



Clinical Laserthermia Systems’ business update: focus on accelerating commercial roll-out and updated sales ambitions

Lund, Sverige – Clinical Laserthermia Systems AB (publ) (CLS) will give an update at today’s business update event, presenting the company’s strategic and its commercial roll-out, and provide an updated sales ambition.

Highlights that CLS will present at today’s business update event starting at 14:00 CET include near-term milestones for 2024-2026 to achieve the Company’s vision:

Urology market segment

- Entering into new agreements with commercial partners for continued expansion of sales and distribution in all regions to achieve 20 active users in the US and 15 active users in Europe by 2025.
- Launch CLS prostate cancer offering in the Asia-Pacific region, starting in Singapore with the ambition to enter into three to five new commercial agreements with end customers per year and one to two new agreements with commercial partners for continued expansion of sales and distribution in the region by 2026.
- Continue to develop clinical evidence for CLS’ systems for focal FLA treatment of localized prostate cancer to support continued commercialization.
- Develop a plan for clinical evidence development to obtain a category 1 reimbursement code in the US, for focal FLA treatment of localized prostate cancer, with a competitive reimbursement level and increase reimbursement rate for CLS category 3 reimbursement code in the U.S. for focal FLA treatment of localized prostate cancer and to obtain reimbursement codes in selected countries in Europe.
- Apply for market approval in the U.S. for CLS MRI-based treatment systems for focal FLA treatment of localized prostate cancer in radiology departments.

Neurosurgery market segment:

- Expand the addressable market in the U.S. by adding requested features to the Prism Neuro Laser Therapy System in collaboration with Clearpoint Neuro to be able to initiate the North American full market launch of Prism Neuro Laser Therapy System in 2024 to achieve at least six to eight new commercial customer installations per year until 2026.
- Expansion of clinical evidence development for MDR CE marking of the Prism Neuro Laser Therapy System in Europe.

Other strategic initiatives:

- Ensure certification and CE marking of CLS products in Europe according to MDR.
- Continue to secure IP assets linked to CLS's products and production to ensure scalability in the company's growth.
- Conduct recruitments and enter into partnerships to ensure the skills and resources necessary to achieve CLS's commercial goals in Europe, the US and Asia-Pacific.
- Entering into agreements with suppliers of critical components and materials to secure production capacity and security of supply in the supply chain.

Sales ambitions:

CLS's goal is to achieve a positive operating profit (EBITDA) during the financial year 2026. To achieve this, the Company estimates that sales of just over SEK 100 million are required in the same year, with a focus on the US market, which represents approximately 70 percent of total sales, and increased sales in the EU and start-up in the Asia-Pacific region during the first half of 2024. More than 60 percent of sales are expected to come from the urology segment.

"As we enter 2024, CLS is well positioned to increase revenue by meeting the needs of the market. During the second half of 2023, we saw continued sales and we expect to further increase the number of treatments and customers primarily focusing on the North American market. CLS and Clearpoint Neuro will together, invest in the Prism Neuro Laser Therapy System to expand the addressable North American neurosurgery market in 2024. We are also ready to unlock the potential in Europe, where we continue to expand our distribution network and accelerate customer processing. We also expect to be able to open the market in the Asia-Pacific region through our product approval in Singapore, being the CLS's hub in the region," said Dan J. Mogren, CEO of CLS.

At today's investor event, Dan J. Mogren, CEO, and members of the management team will present the company's strategic and its commercial roll-out and long-term sales ambitions.

The presentations will be held in English. Following the presentations, there will be a Q&A session moderated by Redeye analyst Gustaf Meyer. Viewers will have the opportunity to ask questions via the webcast chat.

Date and time

Wednesday January 17, 2024, at 14:00-15:30 CET.

Link:

The webcast can be followed live via the link: <http://www.redeye.se/events/964148/business-update-clinical-laserthermia-systems>

After the event, there will be a recording available at www.clinicallaser.se/.

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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

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