

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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) May 6, 2026

KORU Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

0-12305
(Commission
File Number)

13-3044880
(IRS Employer
Identification No.)

100 Corporate Drive, Mahwah, NJ
(Address of principal executive offices)

07430
(Zip Code)

Registrant's telephone number, including area code **(845) 469-2042**

(Former name or former address, if changed since last report)

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 (see General Instruction A.2. below):

- 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:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
common stock, \$0.01 par value	KRMD	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in 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.

(a) Public Announcement or Release.

On May 6, 2026, KORU Medical Systems, Inc. (the "Company") issued a press release announcing its financial results for the first fiscal quarter ended March 31, 2026 and reiterating financial guidance for the fiscal year ended December 31, 2026. The Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K. A related conference call will be held on May 6, 2026 at 4:30pm Eastern Time.

KORU Medical is making reference to non-GAAP financial measures in both the press release and the conference call. Our management believes that investors' understanding of KORU Medical's performance is enhanced by disclosing the non-GAAP financial measures of "adjusted EBITDA" and "adjusted diluted EPS" (each as defined below) as a reasonable basis for comparison of our ongoing results of operations. KORU Medical strongly encourages investors to review its consolidated financial statements and publicly filed reports in their entirety and cautions investors that the non-GAAP measures used by KORU Medical may differ from similar measures used by other companies, even when similar terms are used to identify such measures. Non-GAAP measures should not be considered replacements for, and should be read together with, the most comparable GAAP financial measures. A reconciliation of GAAP to non-GAAP results is provided in the attached Exhibit 99.1 press release.

We define adjusted EBITDA as earnings (net (loss)/income) before depreciation and amortization, interest (income), net, litigation expense and stock-based compensation expense. We believe that adjusted EBITDA is used by investors and other users of our financial statements as a supplemental financial measure that, when viewed with our GAAP results and the accompanying reconciliation, we believe provides additional information that is useful to gain an understanding of the factors and trends affecting our business. We also believe the disclosure of adjusted EBITDA helps investors meaningfully

evaluate and compare our cash flow generating capacity from quarter to quarter and year to year. Adjusted EBITDA is used by management as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

We present adjusted diluted earnings per share (“adjusted diluted EPS”) after eliminating items that we believe are not part of our ordinary operations and affect the comparability of the periods presented. Adjusted diluted EPS includes adjustments from reported diluted earnings per share for depreciation and amortization, interest (income), net, litigation expense and stock-based compensation expense. We believe adjustments for these items allow investors to better understand our underlying operating results and facilitate comparisons between the periods shown. Management uses adjusted diluted EPS as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

The information contained in this Item 2.02 of the Form 8-K shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended (the “Securities Act”), or the Exchange Act, except as expressly set forth by specific reference in such filing.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated May 6, 2026
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

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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.

KORU Medical Systems, Inc.
(Registrant)

Date: May 6, 2026

By: /s/ Linda Tharby
Linda Tharby
Chief Executive Officer

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EXHIBIT 99.1



KORU Medical Systems Announces First Quarter 2026 Results

MAHWAH, NJ – May 6, 2026 – KORU Medical Systems, Inc. (NASDAQ: KRMD) (“KORU Medical” or the “Company”), a leading medical technology company focused on the development, manufacturing, and commercialization of innovative and patient-centric large volume subcutaneous infusion solutions, today reported financial results for the first quarter ended March 31, 2026. The Company also reiterated guidance for the full year 2026.

Recent Highlights

- First quarter 2026 net revenues of \$11.8 million grew 22% over the prior year period
- First quarter 2026 gross profit grew 20% over the prior year period to \$7.2 million, with gross margin of 61.5%
- First quarter 2026 net loss improved 31% to (\$0.8) million
- Ending cash balance of \$8.8 million reflects cash usage of approximately \$0.1 million in the first quarter of 2026
- Submitted 510(k) application for use of the Freedom Infusion System with deferoxamine
- Two existing non-Ig pharma collaborations advanced to Phase III clinical trials

“We are proud to deliver a record start to 2026, with \$11.8 million in revenue, representing 22% growth,” said Linda Tharby, CEO of KORU Medical. “Our Core business continues to outperform the underlying SCIg market, driven increased share gains in current and new accounts. Internationally, momentum remains robust as we expand into prefilled syringe markets with our patient-preferred Freedom Infusion System. With a growing recurring patient base and scalable commercial model, Koru is well positioned for further success.”

