# 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) November 13, 2024

# KORU Medical Systems, Inc. (Exact name of registrant as specified in its charter)

<u>Delaware</u>	<u>0-12305</u>	<u>13-3044880</u>
(State or other jurisdiction	(Commission	(IRS Employer
of incorporation)	File Number)	Identification No.)
100 0	Corporate Drive, Mahwah, NJ	<u>07430</u>
(Addre	ess of principal executive offices)	(Zip Code)
Registrant's	telephone number, including area	code (845) 469-2042
(Former	name or former address, if change	ed since last report)
Check the appropriate box below if the For under any of the following provisions (see Go	2	taneously satisfy the filing obligation of the registrant
[_] Written communications pursuant to Rule	e 425 under the Securities Act (17	CFR 230.425)
[] Soliciting material pursuant to Rule 14a-	12 under the Exchange Act (17 CF	R 240.14a-12)
[ ] Pre-commencement communications pur	suant to Rule 14d-2(b) under the E	Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pur	rsuant to Rule 13e-4(c) under the E	exchange Act (17 CFR 240.13e-4(c))
Securities registered pursuant to Section 12(b	o) of the Act:	
<u>Title of each class</u> common stock, \$0.01 par value	Trading symbol(s) KRMD	Name of each exchange on which registered The Nasdaq Stock Market
Indicate by check mark whether the registrar Act of 1933 (§230.405 of this chapter) or Rul		y as defined in as defined in Rule 405 of the Securities e Act of 1934 (§240.12b-2 of this chapter).
		Emerging growth company [_]
	,	s elected not to use the extended transition period for rsuant to Section 13(a) of the Exchange Act.

#### ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On November 13, 2024, KORU Medical Systems, Inc. ("KORU Medical" or "we") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2024. A related conference call will be held on November 13, 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, allowance for nonrealization of deferred tax assets, interest (income)/expense, net, 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, 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.

Exhibit No. Description

99.1 <u>Press Release dated November 13, 2024</u>

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: November 13, 2024

By: \( \frac{\slink \text{L inda Tharby}}{\text{L inda Tharby}} \)

Linda Tharby

President and Chief Executive Officer

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#### **EXHIBIT 99.1**



# KORU MEDICAL SYSTEMS, INC. ANNOUNCES 2024 Q3 FINANCIAL RESULTS, THIRD CONSECUTIVE OUARTER OF DOUBLE-DIGIT GROWTH; RAISES FULL YEAR 2024 GUIDANCE

MAHWAH, NJ – November 13, 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 third quarter ended September 30, 2024, and raised full year 2024 revenue, gross margin, and year-end cash guidance.

### **Recent Highlights**

- Third quarter 2024 net revenues of \$8.2 million, a 17% increase over the prior year period
- Core business (U.S. and International) growth of 11% and novel therapies growth of 276% over the prior year period
- Gross profit of \$5.2 million, a 19% increase over the prior year period, and gross margin of 63%, a 140-basis point improvement over the prior year period
- Ending cash balance of \$8.8 million and year-to-date cash burn of \$2.7 million, a 60% improvement over the prior year period
- Presented data at Partnership Opportunities in Drug Delivery (PODD) Conference demonstrating 97% nursing preference for KORU's FreedomEdge<sup>®</sup> system over manual push for subcutaneous oncology infusion clinic administration
- Raising full year 2024 net revenue guidance to \$32.75 \$33.25 million, representing growth of 15% 17% over the prior year; raising full year gross margin guidance to 62% 63%, representing an improvement of 340 440 basis points over the prior year; and raising full year ending cash balance guidance to greater than \$8.8 million

"We are pleased to deliver another quarter of strong results representing solid execution by the team across all of our businesses and operations," said Linda Tharby, KORU Medical's President and CEO. "Revenue of \$8.2 million represents the third consecutive quarter of double-digit growth, while improving our gross margin and driving improved operating leverage. We see strength in our recurring chronic subcutaneous immunoglobulin (SCIg) patient base, and we continue to further drive collaborations in our novel therapies business as more drugs move to subcutaneous administration. We are excited by the progress we continue to make in executing against our long-term strategies and growth objectives which has enabled us to raise guidance for our 2024 revenue, gross margin, and year-end cash-balance."

