

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 7, 2025

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 7, 2025, KORU Medical Systems, Inc. (the "Company") issued a press release announcing its financial results for the first quarter ended March 31, 2025 and updated financial guidance for the fiscal year ended December 31, 2025. 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 7, 2025 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 interest (income)/expense, net, depreciation and amortization, reorganization charges, litigation expenses, 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 interest (income)/expense, net, depreciation and amortization, reorganization expenses, litigation expenses, 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 7, 2025
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 7, 2025

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

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EXHIBIT 99.1



KORU MEDICAL SYSTEMS ANNOUNCES RECORD Q1 2025 FINANCIAL RESULTS AND RAISES 2025 REVENUE GUIDANCE

MAHWAH, NJ – May 7, 2025 – KORU Medical Systems, Inc. (NASDAQ: KRMD) (“KORU Medical” or the “Company”), a leading medical technology company focused on 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, 2025.

Recent Highlights

- First quarter 2025 net revenues of \$9.6 million, an 18% increase over the prior year period
- Core business (Domestic and International) net revenues of \$9.4 million, a 21% increase over the prior year period
- Gross profit of \$6.0 million, a 19% increase over the prior year period, and gross margin of 62.8%, a 50-basis point improvement over the prior year period
- Ending cash balance of \$8.7 million and quarterly cash usage of \$0.8 million
- Announcing plans to submit for FDA 510(k) clearance for 2 commercialized drugs with the Freedom Infusion System™ in 2025
- Raising full year 2025 revenue guidance to \$38.5 – \$39.5 million from prior range of \$38.0 - \$39.0 million; reiterating full year gross margin guidance of 61% - 63%, and positive cash flow from operations for full year 2025

“We are off to a strong start this year, with over 20% growth in our core business driven by new patient starts and continued market share gains both domestically and internationally, all contributing to the expansion of our recurring revenue base,” said Linda Tharby, President and CEO of KORU Medical. “We are also advancing our novel therapies pipeline and announcing plans to submit two previously commercialized drugs for 510(k) clearance with the Freedom Infusion system by year-end. Despite a challenging macroeconomic backdrop, the positive momentum in our business gives us confidence in our ability to deliver through the remainder of the year, and we are raising our full-year revenue guidance accordingly.”

2025 First Quarter Financial Results

	Three Months Ended March 31,		Change from Prior Year		% of Net Revenues	
	2025	2024	\$	%	2025	2024
Net Revenues						
Domestic Core	\$ 6,927,964	\$ 5,953,865	\$ 974,099	16.4%	71.9%	72.6%
International Core	2,428,662	1,790,483	638,179	35.6%	25.2%	21.8%
Total Core	9,356,626	7,744,348	1,612,278	20.8%	97.1%	94.5%
Pharma Services and Clinical Trials	278,449	453,450	(175,001)	(38.6%)	2.9%	5.5%
Total	\$ 9,635,075	\$ 8,197,798	\$ 1,437,277	17.5%	100%	100%

Total net revenues increased \$1.4 million, or 17.5%, to \$9.6 million for the three months ended March 31, 2025, as compared to \$8.2 million in the prior year period. Domestic core revenues were \$6.9 million, an increase of 16.4% over the prior year period, primarily due to higher pump and 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 \$2.4 million, an increase of 35.6% over the prior year period, primarily due to higher pump and consumable volumes, driven by geographical expansion and a tender win with an Ig pharma partner. International growth was impacted by approximately \$0.4 million of distributor stocking to support expansion, compared to \$0.3 million of distributor stocking in the prior year as a result of the BSI regulatory review process. Pharma services and clinical trials net revenues were \$0.3 million, a decrease of 38.6% over the prior year period, primarily due to lower clinical trial revenue.

