

November 13, 2024



KORU Medical Systems, Inc. Announces 2024 Q3 Financial Results, Third Consecutive Quarter of Double-Digit Growth; Raises Full Year 2024 Guidance

MAHWAH, N.J.--(BUSINESS WIRE)-- **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® 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

	Three Months Ended September 30,		Change from Prior Year		% of Net Revenues	
	2024	2023	\$	%	2024	2023
Net Revenues						
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 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.

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 HlGH-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.

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS

	September 30, 2024 (UNAUDITED)	December 31, 2023
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)
Accumulated deficit	(27,817,763)	(23,312,273)
TOTAL STOCKHOLDERS' EQUITY	17,733,480	20,353,771
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 27,390,032	\$ 28,460,972

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
NET REVENUES	\$ 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

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

For the
Nine Months Ended
September 30,

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	\$ 46,014	\$ 34,773
Income taxes	\$ —	\$ 3,160

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 September 30,		Nine Months Ended 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 to Non-GAAP Adjusted Diluted EPS:	Three Months Ended September 30,		Nine Months Ended September 30,	
	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)

**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.

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