# 2024 Third Quarter Financial Results

	Thr	ee Months En	ded Se	eptember 30,	Change from Prior Year			% of Net I	Revenues
	2024 2023 \$		%	2024	2023				
Net Revenues		<u>.</u>							
Domestic Core	\$	6,447,469	\$	5,773,863	\$	673,606	11.7%	78.8%	82.4%
International Core		1,121,196		1,066,567		54,629	5.1%	13.7%	15.2%
Total Core		7,568,665		6,840,430		728,235	10.6%	92.5%	97.7%
Novel Therapies		611,312		162,768		448,544	275.6%	7.5%	2.3%
Total	\$	8,179,977	\$	7,003,198	\$	1,176,778	16.8%	100%	100%

Total net revenues for the third quarter of 2024 were \$8.2 million, an increase of \$1.2 million, or 16.8% over the prior year period. Domestic core revenues were \$6.4 million, an increase of 11.7% over the prior year period, primarily due to higher consumable and pump volumes driven by new patients starts and market share gains. International core revenues were \$1.1 million, an increase of 5.1% over the prior year period, primarily due to higher consumable volumes driven largely by increased Ig supply, increased penetration within certain approved indications, and geographic expansion. Partially offsetting the growth were lower orders from a distribution partner that expedited \$0.3 million orders in the second quarter of 2024 related to the BSI regulatory review which has since been successfully appealed. Novel Therapies revenues for the third quarter of 2024 were \$0.6 million, an increase of 275.6% over the prior year period, primarily driven by clinical trial orders and progress on NRE milestones completed for multiple collaboration agreements.

Gross profit for the third quarter of 2024 was \$5.2 million, an increase of \$0.8 million, or 19%, over the prior year period. Gross margin in the third quarter of 2024 was 63.4%, an increase of 140 basis points, compared to 62.0% in the prior year period. The increase in gross margin was primarily driven by a favorable sales mix of clinical trial orders, improved NRE mix of more profitable services, and increased average selling prices when compared to the prior year period.

Total operating expenses for the third quarter of 2024 were \$6.9 million, an increase of \$0.8 million, or 12.3%, over the prior year period primarily driven by compensation related to new hires, bonus accruals, and severance for the elimination of the CTO role.

Net loss for the third quarter of 2024 was \$1.6 million, or (\$0.03) per diluted share, compared to a net loss of \$1.4 million, or (\$0.03) per diluted share, for the prior year period, primarily driven by an increase in operating expenses of \$0.8 million, and a prior year tax benefit of \$0.2 million offset by an increase in gross profit of \$0.8 million. Adjusted EBITDA for the third quarter of 2024 was (\$0.4)

million, or (\$0.01) per diluted share, compared to adjusted EBITDA of (\$0.9) million, or (\$0.02) per diluted share, for the 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 \$8.8 million as of September 30, 2024, reflecting cash usage of \$1.7 million in the third quarter of 2024

#### 2024 Guidance

- Raising full year 2024 net revenue guidance to \$32.75 \$33.25, representing growth of 15% 17%; increased from
  previously issued guidance of \$32.0 \$32.5 million, or 12% 14%
- Raising full year 2024 gross margin guidance to 62% 63%; increased from previously issued guidance of 61% 62%
- Raising guidance of 2024 year-end cash balance to greater than \$8.8 million increased from previously issued guidance of greater than \$8.0 million year-end cash balance
- Reiterating 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, November 13, 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.

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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-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 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, oncology biologic clinic entry, launch an expanded nephrology indication, success of Novel Therapies collaborations and related commercial launches, 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, approval and commercialization of new drug indications, 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, 2023, 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 November 13, 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:**

