

March 13, 2024



KORU Medical Systems, Inc. Announces 2023 Fourth Quarter, Full Year Financial Results, and 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 fourth quarter and full year ended December 31, 2023. The Company also issued guidance for the full year 2024.

Recent Highlights

- Fourth quarter 2023 net revenues of \$7.2 million, a 2% decrease from the prior year; Full year 2023 net revenues of \$28.5 million, a 2% increase over the prior year
- Full year 6.7% Core business growth (U.S. and International) driven by overall SCIg market growth, share gains and expansion in new geographies
- Fourth quarter gross margin of 60.3%, reflecting year-over-year improvement of 470 basis points; Full year gross margin of 58.6%, reflecting year-over-year improvement of 350 basis points
- Positive cash flow of \$0.7 million in the fourth quarter of 2023, ending the year with a cash balance of \$11.5 million
- Entered 3 Novel Therapies collaborations during 2023 and announced 2 new collaborations in the first quarter of 2024
- Recorded a non-cash valuation allowance against deferred tax assets of \$6.0 million. Net loss for the year, which included this allowance, was (\$13.7) million, or (\$0.30) per share. Adjusted EBITDA was (\$6.0) million, or (\$0.13) per share vs. (\$6.1) million or (\$0.14) in the prior year.
- Signed a \$10 million credit facility with HSBC USA to replace an expired \$3.5 million revolver agreement; the credit facility will be reserved for strategic growth capital
- Issued full year 2024 net revenues guidance of \$31.2-\$32.2 million, representing 10-13% growth

"I am proud of the KORU team for delivering a solid end to 2023, led by performance in our Core business. Entry into multiple geographic markets drove international sales, and in the US, we hit a key milestone with the FDA clearance and launch of the 50mL prefill pump platform, which we anticipate will be a significant growth driver in 2024. Additionally, we saw double-digit growth in our end-user specialty pharmacy sales, reflective of share gains and a growing Ig market," said Linda Tharby, KORU Medical's President and CEO. "Within our Novel Therapies business, we recently announced collaborations for two late-stage therapies. On the operational side, we increased gross margins, were cash flow positive in the fourth quarter and finished the year with a significantly lower cash burn than the prior

year. We are excited by the momentum we are carrying into 2024; we remain focused on the execution of our Vision 2026 strategy, and positioning KORU for growth, profitability and value creation for our customers and shareholders.”

2023 Fourth Quarter Financial Results

	Three Months Ended December 31,		Change from Prior Year		% of Total	
	2023	2022	\$	%	2023	2022
Net Revenues						
Domestic Core	\$ 5,565,349	\$ 5,314,836	\$ 250,513	4.7%	77.4%	72.4%
International Core	1,315,036	1,221,540	93,496	7.7%	18.3%	16.6%
Novel Therapies	305,547	808,305	(502,758)	(62.2%)	4.3%	11.0%
Total	\$ 7,185,932	\$ 7,344,681	\$ (158,749)	(2.2%)		

Total net revenues decreased \$0.2 million, or 2.2%, for the three months ended December 31, 2023, as compared with the same period last year. Domestic Core net revenues increased by 4.7% year-over-year, driven by growth in pumps and consumables, due to competitive share gain in new accounts. International Core net revenues increased by 7.7%, driven by strong SCIG volume and growth in several OUS geographies as we continue to expand into new markets. Novel Therapies net revenues declined by 62% year-over-year, primarily driven by the completion of a large milestone for a pharmaceutical NRE agreement in 2022.

Gross profit increased \$0.3 million or 6.2% for the three months ended December 31, 2023, as compared with the same period last year. Gross profit stated as a percentage of net revenues increased to 60.3% for the fourth quarter of 2023 compared to 55.5% in the fourth quarter of 2022. The increase was primarily driven by production efficiencies from the completion of an outsourced manufacturing initiative and consolidation of our manufacturing sites. Allowing for a one-time inventory adjustment for a product discontinuation, adjusted gross margin for the fourth quarter of 2023 was 63.1%. A reconciliation of adjusted gross margin to the most directly comparable GAAP measure is provided at the end of this press release.

Total operating expenses for the fourth quarter of 2023 were \$6.7 million, an increase of \$0.1 million or 1.6%, compared to \$6.6 million in the prior year period. The increase was driven primarily by the hiring of our new Chief Commercial Officer to lead our Core business growth strategy, partially offset by efficiencies in insourcing R&D.

