

Occlutech Year-end report 2022 – Significant uptick in sales growth as transformation processes are reaching an end

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 Year-end report 2022:

I am pleased to report that in the fourth quarter of 2022, we have seen a very positive trend in our growth. This is due to significant progress in several transformation processes, such as the MDR transition, SAP implementation and streamlining of our organization. These processes will still continue in 2023, but will take significantly less time and resources going forward. We are now equipped to accelerate growth and profitability in current markets as we progress in our clinical trials on the large US market.

Accelerating revenue growth

Revenue for the quarter increased by 19.2 percent and totaled EUR 8,445 thousand (7,082). Despite being affected by both Covid-19 in the first half of the year and transformation processes, revenue increased with 9.5 percent for the full year. December was our second strongest month in the year with a revenue growth of 42 percent compared to December previous year. Our main markets are now returning to pre-pandemic levels which positively impacted our direct sales which increased by 17 percent in the quarter.

We remain confident that the lucrative US market will positively impact Occlutech's growth and profitability once we launch commercially. To pave the way for this, we are continuing to develop our commercialization and marketing strategy as planned with our US partner, B. Braun Interventional Systems Inc, regarding our ASD Occluder. The mandatory FDA site audits have been completed, but some feedback from these inspections is still pending. However, we anticipate being granted FDA approval in 2023, which will mark the beginning of our US market launch, a prioritized market in our strategic planning going forward.

Clinical studies progressing

Occlutech is making significant clinical research investments to support new product initiatives and provide data to lay the foundation for global market access. To facilitate this, Jozef Bartunek has been appointed as Chief Medical Officer and has joined the Executive Management Team. He brings a strong professional background as Interventional Cardiologist and Heart Failure Specialist. Besides that, he has been involved in several medtech start-ups and has a degree in Biodesign. Jozef will be instrumental in the support of our clinical studies as well as in the implementation of global clinical

strategies to ensure the best possible commercial success.

Our approved US pivotal study of the Atrial Flow Regulator (AFR), FROST-HF (heart failure), recently enrolled the first patient. This is a huge milestone for Occlutech and will allow us to further grow our footprint into the US market - which stands for the largest portion of the total structural heart and heart failure devices market.

Finally, we are continuing our patient enrollment into our US study OCCLUFLEX, investigating the safety and efficiency of the PFO Occluder. The first patients in the US and Canada were enrolled in Q2 2022, and we recently enrolled the first patient in Europe.

Focus on sales and profitability

During the past year, we have been undergoing significant transformation processes. In September, we were able to resolve a bottleneck caused by the MDR transition, and in October, we successfully went live with SAP in four of our main sites. We also adapted our organization structure to better facilitate sales growth. Now that the most time and resource consuming parts in these processes are past us, we can dedicate more time and energy towards accelerating Occlutech's growth and profitability potential. This is evidenced by the large increase in growth that we saw in Q4, and particularly in December. We are confident that our improved processes and recent additions of competencies to our organization will help us reach our full potential for growth and profitability.

Future outlook

In April, we secured long-term financing through a bond programme with a total frame of EUR 75 million to continue the work towards our future plans and ambitions.

As we look ahead to 2023, I am confident that Occlutech is well-positioned to take advantage of the opportunities that lie ahead. We have a strong foundation and a talented team of professionals who are dedicated to delivering innovative solutions that improve the quality of life for people around the world.

We have exciting plans for 2023, including expanding our product portfolio, launching new initiatives, and continuing to build on our relationships with key stakeholders. We are also exploring new partnerships and collaborations to further strengthen our position in the market. With these efforts, I am confident that Occlutech will continue its journey towards becoming a leader in medical technology and improving lives around the world.

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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 155,000 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.

Attachments

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