Louisa Smith investor@korumedical.com

# KORU MEDICAL SYSTEMS, INC. BALANCE SHEETS

	Se	eptember 30, 2024	D	ecember 31, 2023
	<u>(</u> (	UNAUDITED)		
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$	8,806,310	\$	11,482,240
Accounts receivable less allowance for credit losses of \$0 as of September 30, 2024 and				
\$24,777 as of December 31, 2023		5,164,700		4,045,211
Inventory		3,928,318		3,481,301
Other receivables		74,312		28,889
Prepaid expenses		955,213		1,218,288
TOTAL CURRENT ASSETS		18,928,853		20,255,929
Property and equipment, net		4,552,176		3,837,657
Intangible assets, net of accumulated amortization of \$441,186 and \$390,341 as of September				
30, 2024 and December 31, 2023, respectively		746,302		754,361
Operating lease right-of-use assets		3,063,731		3,514,055
Other assets		98,970		98,970
TOTAL ASSETS	\$	27,390,032	\$	28,460,972
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES				
Accounts payable	\$	1,670,300	\$	975,193
Accrued expenses		2,792,967		1,711,427
Note payable		401,993		314,344
Other liabilities		181,745		512,520
Accrued payroll and related taxes		766,867		462,941
Financing lease liability – current		114,297		109,540
Operating lease liability – current		395,954		368,313
TOTAL CURRENT LIABILITIES		6,324,123		4,454,278
Financing lease liability, net of current portion		230,332		316,623
Operating lease liability, net of current portion		3,102,097		3,336,300
TOTAL LIABILITIES		9,656,552		8,107,201
STOCKHOLDERS' EQUITY				
Common stock, \$0.01 par value, 75,000,000 shares authorized, 49,275,830 and 49,059,583 shares issued 45,837,304 and 45,639,081 shares outstanding as of September 30, 2024,				
and December 31, 2023, respectively		492,758		490,899
Additional paid-in capital		48,940,978		47,018,707
Treasury stock, 3,438,526 and 3,420,502 shares as of September 30, 2024 and December 31, 2023, respectively, at cost		(3,882,493)		(3,843,562
· •		(27,817,763)		(23,312,273
Accumulated deficit		17,733,480		20,353,771
Accumulated deficit TOTAL STOCKHOLDERS' EQUITY		1 / / 3 3 4 8 0		

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

		Three Mor Septem			Nine Months Ended September 30,				
		2024 2023		2023	2024			2023	
NET REVENUES	S	8,179,977	\$	7,003,198	\$	24,807,864	\$	21,331,734	
Cost of goods sold		2,993,986		2,661,021		9,038,825		8,954,398	
Gross Profit		5,185,991		4,342,177		15,769,038		12,377,336	
OPERATING EXPENSES									
Selling, general and administrative		5,127,658		4,623,928		15,804,966		15,352,972	
Research and development		1,533,845		1,293,256		4,143,751		4,454,739	
Depreciation and amortization		227,785		216,014		677,019		642,050	
Total Operating Expenses		6,889,288		6,133,198		20,625,736		20,449,761	
Net Operating Loss		(1,703,297)		(1,791,021)		(4,856,698)		(8,072,425)	
Non-Operating Income/(Expense)									
Gain/(Loss) on currency exchange		9,485		(9,390)		(12,674)		(12,542)	
Loss on disposal of fixed assets, net		_		(3,527)		(300)		(59,806)	
Interest income, net		112,995		135,429		364,183		392,098	
TOTAL OTHER INCOME		122,480		122,512		351,208		319,750	

LOSS BEFORE INCOME TAXES	(1,580,817)	(1,668,509)	(4,505,490)	(7,752,675)
Income Tax Benefit		300,247		1,477,642
NET LOSS	\$ (1,580,817)	\$ (1,368,262)	\$ (4,505,490)	\$ (6,275,033)
NET LOSS PER SHARE				
Basic & Diluted	\$ (0.03)	\$ (0.03)	\$ (0.10)	\$ (0.14)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic & Diluted	45,851,019	45,639,081	45,791,756	45,578,314
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# KORU MEDICAL SYSTEMS, INC. STATEMENTS OF CASH FLOWS (UNAUDITED)