Net loss for the fourth quarter of 2023 was \$7.5 million, or \$(0.16) per diluted share, compared to a net loss of \$2.0 million, or \$(0.04) per diluted share for the same period of 2022. Net loss included a tax valuation allowance of \$6.0 million for the fourth quarter of 2023. Adjusted EBITDA for the quarter was (\$1.0 million), or \$(0.02) per diluted share versus (\$1.6 million), or \$(0.04) in the prior year. A reconciliation of adjusted EBITDA and adjusted diluted EPS to the most directly comparable GAAP measures is provided at the end of this press release.

2023 Full Year Financial Results

	Years Ended December 31,		Change from Prior Year		% of Total	
	2023	2022	\$	%	2023	2022
Net Revenues						
Domestic Core	\$ 22,446,519	\$ 21,205,204	\$ 1,241,315	5.9%	78.7%	76.0%
International Core	4,596,097	4,164,714	431,383	10.4%	16.1%	14.9%
Novel Therapies	1,475,050	2,526,119	(1,051,069)	(41.6%)	5.2%	9.1%
Total	<u>\$ 28,517,666</u>	<u>\$ 27,896,037</u>	<u>\$ 621,629</u>	2.2%		

Total net revenues increased \$0.6 million, or 2.2%, for the year ended December 31, 2023, as compared with the same period last year. Domestic Core growth of 5.9% was driven by volume growth in pumps and consumables attributed to share gains. International Core growth of 10.4% was driven by increased volume across several EU markets and the entry into multiple new geographic markets. The growth in Core offset a 41.6% year-over-year decline in Novel Therapies net revenues, primarily driven by the completion of a large milestone for a pharmaceutical NRE agreement in 2022.

Gross profit increased \$1.3 million or 8.7% for the year ended December 31, 2023, compared to the same period in 2022. Gross profit as a percentage of net revenues increased to 58.6% compared to 55.1% from the prior year. The increase was driven by improvements in manufacturing productivity and product mix. Allowing for a one-time inventory adjustment for a product discontinuation, adjusted gross margin for the year ended 2023 was 59.6%. A reconciliation of adjusted gross margin to the most directly comparable GAAP measure is provided at the end of this press release.

Selling, general and administrative expenses decreased \$0.2 million, or 1.2%, during the year ended December 31, 2023, compared to the same period last year, primarily driven by lower executive restructuring costs partially offset by an increase of new hires in commercial business development and medical affairs.

Research and development expenses increased \$0.8 million, or 15.9%, during the year ended December 31, 2023, compared with the same period last year, primarily due to compensation and expenses to support new hires focused on new product development.

Net loss for the full year 2023 was \$13.7 million, or \$(0.30) per diluted share, compared to a net loss of \$8.7 million, or \$(0.19) per diluted share for the same period of 2022. Net loss included a tax valuation allowance of \$6.0 million for the full year 2023. Adjusted EBITDA for the full year was (\$6.0) million, or \$(0.13) per diluted share versus (\$6.1) million or \$(0.14) in the prior year. A reconciliation of adjusted EBITDA and adjusted diluted EPS to the most directly comparable GAAP measures is provided at the end of this press release.

Cash and cash equivalents were \$11.5 million as of December 31, 2023, reflecting positive cash flow of \$0.7 million in the fourth quarter and a reduction of cash burn to \$5.9 million in 2023 from \$8 million in 2022.

Subsequent Events

The Company has entered into a \$5M revolving credit facility and a \$5M term loan facility with HSBC Bank USA, which replaced a \$3.5M revolving credit facility with a regional bank that expired in August of 2023. This new debt facility provides KORU Medical with additional capital flexibility to support a reserve for growth and strategic opportunities.

The Company has received an assessment report from its notified body in the EU, BSI, stating that, following BSI's review of technical documentation submitted by the Company in connection with a prior audit nonconformance, a recommendation for continued certification cannot be made. The Company has filed an appeal to this determination. Management believes that the Company's appeal will be successful in limiting the scope of the suspension to have minimal impact on the Company's revenues, if any.

Assumptions and Guidance for Full Year 2024

KORU Medical's guidance for the full year 2024 reflects numerous assumptions that could affect its business, based on the information management has as of this date. Management will discuss its outlook and several of its assumptions on its fourth quarter 2023 earnings call.

