

KORU Medical Systems, Inc. Announces 2024 Q2 Financial Results, a Record Quarter With 22% Revenue 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 second quarter ended June 30, 2024 and raised full year 2024 revenue and gross margin guidance.

Financial Highlights

- Second quarter 2024 net revenues of \$8.4 million, a 22% increase over the prior year with record-high quarterly revenues
- Core business (U.S. and International) growth of 20% over the prior year driven by overall SCIg market growth, share gains, and geographic expansion
- Gross profit of \$5.5 million, a 41% increase over the prior year, and gross margin of 65%, reflecting year-over-year improvement of 890 basis points
- Ending cash balance of \$10.5 million and quarterly cash usage of \$0.3 million driven by improved net income, increased operating leverage, and working capital improvements
- Raising full year 2024 revenue guidance to \$32.0-\$32.5 million, representing yearover-year growth of 12-14%; raising full year gross margin guidance to 61-62%

Business Highlights

- Received regulatory clearance of FreedomEdge® Infusion System for use in Japan
- Successfully passed feasibility for oncology biologic, progressing pathway to an infusion clinic entry in 2025
- Entered Phase III clinical trial for an expanded nephrology indication expected to launch in 2026
- Announced collaboration with SCHOTT Pharma to drive market expansion and optimize drug delivery in large volume subcutaneous infusion

"We delivered a great quarter, highlighted by strong double-digit growth, progress in our Novel Therapies pipeline and increased operating leverage," said Linda Tharby, KORU Medical's President and CEO. "Our US Core business continues to capture share gains in a growing SCIg market. Internationally, we are increasing penetration and expanding in new geographies. We also continue to progress our Novel Therapies pipeline collaborations with a clear line of sight to multiple commercial launches over the next several years. We have

accomplished this while also delivering on gross margin expansion and operating leverage. I'm proud of the KORU team and, as a result of our strong performance in the first half of 2024 and our confidence in continued execution moving forward, we are raising our full year 2024 revenue and gross margin guidance."

2024 Second Quarter Financial Results

	TI	Three Months Ended June 30,				hange from Price	% of Net Revenues		
		2024		2023		\$	%	2024	2023
Net Revenues					-				
Domestic Core	\$	6,156,098	\$	5,388,172	\$	767,926	14.3%	73.0%	77.7%
International Core		1,628,191		1,117,004		511,187	45.8%	19.3%	16.1%
Total Core		7,784,289		6,505,176		1,279,113	19.7%	92.3%	93.8%
Novel Therapies		645,800		430,754		215,046	49.9%	7.7%	6.2%
Total	\$	8,430,089	\$	6,935,930	\$	1,494,159	21.5%	100%	100%

Total net revenues increased \$1.5 million, or 21.5%, to \$8.4 million for the three months ended June 30, 2024, as compared with the same period in 2023. Domestic Core revenues increased by 14.3% to \$6.2 million, primarily due to higher consumable and pump volumes driven by new patients starts and share gains. International Core revenues increased by 45.8% to \$1.6 million, primarily due to higher consumable and pump volumes driven largely by increased Ig supply, increased penetration within certain approved indications, and geographic expansion. International orders were expedited for certain distribution partners of \$0.3 million in the second quarter of 2024 related to the BSI regulatory review process which has since been successfully appealed. Novel Therapies net revenues increased by 49.9% to \$0.6 million in the second quarter of 2024, primarily driven by Phase III clinical trial orders and milestone completion from our collaboration agreements.

Gross profit increased \$1.6 million, or 41%, to \$5.5 million in the three months ended June 30, 2024, compared to \$3.9 million in the same period in 2023. Gross margin increased to 65.0% in the second quarter of 2024 compared to 56.1% in the second quarter of 2023. The increase in gross margin was primarily driven by increased production efficiencies, favorable sales mix driven by clinical trial orders, and increased average selling prices when compared to the prior year period. We also had a positive inventory valuation adjustment of \$0.1 million during the second quarter of 2024 which is not expected to recur in 2024.

Total operating expenses for the second quarter of 2024 were \$6.7 million, a decrease of \$0.4 million, or 6.2%, compared to \$7.1 million in the prior year period driven primarily by a decrease of \$0.5 million in research and development expenses primarily due to timing of project spend.

Net loss for the second quarter of 2024 was \$1.0 million, or \$(0.02) per diluted share, compared to a net loss of \$2.5 million, or \$(0.05) per diluted share, for the same period of 2023, primarily driven by an increase in gross profit of \$1.6 million and an interest income of \$0.1 million, partially offset by a decrease in tax benefit of \$0.6 million and in operating expenses of \$0.4 million. Adjusted EBITDA for the second quarter of 2024 was \$(0.4) million, or \$(0.01) per diluted share, compared to adjusted EBITDA of \$(2.3) 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 \$10.5 million as of June 30, 2024, reflecting cash usage of

\$0.3 million in the second quarter of 2024.

