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): November 10, 2026

Carlsmed, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-42756**	**83-1081863**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

1800 Aston Ave, Suite 100 **Carlsbad, California**	**92008**
(Address of Principal Executive Offices)	**(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 November 10, 2026, Carlsmed, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2026. 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

Exhibit No.	Description
99.1*	Press Release of Carlsmed, Inc., dated November 10, 2026
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: November 10, 2026

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

Carlsmed® Reports Third Quarter 2026 Financial Results and Raises Full-Year Guidance

Third quarter 2026 revenue of $21.6 million, representing 65% growth year-over-year

Full year 2026 revenue guidance raised to $78 million to $80 million

CARLSBAD, CALIFORNIA, NOVEMBER 10, 2026 (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 third quarter ended September 30, 2026.

"The third quarter represented strong execution against our long-term strategy as we delivered 65% revenue growth and advanced our leadership position in AI-enabled personalized surgery as we grew our surgeon user base by more than 60% over the prior year," said Mike Cordonnier, Chairman and CEO of Carlsmed. "We broadened our personalized surgery platform, strengthened our leadership team, and secured new inpatient CMS reimbursement for our aprevo® lumbar spine fusion procedure. Taken together with our differentiated, capital-light model, these accomplishments reinforce our foundation for sustainable, profitable long-term growth as we head into 2027."

Recent Business Highlights

- CMS Inpatient Prospective Payment System (IPPS) rule for fiscal year 2027 became effective October 1, 2026, with increased reimbursement for inpatient aprevo® lumbar procedures.
- Launched aprevo® Lumbar Bi-lateral Posterior System in October, which the Company estimates addresses approximately 30,000 U.S. lumbar fusion procedures annually.
- Further strengthened leadership team to drive productivity, scale, and patient-centric innovation with the promotion of Jeff Bertolini to Chief Operating Officer, the appointment of Rich Heppenstall as Chief Financial Officer, and the addition of Tony Jarc, Ph.D., as Chief Product and AI Officer.
- Raised full-year 2026 revenue guidance to a range of $78 million to $80 million, over 56% growth at the midpoint versus full-year 2025.

Third Quarter 2026 Financial Results

- Revenue was $21.6 million for the third quarter of 2026, a 65% increase compared to $13.1 million in the third quarter of 2025.
- Gross profit for the third quarter of 2026 was $16.7 million compared to $9.9 million for the third quarter of 2025. Gross margin was 77.3% for the third quarter of 2026, compared with 75.9% in the third quarter of 2025.
- Operating expenses were $29.4 million for the third quarter of 2026, compared with $19.0 million for the third quarter of 2025, and included $2.8 million in expenses related to executive transition costs and the expected resolution of certain legal matters. Operating expenses consisted of:

    - Research and development expenses of $6.4 million for the third quarter of 2026, compared with $4.4 million for the third quarter of 2025.
    - Sales and marketing expenses of $13.0 million for the third quarter of 2026, compared with $9.6 million for the third quarter of 2025.
    - General and administrative expenses of $10.0 million for the third quarter of 2026, compared with $4.9 million for the third quarter of 2025.
- Net loss was ($12.2) million for the third quarter of 2026, compared to ($8.5) million for the third quarter of 2025.
- Adjusted EBITDA was ($7.3) million for the third quarter of 2026, compared to ($8.2) million for the third quarter of 2025.
- Cash and cash equivalents, restricted cash, short-term investments, and marketable securities were $80.3 million as of September 30, 2026.

2026 Financial Outlook

Revenue for the full year 2026 is expected to be in the range of $78 million to $80 million, representing growth of over 56% at the midpoint. This compares to prior annual revenue guidance of $74 to $78 million.

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 performance. A live webcast of the conference call will be available in the Events & Presentations section of the Company's investor website at investors.carlsmed.com. A replay will be archived on the Company's website following completion of the call.

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 EBITDA, adjusted EBITDA, adjusted net loss and adjusted net loss per share. 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 EBITDA as net income (loss), adjusted to exclude: (i) net interest (income) expense, (ii) income tax expense (benefit), (iii) depreciation expense from property and equipment, and (iv) amortization expense from long-lived assets. We define "Adjusted EBITDA" as EBITDA adjusted to exclude (i) stock-based compensation expense, (ii) acquisition and transaction costs, (iii) acquired intangible asset amortization and impairments, (iv) restructuring and cost reduction initiatives, (v) executive transition costs, (vi) legal settlements net of proceeds from insurance in excess of legal fees, (vii) changes in fair value of warrant liabilities and gains and losses on debt extinguishments or modifications, and (viii) non-operating investment gains and losses.