Adam Kalbermatten, President and Chief Commercial Officer, added, “Equally exciting to our strength in core markets is the momentum we are building in new drug categories with our support of late-stage molecules through their regulatory pathways, including compelling oncology opportunities ahead. A strong team, a clear strategic roadmap, and an expanding platform to access new therapies and new geographies, makes me confident in our long-term strategy and the strong foundation we have built to execute.”

2026 First Quarter Financial Results

	Three Months Ending March 31,		Change from Prior Year		% of Net Revenues	
	2026	2025	\$	%	2026	2025
Net Revenues						
Domestic Core	\$ 7,739,872	\$ 6,927,964	\$ 811,908	11.7%	65.8%	71.9%
International Core	3,284,041	2,428,662	855,379	35.2%	27.9%	25.2%
Total Core	11,023,913	9,356,626	1,667,287	17.8%	93.7%	97.1%
Pharma Services and Clinical Trials	740,711	278,449	462,262	166.0%	6.3%	2.9%
Total	\$ 11,764,624	\$ 9,635,075	\$ 2,129,549	22.1%	100%	100%

Total net revenues increased \$2.1 million, or 22.1%, to \$11.8 million for the three months ending March 31, 2026, as compared to \$9.6 million in the prior year period. Domestic core revenues were \$7.7 million, an increase of 11.7% over the prior year period, primarily due to higher consumable volumes, driven by new patient starts and market share gains within new and existing accounts, supported by a strong underlying SCIg market. International core revenues were \$3.3 million, an increase of 35.2% over the prior year period, primarily due to higher pump and consumable volumes, driven by distributor purchases supporting pre-filled syringe (PFS) conversions for a key EU market. Pharma services and clinical trials net revenues were \$0.7 million, an increase of 166.0% over the prior year period, primarily due to higher clinical trial product revenues for advancing existing collaborations.

Gross profit increased \$1.2 million, or 19.6%, to \$7.2 million in the three months ending March 31, 2026, as compared to \$6.0 million in the prior year period. Gross margin decreased to 61.5% in the three months ending March 31, 2026, as compared to 62.8% in the prior year period. The decrease in gross margin was primarily driven by higher production costs based on timing of production runs in the prior quarter that were amortized in the three months ended March 31, 2026, and tariff-related charges that did not occur in the prior year period, partially offset by a favorable geographic sales mix.

Total operating expenses increased \$0.8 million, or 11.0%, to \$8.1 million for the first quarter of 2026 primarily driven by an increase of \$0.6 million in selling, general, and administrative expenses, and an increase of \$0.2 million in research and development expenses. The increase in selling, general and administrative expenses was primarily driven by increases in legal fees and compensation expenses related to salary and stock compensation, partially offset by lower temporary labor expenses.

Net loss decreased \$0.4 million to \$0.8 million or (\$0.02) per diluted share for the first quarter of 2026, compared to a net loss of \$1.2 million, or (\$0.03) per diluted share, for the prior year period. Adjusted EBITDA for the quarter was (\$0.01) million, or \$0.00 per diluted share versus (\$0.2) million or (\$0.00) per diluted share in the prior year period. A reconciliation of adjusted EBITDA and adjusted diluted EPS to the most directly comparable GAAP measures is provided at the end of this press release.

Cash and cash equivalents were \$8.8 million as of March 31, 2026, reflecting cash usage of \$0.1 million in the first quarter of 2026.

Reiterating 2026 Guidance

KORU Medical expects:

- Reiterating full year 2026 net revenues between \$47.5 - \$50.0 million representing growth of 15% - 22%
- Reiterating full year 2026 gross margin between 61 - 63%
- Reiterating positive adjusted EBITDA and positive cash flow for the full year 2026

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results and provide a corporate update on Wednesday, May 6, 2026, at 4:30 PM ET.

To participate in the call, please dial (877) 407-0784 (domestic) or (201) 689-8560 (international). The live webcast will be available on the IR Calendar on the News/Events page of the Investors section of KORU Medical's website.