2024 Guidance

- Raising full year 2024 net revenue guidance to \$32.0 \$32.5, representing growth of 12-14%; increased from previously issued guidance of \$31.2 - \$32.2 million, or 10% to 13%
- Raising full year 2024 gross margin guidance to 61% 62%; increased from previously issued guidance of 59% - 61%
- Reaffirming guidance of 2024 year-end cash balance greater than \$8.0 million and achieving 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, August 7, 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 HIgH-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.

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, 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 August 7, 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 (UNAUDITED)

	June 30, 2024		D	2023	
ASSETS					
CURRENT ASSETS					
Cash and cash equivalents	\$	10,458,001	\$	11,482,240	
Accounts receivable less allowance for credit losses of \$24,777 as of June 30, 2024 and December 31, 2023		5,846,082		4,045,211	
Inventory		2,588,750		3,481,301	
Other receivables		_		28,889	
Prepaid expenses		472,864		1,218,288	
TOTAL CURRENT ASSETS		19,365,697		20,255,929	
Property and equipment, net	_	3,678,984		3,837,657	
Intangible assets, net of accumulated amortization of \$423,834 and \$390,341 as of June 30, 2024 and December 31, 2023, respectively		745,084		754,361	
Operating lease right-of-use assets		3,414,831		3,514,055	
Deferred income tax assets, net of allowance for non-realization of deferred tax assets of \$6,581,206 and \$6,002,777 as of June 30, 2024 and December 31, 2023, respectively		_		_	
Other assets		98,970		98,970	
TOTAL ASSETS	\$	27,303,566	\$	28,460,972	
LIABILITIES AND STOCKHOLDERS' EQUITY					
CURRENT LIABILITIES					
Accounts payable	\$	1,595,691	\$	975,193	
Accrued expenses		2,144,722		1,711,427	
Note payable				314,344	
Other liabilities		447,788		512,520	
Accrued payroll and related taxes		444,251		462,941	
Financing lease liability – current		112,689		109,540	
Operating lease liability – current		391,699	_	368,313	
TOTAL CURRENT LIABILITIES		5,136,840		4,454,278	
Financing lease liability, net of current portion		259,479		316,623	
Operating lease liability, net of current portion		3,202,697		3,336,300	
TOTAL LIABILITIES		8,599,016		8,107,201	
STOCKHOLDERS' EQUITY					
Common stock, \$0.01 par value, 75,000,000 shares authorized, 49,257,812 and 49,089,864 shares issued 45,819,286 and 45,669,362 shares outstanding as of June 30, 2024, and December 31, 2023, respectively		492,398		490,899	
Additional paid-in capital		•			
·		48,331,591		47,018,707	
Treasury stock, 3,438,526 shares as of June 30, 2024 and December 31, 2023, at cost		(3,882,493) (26,236,946 ₎		(3,843,562	
Accumulated deficit				(23,312,273	
TOTAL STOCKHOLDERS' EQUITY		18,704,550		20,353,771	
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	27,303,566	\$	28,460,972	

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

		nths Ended ne 30,		Six Month June			
	2024		2023		2024		2023
NET REVENUES	\$ 8,430,089	\$	6,935,931	\$	16,627,887	\$	14,328,536
Cost of goods sold	2,950,339		3,047,807		6,044,839		6,293,377
Gross Profit	5,479,750		3,888,124		10,583,048		8,035,159
OPERATING EXPENSES							
Selling, general and administrative	5,319,688		5,303,167		10,677,308		10,729,044
Research and development	1,134,232		1,596,614		2,609,907		3,161,483
Depreciation and amortization	217,864		212,919		449,233		426,036
Total Operating Expenses	6,671,784		7,112,700		13,736,448		14,316,563
Net Operating Loss	(1,192,034)		(3,224,576)		(3,153,400)		(6,281,404)
Non-Operating Income/(Expense)							
Loss on currency exchange	(10,680)		(2,472)		(22,159)		(3,152)
Loss on disposal of fixed assets, net	_		_		(300)		(56,279)
Interest income, net	 213,999		131,167		251,186		256,669
TOTAL OTHER INCOME	 203,319		128,695		228,727		197,238
LOSS BEFORE INCOME TAXES	(988,715)		(3,095,881)		(2,924,673)		(6,084,166)
Income Tax Benefit	 _		599,995		<u> </u>		1,177,395
NET LOSS	\$ (988,715)	\$	(2,495,886)	\$	(2,924,673)	\$	(4,906,771)
NET LOSS PER SHARE							
Basic	\$ (0.02)	\$	(0.05)	\$	(0.06)	\$	(0.11)
Diluted	\$ (0.02)	\$	(0.05)	\$	(0.06)	\$	(0.11)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING							
Basic	45,811,373		45,606,603		45,761,799		45,547,427
Diluted	45,811,373	_	45,606,603		45,761,799	_	45,547,427

