



PRESS RELEASE
February 23, 2024

Clinical Laserthermia Systems AB publishes Year-end report January – December 2023

Summary of the interim report (relates to the Group)

Full year (01/01/2023–12/31/2023)

- Net sales totaled SEK 8,273,000 (SEK 6,268,000).
- Operating profit/loss totaled SEK –65,933,000 (SEK -67,442,000)
- Profit/loss after financial items totaled SEK –80,875,000 (SEK -71,265,000).
- Basic and diluted earnings per share totaled SEK -0.12 (SEK -0.85).
- The equity ratio at December 31, 2023, was 75,4% (18,6%).

The fourth quarter (10/01/2023 – 12/31/2023)

- Net sales totaled SEK 4,456,000 (SEK 4,295,000).
- Operating profit/loss totaled SEK –20,408,000 (SEK -18,226,000)
- Profit/loss after financial items totaled SEK –25,648,000 (SEK -19,618,000).
- Basic and diluted earnings per share totaled SEK -0.02 (SEK -0.15).
- The equity ratio at December 31, 2023, was 75,4% (18,6%).

Significant events in the fourth quarter of 2023

- CLS signed Mobile Service Provider (MSP) Agreements with Kearney Urology Center PC of Kearny, Nebraska, USA, and KASRAEIAN Urology of Jacksonville, FL, USA, for image guided focal laser ablation (FLA) of localized prostate cancer. CLS will provide the TRANBERG® Thermal Therapy System, including sterile disposables, training, and on-site clinical and technical support on a pay-per-procedure basis.
- CLS selected Quest International, a global aftermarket technical service provider to OEMs, to provide service and logistics operations for the US market. Under the agreement, Quest will provide end-to-end white glove service management, including field services, depot repair, and warehousing and logistics support for CLS's TRANBERG Thermal Therapy System.
- CLS and US based HALO Diagnostics, a leader in precision diagnostics and image-guided therapies (HALO Dx), entered an agreement to initiate a clinical study using the TRANBERG Thermal Therapy System to perform image-guided FLA of low-to-intermediate risk prostate cancer in 25 patients. According to the agreement, HALO Diagnostics will purchase the TRANBERG sterile disposables required for the study.
- CLS entered into an exclusive distribution agreement with Avanco Advanced Medical Solutions to market and sell CLS's TRANBERG product portfolio for image-guided FLA of localized prostate cancer in Portugal.
- CLS announced its participation in a national French study together with Urolib (urological team of the Medical Center Chateau Galland (MCCG)) in Besançon, and that the first patient was safely treated with CLS TRANBERG Thermal Therapy system for laser ablation of prostate cancer. Disposables and accessories will be purchased from CLS during the study.
- Kristian Waldeck was appointed VP Medical Affairs and member of the company's management team.

Significant events after the end of the period

- CLS received an order for ClearPoint Prism™ Neuro Laser Therapy System products from ClearPoint Neuro, Inc (Nasdaq:CLPT). The order has a value of approximately SEK 8.1 million.
- CLS obtained market approval for its portfolio of TRANBERG Thermal Therapy Systems from the Singapore Health Science Authority and initiated the process of commercialization in the Asia Pacific region.

- CLS hosted a business update, including presentations of the company's strategic and commercial roll-out as well as an updated sales ambition to achieve a positive operating profit (EBITDA) during the 2026 financial year.
- CLS signed a new agreement with Image Guided Therapy SA (IGT) under which CLS will acquire all rights to IGT's technology for MRI-based temperature measurement and control of laser-based tissue ablation.

Comments from CEO Dan J. Mogren

2023 was an exciting year for CLS. Revenues grew by 32% driven foremost by the urology segment and the recently implemented Mobile Service Provider model. During the fourth quarter we announced that two additional clinics signed Mobile Service Provider agreements in the US. In December we received a new order for products from our US neurosurgery partner, ClearPoint Neuro, followed by a further order following the end of the quarter. Also following the end of the quarter, we obtained approval from the Singapore Health Sciences Authority for our entire portfolio of TRANBERG Thermal Therapy products, opening up the Asia Pacific market for CLS.

Strong revenue growth with continued focus on costs

CLS revenues grew strongly in 2023 with our urology market segment leading the way and our neurosurgery market segment revenues maintaining their 2022 level. While the US continued to be the main source of sales, the signing of a new distribution agreement in Europe and the important approval of our TRANBERG Thermal Therapy products in Singapore means we are in a position to spread sales of our products globally.

During the quarter we saw the benefits of the cost efficiency projects we have implemented. Costs were in line with our expectations and by reducing other external costs, we have been able to invest for growth in the US business. With the boost in sales and improved margins, our operating profit has improved against the previous year.

Investment in MSP model delivers results

During the fourth quarter we finalized two agreements in the US for our Mobile Service Provider model. The first was with the Kearney Urology Center PC, and the second with the Florida based KASRAEIAN Urology. We have been working intensively with both Kearney and KASRAEIAN to equip their facilities, train their staff, and identify patients. We expect the revenues from these agreements to start in the first quarter of 2024.

In addition to these two agreements, we have several potential MSP agreements in the pipeline. The fact that we have been able to reach these agreements within less than a year of launching the MSP model validates the investments we have made. It is clear our customers appreciate and value our MSP services.

