



PRESS RELEASE
17 November 2023

CLS publishes interim report January – September 2023

Summary of the interim report (relates to the Group)

First nine months (01/01/2023–09/30/2023)

- Net sales totaled SEK 3,817,000 (SEK 1,973,000).
- Profit/loss after financial items totaled SEK –55,227,000 (SEK -62,192,000).
- Basic and diluted earnings per share totaled SEK -0.12 (SEK -0.9).
- The equity ratio at September 30, 2023, was 86% (34%).

The third quarter (07/01/2023 – 09/30/2023)

- Net sales totaled SEK 1,978,000 (SEK 884,000).
- Profit/loss after financial items totaled SEK –17,247,000 (SEK -30,374,000).
- Basic and diluted earnings per share totaled SEK -0.2 (SEK -0.42).
- The equity ratio at September 30, 2023, was 86% (34%).

Significant events in the third quarter of 2023

- CLS' rights issue, which closed on July 3, raised SEK 114.2 million before issue costs. Through the rights Issue, a total of 1,141,558,050 B-shares and 228,311,610 warrants of series TO 6 B were issued. With the issue proceeds received, CLS paid off SEK 49 million on the previous loans from Buntel AB, Lubrica Equity AB and Formue Nord Fokus A/S. A directed offset issue was carried out to underwriters who chose to receive underwriting remuneration in the form of new units, consisting of a total of 31,356,000 new B-shares and 6,271,200 new free of charge warrants of series TO 6 B, in the Company.
- CLS and Focalyx entered a co-marketing agreement to sell and market an integrated, minimally invasive, fusion-guided focal laser ablation treatment. The image guidance system will be offered to urology clinics under a Mobile Service Provider Agreement.
- Rolf Ho Bornschein has decided to leave his role as CFO at CLS and Katarina Lundqvist assumes the role as Interim CFO. Katarina has held senior positions at science companies active on global markets.
- CLS announced enrollment completion of initial phase of clinical trial at Radboud University Medical Center. Further CLS and RUMC have agreed to extend the study with an additional 5 patients to be treated with MR-guided focal laser ablation.

Significant events after the end of the period

- CLS signed a Mobile Service Provider agreement with Kearney Urology Center PC of Kearny, Nebraska, USA, whereby CLS will provide the TRANBERG Thermal Therapy System, including sterile disposables, training and on-site clinical and technical support to Kearny Physicians and staff on a pay-per-procedure basis, for image guided focal laser ablation (FLA) of localized prostate cancer.
- 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 focal laser ablation (FLA) of low-to-intermediate risk prostate cancer in 25 patients. According to the agreement, HALO Diagnostics will be purchasing the TRANBERG sterile disposables required for the study.
- CLS signed a Mobile Service Provider (MSP) Agreement with KASRAEIAN Urology of Jacksonville, FL in USA. Under the agreement, CLS provides the TRANBERG Thermal Therapy System in a bundled service offering, including sterile disposables, training, and on-site clinical and technical support to KASRAEIAN Urology physicians and staff on a pay-per-procedure basis, for image guided focal laser ablation (FLA) of localized prostate cancer.

- CLS entered into an exclusive distribution agreement with Avanco Advanced Medical Solutions to market and sell CLS's TRANBERG product portfolio in the urology market in Portugal for image-guided focal laser ablation (FLA) of localized prostate cancer.

Comments from CEO Dan J. Mogren

The third quarter saw continued revenue growth driven primarily by the US market. Total revenues have nearly doubled when compared to the same period last year and we are on track to achieve our target revenues in 2025. We are excited that our intense efforts in the US around our Mobile Service Provider model for the minimally invasive treatment of prostate cancer are now bearing fruit. With the completion of the rights issue in July, we are now well positioned to continue to grow across the US as well as unlock the potential of Europe and the Asia Pacific

Debt free and optimizing our cost base

The rights issue which closed on 3 July 2023 raised approximately SEK 114.2 million before issue costs. The proceeds were used to retire our outstanding debt. This leaves us in a much stronger financial position and allows us to focus on the commercialization of our products in urology and neurosurgery. It also leaves us better positioned to attract new strategic partners and investors to support our continued growth. We are grateful for the support received from existing shareholders and welcome our new shareholders onboard.

We successfully managed to reduce costs to improve the overall financial result of the group and to free up investment for our commercial organization, in particular the US. The cost developments are in line with our plan, financing investment in our organization with cost savings in external costs. Overall, the cost trend is in line with our expectations and is trending positively towards our full-year target. Managing and optimizing our cost base continues to be a priority. Not only does this make us a more effective organization, it also gives us additional scope and flexibility to fund important growth initiatives across the US, Europe and, in the future, Asia Pacific.

We also saw a positive trend in sales driven by the commercial efforts in the US (urology), with recurring sales from our first commercial customer operating in the Urology Concierge segment, as well as sales to the National Institutes of Health Clinical Center.

Mobile Service Provider Model focus paying off

We are particularly pleased with the progress of our Mobile Service Provider (MSP) model which is an important complement to our model of selling disposables to customers who have purchased the TRANBERG Thermal Therapy System. We were able to announce the first customer for our MSP offering in April of this year and, following the end of the third quarter, we announced additional MSP agreements with the Kearney Urology Center PC and KASRAEIAN Urology, both located in the US.

Our MSP offering was further strengthened in August with the announcement of a co-marketing agreement with Focalyx. Under this agreement, the Focalyx Fusion image-guidance system will form part of the menu of options from which MSP customers can choose. At the same time, Focalyx customers will have the opportunity to benefit from the TRANBERG Thermal Therapy System for laser ablation of prostate tumors.

