



Half-year Report
01/01/2025–06/30/2025

Clinical Laserthermia Systems AB (publ)
Reg. no. 556705-8903

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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

CLS in brief

CLS is an international provider of image-guided laser-based therapy systems for minimally invasive and precise tissue ablation, marketed and sold to medical professionals through strategic partnerships.

Product offering

CLS offers products that, through minimally invasive access, safely and effectively remove diseased, or disease generating, tissue without damaging surrounding tissues or organs. CLS's therapy systems deliver and deposit laser energy in the targeted tissue resulting in precise tissue ablation. This minimally invasive procedure is beneficial as recovery typically is quicker than traditional surgery and the patient can return home early.

CLS's laser ablation platform consists of medical laser units with integrated functions for advanced image-based monitoring and control of treatment and associated disposable instruments. CLS commercial product portfolio that uses CLS laser ablation platform includes the following brands:

- ClearPoint Prism Neuro Laser Therapy System for use within Neurosurgery
- TRANBERG Thermal Therapy System for use outside of Neurosurgery

CLS's platform operates with solutions from major imaging and guidance technology suppliers on the market.

Market opportunity

The ablation technology market is experiencing robust growth driven by key factors. First, the rising incidence of chronic diseases, such as cancer, cardiovascular and other functional disorders, necessitates effective treatment options, boosting demand for ablation procedures. Second, technological advancements in ablation techniques, such as the ones by CLS, are improving safety and efficacy, attracting both patients and healthcare providers. The shift towards minimally invasive procedures is significant; these techniques offer faster recovery times and fewer complications, making them increasingly popular in clinical settings. Together, these factors create a favorable environment for the expansion of the ablation technology market, enabling continued innovation and adoption across healthcare systems.

In neurosurgery, traditional surgery cannot safely reach all structures in the brain and can therefore often not be used in treatment of brain lesions in patients with, for example, drug-resistant epilepsy, brain tumors or radiation necrosis. Therefore, there is a demand for less invasive procedures with a high degree of treatment accuracy. The existing competitive landscape includes only a few competing ablative technologies, with none of them offering the "complete eco system" required for streamlining and standardizing these procedures. Reimbursement is available for several procedures, including NeuroLITT.

Business and revenue models

Through its commercial partnership model, CLS is currently targeting the NeuroLITT market within neurosurgery in collaboration with its strategic exclusive global partner Clearpoint Neuro Inc. which today markets and sells ClearPoint Prism Neuro Laser Therapy Systems directly to clinics in the U.S. CLS imports products into the U.S market through its wholly owned subsidiary CLS Americas Inc.

CLS revenue model is that of "razor-razorblade" and includes recurrent sales of capital equipment and consumables in the form of proprietary sterile disposables, as well as service & maintenance.

Strategic initiatives

CLS's overall strategy is to grow its business through its commercial partnership model and expand it across therapy-enabling organizations in attractive market segments also outside of neurosurgery, ensuring broader market reach. The company's products have marketing approval in Europe (CE), the US (510(k)/FDA) and Singapore (SMDR) in the indications for which the certificates are granted.

Sales ambitions & objectives

To best manage the risks associated with reaching a positive cashflow at the end of 2026, CLS is dedicating all resources to accelerating the commercialization of its neurosurgery segment through its strategic partner, ClearPoint Neuro Inc., while enhancing its cost-cutting initiative to further streamline operations, ensuring the Company operates with maximum efficiency and focus.

Mid-term, CLS ambition is to expand its commercial partnership model to generate sales revenues from therapy-enabling organizations, in attractive market segments, also outside of neurosurgery.

CLS's long-term commercial objective is to also commercialize the company's product portfolio in the use of imILT for an enhanced immunostimulatory effect in the treatment of cancer.

Company structure and shareholdings

CLS has had a wholly owned subsidiary in the United States (CLS Americas Inc.) since 2014 and a wholly owned subsidiary in Germany (CLS GmbH) since 2017. In 2020, CLS registered, together with Advanced Medical Systems Pte Ltd. (AMS), the joint venture company CLS Asia Pacific Pte Ltd. in Singapore. CLS holds 50% of the shares in this company.

Development of earnings and position

CLS is experiencing increasing revenues from sales. The company's operating expenses consist primarily of expenses for personnel, manufacturing, product development, regulatory compliance and quality assurance.

The share

CLS's class B share was listed on Nasdaq Stockholm First North on March 21, 2017. On June 30, 2025, the number of shares in the company was 25,666,594 of which 3,000 were unlisted Class A shares, and the number of votes was 25,693,594. The share capital totaled approximately SEK 59,279,057.

