
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 28, 2025

Carlsmed, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-42756
(Commission File Number)

83-1081863
(IRS Employer
Identification No.)

1800 Aston Ave, Suite 100
Carlsbad, California
(Address of Principal Executive Offices)

92008
(Zip Code)

Registrant's Telephone Number, Including Area Code: (760) 766-1923

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.00001 par value per share	CARL	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 2.02 Results of Operations and Financial Condition.

On August 28, 2025, the Company issued a press release announcing its financial results for the quarter ended June 30, 2025. The full text of the press release is furnished hereto as Exhibit 99.1 and is incorporated herein by reference.

The foregoing information in this Item 2.02 (including Exhibit 99.1) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(a) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1*	Press Release of Carlsmed, Inc., dated August 28, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CARLSMED, INC.

Date: August 28, 2025

By: /s/Michael Cordonnier
Michael Cordonnier
Chief Executive Officer and President

Carlsmed® Reports Second Quarter 2025 Financial Results*Q2'25 revenue of \$12.1 million, 99% YOY growth**Full year revenue guidance of \$45.5M - \$47.5M*

CARLSBAD, Calif., August 28, 2025 (GLOBE NEWSWIRE) -- Carlsmed, Inc. (Nasdaq: CARL) ("Carlsmed" or the "Company"), a medical technology company pioneering AI-enabled personalized spine surgery solutions, today reported financial results for the second quarter ended June 30, 2025.

"Our strong commercial performance was driven by the continued adoption of our highly differentiated AI-enabled aprevo® technology platform and growing recognition of its ability to deliver more favorable patient outcomes than legacy devices," said Mike Cordonnier, Chairman and CEO of Carlsmed. "Building upon our momentum in personalized lumbar fusion surgery, in July we successfully completed the first personalized cervical spine surgery using our aprevo® technology platform, launching in 2026. We enter the second half of 2025 well positioned for continued scale as we become the new standard of care in spine fusion surgery."

Second Quarter Financial Results & Recent Highlights

- Revenue was \$12.1 million for the second quarter of 2025; a 99% increase compared to \$6.1 million for the second quarter of 2024. This increase was driven by the increased number of surgical procedures utilizing the aprevo® technology platform in the second quarter of 2025, with average revenue per procedure flat between these periods.
 - Gross profit for the second quarter of 2025 was \$8.9 million compared to \$4.6 million for the second quarter of 2024, due to our increased revenue. Gross margin was 73.4% for the second quarter of 2025, compared with 75.0% for the second quarter of 2024; this decrease was primarily driven by expedite production fees charged by our contract manufacturer in the second quarter to meet customer timing requirements.
 - Operating expenses were \$15.4 million for the second quarter of 2025, compared with \$10.9 million for the second quarter of 2024.
 - Research and development expenses were \$4.2 million for the second quarter of 2025, compared with \$4.0 million for the second quarter of 2024. This increase was primarily driven by higher personnel costs to support product development and artificial intelligence initiatives, partially offset by lower prototype and materials costs and reduced COMPASS registry costs following enrollment completion in second half of 2024.
 - Sales and marketing expenses were \$7.9 million for the second quarter of 2025, compared with \$4.9 million for the second quarter of 2024. This increase was primarily driven by personnel additions and variable sales expenses associated with our revenue growth, as well as an increase in marketing expenses.
 - General and administrative expenses were \$3.3 million for the second quarter of 2025, compared with \$2.0 million for the second quarter of 2024. This increase was primarily due to personnel additions to support business growth and costs associated with the transition to being a publicly traded company, including associated legal, accounting, and other professional fees.
 - Net loss was \$6.8 million for the second quarter of 2025, compared to a \$6.3 million net loss for the second quarter of 2024.
 - Adjusted EBITDA loss was \$6.2 million for the second quarters of 2025 and 2024.
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- Cash and cash equivalents were \$33.5 million as of June 30, 2025. The Company received \$93.5 million of net proceeds, after deducting underwriting discounts and commissions and before other additional offering expenses, from its initial public offering in July 2025.
- The first personalized cervical spine surgery using the AI-enabled aprevo® technology platform was performed.
- aprevo® cervical procedures received CMS New Technology Add-On Payment (NTAP) reimbursement, in effect October 1, 2025.

2025 Full Year Financial Outlook

- Revenue for the full year 2025 is expected to be in the range of \$45.5 million to \$47.5 million, representing growth of 67% to 75% over 2024.