The MSP model shortens the time for customer acquisition and lowers the barriers to entry for customers. Under MSP agreements, CLS provides the TRANBERG Thermal Therapy System, with consumable accessories, training, and on-site clinical and technical support. Our customers can choose from a menu of different services and pay on a fee per procedure basis. This means that there are no capex requirements for clinics wanting to provide laser ablation therapy to treat localized prostate cancer using the TRANBERG Thermal Therapy System and for which our customers are willing to pay a higher fee per procedure to CLS.

Continued focus on collaboration partners in the US

During the quarter we continued our important research collaboration with the US National Institutes of Health Clinical Center. This collaboration, announced in April of this year, is evaluating the TRANBERG Thermal Therapy System for the treatment of prostate cancer. A successful conclusion of this collaboration will result in critical publications in academic literature validating laser ablation using the TRANBERG Thermal Therapy System as a safe and efficient focal therapy in localized prostate cancer. At the same time, we have continued to work closely throughout the quarter with the rapidly expanding HALO Precision Diagnostics on the TRANBERG Thermal Therapy System post-market study, an effort resulting in a joint announcement of its start in early November.

Neurosurgery in US

The four clinics currently included as part of the limited market release of the ClearPoint Prism Neuro Laser Therapy System continue to provide valuable feedback that will also enable future system optimization. So far, the overall feedback is very positive and ClearPoint Neuro Inc., our commercialization partner, is supporting the four clinics while also working to expand the limited market release program with additional clinics. The unique collaboration with ClearPoint Neuro Inc. combines CLS ablation technology platform consisting of the mobile laser unit, Thermoguide Workstation and non-cooled laser applicators, with ClearPoint Neuro Inc.'s navigation technology, for the treatment of, primarily, brain tumors and drug-resistant epilepsy.

During the quarter, ClearPoint Neuro Inc. exhibited the ClearPoint Prism Neuro Laser Therapy System at the Congress of Neurological Surgeon 2023 meeting and also conducted a demonstration at the Mayo Clinic Rochester Stimulation Therapies for Epilepsy 2023 course in Minnesota.

Extension of Radboud University Medical Center trial

In September we announced that the Radboud University Medical Center in Nijmegen, the Netherlands, had agreed to extend the investigator-initiated trial of TRANBERG Thermal Therapy System with Thermoguide Workstation for MR guided focal laser ablation. A total of ten patients with prostate cancer were safely treated in the initial phase of the trial which was conducted using the guidance system from our strategic partner, Soteria Medical BV. In the extended investigator-initiated trial, the investigators will utilize the TRANBERG Thermal Therapy System with Thermoguide Workstation and take a freehand approach to access the tumor.

Adding sales channels in Europe

The third quarter also saw us continuing to identify potential sites in Europe both for further trials and clinical treatment. Another focus in Europe during the quarter has been assessing potential distributors and partners. Identifying distributors is important for us and any candidates must have a strong track record and meet our requirements and standards. This process led to CLS entering an agreement in early November with Avanco – Advanced Medical Solutions, a company with a history of supplying the urology market with innovative solutions, giving them the exclusive rights to sell and distribute our TRANBERG products on the Portuguese market.

Tapping into the Asia Pacific market

We believe that we are nearing the end of the product approval process in Singapore. This has been a long and thorough process, and we hope once approval is granted in Singapore, it will be possible to have speedier approvals in other markets in the region. Expanding into Asia Pacific will allow us to diversify our geographical footprint and we expect the region will be an important contributor to achieving our revenue goal of 100 mSEK.

A strong team

I am always impressed by the hard work and dedication of the CLS team, and this quarter has been no different. Our ability to respond to market needs and grow our revenues is a testament to that work and dedication. In September we announced that Katarina Lundqvist would fill the role of Interim CFO at CLS following the resignation of Rolf Ho Bornschein. Katarina has extensive experience from finance director roles in international, pharmaceutical, and MedTech companies and has fitted seamlessly into the role.

Looking ahead

With our strengthened financial position following the closure of the rights issue and retirement of our debt, we are well positioned to achieve CLS's goal of improved care and increased quality of life for patients with cancer and neurological diseases.

As we continue on our commercialization pathway, our primary focus will remain on the US market. The announcements we have made following the end of the third quarter show the opportunity that exists to build on the momentum around the Mobile Service Provider model and we anticipate being able to bring further customers onboard. The MSP model will run side-by-side with our model based on sales of the TRANBERG Thermal Therapy System and recurring revenue through our customers' purchase of disposables. We will continue to work with ClearPoint Neuro to monitor the results of the limited market release and hope to continue adding new sites. As we expect the product approval process in Singapore is nearing completion, we will also look at developing the Asia Pacific region, while in Europe we will continue the work to add new customers and expand our distributor network.

The revenue growth we achieved in the third quarter as well as continued success in the US market shows that our model works and that the finetuning of our commercialization roll-out is moving us towards achieving our revenue target in 2025. We look forward to you being a part of this exciting journey.

Dan J. Mogren

CEO, Clinical Laserthermia Systems

This disclosure contains information that Clinical Laserthermia Systems AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out below on 17 November 2023, at CET 08:30.

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About CLS

Clinical Laserthermia Systems AB (publ) develops and sells the TRANBERG® Thermal Therapy Systems, including Thermoguide Workstation and sterile disposables, for minimally invasive treatment of cancer 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 used in studies for treatment with imILT®, the Company's interstitial laser thermotherapy for immunostimulant ablation with potential abscopal effects. CLS is headquartered in Lund and has subsidiaries in Germany, the US and Singapore. CLS is listed on the Nasdaq First North Growth Market under the symbol CLS B. The Certified Advisor (CA) is FNCA Sweden AB.

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