Basis of preparation for the interim report

The interim report has been prepared in accordance with IAS 34 and thus using the same accounting policies and assessments as in the company's most recent annual report, i.e. in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU.

Auditor's review

The interim report has not been reviewed by the company's auditor.

Financial calendar

Interim Report 3/25 January – September	11/14/2025
Year-end report 2025	02/20/2026

Submission of interim report

Lund, August 22, 2025
Clinical Laserthermia Systems AB
Board of Directors

The information was submitted for publication, through the agency of the contact person stated below, on August 22, 2025, at 08:30 CET.

The report will be published on the CLS website under IR. Direct link to the report <https://clinicallaser.se/financial-reports/>

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Financial overview

Consolidated income statement and other comprehensive income for the period

(SEK thousands)	Note	04/01/25– 06/30/25 (3 months)	04/01/24– 06/30/24 (3 months)	01/01/25– 06/30/25 (6 months)	01/01/24– 06/30/24 (6 months)
Net sales		9,362	5,622	13,858	8,762
Change in finished goods in inventory		358	-450	898	-1,616
Other operating income		24	191	172	329
Operating expenses					
Merchandise		-3,157	-2,302	-5,312	-4,952
Other external expenses		-4,320	-9,119	-10,206	-18,940
Personnel expenses		-4,497	-6,072	-8,867	-11,999
Depreciation of property, plant and equipment		-604	-604	-1,208	-1,207
Other operating expenses		-73	-139	-110	-242
Total costs		-12,651	-18,236	-25,703	-37,340
Operating profit/loss		-2,907	-12,873	-10,775	-29,865
Profit/loss from financial items					
Profit/loss from other securities and receivables held as non-current assets	1	-3,409	-698	-10,715	3,730
Other interest and similar income		-32	-1	-88	1
Interest and similar expenses			-20		-29
Profit/loss after financial items		-6,348	-13,592	-21,578	-26,163
Deferred tax					
Profit/loss for the period		-6,348	-13,592	-21,578	-26,163
Minority share of profit/loss for the period			2	5	176
Profit/loss for the period		-6,348	-13,590	-21,573	-25,987
Other comprehensive income					
Items that may be reclassified to the income statement					
Translation of foreign subsidiaries		-526	113	-616	-914
Comprehensive income for the period		-6,874	-13,477	-22,189	-26,901

Consolidated statement of financial position at end of period

(SEK thousands)	Note	06/30/25	12/31/24
Assets			
Fixed assets			
<i>Intangible fixed assets</i>			
Capitalized expenditure for research and development, and similar work		7,338	10,925
Comsessions, patents, licenses, trademarks and similar rights		5,103	2,559
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings		3,416	4,579
Advances fixed assets		9,208	8,362
Right-of-use assets		199	199
<i>Financial fixed assets</i>			
Deferred tax assets	2	12,431	13,528
Total non-current assets		37,695	40,152
Current assets			
<i>Inventories etc.</i>			
Finished goods in inventory		4,006	3,903
Advances to suppliers		3,788	4,248
<i>Current receivables</i>			
Accounts receivable		7,874	4,591
Other receivables		1,820	2,177
Prepayments and accrued income		711	983
Cash and bank balances		16,202	22,506
Total current assets		34,401	38,408
Total assets		72,096	78,560

Consolidated statement of financial position at end of period, cont'd

(SEK thousands)	06/30/25	12/31/24
Equity and liabilities		
Equity		
<i>Equity attributable to parent company shareholders</i>		
Share capital	58,522	46,576
Development expenditure fund	1,846	2,110
Other paid-in capital	3,078	39,949
Reserves	-649	-33
Retained earnings	26,002	27,742
Profit/loss for the period	-21,573	-47,622
Equity attributable to parent company shareholders	67,226	68,722
Minority share	-2,799	-3,036
Total equity	64,427	65,686
Long-term leasecontract	8	8
Current liabilities		
Accounts payable	2,801	6,295
Short-term leasecontract	216	216
Current tax liabilities	76	70
Other liabilities	1,421	1,447
Accruals and deferred income	3,147	4,838
	7,661	12,866
Total equity and liabilities	72,096	78,560

Consolidated statement of changes in equity

01/01/2024–12/31/2024

(SEK thousands)	Share capital	Other paid-in capital	Reserves	Retained earnings incl. profit/loss for the year
At beginning of year	15,425	12,435	918	14,750
New share issue	31,151	53,251		
Costs emission		-13,302		
Reversal as a result of amortization of development expenses for the year		-527		527
Change in deferred tax				5,705
Rebooking of share premium service		-9,798		9,798
Translation differences			-951	-3,038
Profit/loss for the year				-47,622
Minority share				-3,036
At end of year	46,576	42,059	-33	-22,916