Webcast & Conference Call Details

Carlsmed will host a conference call and concurrent webcast today at 4:30 pm Eastern Time (1:30 pm Pacific Time), to review the Company's second quarter and first half of 2025 performance. To access the webcast, please use the following link, which will provide you with dial-in details <https://edge.media-server.com/mmc/p/y7ki9icw>.

Non-GAAP Financial Measures

This press release contains certain financial information that is not presented in conformity with U.S. generally accepted accounting principles ("GAAP"), including Adjusted EBITDA. The non-GAAP financial measures are provided as supplemental information to Carlsmed's financial measures presented in this press release that are calculated and presented in accordance with GAAP.

The Company calculates Adjusted EBITDA as net income (loss), as adjusted to exclude (i) net interest expense and income, (ii) income tax expense (benefit), (iii) depreciation and amortization expense, (iv) stock-based compensation expense and (v) change in fair value of warrant liabilities.

This non-GAAP measure is presented because management believes it allows investors to view the Company's performance in a manner similar to the method used by management to evaluate financial performance for both strategic and annual operating planning. Management believes that to properly understand short-term and long-term financial trends, it is helpful for investors to understand the impact of the items excluded from the calculation of Adjusted EBITDA, in addition to considering the Company's GAAP financial measures. The excluded items vary in frequency and/or impact on our results of operations and management believes that the excluded items are not reflective of the Company's ongoing core business operations and financial condition. Excluding such items allows investors and analysts to compare our operating performance to other companies in our industry and to compare the Company's period-over-period results.

The non-GAAP financial measures used by Carlsmed may not be the same or calculated in the same manner as those used and calculated by other companies. Non-GAAP financial measures have limitations as analytical tools and should not be considered in isolation or as a substitute for Carlsmed's financial results prepared and reported in accordance with GAAP. This non-GAAP measure has limitations as an analytical tool and should not be construed as an inference that the Company's future results will be unaffected by unusual or non-recurring items. We urge investors to review the reconciliation of these non-GAAP financial measures to the comparable GAAP financial measures included in this press release, and not to rely on any single financial measure to evaluate our business. A reconciliation of Adjusted EBITDA reported in this press release to the most comparable GAAP measure for the respective periods appears in the table captioned "Reconciliation of GAAP Net Income (Loss) to Adjusted EBITDA" later in this release. Within the accompanying financial tables presented, certain columns and rows may not add due to the use of rounded numbers.

About Carlsmed

Carlsmed is a medical technology company pioneering AI-enabled personalized spine surgery solutions with a mission to improve outcomes and decrease the cost of healthcare for spine surgery and beyond.

Forward Looking Statement

Any statements in this press release about future expectations, plans and prospects, including statements about the Carlsmed's ability to scale the impact of its aprevo® technology platform and advance its personalized spine surgery platform to transform patient outcomes and drive long-term growth, Carlsmed's current expectation of commercially launching aprevo® cervical in the United States in 2026, the number ranges presented in our 2025 Full Year Financial Outlook, and other statements containing the words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "project," "target," "potential," "likely," "will," "would," "could," "should," "continue," and similar expressions, constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including such important factors as are set forth under the caption "Risk Factors" in the Carlsmed's Registration Statement on Form S-1 on file with the U.S. Securities and Exchange Commission. The forward-looking statements included in this press release represent Carlsmed's views as of the date of this press release. Carlsmed anticipates that subsequent events and developments will cause its views to change. However, while Carlsmed may elect to update these forward-looking statements at some point in the future, it specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Carlsmed's views as of any date subsequent to the date of this press release.

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CARLSMED, INC.

CONDENSED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2025	2024	2025	2024
Revenue	\$ 12,083	\$ 6,081	\$ 22,272	\$ 11,167
Cost of sales	3,214	1,519	5,767	2,941
Gross profit	8,869	4,562	16,505	8,226
Operating expenses:				
Research and development	4,160	3,998	7,310	7,254
Sales and marketing	7,869	4,873	14,608	8,470
General and administrative	3,342	2,010	6,808	4,150
Total operating expenses	15,371	10,881	28,726	19,874
Loss from operations	(6,502)	(6,319)	(12,221)	(11,648)
Other income (expense):				
Interest expense	(363)	(325)	(720)	(541)
Interest income	336	428	716	526
Change in fair value of warrant liabilities	(237)	(61)	(270)	(61)
Total other income (expense), net	(264)	42	(274)	(76)
Net loss and comprehensive loss	(6,766)	(6,277)	(12,495)	(11,724)
Deemed dividend to preferred stockholders	—	—	(584)	—
Net loss attributable to common stockholders	<u>\$ (6,766)</u>	<u>\$ (6,277)</u>	<u>\$ (13,079)</u>	<u>\$ (11,724)</u>
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.47)	\$ (1.55)	\$ (2.94)	\$ (2.91)
Weighted-average number of common shares used to compute basic and diluted net loss per share	4,589,717	4,053,063	4,445,384	4,024,815

CARLSMED, INC.

