

Occlutech Q2 Update: Strong Growth, Efficiency, and Strategic Execution

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.

Following on from an exciting start to the year, I am pleased to share with you the highlights of our robust Q2 performance, which reflects our commitment to growth, efficiency, and strategic execution.

Growth in distributor markets and significant cost reductions

We achieved strong growth in distributor markets, with a remarkable 47.2% increase driven by contributions from nearly all areas. Our direct markets also saw a solid 15.7% growth, demonstrating the strength of our business model.

Our gross margin stood at 65.7%, influenced by our strategic shift from direct to distribution models in certain geographies and continued expansion in high-potential, lower-margin regions like the Middle East and Africa and Latin America. Despite these shifts, our focus on efficiency has yielded significant cost reductions, leading to a vastly improved EBITDA of EUR -1.201 compared to EUR -5.405 in the same period last year. This improvement underscores the effectiveness and scalability of the systems we have implemented over the past years.

Congress season in full swing

The congress season in Q2 was a standout period for us, marked by our presence and influence at several prestigious events. Our participation at the European Society of Cardiology (ESC), the Association for European Pediatric and Congenital Cardiology (AEPC), Euro-PCR, and CSI Frankfurt was particularly noteworthy.

At these events, we engaged in a variety of high-impact activities, including live case demonstrations, expert talks, and comprehensive seminars. These engagements not only showcased our therapies but also provided platforms for meaningful interactions with leading experts, healthcare professionals, and key stakeholders in the industry. The exposure and recognition gained from these events have been instrumental in driving our business forward, fostering new relationships and enhancing our reputation as a leader in Interventional Cardiology.

Driving ASD forward in the U.S.

The ASD phased launch in the U.S., in partnership with B Braun Interventional Systems (BIS), commenced successfully. We eagerly anticipate the broader rollout in September,

which will begin at the Pediatric and Congenital Interventional Cardiovascular Society (PICS) Annual Symposium in San Diego, where the BIS/Occlutech team will be introducing our product in full. This symposium is a key event in the field, bringing together leading experts and practitioners.

Competitor Heart Failure data anticipated to stimulate wider therapeutic field

Notably, new clinical data on the interatrial shunt from V-Wave, published in April, showed a neutral outcome for the overall population.

Impressive results were observed in the HFrEF population, showing a 45% reduction in cardiovascular events and a 52% decrease in heart failure hospitalizations, highlighting an addressable potential market of 400,000 patients per year in the USA and Europe. We will continue to monitor this space closely and decide on next steps as further information becomes available.

Operational excellence and clinical advancements

Our PFO clinical trial, OCCLUFLEX, for U.S. approval is progressing as planned, with timelines remaining on track. Operationally, we have successfully navigated global supply chain bottlenecks and the transitions required by the Medical Device Regulation (MDR), ensuring timely deliveries and adherence to all MDR timelines. Our inventory levels, which temporarily increased to bridge re-certification periods, are now stabilizing and will continue to reduce as we continue to make steady progress in the transition.

We successfully secured approval for the distribution and sale of the ODS III in Japan. This milestone represents a major advancement that will support our position as market leader in the Japanese market. The result of a collaborative effort, the submission project is a true example of the strong relationships we hold with our distribution partners. Achieving this important milestone is a testament to the exceptional teamwork and dedication of all involved.

Another notable achievement of operational excellence was due to our regulatory team which successfully secured DEKRA recertification of our Jena site. DEKRA evaluated the safety of numerous processes throughout our facility, ensuring the safety of human interaction with technology and the environment.

Investment updates and AGM highlights

As we move forward, we continue to raise equity and are actively evaluating various strategic paths to sustain and build on our current momentum. Our commitment to growth and innovation remains unwavering, and we are exploring opportunities that will drive long-term value for our shareholders.

In May, we had the pleasure of hosting our AGM, which saw excellent participation and engagement from our shareholders. We are grateful to everyone who attended and contributed to the fruitful discussions and exchanges.

The road to Q3 and beyond

Our focus remains steadfast on growth and profitability, with ongoing and upcoming efficiency measures supporting our development. We have a clear path forward: clinical trial enrollment for the U.S. PFO PMA study is set to conclude by late 2024, SAP is demonstrating positive effects, and we are achieving ongoing cost reductions alongside growth.

The achievements and progress detailed here are a testament to the dedication and hard work of our entire team, as well as the strong foundation we have built together. I extend my heartfelt thanks to all our employees for their hard work and dedication, and to our shareholders for their continued trust and support.

We are excited about the future and look forward to sharing our ongoing progress with you. To receive a PDF copy 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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