KORU Medical expects:

- Full year 2024 net revenue between \$31.2 and \$32.2 million, representing growth in the range of 10% to 13%
 - SCIg market growth of mid-to-high single digits
 - Three new Novel Therapies collaborations
 - Prefilled syringe market penetration of approximately 20%-25%
- Gross margin between 59% and 61% for the full year 2024
 - Geographic expansion into lower ASP markets
 - Supply chain inflationary pricing pressure
 - Production line start-up in Q4 for new product introduction
- 2024 year-end cash balance greater than \$8.0 million
 - Operating expenses of approximately \$23.5- \$24.0 million, exclusive of stock compensation expense
 - Cash flow breakeven in the fourth quarter of 2024 and cash flow positive for full year 2025
 - Ending cash balance is exclusive of the new \$10 million credit facility, which will be reserved for strategic growth capital opportunities

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, March 13, 2024, at 4:30 PM ET.

To participate in the call, please dial (844) 826-3035 (domestic) or (412) 317-5195 (international) and provide conference ID: 6447448. 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 gross margin," "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™. 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, 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, 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 March 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

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 11,482,240	\$ 17,408,257
Accounts receivable less allowance for doubtful accounts of \$24,777 and \$21,459 for December 31, 2023, and December 31, 2022, respectively	4,045,211	3,558,884
Inventory	3,481,301	6,404,867
Other receivables	28,889	972,396
Prepaid expenses and other	1,218,288	1,457,232
TOTAL CURRENT ASSETS	20,255,929	29,801,636
Property and equipment, net	3,837,657	3,886,975
Intangible assets, net of accumulated amortization of \$390,341 and \$325,872 at December 31, 2023 and December 31, 2022, respectively	754,361	787,182
Operating lease right-of-use assets	3,514,055	3,786,545
Deferred income tax assets, net allowance for non-realization of deferred tax assets of \$6,002,777 and zero for December 31, 2023 and December 31, 2022, respectively	—	3,967,480
Other assets	98,970	102,625
TOTAL ASSETS	\$ 28,460,972	\$ 42,332,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 975,193	\$ 2,391,799
Accrued expenses	1,711,427	2,889,941
Note Payable	314,344	433,295
Other liabilities	512,520	257,337
Accrued payroll and related taxes	462,941	542,399
Finance lease liability – current	109,540	98,335
Operating lease liability – current	368,313	345,834
TOTAL CURRENT LIABILITIES	4,454,278	6,958,940
Finance lease liability, net current portion	316,623	394,283
Operating lease liability, net of current portion	3,336,300	3,653,257
TOTAL LIABILITIES	8,107,201	11,006,480
Commitments and contingencies (Refer to Note 8)		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 49,089,864 and 48,861,891 shares issued; 45,669,362 and 45,441,389 shares outstanding at December 31, 2023, and December 31, 2022, respectively	490,899	488,619
Additional paid-in capital	47,018,707	44,252,117
Treasury stock, 3,420,502 shares at December 31, 2023 and December 31, 2022, at cost	(3,843,562)	(3,843,562)
Retained Deficit	(23,312,273)	(9,571,211)
TOTAL STOCKHOLDERS' EQUITY	20,353,771	31,325,963
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 28,460,972	\$ 42,332,443

See accompanying Notes to Financial Statements.

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF OPERATIONS

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
NET REVENUES	\$ 7,185,932	\$ 7,344,681	\$ 28,517,666	\$ 27,896,037
Cost of goods sold	2,854,987	3,266,535	11,809,384	12,527,051
Gross Profit	4,330,946	4,078,146	16,708,282	15,368,986
OPERATING EXPENSES				
Selling, general and administrative	5,012,646	4,761,173	20,365,617	20,606,507
Research and development	1,287,515	1,640,732	5,742,254	4,956,215
Depreciation and amortization	228,340	187,658	870,390	587,137
Total Operating Expenses	6,528,501	6,589,563	26,978,261	26,149,859
Net Operating Loss	(2,197,555)	(2,511,417)	(10,269,979)	(10,780,873)
Non-Operating (Expense)/Income				
(Loss)/Gain on currency exchange	7,418	(977)	(5,124)	(39,874)
Loss on disposal of fixed assets, net	—	—	(59,807)	—
Interest (expense)/income, net	169,230	101,008	561,328	145,587
TOTAL OTHER (EXPENSE)/INCOME	176,648	100,031	496,397	105,713
LOSS BEFORE INCOME TAXES	(2,020,907)	(2,411,386)	(9,773,582)	(10,675,160)
Income Tax Benefit/(Expense)	(5,445,123)	434,659	(3,967,480)	2,014,018
NET LOSS	\$ (7,466,029)	\$ (1,976,727)	\$ (13,741,062)	\$ (8,661,142)
NET LOSS PER SHARE				
Basic	\$ (0.16)	\$ (0.04)	\$ (0.30)	\$ (0.19)
Diluted	\$ (0.16)	\$ (0.04)	\$ (0.30)	\$ (0.19)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	45,669,691	45,372,132	45,601,346	45,002,074
Diluted	45,669,691	45,372,132	45,601,346	45,002,074

