



PRESS RELEASE

22 August 2025

# CLS publishes half-year report January – June 2025

**Lund, Sweden – Clinical Laserthermia Systems AB (publ) ("CLS" or the "Company") today publishes its half year report January – June 2025.**

## **Second Quarter Highlights**

- Record sales revenue of SEK 9,4M, a 67% year-over-year increase compared with the second quarter 2024
- Minimal short-term impact from U.S.–EU tariffs
- US-FDA review underway for expanded labeling of ClearPoint Prism® to include 1.5T MRI compatibility, doubling the TAM in U.S
- Strong team and partner performance, continued market expansion, and a structurally lower cost base
- Board of directors strenghted with expertise in the neuro market and supply chain management to support continued growth
- Financial position remains on track ahead of TO8B warrant exercise in September

## **Summary of the interim report (relates to the Group)**

### **First six months (01/01/2025–06/30/2025)**

- Net sales totaled SEK 13,858,000 (SEK 8,762,000).
- Operating profit totaled SEK -10,775,000 (SEK -29,865,000).
- Profit/loss after financial items totaled SEK -21,578,000 (SEK -26,163,000).
- Basic and diluted earnings per share totaled SEK -0,92 (SEK -3,46).
- The equity ratio on June 30, 2025, was 90% (63%).

### **The second quarter (04/01/2025–06/30/2025)**

- Net sales totaled SEK 9,362,000 (SEK 5,622,000).
- Operating profit totaled SEK -2,907,000 (SEK -12,873,000).
- Profit/loss after financial items totaled SEK -6,348,000 (SEK -13,592,000).
- Basic and diluted earnings per share totaled SEK -0,28 (SEK -1,87).

- The equity ratio on June 30, 2025, was 90% (63%).

### **Significant events in the second quarter of 2025**

- CLS announced the submission of its 510(k) application to the U.S. Food and Drug Administration (FDA) for expanding the indication of ClearPoint Prism to also include 1.5 T MRI guidance.
- At the Annual General Meeting, held 27 June 2025, the meeting resolved to re-elect Peter Max as a member of the Board of Directors and to elect Lena Höglund, Veronica Byfield, Thomas Binzer and Jerker Nygren. Peter Max was re-elected as Chairman of the Board.

### **Significant events after the end of the period**

- There were no significant events following the end of the quarter.

### **Comments from CEO Dan J. Mogren**

The second quarter of 2025 reflects continued strong execution of our strategic and operational priorities and with sales in the quarter at record levels.

#### **Continued Revenue Growth & Cost Discipline**

Revenue grew by 67% compared to Q2 last year, driven by a particularly strong performance in our neurosurgery segment and exceptionally high sales volumes to our partner Clearpoint Neuro.

This growth, combined with continued cost discipline, resulted in a gross margin of 70%, well above our full-year target of 60%, and a reduction in operating expenses of more than 30% versus the second quarter of 2024.

For the first six months, Revenue growth was 58%, Gross Margin 69% and OPEX reduced more than 30% vs. 2024.

#### **U.S.-EU Trade Deal**

The recently announced U.S.–EU trade deal establishes a general 15% tariff ceiling on most EU goods, but the treatment of medical devices remains uncertain. While discussions continue and the impact on our business is minimal today, we continue to monitor the development.

#### **510(k) Submission under review by US-FDA**

In late April, CLS submitted its 510(k) application to U.S. FDA to expand the labeling of the ClearPoint Prism® Neuro Laser Therapy System to include image guidance also with 1.5T MRI scanners. The application is currently under FDA review. Upon clearance, this label expansion would significantly broaden patient access to MRI-guided laser interstitial thermal therapy (NeuroLITT), allowing for accelerating adoption and growth even further.

#### **Strengthening of the Board of Directors**

In the second quarter, CLS also strengthened its governance with the election of four new members to the Board of Directors, as approved by our shareholders at the AGM on June 27. I am pleased that Peter Max continues in his role as Chairman, providing continuity as we welcome new perspectives and expertise within areas important to CLS, such as the neuro market and supply chain management, to support the company's next phase of growth.

#### **Outlook Remains Strong**

Our long-term growth outlook remains strong, supported by solid partner relationships, continued market expansion in neurosurgery, and a robust pipeline of opportunities.

With revenue growth and margins both exceeding targets, and our cost base structurally lower, we are confident in our ability to sustain high double-digit growth for 2025.

Our financial position remains on plan, positioning CLS well ahead of the planned TO8B warrant exercise in September and enabling us to continue creating value for shareholders while advancing the commercial rollout of our technology with our strategic upstream and downstream partners.

### **CLS Vision**

In a rapidly evolving global environment, it is essential for CLS to combine strong operational execution with a clear long-term vision. Our commitment is to ensure that shareholders, partners, and clinicians remain aligned with the transformative journey we are pursuing.

Surgery is entering a new era. Advances in imaging, artificial intelligence, and minimally invasive techniques are converging with the growing medical need created by an increasing incidence of disorders worldwide that require surgery. Together, these factors are accelerating the adoption of image-guided minimally invasive surgery — not only to enhance surgical precision, but also to shorten recovery times, reduce healthcare costs, and improve patient outcomes.

CLS's vision is to be at the forefront of this transformation. Through our synergistic partnership with Clearpoint Neuro, we are uniquely positioned to lead the global adoption of MR image-guided laser interstitial thermal therapy (NeuroLITT) within neurosurgery. By combining CLS's precision laser ablation technology with Clearpoint Neuro's advanced neuro-navigation systems, we enable clinicians to safely and effectively treat patients with conditions that have previously been difficult to manage. This sets the stage for a new standard of care in neurosurgery.

Looking ahead, we remain committed to building a sustainable business model with recurring revenues, expanding access to our technology, and creating long-term value for patients, healthcare providers, and shareholders alike.

### **Shareholder Value**

The commitment of our shareholders is instrumental in our progress and in driving our mission to revolutionize the surgical treatment with image-guided precision laser technology. We believe our journey forward will not only advance surgical treatment but also create significant value for our shareholders.

Thank you for your continued support, and we look forward to your active participation in the exciting developments to come.

### **Dan J. Mogren**

CEO, Clinical Laserthermia Systems AB

*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 22 August 2025, at CEST 08:30.*

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### **About CLS**

*Clinical Laserthermia Systems AB (publ), develops and sells TRANBERG® Thermal Therapy System and ClearPoint Prism® Neuro Laser Therapy System with sterile disposables, for minimally invasive treatment of cancer tumors and drug-resistant epilepsy. The products are marketed and sold through partners for image-guided laser ablation and are used in studies for treatment with imILT®, the company's interstitial laser thermotherapy for immune stimulating ablation with potential abscopal treatment effect. CLS is headquartered in Lund, Sweden, with subsidiaries in Germany, the United States and a marketing company in Singapore. CLS is*

*listed on Nasdaq First North Growth Market under the symbol CLS B. Certified adviser (CA) is FNCA Sweden AB.*

*For more information about CLS, please visit the Company's website: [www.clinicallaser.se](http://www.clinicallaser.se)*