		For the Nine Months E September 3			
		2024		2023	
CASH FLOWS FROM OPERATING ACTIVITIES					
Net Loss	\$	(4,505,490)	\$	(6,275,033)	
Adjustments to reconcile net loss to net cash used in operating activities:					
Stock-based compensation expense and warrant expense		1,924,131		2,379,613	
Depreciation and amortization		677,019		642,050	
Deferred income taxes		_		(1,477,643)	
Loss on disposal of fixed assets		300		59,806	
Non-cash lease adjustments		243,762		(16,489)	
Changes in operating assets and liabilities:		,		` ' '	
Accounts receivable		(1,119,490)		(332,975)	
Inventory		(447,017)		1,727,954	
Prepaid expenses and other assets		217,652		87,540	
Other liabilities		(330,773)		243,283	
Accounts payable		695,107		(1,446,180)	
Accrued payroll and related taxes		303,927		(149,872)	
Accrued expenses		1,081,539		(1,431,412)	
NET CASH USED IN OPERATING ACTIVITIES	_	(1,259,333)		(5,989,358)	
CASH FLOWS FROM INVESTING ACTIVITIES					
Purchases of property and equipment		(1,340,994)		(586,897)	
Purchases of intangible assets		(42,786)		(19,312)	
NET CASH USED IN INVESTING ACTIVITIES	_	(1,383,780)		(606,209)	
CASH FLOWS FROM FINANCING ACTIVITIES					
Borrowings from insurance finance indebtedness		487,516		565,172	
Payments on insurance finance indebtedness		(399,867)		(532,441)	
Payments on finance lease liability		(81,534)		(73,243)	
Payments for taxes related to net share settlement of equity awards		(38,932)			
NET CASH USED IN FINANCING ACTIVITIES		(32,817)		(40,512)	
NET DECREASE IN CASH AND CASH EQUIVALENTS		(2,675,930)		(6,636,079)	
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		11,482,240		17,408,257	
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	8,806,310	\$	10,772,178	
Supplemental Information					
Cash paid during the periods for:					
Interest	S	46,014	\$	34,773	
Income taxes	\$ \$		\$	3,160	
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KORU MEDICAL SYSTEMS, INC. SUPPLEMENTAL INFORMATION (UNAUDITED)

Reconciliation of GAAP Net (Loss) to Non-GAAP Adjusted EBITDA:		Septem	30,	September 30,				
		2024		2023		2024		2023
GAAP Net Loss	\$	(1,580,817)	\$	(1,368,262)	\$	(4,505,490)	\$	(6,275,033)
Tax Benefit		(314,095)		(300,247)		(892,524)		(1,477,642)
Allowance for Tax Benefit		314,095		_		892,524		_
Reorganization Charges		396,926		_		496,255		_
Depreciation and Amortization		227,785		216,014		677,019		642,050
Interest Income, Net		(112,997)		(135,429)		(364,183)		(392,098)
Manufacturing Initiative Expense		_		_		_		55,361
Stock-based Compensation Expense		634,608		697,658		1,948,992		2,379,613
Non-GAAP Adjusted EBITDA	\$	(434,495)	\$	(890,266)	\$	(1,747,407)	\$	(5,067,749)
Weighted average number of common shares		45,851,019		45,606,603		45,791,756		45,547,427

Reconciliation of Reported Diluted EPS	Three Months Ended September 30,					Nine Months Ended September 30,				
to Non-GAAP Adjusted Diluted EPS:		2024		2023		2024		2023		
Reported Diluted Earnings Per Share	\$	(0.03)	\$	(0.03)	\$	(0.10)	\$	(0.14)		
Tax Benefit		(0.01)		(0.01)		(0.02)		(0.03)		
Allowance for Tax Benefit		0.01		_		0.02		_		
Reorganization Charges		0.01		_		0.01		_		
Depreciation and Amortization		_		_		0.01		0.01		
Interest Income, Net		_		_		(0.01)		(0.01)		
Manufacturing Initiative Expense		_		_		_		_		
Stock-based Compensation Expense		0.01		0.02		0.04		0.05		
Non-GAAP Adjusted Diluted Earnings Per Share	\$	(0.01)	\$	(0.02)	\$	(0.05)	\$	(0.12)		

<sup>\*</sup>Numbers presented are rounded to the nearest whole cent

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 third quarter ended 2024 in the amount of \$0.3 million. It was determined that no valuation allowance was necessary in the third quarter ended 2023.

Reorganization Charges. We have excluded the effect of reorganization charges in calculating our non-GAAP measures. In 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.

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 equity-based awards for executives, employees, consultants, and directors. Depending upon the size, timing and the terms of the grants, the non-cash compensation expense may vary significantly but is expected to recur in future periods.