We define “Adjusted Net Loss” as net loss, adjusted to exclude: (i) acquisition and transaction costs, (ii) acquired intangible asset amortization and impairments, (iii) restructuring and cost reduction initiatives, (iv) executive transition costs, (v) legal settlements net of proceeds from insurance in excess of legal fees, (vi) change in fair value of warrant liabilities and gains and losses on debt extinguishments or modifications, and (vii) non-operating investment gains and losses. We define “Adjusted Net Loss Per Share” as Adjusted Net Loss divided by the weighted-average number of shares of common stock outstanding during the period, adjusted to exclude shares that were accelerated upon executive severance. Each item excluded in a period is separately identified and quantified in the reconciliation that follows.

These non-GAAP measures are presented because management believes they allow 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 non-GAAP metrics, in addition to considering the Company’s GAAP financial measures. 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. These non-GAAP measures 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. Reconciliations of EBITDA and adjusted EBITDA, as well as Adjusted Net Loss and Adjusted Net Loss Per Share, are reported in this press release to the most comparable GAAP measure for the respective periods and appears in the table captioned “Reconciliation of GAAP Net Loss to Adjusted EBITDA” and “Reconciliation of GAAP Net Loss to Adjusted Net Loss Per Share” respectively. 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 Statements

Any statements in this press release about future expectations, plans and prospects, including statements about Carlsmed’s growth prospects and future performance, the ability of Carlsmed to achieve profitability in the near term or at all, the scalability of Carlsmed’s business, our expectations regarding potential market size, Carlsmed’s ability to continue improving our products and technology and to develop new products, the impact of the recent CMS ruling on Carlsmed’s business, the revenue ranges presented in our 2026 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 Carlsmed’s Annual Report on Form 10-K for the year ended December 31, 2025, and subsequent Quarterly Reports on Form 10-Q 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 September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenue	$ 21,554	$ 13,074	$ 56,610	$ 35,346
Cost of sales	4,889	3,147	12,978	8,914
Gross profit	16,665	9,927	43,632	26,432
Operating expenses:				
Research and development	6,380	4,445	17,598	11,755
Sales and marketing	13,004	9,610	35,221	24,218
General and administrative	9,982	4,907	23,826	11,715
Total operating expenses	29,366	18,962	76,645	47,688
Loss from operations	(12,701)	(9,035)	(33,013)	(21,256)
Other income (expense):				
Interest expense	(316)	(380)	(940)	(1,100)
Interest income	772	954	2,502	1,670
Change in fair value of warrant liabilities	—	(65)	—	(335)
Total other income (expense), net	456	509	1,562	235
Net loss	(12,245)	(8,526)	(31,451)	(21,021)
Deemed dividend to preferred stockholders	—	—	—	(584)
Net loss attributable to common stockholders	$ (12,245)	$ (8,526)	$ (31,451)	$ (21,605)
Net loss	$ (12,245)	$ (8,526)	$ (31,451)	$ (21,021)
Other comprehensive loss:				
Unrealized loss on available-for-sale debt securities	(21)	—	(38)	—
Total other comprehensive loss	(21)	—	(38)	—
Total comprehensive loss	$ (12,266)	$ (8,526)	$ (31,489)	$ (21,021)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.45)	$ (0.40)	$ (1.16)	$ (2.15)
Weighted-average number of common shares used to compute basic and diluted net loss per share	27,303,162	21,081,330	27,104,729	10,051,623

CARLSMED, INC.

