

Occlutech Q1 2023 – Growth momentum with increased sales and marketing activities

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 Q1 report 2023:

I am pleased to report that we continued to see a positive growth trend in Q1 2023, with significant growth in our direct markets. We are also steadily progressing in our transformation processes as we implement robustness in our organization.

Growth momentum and good conditions

Revenue for Q1 2023 increased by 10.3 percent, totaling EUR 8,949 thousand (8,114). We saw strong growth in our main markets, especially Europe, which grew by 10.9 percent. Distributor markets were partly impacted by the war in Ukraine and related trade restrictions, but our direct sales showed positive momentum as they increased by 20.9 percent in the quarter compared to last year. I am also glad to say that March was the strongest month in Occlutech's history, further indicating this trend.

At the end of the quarter, we secured a long-term financing agreement with a subscription commitment of bonds at an aggregated amount of EUR 40 million under a total framework of EUR 75 million. This will allow us to pursue our important studies, start preparing to enter the large US market, and accelerate our growth in our main markets.

Clinical studies moving forward

Occlutech is continuing to invest in clinical studies and R&D, while reviewing and implementing regulatory and clinical strategies for all our products. During the quarter, Dr. Morwan Choli joined Occlutech's Executive Management Team as VP of Regulatory Affairs & Quality. With his experience in device testing, certification processes and collaboration with Notified Bodies, he will contribute to our product and marketing strategies as we advance. In order to support the clinical studies additional resources have been joining the clinical team.

One of our most important studies, the US pivotal study of the Atrial Flow Regulator (AFR) device, FROST-HF (heart failure), enrolled the first patient in March. It is a significant milestone for Occlutech and we are now engaging in substantial work around the clinical strategy for the AFR and how to progress successfully.

During the quarter, we also enrolled our first patient in Europe in our US study OCCLUFLEX, investigating the safety and efficiency of the Patent Foramen Ovale (PFO) Occluder. The

first patients in the US and Canada were enrolled in Q2, 2022.

Regarding the Atrial Septal Defect (ASD) Occluder, we are continuing our work for a Premarket Approval (PMA) in the US. However, we will likely see a delay due to the adaptation of processes to FDA standards. Nevertheless, as soon as we receive a PMA, we will be ready to launch commercially with our US partner B. Braun Interventional Systems Inc. The US is still a prioritized market in our strategic planning going forward, and we are eager to expand our presence there.

The Medical Device Regulation (MDR) preparation is progressing according to plan. Though, we are experiencing a slightly longer response time from Notified Bodies, which strains the certification process for some of our accessories. As we are continuously implementing more robust processes with supporting functions, including SAP, we are streamlining our operations to be more effective.

Sales, marketing and innovation

We are increasing our work and hires in sales and marketing to ramp up growth as we see signs of improved market conditions in front of us. For example, we are currently setting up advisory boards in our three main market segments to enhance business development and innovation around each of our product areas.

In January, we had our annual kick-off meeting in Barcelona, where a review of 2022 and looking at 2023 and beyond were our main topics. We are now seeing positive salesforce engagement in the company as we are creating a stronger alignment between our sales and marketing teams to ensure clear responsibilities and deliverables.

Future outlook

As we have had a positive start in 2023, Occlutech is well-positioned to take advantage of the opportunities that lie ahead. We are looking forward to increasing our sales and growth, exploring new product initiatives, and discovering new advantageous partnerships. But most importantly, we will continue our dedicated work to deliver innovative solutions that improve the quality of life for people around the world.

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.

Lars Nordenskjöld
CFO
E-post: lars.nordenskjold@occlutech.com
Telefon: +46 763 20 04 34

Sabine Bois
CEO
Email: sabine.bois@occlutech.com

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

[Occlutech Q1 2023 – Growth momentum with increased sales and marketing activities](#)