corporate governance and internal control processes in place.

As we embark on our growth journey, internal efficiency will be paramount to having solid internal processes. It is therefore extremely encouraging to report that full technical implementation of SAP has now been completed and will serve as a basis to streamline and optimize internal processes further. This will lead to process harmonization and synergies and help us to cut down on business process outsourcing costs.

It has been a whirlwind year for us all. I know how hard the team has worked and continues to work, and I want to thank everybody, and in particular our shareholders and investors, that have contributed towards and remain committed to realizing our ambitions.

To receive a copy (pdf) of our quarterly reports, please submit your details via the form on the Occlutech website.

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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 175,000 products sold. The company markets and sells its products in around 85 countries. The company has approximately 330 employees and is a public limited liability company registered in Switzerland. For more information: www.occlutech.com.

Attachments

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