

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 1, 2024

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.

On May 1, 2024, KORU Medical Systems, Inc. (“KORU Medical” or “we”) issued a press release announcing its financial results for the fiscal quarter ended March 31, 2024. A related conference call will be held on May 1, 2024 at 4:30 pm 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 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 expense/(income), net, income tax (benefit)/expense, depreciation and amortization, reorganization charges, discontinued product expense, allowance for nonrealization of deferred tax assets, manufacturing initiative 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 diluted earnings per share after eliminating items that we believe are not part of our ordinary operations and affect the comparability of the periods presented (“Adjusted EPS”). Adjusted EPS includes adjustments for income tax (benefit)/expense, depreciation and amortization, reorganization charges, discontinued product expense, allowance for nonrealization of deferred tax assets, manufacturing initiative 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 EPS as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated May 1, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 1, 2024

By: /s/ Linda Tharby
Linda Tharby

President and Chief Executive Officer

EXHIBIT 99.1



KORU MEDICAL SYSTEMS, INC. ANNOUNCES 2024 FIRST QUARTER FINANCIAL RESULTS
DELIVERING DOUBLE-DIGIT REVENUE GROWTH

MAHWAH, NJ – May 1, 2024 – 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, 2024.

Recent Highlights

- First quarter 2024 net revenues of \$8.2 million, an 11% increase over the prior year and record high quarterly revenues
- Core business (U.S. and International) growth of 14% over the prior year, driven by overall SCIg market growth, share gains, and geographic expansion
- Entered a Novel Therapies collaboration with an oncology drug therapy, bringing total collaborations to 16, with 3 signed year-to-date
- Gross profit of \$5.1 million, a 23% increase over the prior year, and gross margin of 62%, reflecting year-over-year improvement of 620 basis points
- Ending cash balance of \$10.8 million and quarterly cash usage of \$0.7 million driven by increased operating leverage and working capital improvements
- Reaffirmed full year 2024 revenue guidance of \$31.2 million to \$32.2 million, representing growth of 10% to 13% over the prior year.

“We are excited by a strong start to the year, with double-digit record revenue growth in our Core business and the addition of a new oncology collaboration in our Novel Therapies business,” said Linda Tharby, KORU Medical’s President and CEO. “The Core business saw another quarter of sequential growth in the subcutaneous immunoglobulin market, increasing prefill adoption rates, and further geographic expansion. As a part of our Novel Therapies strategy to expand the Freedom subcutaneous infusion system to new drug therapies, we are proud of the progress we’ve made in diversifying our drug pipeline and signing three new collaborations year-to-date. We also continued to drive operating leverage evidenced this quarter by gross margin expansion and a significant reduction in cash usage over the prior year. We are committed to our strategic growth agenda and providing increased value to our customers, patients, and shareholders.”

2024 First Quarter Financial Results

	<u>Three Months Ended March 31,</u>		<u>Change from Prior Year</u>		<u>% of Net Revenues</u>	
	<u>2024</u>	<u>2023</u>	<u>\$</u>	<u>%</u>	<u>2024</u>	<u>2023</u>
Net Revenues						
Domestic Core	\$ 5,953,865	\$ 5,719,135	\$ 234,730	4.1%	72.7%	77.4%
International Core	1,790,483	1,097,490	692,993	63.1%	21.8%	14.8%
Total Core	7,744,348	6,816,625	927,723	13.6%	94.5%	92.2%
Novel Therapies	453,450	575,980	(122,530)	(21.3%)	5.5%	7.8%
Total	\$ 8,197,798	\$ 7,392,605	\$ 805,193	10.9%	100%	100%

Total net revenues increased \$0.8 million, or 10.9%, to \$8.2 million for the three months ended March 31, 2024, as compared with the same period in 2023. Domestic Core revenues increased by 4.1% from higher consumable volumes driven by new patients starts and share gains. International Core revenues increased by 63.1%, from higher consumable and pump volumes driven largely by increased Ig supply, increased penetration within approved indications, and geographic expansion. International orders were expedited for certain distribution partners of \$0.26 million in March 2024 to ensure adequate inventory to fulfill patient needs in the event of a supply disruption related to the BSI regulatory review process. Novel Therapies net revenues declined by 21.3% primarily driven by a milestone completion for a collaboration agreement in the prior year period.