Non-GAAP Measures

This press release includes the non-GAAP financial measures "adjusted diluted EPS" and "adjusted EBITDA" that are not in accordance with, nor an alternate to, generally accepted accounting principles and may be different from non-GAAP measures used by other companies. These non-GAAP measures are not based on any comprehensive set of accounting rules or principles. Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. They are limited in value because they exclude charges that have a material effect on KORU Medical's reported results and, therefore, should not be relied upon as the sole financial measures to evaluate the Company's financial results. Non-GAAP financial measures are meant to supplement, and to be viewed in conjunction with GAAP financial results. Reconciliations of the Company's non-GAAP measures are included at the end of this press release.

About KORU Medical Systems

KORU Medical Systems develops, manufactures, and commercializes innovative and patient-centric large volume subcutaneous infusion solutions that improve quality of life for patients around the world. The Freedom Syringe Infusion System (the "Freedom System") currently includes the Freedom60[®] and FreedomEDGE[®] Syringe Infusion Drivers, Precision Flow Rate Tubing[™] and High-Flo Subcutaneous Safety Needle Sets[™]. The Freedom System, which received its first FDA clearance in 1994, is used for self-administration in the home by the patient and/or delivery in an ambulatory infusion center by a healthcare professional. Through its Pharma Service and Clinical Trials business, KORU Medical provides products for use by biopharmaceutical companies in feasibility/clinical trials during the drug development process and, as needed, is capable of customizing the Freedom System for clinical and commercial use across multiple drug categories. For more information, please visit www.korumedical.com.

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Forward-looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. All statements that are not historical fact are forward-looking statements, including, but not limited to, financial guidance and expected operating performance for fiscal 2026. Forward-looking statements discuss the Company's current expectations and projections relating to its financial position, results of operations, plans, objectives, future performance, and business. Forward-looking statements can be identified by words such as "guidance", "expect" and "will". Actual results may differ materially from the results predicted and reported results should not be considered as an indication of future performance. The potential risks and uncertainties that could cause actual results to differ from the results predicted include, among others, uncertainties associated with inflation, tariffs, war and other geopolitical conflicts, customer ordering patterns, availability and costs of raw materials and labor and our ability to recover such costs, future operating results, growth of new patient starts and the Ig market, our compliance with Food and Drug Administration and foreign authority regulations and the outcome of regulatory audits, introduction and adoption of competitive products, acceptance of and demand for new and existing products, ability to penetrate new markets, success in enforcing and obtaining patents, reimbursement related risks, government regulation of the home health care industry, success of our research and development effort, expanding the market of the Freedom System, demand in the SCIG market, availability of sufficient capital if or when needed, dependence on key personnel, the impact of recent accounting pronouncements, and those risks and uncertainties included under the captions "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2025, which is on file with the SEC and available on our website at www.korumedical.com/investors and on the SEC website at www.sec.gov. All information provided in this release and in the attachments is as of May 6, 2026. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof. We undertake no duty to update this information unless required by law.

Investor Contact:

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investor@korumedical.com

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	2026 (UNAUDITED)	2025
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 8,767,774	\$ 8,872,212
Accounts receivable	5,982,536	6,209,950
Inventory, net	4,476,304	3,678,131
Other receivables	335,206	319,955
Prepaid expenses	1,026,614	908,542
TOTAL CURRENT ASSETS	20,588,434	19,988,790
Property and equipment, net	4,335,882	4,471,386
Intangible assets, net of accumulated amortization of \$545,302 and \$527,949 as of March 31, 2026 and December 31, 2025, respectively	711,211	684,841
Operating lease right-of-use assets	2,857,341	2,956,192
Other assets	98,970	98,970
TOTAL ASSETS	\$ 28,591,838	\$ 28,200,179
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 2,635,701	\$ 2,267,473
Accrued expenses	5,271,100	4,828,830
Other liabilities	11,068	27,722
Accrued payroll and related taxes	385,890	531,972
Financing lease liability	126,323	124,913
Operating lease liability	421,727	413,448
TOTAL CURRENT LIABILITIES	8,851,809	8,194,358
Financing lease liability, net of current portion	46,560	78,675
Operating lease liability, net of current portion	2,771,115	2,879,224
TOTAL LIABILITIES	11,669,484	11,152,257
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 49,933,502 and 49,790,934 shares issued 46,133,000 and 46,370,432 shares outstanding as of March 31, 2026, and December 31, 2025, respectively	499,335	497,909
Additional paid-in capital	54,795,722	52,449,339
Treasury stock, 3,818,526 and 3,438,526 shares as of March 31, 2026 and December 31, 2025, respectively, at cost	(5,548,793)	(3,882,494)
Accumulated deficit	(32,823,910)	(32,016,832)
TOTAL STOCKHOLDERS' EQUITY	16,922,354	17,047,922
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 28,591,838	\$ 28,200,179

