



Interim Report
01/01/2025–09/30/2025

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

Highlights of the Third Quarter Interim Report

During the third quarter, CLS continued to strengthen its operational and financial position while producing and delivering products, development, and support services for growing the adoption and installed base of its product portfolio.

- The company achieved a key regulatory milestone in the US-FDA clearance of the expanded labeling of CLS ClearPoint Prism® branded Neuro Laser Therapy System to include both 3.0T and 1.5T MR image guidance and that significantly expands the market opportunity in neurosurgery.
- By strict cost control and higher operational efficiency, CLS delivered an improvement in operating profit of SEK 2,3 million compared to third quarter 2024.
- For the first nine months, CLS neuro business grew by 38 percent while total revenue grew by 18 percent.
- Revenue for the quarter amounted to SEK 2.8 million, a reduction compared with the same period last year, impacted mainly by timing of deliveries, late arrival of the expanded clearance for CLS ClearPoint Prism® branded Neuro Laser Therapy System at the end of the quarter, and lower sales in the urology segment.
- Following the strategic decision to close CLS direct sales operation within the urology segment by end of 2024, the revenue declined by 61% compared to the third quarter of 2024.
- Operating profit improved by SEK 21.4 million for the first nine months compared with the same period last year.
- CLS strengthened its financial base through the full subscription of warrants of series TO8B, adding SEK 20.9 million in gross proceeds. Combined with the capital raised in February, this completes the SEK 37 million financing package announced earlier this year, aimed at ensuring that CLS is capitalized to execute its growth strategy.
- The strengthening of the Swedish Krona during 2025 has impacted the intercompany loans, YTD revaluation is SEK 11,4 million. The Q3 reporting also includes a correction of SEK 789 thousand for late received supplier invoices from 2024.
- CLS remains debt-free and maintains a positive operational cash flow trend supported by lower operating expenses.

Summary of the interim report (relates to the Group)

(SEK thousands)	2025 Jul - Sep	2024 Jul - Sep	2025 Jan - Sep	2024 Jan - Sep	2024 Full Year
Net Sales	2,799	5,409	16,657	14,171	18,783
Operating Profit	-7,419	-9,684	-18,194	-39,549	-54,254
Profit/Loss for the period	-8,137	-12,966	-29,710	-38,953	-47,623
Earnings per share (SEK)	-0,3	-1,0	-1,2	-4,1	-4,3
Equity Ratio	89%	85%	89%	85%	84%

Comments from CEO Dan J. Mogren

In September, we achieved a key milestone when the U.S. Food and Drug Administration (FDA) granted expanded clearance for CLS ClearPoint Prism® branded Neuro Laser Therapy System to include both 3.0T and 1.5T MRI scanners. This approval more than doubles the addressable U.S. market for Neuro LITT procedures and positions CLS and ClearPoint Neuro for accelerated adoption in hospitals that previously could not access the technology.

The clearance represents not only an important commercial inflection point but also validation of the clinical versatility of our laser therapy platform. The first installations of the 1.5T labeled PRISM system are expected in the fourth quarter of this year.

In early October we announced positive results from the clinical safety study on laser ablation, performed using CLS Prism branded LITT platform in patients with malignant brain tumor. The study was conducted at Skåne University Hospital and presented in October at the CNS annual meeting in Los Angeles.

Patients in the study showed increased median survival compared to a matched control group treated with open surgery. We are very pleased that the primary clinical safety objectives of the study were successfully achieved and by positive feedback from the neurosurgeons that the system is easy to use with a reproducible workflow enabling a median ablation time of 6.5 minutes.

Further empowered by the recent successful regulatory and clinical study achievements, and in awareness of the current challenging trade climate between Europe and the U.S, we have intensified conversations with our upstream and downstream partners to align on an accelerated growth scenario going forward.

In line with our growth strategy, the company has decided to actively start expanding the partnership model outside of neurosurgery. This decision aims to broaden the company's commercial base and create a diversified, more balanced and predictable growth platform going forward.

Looking ahead, our priorities remain clear:

- Support a broader U.S. adoption of the ClearPoint Prism® system under the expanded FDA clearance including both 3.0T & 1.5T MRI image guidance and through the commercial program of our partner ClearPoint Neuro.
- Advance prioritized Prism improvements, and regulatory initiatives in Europe, to further expand and strengthen our market position in neurosurgery.
- Expand our partnership model outside of neurosurgery to capture additional business opportunities, reduce risk and add stability in our business.
- Continue optimizing margins and cost structure in our move toward sustainable profitability.

With strong clinical momentum, lowered barriers to adoption and market expansion, a focused organization, and a solid financial foundation, CLS is well positioned to deliver on its mission — to make minimally invasive laser therapy available to more patients worldwide.