CONDENSED BALANCE SHEETS

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

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 35,945	$ 85,793
Restricted cash	100	100
Short-term investments	24,000	24,000
Marketable securities	20,262	—
Accounts receivable, net of allowances of $1,495 and $1,653, as of September 30, 2026 and December 31, 2025, respectively	16,884	11,362
Inventory	2,987	1,845
Prepaid expenses and other current assets	5,377	3,573
Total current assets	105,555	126,673
Property and equipment, net	3,611	1,487
Operating lease right-of-use assets	5,707	1,826
Other assets	397	134
Total assets	$ 115,270	$ 130,120
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,311	$ 4,481
Accrued liabilities	6,766	3,287
Accrued compensation	7,371	5,760
Short-term operating lease liabilities	789	752
Total current liabilities	18,237	14,280
Long-term portion of term loan, net	15,400	15,346
Long-term operating lease liabilities	5,596	1,316
Other long-term liabilities	363	309
Total liabilities	39,596	31,251
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and zero shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Common stock, $0.00001 par value; 600,000,000 shares authorized and 27,387,646 shares issued and outstanding as of September 30, 2026; 600,000,000 shares authorized, 26,664,243 shares issued, and 26,604,505 shares outstanding as of December 31, 2025	—	—
Additional paid-in capital	207,968	199,674
Accumulated deficit	(132,256)	(100,805)
Accumulated other comprehensive loss	(38)	—
Total stockholders' equity	75,674	98,869
Total liabilities and stockholders' equity	$ 115,270	$ 130,120

RECONCILIATION OF GAAP NET LOSS

TO ADJUSTED EBITDA
(unaudited)

(in thousands, except percentages)	Three Months Ended September 30, 2026	2025	$ Change	% Change
Net loss	$ (12,245)	$ (8,526)	$ (3,719)	43.6 %
Interest (income) expense	(456)	(574)	118	(20.6) %
Income taxes	—	—	—	**
Depreciation and amortization	126	82	44	53.7 %
EBITDA	(12,575)	(9,018)	(3,557)	39.4 %
Stock-based compensation	2,466	704	1,762	250.3 %
Executive transition costs	2,390	—	2,390	**
Legal settlements	450	—	450	**
Change in fair value of warrant liabilities	—	65	(65)	(100.0) %
Adjusted EBITDA	$ (7,269)	$ (8,249)	$ 980	(11.9) %

(in thousands, except percentages)	Nine Months Ended September 30, 2026	2025	$ Change	% Change
Net loss	$ (31,451)	$ (21,021)	$ (10,430)	49.6 %
Interest (income) expense	(1,562)	(570)	(992)	174.0 %
Income taxes	—	—	—	**
Depreciation and amortization	355	183	172	94.0 %
EBITDA	(32,658)	(21,408)	(11,250)	52.6 %
Stock-based compensation	6,366	1,137	5,229	459.9 %
Executive transition costs	2,390	—	2,390	**
Legal settlements	450	—	450	**
Change in fair value of warrant liabilities	—	335	(335)	(100.0) %
Adjusted EBITDA	$ (23,452)	$ (19,936)	$ (3,516)	17.6 %

**Prior year amount was $0, percentage change not meaningful

RECONCILIATION OF GAAP NET LOSS

TO ADJUSTED NET LOSS PER SHARE

(unaudited)

(in thousands, except share, per share amounts, and percentages)	Three Months Ended September 30, 2026	2025	Change	% Change
Net loss	$ (12,245)	$ (8,526)	$ (3,719)	43.6 %
Executive transition costs	2,390	—	2,390	**
Legal settlements	450	—	450	**
Change in fair value of warrant liabilities	—	65	(65)	(100.0) %
Adjusted Net Loss	(9,405)	(8,461)	(944)	11.2 %
Weighted average common shares outstanding	27,303,162	21,081,330	6,221,832	29.5 %
Less: accelerated shares from executive transition	(959)	—	(959)	**
Adjusted weighted average common shares outstanding	27,302,203	21,081,330	6,220,873	29.5 %
Adjusted Net Loss Per Share	$ (0.34)	$ (0.40)	$ 0.06	(15.0) %

(in thousands, except share, per share amounts, and percentages)	Nine Months Ended September 30, 2026	2025	Change	% Change
Net loss	$ (31,451)	$ (21,021)	$ (10,430)	49.6 %
Executive transition costs	2,390	—	2,390	**
Legal settlements	450	—	450	**
Change in fair value of warrant liabilities	—	335	(335)	(100.0) %
Adjusted Net Loss	(28,611)	(20,686)	(7,925)	38.3 %
Weighted average common shares outstanding	27,104,729	10,051,623	17,053,106	169.7 %
Less: accelerated shares from executive transition	(323)	—	(323)	**
Adjusted weighted average common shares outstanding	27,104,406	10,051,623	17,052,783	169.7 %
Adjusted Net Loss Per Share	$ (1.06)	$ (2.06)	$ 1.00	(48.5) %

**Prior year amount was $0, percentage change not meaningful