

Occlutech Q3 2022 – Revenue growth, increased market activity and operational preparations

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 Q3 2022:

During the third quarter, we have continued to strengthen the management team and develop our operational capabilities. Also, our clinical trials are moving forward, and we have taken important steps on the regulatory arena. All things considered, we are well positioned to continue to increase sales as the global MedTech industry is ready to start expanding again. During the Covid-19 pandemic, most elective surgery in Europe and North America was brought to a halt. In 2022, the industry is expected to reach pre-pandemic levels again with all signs on growth for the coming year. Occlutech is ready to take advantage of this opportunity.

Revenue growth in the quarter despite challenging climate

Occlutech's revenue for the quarter increased by 2.4 percent and totaled EUR 7,530 thousand (7,353), still affected by the MDR recertification process, which had an impact on supply availability, and delayed orders. However, the recertification issue was resolved in the second half of September due to great teamwork across all functions. Our main markets are now returning to pre-pandemic levels. This positively impacted our direct sales, which increased by 7 percent in September. Americas continued its strong growth, growing 42.2 percent compared to the same quarter last year. APAC grew by 36.9 percent, with strong sales in Australia and Vietnam. Overall, the medical device market is expected to grow again in 2023 as clinical staff shortages are easing after the pandemic.

Clinical development moving forward

Our current clinical trials are progressing well. Regarding the ASD Occluder, FDA Audits have been completed for all sites, and we are now moving closer to approval. We are awaiting the approval by the first half of 2023, and we are simultaneously preparing for market launch. Together with our distribution partner, B. Braun Interventional Systems Inc., we are setting up commercialization and marketing plans and training sales staff.

The amended protocol reflecting take-aways from the CORVIA study REDUCE-HF, has been approved for the US pivotal study of the Atrial Flow Regulator, FROST-HF (heart failure), and we expect our first patient enrollment the next weeks. This will be an important milestone in the future US expansion plan as it will allow us to enter a potential multi-billion market.

As we have mentioned in our last report, we started enrolling patients in our US PFO study OCCLUFLEX with our first hospitals in the US and Canada. Enrollment of patients is continuing as planned, with European hospital sites being added.

Increased market activity and sales focus

During the quarter, we have been scaling up our marketing activities with intensified direct customer interaction, and increased presence in congresses as the opportunity for in-person events has returned. In September, we visited both the PICS Society Symposium in Chicago and the TCT conference in Boston, giving us great exposure to our market. We have also been hiring new members to our Executive Management Team, bringing significant experience that will contribute to Occlutech's future growth. Our new Chief Commercial Officer, Jose de la Cortina, has extensive experience in global sales and commercial strategies, and our new VP of Global Marketing & Business Development, Mathias Bouzereau, has vast experience in leadership positions in congenital therapies and strategic marketing. Together with our newly appointed Chief Medical Officer, Jozef Bartunek, they will contribute to Occlutech's focus on growth, business development, and successful trials.

Future outlook

As we are reaching the end of 2022, I am excited about the prospects for Occlutech. We are steadily progressing in all our clinical trials and we expect the first patient in our critical US study, FROST-HF. The market environment is becoming more favorable for the medical device industry, and it is expected to return to growth after the pandemic. Besides this, we are adding important experiences to the company to seize this opportunity. Thank you for being part of this journey, as we aim to improve the quality of life for people, enhance health economics in society and create long-term value for you as a shareholder.

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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 150,000 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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