

Occlutech Q3 2024 Performance Update: Strong Growth & Increased Efficiency

Occlutech Holding AG (Occlutech) is a leading specialist provider of minimally invasive structural heart implants. The company sells and markets its products in around 80 countries and the global addressable market for congenital and structural heart devices provides a significant growth opportunity.

As we close the third quarter, I am pleased to report that Occlutech continues to maintain strong growth while enhancing cost efficiency. Our sales performance saw growth of 20.7% during a period that can present challenges in some of our direct markets.

Executive Management and Board Changes

Before discussing our financial performance, I want to address recent Executive Management and Board changes. Sabine Bois has stepped down, and I am honored to return as CEO of Occlutech. I would like to recognize Sabine's leadership during a period of significant transformation and express my appreciation for her efforts in positioning the company for future growth.

I also want to take a moment to acknowledge Michel Lussier, who stepped down from the board. His dedication and valuable contributions have played a key role in our progress, and we extend our sincere thanks and best wishes for his future endeavors.

LAA Distribution Deal

We are excited about our recently signed distribution deal with Eclipse Medical for the Omega LAA occluder in Germany. This strategic partnership complements our current offerings and opens a rapidly growing market for us that will be an incremental avenue for growth. Our strong, established presence in the German market, combined with the trust we' ve built with physicians, many of whom are the same specialists implanting PFO devices, made us the ideal partner for this distribution agreement.

Congress Season Highlights: SOLACI and PICS San Diego

This quarter marked the restart of the congress season, beginning with SOLACI, the largest congress in Latin America, where we showcased our latest advancements and engaged with key stakeholders in the region. Following SOLACI, we made a significant impact at PICS San Diego, which served as our official launch of U.S. operations following FDA approval of the ASD Occluder in December 2023. During this event, we presented live cases, facilitated vibrant discussions, and hosted a successful launch dinner that brought together top pediatric interventional cardiologists. These activities have energized our team and set a promising stage for future developments in the U.S. and beyond.

Operational Stability and Focus Areas

On the operational side, we remain stable, though some areas, particularly related to OEM product supply shortages, require continued attention. Our focus on process optimization and improving site structure has yielded positive results, with reductions in lead times for both manufacturing and quality control lead times.

Regulatory Progress

Regarding regulatory affairs, I'm happy to share that our MDR process is proceeding as planned. We expect three certifications – for ASD, PFO, and AFR – to finalize within the next six months. Additionally, we achieved a major milestone with the FDA's Small Business Designation, thus reducing costs for our PFO approval submissions. We remain on track for PFO approval in the U.S. by the end of 2026.

Looking Ahead

Given our strong growth and positive trajectory toward profitability, we have decided to explore additional financing options from existing shareholders. Thank you for your continued support as we focus on delivering long-term value and growth. As I take over the reins, the company is well-positioned for continued success and growth. Here's to a strong finish for 2024.

We are excited about the future and look forward to sharing our ongoing progress. To receive a PDF copy of our quarterly reports, please submit your details via the form on the Occlutech website.

Tor Peters CEO tor.peters@occlutech.com

Johan Sundell CFO johan.sundell@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 approximately 200,000 products sold. The company markets and sells its products in around 80 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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