New orders and positive feedback for our US neurosurgery business

In December 2023, Clear Point Neuro placed an initial order of SEK 2.4 million for products associated with the ClearPoint Prism Neuro Laser Therapy System. This was followed by an additional order for SEK 8.1 million following the end of the quarter, bringing the combined value of the orders to approximately SEK 10.5 million.

Together with ClearPoint Neuro, our US partner, we continue to receive positive feedback following the limited market release of our ClearPoint Prism Neuro Laser Therapy System. Based on the reports we have received, the ClearPoint Prism Neuro Laser Therapy System outperforms competitor systems on fundamentals, such as workflow and technology. The limited market release has also identified several enhancements that have the potential to increase revenues by giving us access to over 90% of the NeuroLITT market in the US, up from 10-15% today. Implementing these enhancements will have an impact on our cost base over 2024 and 2025, but we believe that these investments will have a significant benefit for our NeuroLITT business in the future.

Continued expansion in Europe and entry into the Asia Pacific market

In November, we announced an agreement with Avanco Advanced Medical Solutions to market and sell CLS TRANBERG Thermal Therapy products for the minimally invasive treatment of prostate cancer in Portugal. We anticipate the first revenues from this partnership during the course of 2024 once familiarization with our products and identification of possible clinics is completed.

In an important development for CLS following the end of the quarter, the Singapore Health Sciences Authority granted approval for our entire portfolio of TRANBERG Thermal Therapy products. While this process has taken longer than expected, it is a significant step for our business. Singapore is a leading hub for high-quality healthcare in the Asia Pacific and will act as the base and gateway for us to expand our business in the region and seek approvals in other jurisdictions.

Safeguarding our core technology and IP

Following the end of the quarter, CLS filed a patent application to expand and extend protection for the company's technology. This application includes protections for critical improvements to the CLS non-cooled laser applicator that CLS believes are patentable. If the patent application is approved, protection is provided for the improvements until 2044. In addition, we are currently working on transitioning to the EU MDR certification and anticipate that this will be in place no later than 2025. This is an important milestone for CLS that adds significant value to the company as it reduces the overall regulatory risk.

New clinical studies for treatment of prostate cancer

The fourth quarter saw a number of new clinical studies announced involving the TRANBERG Thermal Therapy System for the treatment of prostate cancer. In November we announced an agreement with HALO Diagnostics in the US to initiate a clinical study using the TRANBERG Thermal Therapy System to perform image-guided focal laser ablation in 25 patients.

We reported in December that first patient was treated with the CLS TRANBERG Thermal Therapy system as part of the nation-wide IRMPROFT study in France. This study will involve purchasing the accessories and disposables needed for the study from CLS.

During the quarter two additional patients were treated as part of the Skåne University Hospital study of MRI guided LITT treatment of glioblastoma using the ClearPoint Prism Neuro Laser Therapy System. This brings the total number of patients treated in the study to eight of the planned fifteen.

Strengthening the CLS Team

In December we welcomed Kristian Waldeck as VP Medical Affairs and member of the company's management team. Part of Kristian's role will be to strengthen our communication around clinical trials to ensure that the purpose and outcomes of these trials are known and available to all our stakeholders. Kristian takes over from Hoda Tawfik whom I would like to thank for her outstanding service during her time with CLS. Hoda will continue to support CLS on a consulting basis in selected projects.

Looking forward to an exciting 2024

During 2023, we identified several ways to expand our addressable markets and optimize reimbursement potential. To unlock these opportunities in 2024, strategic investments are necessary during the coming year, especially within the neuro business segment. These investments, in combination with the delay in obtaining the Singaporean market approval, means our goal to achieve a positive operating profit (EBITDA) has been pushed forward into 2026.

We are excited about the opportunities that lie ahead in 2024. With regulatory approval in Singapore, we are looking forward to starting the process of unlocking the potential of the Asia Pacific prostate market. Important clinical trial results in the coming years will allow us to expand our reach in the treatment of prostate cancer and we expect to start up new MSP agreements in the US as well as work to identify and enter into agreements with additional commercial partners for our TRANBERG Thermal Therapy System. We also expect to see the ongoing limited market release of the ClearPoint Prism Neuro Laser Therapy System in the U.S shift into a full market release as a result of our strategic investments within the neurosurgery business.

After an exciting end to 2023, we look forward to you being part of an even more exciting 2024.

Dan J. Mogren

CEO, Clinical Laserthermia Systems

This disclosure contains information that CLS is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person set out below, on February 23, 2024 at 08:30 CET.

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About CLS

Clinical Laserthermia Systems AB (publ) develops and sells TRANBERG® Thermal Therapy System, including Thermoguide Workstation and sterile disposables, for minimally invasive treatment of cancerous tumors and drug-resistant epilepsy, according to regulatory approvals in the EU and the US. The products are marketed for image-guided laser ablation and are used in studies for treatment with imILT®, the Company's interstitial laser thermotherapy for immunostimulatory ablation with potential abscopal effects. CLS is headquartered in Lund, Sweden, and has subsidiaries in Germany, the USA and Singapore. CLS is listed on Nasdaq First North Growth Market under the ticker CLS B. Certified Advisor (CA) is FNCA Sweden AB.

For more information about CLS, please visit the company's website: www.clinicallaser.se