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**KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF OPERATIONS
(UNAUDITED)**

	Three Months Ended March 31,	
	2026	2025
NET REVENUES	\$ 11,764,624	\$ 9,635,075
Cost of goods sold	4,533,235	3,588,740
Gross Profit	7,231,389	6,046,335
OPERATING EXPENSES		
Selling, general and administrative	6,582,178	5,959,374
Research and development	1,316,603	1,114,609
Depreciation and amortization	197,531	217,357
Total Operating Expenses	8,096,312	7,291,340
Net Operating Loss	(864,923)	(1,245,005)
Non-Operating Income/(Expense)		
Gain/(Loss) on currency exchange	(23,150)	5,588
Interest income, net	80,995	73,180
TOTAL OTHER INCOME	57,845	78,768
LOSS BEFORE INCOME TAXES	(807,078)	(1,166,237)
Income Tax Refund (Expense)	—	—
NET LOSS	\$ (807,078)	\$ (1,166,237)

NET LOSS PER SHARE				
Basic & Diluted	\$	(0.02)	\$	(0.03)

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING		
Basic & Diluted	46,364,905	45,981,826

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**KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF CASH FLOWS
(UNAUDITED)**

	For the Three Months Ended March 31,	
	2026	2025
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (807,078)	\$ (1,166,237)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense and warrant expense	681,510	697,590
Depreciation and amortization	197,531	217,357
Non-cash leasing charges	(979)	—
Changes in operating assets and liabilities:		
Accounts receivable	227,414	(228,661)
Inventory	(798,173)	(474,977)
Prepaid expenses and other assets	(133,323)	(8,094)
Other liabilities	(16,655)	80,828
Accounts payable	368,228	363,608
Accrued payroll and related taxes	(146,081)	227,316
Accrued expenses	442,269	53,803
NET CASH FROM/(USED IN) OPERATING ACTIVITIES	14,663	(237,467)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(46,163)	(443,438)
Purchases of intangible assets	(43,722)	(3,400)
NET CASH USED IN INVESTING ACTIVITIES	(89,885)	(446,838)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on insurance finance indebtedness	—	(133,973)
Payments on finance lease liability, net of asset	(29,216)	(26,835)
NET CASH USED IN FINANCING ACTIVITIES	(29,216)	(160,808)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(104,438)	(845,113)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	8,872,212	9,580,947
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 8,767,774	\$ 8,735,834
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 2,155	\$ 5,385

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**KORU MEDICAL SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)**

A reconciliation of our non-GAAP measures is below:

	Three Months Ended March 31,	
	2026	2025
Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA:		
GAAP Net Loss	\$ (807,078)	\$ (1,166,237)
Depreciation and Amortization*	197,531	217,357
Interest (Income), Net	(80,996)	(73,180)
Litigation Expense	—	133,411
Stock-based Compensation Expense*	681,510	697,590
Adjusted EBITDA	\$ (9,032)	\$ (191,059)
Weighted average number of common shares	46,364,905	45,981,826

Three Months Ended

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:	March 31,	
	2026	2025
Reported Diluted Earnings Per Share	\$ (0.02)	\$ (0.03)
Depreciation and Amortization*	0.00	0.00
Interest (Income), Net	(0.00)	(0.00)
Litigation Expense	—	0.00
Stock-based Compensation Expense*	0.01	0.02
Adjusted Diluted Earnings Per Share	\$ (0.00)	\$ (0.00)

**Numbers presented are rounded to the nearest whole cent and percentage*

Stock-based Compensation Expense. We have excluded the effect of stock-based compensation expense in calculating our non-GAAP measures. We record non-cash compensation expenses related to grants of options and restricted shares for executives, employees and consultants, and grants of shares to our board of directors. Depending upon the size, timing and the terms of the grants, the non-cash compensation expense may vary significantly but will recur in future periods.

Litigation Expense. We have excluded the effect of start-up litigation expense in calculating our non-GAAP measures. In the first quarter 2025 we incurred legal fees with respect to a claim filed by the Company alleging patent infringement, which we would not have otherwise incurred in the period presented as part of continuing operations.