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

Significant events in the third quarter of 2025

- CLS announced that the U.S. Food and Drug Administration (FDA) has granted clearance for expansion of the labeling of ClearPoint Prism® Neuro Laser Therapy System. In addition to the existing clearance for use with 3.0 Tesla (3.0T) magnetic resonance imaging (MRI) guidance, the system is now also cleared for use with 1.5T MRI guidance. The expanded clearance significantly broadens the accessibility of the Prism Neuro Laser Therapy System for U.S. hospitals and patients, as approximately half of all MRI-guided neurosurgical procedures are performed using 1.5T scanners. The approval thereby more than doubles the addressable U.S. market for Neuro Laser Interstitial Thermal Therapy (Neuro LITT) procedures.

Significant events after the end of the period

- CLS raised SEK 20.9 million through full subscription of Warrants of Series TO 8B. All 5,500,000 warrants of series TO 8B, issued in connection with the directed share issue in February 2025, have been exercised. The exercise added SEK 20.9 million before transaction costs to CLS, corresponding to a subscription rate of 100 percent. The total number of shares in CLS will amount to 31,166,594, corresponding to a share capital of approximately SEK 71,981,747.85.
- CLS announced positive results from a clinical safety study on laser ablation, performed using CLS proprietary LITT platform in patients with malignant brain tumor, conducted at Skåne University Hospital. Patients had increased median survival compared to a matched control group treated with open surgery. The study's primary objective – to investigate whether the CLS proprietary LITT platform was safe and feasible in the treatment of brain tumors – was successfully achieved. The study, that was conducted by neurosurgeons at Skåne University Hospital, was sponsored by CLS and co-funded by ClearPoint Neuro, Inc. The laser ablations were guided by 3T MR imaging and neuro navigation was performed using ClearPoint® Neuro Navigation System, ClearPoint Neuro Inc.

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 surgical 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 in brief

CLS's class B share was listed on Nasdaq Stockholm First North on March 21, 2017. On September 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.

After Q3 the TO 8B warrants have been exercised. As of November 14, the number of shares in the company is 31,166,594 of which 3,000 were unlisted Class A shares, and the number of votes is 31,193,594.

Q3 report excludes the result of TO8B in share capital, cash balance and key figures.

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

Year-end report 2025	02/20/2026
Interim Report January – March 2026	05/15/2026
Interim Report January – June 2026	08/14/2026
Interim Report January – September 2026	11/13/2026
Year-end report 2026	02/19/2027

Submission of interim report

Lund, November 14, 2025
Clinical Laserthermia Systems AB
Board of Directors

The information was submitted for publication, through the agency of the contact person stated below, on November 14, 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/>

Contact information:

Dan J. Mogren, CEO Clinical Laserthermia Systems AB (publ)
Tel: +46 (0)705 90 11 40
Email: dan.mogren@clinicallaser.com

Financial overview

Consolidated income statement and other comprehensive income for the period

(SEK thousands)	Note	07/01/25– 09/30/25 (3 months)	07/01/24– 09/30/24 (3 months)	01/01/25– 09/30/25 (9 months)	01/01/24– 09/30/24 (9 months)
Net sales		2,799	5,409	16,657	14,171
Change in finished goods in inventory		828	189	1,726	-1,427
Other operating income		10	-261	182	68
Operating expenses					
Merchandise		-2,391	-971	-7,703	-5,923
Other external expenses		-4,082	-8,923	-14,288	-27,863
Personnel expenses		-3,872	-4,396	-12,739	-16,395
Depreciation of property, plant and equipment		-604	-605	-1,812	-1,812
Other operating expenses		-107	-126	-217	-368
Total costs		-11,056	-15,021	-36,759	-52,361
Operating profit/loss		-7,419	-9,684	-18,194	-39,549
Profit/loss from financial items					
Profit/loss from other securities and receivables held as non-current assets	1	-704	-2,900	-11,419	830
Other interest and similar income		-14		-102	1
Interest and similar expenses			-383		-412
Profit/loss for the period		-8,137	-12,967	-29,715	-39,130
Minority share of profit/loss for the period			1	5	177
Profit/loss for the period		-8,137	-12,966	-29,710	-38,953
Other comprehensive income					
Translation of foreign subsidiaries		-141	78	-757	-836
Comprehensive income for the period		-8,278	-12,888	-30,467	-39,789

Consolidated statement of financial position at end of period

(SEK thousands)	Note	09/30/25	12/31/24
Assets			
Fixed assets			
<i>Intangible fixed assets</i>			
Capitalized expenditure for research and development, and similar work		6,978	10,925
Commissions, patents, licenses, trademarks and similar rights		4,911	2,559
<i>Property, plant and equipment</i>			
Equipment, tools, fixtures and fittings		3,321	4,579
Advances fixed assets		9,822	8,362
Right-of-use assets		199	199
<i>Financial fixed assets</i>			
Deferred tax assets	2	12,308	13,528
Total non-current assets		37,539	40,152
Current assets			
<i>Inventories etc.</i>			
Finished goods in inventory		4,808	3,903
Advances to suppliers		3,148	4,248
<i>Current receivables</i>			
Accounts receivable		3,193	4,591
Other receivables		1,892	2,177
Prepayments and accrued income		352	983
Cash and bank balances		13,198	22,506
Total current assets		26,591	38,408
Total assets		64,130	78,560