01/01/2025–06/30/2025

(SEK thousands)	Share capital	Other paid-in capital	Reserves	Retained earnings incl. profit/loss for the year
At beginning of period	46,576	42,059	-33	-22,916
New share issue	11,946	4,004		
Costs emission		-926		
Reversal as a result of amortization of development expenses for the period		-264		264
Change in deferred tax				-1,097
Rebooking of share premium service		-39,949		39,949
Translation differences			-616	9,802
Profit/loss for the period				-21,573
Minority share				-2,799
At end of period	58,522	4,924	-649	1,630

Consolidated cash flow statement for the period

(SEK thousands)	04/01/25– 06/30/25 (3 months)	04/01/24– 06/30/24 (3 months)	01/01/25– 06/30/25 (6 months)	01/01/24– 06/30/24 (6 months)
OPERATING ACTIVITIES				
Receipts from customers	4,349	3,217	10,558	5,619
Cash paid to suppliers and employees	-15,132	-17,104	-30,875	-40,003
Tax paid	-116	-105	191	-128
Cash flow from operating activities before interest	-10,899	-13,992	-20,126	-34,512
Interest paid		-20		-29
Interest received			3	2
Cash flow from operating activities	-10,899	-14,012	-20,123	-34,539
INVESTING ACTIVITIES				
Acquisition of property, plant and equipment	-703	-1,879	-1,108	-1,879
Acquisition of intangible assets			-97	-6
Cash flow from investing activities	-703	-1,879	-1,205	-1,885
FINANCING ACTIVITIES				
New share issue	-66	-292	15,024	20,563
Proceeds from borrowings		12,500		12,500
Cash flow from financing activities	-66	12,208	15,024	33,063
Cash flow for the period	-11,668	-3,683	-6,304	-3,361
Cash and cash equivalents at beginning of period	27,870	15,653	22,506	15,331
Cash and cash equivalents at end of period	16,202	11,970	16,202	11,970

Parent company income statement for the period

(KSEK)	Note	04/01/25– 06/30/25 (3 months)	04/01/24– 06/30/24 (3 months)	01/01/25– 06/30/25 (6 months)	01/01/24– 06/30/24 (6 months)
Operating income					
Net sales		2,630	745	4,047	1,629
Change in finished goods in inventory		298	-450	898	-1,616
Other operating income		15	167	154	266
Operating expenses					
Merchandise		-3,376	-3,246	-4,884	-5,204
Other external expenses		-3,702	-7,855	-8,852	-14,886
Personnel expenses		-4,303	-3,846	-8,070	-7,605
Depreciation of property, plant and equipment		-601	-601	-1,202	-1,202
Other operating expenses		-73	-139	-110	-242
Total expenses		-12,055	-15,687	-23,118	-29,139
Operating profit/loss		-9,112	-15,225	-18,019	-28,860
Profit/loss from financial items					
Profit/loss from other securities and receivables held as non-current assets		-2,861	471	-9,572	4,899
Other interest and similar income		-32	-578	-88	1
Interest and similar expenses			-2		-2
Profit/loss after financial items		-12,005	-15,334	-27,679	-23,962
Profit/loss for the period		-12,005	-15,334	-27,679	-23,962

Parent company statement of financial position at end of period

(SEK thousands)	06/30/25	12/31/24
Assets		
Non-current assets	107,066	119,456
Current assets	24,704	29,834
Total assets	131,770	149,290
Equity and liabilities		
Equity	125,331	137,985
Long-term Liabilities	8	8
Current liabilities	6,431	11,297
Total equity and liabilities	131,770	149,290

Notes**Note 1 Profit/loss from other securities and receivables held as non-current assets**

The item includes foreign exchange gains on receivables from subsidiaries.

Note 2 Deferred tax assets

In preparing the financial statements, the board of directors of the US subsidiary has estimated that the company will make future profits in the near future and has therefore recognized a deferred tax asset equal to the tax on the tax loss.

Definitions

- ✓ *Earnings per share:* Profit for the period divided by the average number of shares for the period:
Q2: 25,533,401 (including 3,000 unlisted A shares) and for first six months: 23,436,360 (including 3,000 unlisted A shares). The number of shares for 2024 has been recalculated considering the merger of shares (200:1) that was completed on 24 April 2024.
- ✓ *Equity ratio:* Equity divided by total assets.



Clinical Laserthermia Systems AB

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