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

For the Six Months Ended June 30,

	June 30,		
	 2024		2023
CASH FLOWS FROM OPERATING ACTIVITIES			
Net Loss	\$ (2,924,673)	\$	(4,906,771
Adjustments to reconcile net loss to net cash used in operating activities:	,		, , ,
Stock-based compensation expense and warrant expense	1,314,384		1,681,955
Depreciation and amortization	449,233		426,036
Deferred income taxes	_		(1,177,395)
Loss on disposal of fixed assets	300		56,279
Non-cash lease adjustments	(10,994)		(10,994
Changes in operating assets and liabilities:			
Accounts receivable	(1,800,871)		(239,590
Inventory	892,551		1,126,643
Prepaid expenses and other assets	774,313		687,994
Other liabilities	(64,731)		5,916
Accounts payable	620,498		(817,169
Accrued payroll and related taxes	(18,691)		(119,776
Accrued expenses	433,296		(1,527,648
NET CASH USED IN OPERATING ACTIVITIES	(335,385)		(4,814,520
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property and equipment	(257,367)		(375,246
Purchases of intangible assets	(24,216)		(17,298
NET CASH USED IN INVESTING ACTIVITIES	(281,583)		(392,544
CASH FLOWS FROM FINANCING ACTIVITIES			
Payments on insurance finance indebtedness	(314,344)		(433,295
Payments on finance lease liability	(53,995)		(48,493)
Payments for taxes related to net share settlement of equity awards	(38,932)		_
NET CASH USED IN FINANCING ACTIVITIES	(407,271)		(481,788
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,024,239)		(5,688,852
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	11,482,240		17,408,257
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 10,458,001	\$	11,719,405
Supplemental Information			
Cash paid during the periods for:			
Interest	\$ 20,491	\$	20,165
Income taxes	\$ 	\$	3,160
Schedule of Non-Cash Operating, Investing and Financing Activities:			
Issuance of common stock as compensation	\$ 221,182	\$	266,023

KORU MEDICAL SYSTEMS, INC. SUPPLEMENTAL INFORMATION (UNAUDITED)

Three Months Ended

Six Months Ended

(0.02) \$

(0.09)

A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net (Loss)		Inree Mon June	-nded	June 30,					
to Non-GAAP Adjusted EBITDA:		2024	2023		2024		2023		
GAAP Net Loss	\$	(988,715)	\$	(2,495,886)	\$	(2,924,673)	\$	(4,906,771)	
Tax (Benefit)/Expense		(189,754)		(599,995)		(578,429)		(1,177,395)	
Allowance for DTA		189,754		_		578,429		_	
Reorganization Charges		_		_		99,329		_	
Depreciation and Amortization		217,864		212,919		449,233		426,036	
Interest (Income)/Expense, Net		(213,999)		(188,126)		(251,186)		(256,669)	
Stock-based Compensation Expense		614,666		800,733		1,314,384		1,681,955	
Non-GAAP Adjusted EBITDA	\$	(370,184)	\$	(2,270,355)	\$	(1,312,913)	\$	(4,232,844)	
Weighted average number of common shares		45,811,373		45,606,603		45,761,799		45,547,427	
		Three Mon	ths E	Ended	Six Months		ths E	Ended	
Reconciliation of Reported Diluted EPS	June 30,			June 3			30,		
to Non-GAAP Adjusted Diluted EPS:		2024		2023		2024		2023	
Reported Diluted Earnings Per Share	\$	(0.02)	\$	(0.05)	\$	(0.06)	\$	(0.11)	
Depreciation and Amortization		0.00		0.00		0.01		0.01	
Stock-based Compensation Expense		0.01		0.02		0.03		0.04	
Tax (Expense) Adjustment		0.00		(0.01)		0.00		(0.03)	

^{*}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 second quarter ended 2024 in the amount of \$0.2 million. It was determined that no valuation allowance was necessary in the second guarter ended 2023.

(0.01) \$

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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Investor Contact:

Tax (Expense) Adjustment

Non-GAAP Adjusted Diluted Earnings Per Share \$

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Source: KORU Medical Systems, Inc.