Gross profit increased \$0.9 million, or 18.5%, to \$6.0 million in the three months ended March 31, 2025, as compared to \$5.1 million in the prior year period. Gross margin increased to 62.8% in the three months ended March 31, 2025, as compared to 62.3% in the prior year period. The increase in gross margin was primarily driven by favorable changes in product revenue mix.

Total operating expenses for the first quarter of 2025 were \$7.3 million, an increase of \$0.2 million, or 3.2%, over the prior year period driven by increases in compensation-related expenses for temporary staff to support product development and legal fees, partially offset by lower severance and research and development expenses.

Net loss decreased \$0.8 million in the three months ended March 31, 2025, as compared to the prior year period, primarily driven by an increase in gross profit of \$0.9 million, driven by increased revenues, partially offset by operating expense increases of \$0.2 million.

Adjusted EBITDA for the first quarter of 2025 was (\$0.2) million, or (\$0.00) per diluted share, compared to adjusted EBITDA of (\$0.9) million, or (\$0.02) per diluted share, for the prior year period. A reconciliation of adjusted EBITDA and adjusted diluted EPS is provided at the end of this press release.

Cash and cash equivalents were \$8.7 million as of March 31, 2025, reflecting cash usage of \$0.8 million in the first quarter of 2025.

2025 Guidance

- Raising full year 2025 net revenues guidance to \$38.5 - \$39.5, representing growth of 15% - 17% from prior range of \$38.0 - \$39.0 million
- Reiterating full year 2025 gross margin guidance of 61% - 63%
- Reiterating positive cash flow from operations for full year 2025

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 7, 2025, 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.

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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 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-Flow 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 Novel Therapies 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.

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, timing of 510(k) clearances and financial guidance for fiscal 2025. 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”, “plan”, “believe” 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 SCIG market growth, prefilled syringe penetration, plasma supply, clinical trial activity and success, approval and commercialization of new drug indications, the shift to increased healthcare delivery in the home, new patient diagnoses, customer ordering patterns, global health crises, innovation and competition, labor and supply price increases, inflationary impacts, labor supply, tariffs 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, 2024 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, which are 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 7, 2025. 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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KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS

March 31, 2025 (UNAUDITED)	December 31, 2024

ASSETS

CURRENT ASSETS		
Cash and cash equivalents	\$ 8,735,834	\$ 9,580,947
Accounts receivable less allowance for credit losses of \$0 as of March 31, 2025 and December 31, 2024	5,949,411	5,720,750
Inventory	3,278,646	2,803,669
Other receivables	321,167	277,193
Prepaid expenses	713,970	749,851
TOTAL CURRENT ASSETS	18,999,028	19,132,410
Property and equipment, net	4,533,949	4,290,515
Intangible assets, net of accumulated amortization of \$475,891 and \$458,538 as of March 31, 2025 and December 31, 2024, respectively	716,326	730,279
Operating lease right-of-use assets	2,867,894	2,966,341
Other assets	98,970	98,970
TOTAL ASSETS	\$ 27,216,167	\$ 27,218,515
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 2,013,578	\$ 1,649,969
Accrued expenses	3,977,987	3,924,184
Note payable	137,180	271,152
Other liabilities	110,097	29,269
Accrued payroll and related taxes	1,038,717	811,401
Financing lease liability – current	117,105	115,587
Operating lease liability – current	404,613	400,258
TOTAL CURRENT LIABILITIES	7,799,277	7,201,820
Financing lease liability, net of current portion	174,259	202,613
Operating lease liability, net of current portion	2,897,600	3,000,403
TOTAL LIABILITIES	10,871,136	10,404,836
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 49,561,498 and 49,377,617 shares issued 46,140,996 and 45,957,115 shares outstanding as of March 31, 2025, and December 31, 2024, respectively	495,615	493,776
Additional paid-in capital	50,277,053	49,581,303
Treasury stock, 3,438,526 and 3,438,526 shares as of March 31, 2025 and December 31, 2024, respectively, at cost	(3,882,494)	(3,882,494)
Accumulated deficit	(30,545,143)	(29,378,906)
TOTAL STOCKHOLDERS' EQUITY	16,345,031	16,813,679
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 27,216,167	\$ 27,218,515