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

(SEK thousands)	09/30/25	12/31/24
Equity and liabilities		
Equity		
<i>Equity attributable to parent company shareholders</i>		
Share capital	58,522	46,576
Development expenditure fund	1,714	2,110
Other paid-in capital	3,078	39,949
Reserves	-790	-33
Retained earnings	26,746	27,742
Profit/loss for the period	-29,710	-47,622
Equity attributable to parent company shareholders	59,560	68,722
Minority share	-2,739	-3,036
Total equity	56,821	65,686
Long-term leasecontract	8	8
Current liabilities		
Accounts payable	2,829	6,295
Short-term leasecontract	216	216
Current tax liabilities	91	70
Other liabilities	1,326	1,447
Accruals and deferred income	2,839	4,838
	7,301	12,866
Total equity and liabilities	64,130	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

01/01/2025–09/30/2025

(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		-396		396
Change in deferred tax				-1,220
Rebooking of share premium service		-39,949		39,949
Translation differences			-757	10,537
Profit/loss for the period				-29,710
Minority share				-2,739
At end of period	58,522	4,792	-790	-5,703

Consolidated cash flow statement for the period

(SEK thousands)	07/01/25– 09/30/25 (3 months)	07/01/24– 09/30/24 (3 months)	01/01/25– 09/30/25 (9 months)	01/01/24– 09/30/24 (9 months)
OPERATING ACTIVITIES				
Receipts from customers	7,548	5,309	18,106	10,928
Cash paid to suppliers and employees	-9,720	-16,674	-40,595	-56,677
Tax paid	-115	-105	76	-233
Net interest	-105	-383	-102	-410
Cash flow from operating activities	-2,392	-11,853	-22,515	-46,392
INVESTING ACTIVITIES				
Acquisition of property, plant and equipment	-612	-278	-1,720	-2,157
Acquisition of intangible assets		-1,968	-97	-1,974
Cash flow from investing activities	-612	-2,246	-1,817	-4,131
FINANCING ACTIVITIES				
New share issue		30,210	15,024	50,773
Proceeds from borrowings				12,500
Repayment of borrowings		-12,500		-12,500
Cash flow from financing activities		17,710	15,024	50,773
Cash flow for the period	-3,004	3,611	-9,308	250
Cash and cash equivalents at beginning of period	16,202	11,970	22,506	15,331
Cash and cash equivalents at end of period	13,198	15,581	13,198	15,581

Parent company income statement for the period

(SEK thousands)	Note	07/01/25– 09/30/25	07/01/24– 09/30/24	01/01/25– 09/30/25	01/01/24– 09/30/24
		(3 months)	(3 months)	(9 months)	(9 months)
Operating income					
Net sales		1,192	6,057	5,239	7,686
Change in finished goods in inventory		1,124	189	2,022	-1,427
Other operating income		10	33	164	299
Operating expenses					
Merchandise		-2,817	-1,949	-7,701	-7,153
Other external expenses		-3,719	-7,772	-12,571	-22,658
Personnel expenses		-3,872	-3,713	-11,942	-11,318
Depreciation of property, plant and equipment		-601	-602	-1,803	-1,804
Other operating expenses		-107	-126	-217	-368
Total expenses		-11,116	-14,162	-34,234	-43,301
Operating profit/loss		-8,790	-7,883	-26,809	-36,743
Profit/loss from financial items					
Profit/loss from other securities and receivables held as non-current assets		-198	-2,325	-9,770	2,574
Other interest and similar income		-14	1	-102	2
Interest and similar expenses			-378		-380
Profit/loss after financial items		-9,002	-10,585	-36,681	-34,547
Profit/loss for the period		-9,002	-10,585	-36,681	-34,547

Parent company statement of financial position at end of period

(SEK thousands)	09/30/25	12/31/24
Assets		
Non-current assets	99,550	119,456
Current assets	22,968	29,834
Total assets	122,518	149,290
Equity and liabilities		
Equity	116,328	137,985
Long-term Liabilities	8	8
Current liabilities	6,182	11,297
Total equity and liabilities	122,518	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: Q3: 25,666,594 (including 3,000 unlisted A shares) and for first nine months: 24,187,941 (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
Corporate registration number: 556705-8903
Address: Scheelevägen 2, 223 63 Lund
Website: www.clinicallaser.se