Gross profit increased \$1.0 million, or 23%, to \$5.1 million in the three months ended March 31, 2024, compared to \$4.1 million in the same period in 2023. Gross margin increased to 62.3% compared to 56.1% in the first quarter of 2023. The increase in gross margin was primarily driven by production efficiencies from outsourced manufacturing and consolidation of US manufacturing sites.

Total operating expenses for the first quarter of 2024 were \$7.1 million, a decrease of \$0.1 million, or 1.9%, compared to \$7.2 million in the prior year period.

Net loss for the first quarter of 2024 was \$1.9 million, or \$(0.04) per diluted share, compared to a net loss of \$2.4 million, or \$(0.05) per diluted share, for the same period of 2023. Adjusted EBITDA for the first quarter of 2024 was \$(0.9) million, or \$(0.02) per diluted share, compared to adjusted EBITDA of \$(2.0) million, or \$(0.04) per diluted share, for the same period of 2023. A reconciliation of adjusted EBITDA and adjusted diluted EPS is provided at the end of this press release.

Cash and cash equivalents were \$10.8 million as of March 31, 2024, reflecting cash usage of \$0.7 million in the first quarter of 2024.

2024 Guidance

Reaffirming full year 2024 net revenue between \$31.2 and \$32.2 million, representing growth of 10% to 13%

- Gross margin between 59% and 61% for the full year 2024
- 2024 year-end cash balance greater than \$8.0 million
- Cash flow breakeven in the fourth quarter of 2024 and cash flow positive 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 1, 2024 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 EPS", "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 HgH-Flo Subcutaneous Safety Needle Sets™. These devices are used for infusions administered in the home and alternate care settings. 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 2024. 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, the Company's EU certification, 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, 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, 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 1, 2024. 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 (UNAUDITED)

	<u>March 31, 2024</u>	<u>December 31, 2023</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 10,820,317	\$ 11,482,240

Accounts receivable less allowance for doubtful accounts of \$24,777 as of March 31, 2024 and \$24,777 as of December 31, 2023	4,392,511	4,045,211
Inventory	3,147,312	3,481,301
Other receivables	288,714	28,889
Prepaid expenses	830,408	1,218,288
TOTAL CURRENT ASSETS	19,479,262	20,255,929
Property and equipment, net	3,755,530	3,837,657
Intangible assets, net of accumulated amortization of \$406,801 and \$390,341 as of March 31, 2024 and December 31, 2023, respectively	737,901	754,361
Operating lease right-of-use assets	3,428,885	3,514,055
Deferred income tax assets, net of allowance for non-realization of deferred tax assets of \$6,391,452 and \$6,002,777 for March 31, 2024 and December 31, 2023, respectively	—	—
Other assets	98,970	98,970
TOTAL ASSETS	\$ 27,500,548	\$ 28,460,972
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 1,774,185	\$ 975,193
Accrued expenses	1,459,405	1,711,427
Note payable	159,031	314,344
Other liabilities	457,653	512,520
Accrued payroll and related taxes	519,441	462,941
Financing lease liability – current	111,103	109,540
Operating lease liability – current	372,109	368,313
TOTAL CURRENT LIABILITIES	4,852,927	4,454,278
Financing lease liability, net of current portion	288,253	316,623
Operating lease liability, net of current portion	3,241,837	3,336,300
TOTAL LIABILITIES	8,383,017	8,107,201
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 49,143,589 and 49,089,864 shares issued 45,723,087 and 45,669,362 shares outstanding as of March 31, 2024, and December 31, 2023, respectively	491,436	490,899
Additional paid-in capital	47,717,888	47,018,707
Treasury stock, 3,420,502 shares as of March 31, 2024 and December 31, 2023, at cost	(3,843,562)	(3,843,562)
Accumulated deficit	(25,248,231)	(23,312,273)
TOTAL STOCKHOLDERS' EQUITY	19,117,531	20,353,771
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 27,500,548	\$ 28,460,972

The accompanying notes are an integral part of these financial statements.