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

	Three Months Ended March 31,	
	2025	2024
NET REVENUES	\$ 9,635,075	\$ 8,197,798
Cost of goods sold	3,588,740	3,094,500
Gross Profit	6,046,335	5,103,298
OPERATING EXPENSES		
Selling, general and administrative	5,959,374	5,357,620
Research and development	1,114,609	1,475,674
Depreciation and amortization	217,357	231,370
Total Operating Expenses	7,291,340	7,064,664
Net Operating Loss	(1,245,005)	(1,961,366)
Non-Operating Income/(Expense)		
Gain/(Loss) on currency exchange	5,588	(11,479)
Loss on disposal of fixed assets, net	—	(300)
Interest income, net	73,180	37,187
TOTAL OTHER INCOME	78,768	25,408
LOSS BEFORE INCOME TAXES	(1,166,237)	(1,935,958)
Income Tax Benefit	—	—
NET LOSS	\$ (1,166,237)	\$ (1,935,958)
NET LOSS PER SHARE		

Basic & Diluted	\$ (0.03)	\$ (0.04)
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WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING

Basic & Diluted	45,981,826	45,712,224
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**KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF CASH FLOWS
(UNAUDITED)**

	For the Three Months Ended March 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (1,166,237)	\$ (1,935,958)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense and warrant expense	697,590	699,718
Depreciation and amortization	217,357	231,370
Loss on disposal of fixed assets	—	300
Non-cash lease adjustments	—	(5,497)
Changes in operating assets and liabilities:		
Accounts receivable	(228,661)	(607,125)
Inventory	(474,977)	333,989
Prepaid expenses and other assets	(8,094)	387,880
Other liabilities	80,828	(54,867)
Accounts payable	363,608	798,992
Accrued payroll and related taxes	227,316	56,500
Accrued expenses	53,803	(252,022)
NET CASH USED IN OPERATING ACTIVITIES	(237,467)	(346,720)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(443,438)	(133,083)
Purchases of intangible assets	(3,400)	(0)
NET CASH USED IN INVESTING ACTIVITIES	(446,838)	(133,083)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on insurance finance indebtedness	(133,973)	(155,313)
Payments on finance lease liability	(26,835)	(26,807)
NET CASH USED IN FINANCING ACTIVITIES	(160,808)	(182,120)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(845,113)	(661,923)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	9,580,947	11,482,240
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 8,735,834	\$ 10,820,317
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 5,385	\$ 12,296
Income taxes	\$ —	\$ —

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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,	
	2025	2024
Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA:		
GAAP Net Loss	\$ (1,166,237)	\$ (1,935,958)
Depreciation and Amortization	217,357	231,369
Interest (Income), Net	(73,180)	(37,187)
Reorganization Charges	—	99,329
Litigation Expense	133,411	—
Stock-based Compensation Expense	697,590	699,718
Adjusted EBITDA	\$ (191,059)	\$ (942,729)
Weighted average number common shares	45,981,826	45,712,224

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:	Three Months Ended March 31,	
	2025	2024
Reported Diluted Earnings Per Share	\$ (0.03)	\$ (0.04)
Depreciation and Amortization	—	0.01
Interest (Income)/Expense, Net	—	—
Reorganization Charges	—	—
Litigation Expense	—	—
Stock-based Compensation Expense	0.02	0.02
Adjusted Diluted Earnings Per Share	\$ 0.00	\$ (0.02)

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

Reorganization Charges. We have excluded the effect of reorganization charges in calculating our non-GAAP measures. In 2024 and 2025 we incurred severance expenses related to the reorganization of the leadership team, which we would not have otherwise incurred in periods presented as part of continuing operations.

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 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.