CONDENSED BALANCE SHEETS

(in thousands, except for share and par value amounts)
(unaudited)

	June 30, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	\$ 33,472	\$ 40,125
Restricted cash	100	100
Accounts receivable, net of allowances of \$1,576 and \$1,239, as of June 30, 2025 and December 31, 2024, respectively	9,711	6,766
Inventory	1,068	995
Prepaid expenses and other current assets	1,841	1,365
Total current assets	46,192	49,351
Property and equipment, net	972	260
Operating lease right-of-use assets	2,144	1,644
Other assets	3,962	569
Total assets	<u>\$ 53,270</u>	<u>\$ 51,824</u>
Liabilities, Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 2,581	\$ 2,412
Accrued liabilities	3,219	2,687
Accrued compensation	3,113	3,270
Short-term operating lease liabilities	571	449
Total current liabilities	9,484	8,818
Long-term portion of term loan, net	15,431	15,414
Long-term operating lease liabilities	1,705	1,317
Warrant liabilities	727	457
Other long-term liabilities	267	222
Total liabilities	27,614	26,228
Commitments and contingencies (Note 9)		
Series A convertible preferred stock, \$0.00001 par value; 4,902,814 shares authorized, issued, and outstanding, and \$13,767 liquidation preference as of June 30, 2025 and December 31, 2024	13,578	13,578
Series B convertible preferred stock, \$0.00001 par value; 4,393,481 shares authorized, 4,335,051 shares issued and outstanding, and \$30,000 liquidation preference as of June 30, 2025 and December 31, 2024	29,801	29,801
Series C convertible preferred stock, \$0.00001 par value; 6,028,243 and 4,910,500 shares authorized, 6,007,866 and 4,890,123 shares issued and outstanding, and \$64,500 and \$52,500 liquidation preference as of June 30, 2025 and December 31, 2024, respectively	65,350	52,847
Stockholders' deficit:		
Common stock, \$0.00001 par value; 23,679,694 and 21,835,801 shares authorized, 4,681,414 and 4,234,798 shares issued, and 4,603,756 and 4,139,219 shares outstanding as of June 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	593	541
Accumulated deficit	(83,666)	(71,171)
Total stockholders' deficit	(83,073)	(70,630)
Total liabilities, convertible preferred stock, and stockholders' deficit	<u>\$ 53,270</u>	<u>\$ 51,824</u>

RECONCILIATION OF GAAP NET LOSS TO ADJUSTED EBITDA

(unaudited)

(in thousands, except percentages)	Three Months Ended June 30,		\$ Change	% Change
	2025	2024		
Net loss	\$ (6,766)	\$ (6,277)	\$ (489)	7.8 %
Interest (income) expense	27	(103)	130	(126.2) %
Income taxes	—	—	—	—
Depreciation and amortization	61	35	26	74.3 %
EBITDA	(6,678)	(6,345)	(333)	5.2 %
Stock-based compensation	258	52	206	396.2 %
Change in fair value of warrant liabilities	237	61	176	288.5 %
Adjusted EBITDA	\$ (6,183)	\$ (6,232)	\$ 49	(0.8) %

(in thousands, except percentages)	Six Months Ended June 30,		\$ Change	% Change
	2025	2024		
Net loss	\$ (12,495)	\$ (11,724)	\$ (771)	6.6 %
Interest (income) expense	4	15	(11)	(73.3) %
Income taxes	—	—	—	—
Depreciation and amortization	101	75	26	34.7 %
EBITDA	(12,390)	(11,634)	(756)	6.5 %
Stock-based compensation	433	87	346	397.7 %
Change in fair value of warrant liabilities	270	61	209	342.6 %
Adjusted EBITDA	\$ (11,687)	\$ (11,486)	\$ (201)	1.7 %