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

	Three Months Ended	
	March 31,	
	2024	2023
NET REVENUES	\$ 8,197,798	\$ 7,392,605
Cost of goods sold	3,094,500	3,245,570
Gross Profit	5,103,298	4,147,035
OPERATING EXPENSES		
Selling, general and administrative	5,357,620	5,425,877
Research and development	1,475,674	1,564,869
Depreciation and amortization	231,370	213,117
Total Operating Expenses	7,064,664	7,203,863
Net Operating Loss	(1,961,366)	(3,056,828)
Non-Operating Income/(Expense)		
Loss on currency exchange	(11,479)	(680)
Loss on disposal of fixed assets, net	(300)	(56,279)
Interest income, net	37,187	125,502
TOTAL OTHER INCOME	25,408	68,543
LOSS BEFORE INCOME TAXES	(1,935,958)	(2,988,285)
Income Tax Benefit	—	577,400
NET LOSS	\$ (1,935,958)	\$ (2,410,885)

NET LOSS PER SHARE

Basic	\$ (0.04)	\$ (0.05)
Diluted	\$ (0.04)	\$ (0.05)

WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING

Basic	45,712,224	45,487,593
Diluted	45,712,224	45,487,593

The accompanying notes are an integral part of these financial statements.

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

For the
Three Months Ended
March 31,

	<u>2024</u>	<u>2023</u>
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (1,935,958)	\$ (2,410,885)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense and warrant expense	699,718	881,222
Depreciation and amortization	231,370	213,117
Deferred income taxes	—	(577,400)
Loss on disposal of fixed assets	300	56,279
ROU landlord credit	(5,497)	(5,497)
Changes in operating assets and liabilities:		
Increase in Accounts receivable	(607,125)	(647,994)
Decrease / (Increase) in Inventory	333,989	(233,551)
Decrease in Prepaid expenses and other assets	387,880	288,786
(Decrease) / Increase in Other liabilities	(54,867)	4,207
Increase / (Decrease) in Accounts payable	798,992	(888,679)
Increase / (Decrease) in Accrued payroll and related taxes	56,500	(41,984)
Decrease in Accrued expenses	(252,022)	(1,298,204)
NET CASH USED IN OPERATING ACTIVITIES	<u>(346,720)</u>	<u>(4,660,583)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(133,083)	(272,605)
Purchases of intangible assets	(0)	(11,232)
NET CASH USED IN INVESTING ACTIVITIES	<u>(133,083)</u>	<u>(283,837)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on indebtedness	(155,313)	(214,892)
Payments on finance lease liability	(26,807)	(24,080)
NET CASH USED IN FINANCING ACTIVITIES	<u>(182,120)</u>	<u>(238,972)</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS	<u>(661,923)</u>	<u>(5,183,392)</u>
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>11,482,240</u>	<u>17,408,257</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 10,820,317</u>	<u>\$ 12,224,865</u>
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 12,296	\$ 12,326
Income taxes	\$ —	\$ —
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	\$ 123,804	\$ 175,776

The accompanying notes are an integral part of these financial statements.

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KORU MEDICAL SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)

A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA:	Three Months Ended	
	March 31,	
	2024	2023
GAAP Net Loss	\$ (1,935,958)	\$ (2,410,885)
Tax (Benefit)/Expense	(388,675)	(577,400)
Valuation Allowance for DTA	388,675	—
Depreciation and Amortization	231,369	213,117
Interest (Income), Net	(37,187)	(125,502)
Reorganization Charges	99,329	—
Manufacturing Initiative Expenses	—	49,053
Product Discontinuance	—	—
Stock-based Compensation Expense	699,718	881,222
Adjusted EBITDA	\$ (942,729)	\$ (1,970,395)
Weighted average number common shares	45,712,224	45,487,593

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:	Three Months Ended	
	March 31,	
	2024	2023
Reported Diluted Earnings Per Share	\$ (0.04)	\$ (0.05)
Tax (Benefit)/Expense	(0.01)	(0.01)
Valuation Allowance for DTA	0.01	—
Depreciation and Amortization	0.01	0.01
Interest (Income)/Expense, Net	—	—
Reorganization Charges	—	—
Manufacturing Initiative Expenses	—	—
Product Discontinuance	—	—
Stock-based Compensation Expense	0.02	0.02
Adjusted Diluted Earnings Per Share	\$ (0.02)	\$ (0.04)

* 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 2023 and 2024 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.

Manufacturing Initiative Expenses. We have excluded the effect of expenses related to creating manufacturing efficiencies in calculating our non-GAAP measures. We incurred expenses in connection with these initiatives which we would not have otherwise incurred in periods presented as part of our 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.

Allowance for nonrealization of deferred tax assets (DTA). We have excluded the effect of recording a full valuation allowance on our deferred tax assets in the first quarter ended 2024 in the amount of \$0.4 million. It was determined that no valuation allowance was necessary in the first quarter ended 2023.