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (13,741,062)	\$ (8,661,142)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,768,870	3,079,427
Depreciation and amortization	870,390	587,137
Loss on disposal of fixed assets	59,807	—
Deferred income taxes	(2,035,297)	(2,026,226)
Allowance for non-realization of deferred tax asset	6,002,777	—
ROU landlord credit	(21,988)	212,546
Changes in operating assets and liabilities:		
(Increase)/Decrease in accounts receivable	(486,327)	34,002
Decrease/(Increase) in inventory	2,923,566	(298,529)
Decrease/(Increase) in other receivables	943,507	(254,176)
Decrease in prepaid expenses and other assets	242,599	28,776
(Decrease)/Increase in accounts payable	(1,416,606)	1,164,266
(Decrease)/Increase in accrued payroll and related taxes	(79,458)	381,796
Increase in other liabilities	255,183	167,337
(Decrease)/Increase in accrued expenses	(1,178,514)	180,237
NET CASH USED IN OPERATING ACTIVITIES	(4,892,553)	(5,404,549)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(782,949)	(2,761,056)
Purchases of intangible assets	(31,648)	(40,512)
NET CASH USED IN INVESTING ACTIVITIES	(814,597)	(2,801,568)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of equity	—	406,623
Borrowings from indebtedness	565,172	783,799
Payments on indebtedness	(684,123)	(859,087)
Finance lease ROU asset	(33,461)	—
Payments on finance lease liability	(66,455)	(51,850)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(218,867)	279,485
NET DECREASE IN CASH AND CASH EQUIVALENTS	(5,926,017)	(7,926,632)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	17,408,257	25,334,889
CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 11,482,240	\$ 17,408,257
Supplemental Information		
Cash paid during the years for:		
Interest	\$ 50,832	\$ 28,490
Income taxes	\$ 3,160	\$ —
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	\$ 446,349	\$ 513,082

See accompanying Notes to Financial Statements.

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 December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
GAAP Net Loss	\$ (7,466,029)	(1,976,727)	\$ (13,741,062)	\$ (8,661,142)
Tax (Benefit)/Expense	(557,654)	(434,659)	(2,035,297)	(2,014,018)
Valuation Allowance for DTA	6,002,777	—	6,002,777	—
Depreciation and Amortization	228,340	187,658	870,390	587,137
Interest (Income), Net	(169,230)	(101,009)	(561,328)	(145,587)
Reorganization Charges	329,869	—	329,869	765,433
Manufacturing Initiative Expenses	—	184,343	55,361	293,229
Product Discontinuance	280,000	—	280,000	—
Stock-based Compensation Expense	389,256	588,654	2,768,869	3,079,426
Adjusted EBITDA	\$ (962,671)	\$ (1,551,740)	\$ (6,030,421)	\$ (6,095,522)

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Reported Diluted Earnings Per Share	\$ (0.16)	\$ (0.04)	\$ (0.30)	\$ (0.19)
Tax (Benefit)/Expense	(0.01)	(0.01)	(0.04)	(0.05)
Valuation Allowance for DTA	0.13	—	0.13	—
Depreciation and Amortization	—	—	0.02	0.01
Interest (Income)/Expense, Net	—	—	(0.01)	—
Reorganization Charges	0.01	—	0.01	0.02
Manufacturing Initiative Expenses	—	—	—	—
Product Discontinuance	—	—	—	—
Stock-based Compensation Expense	0.01	0.01	0.06	0.07
Adjusted Diluted Earnings Per Share	\$ (0.02)	\$ (0.04)	\$ (0.13)	\$ (0.14)

Reconciliation of GAAP Gross Profit to Adjusted Gross Margin	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Reported Gross Profit stated as a percentage of Net Revenues (Gross Margin)	60.3%	55.6%	58.6%	55.1%
Product Discontinuance	2.8%	0.0%	1.0%	0.0%
Adjusted Gross Profit stated as a percentage of Net Revenues (Adjusted Gross Margin)	63.1%	55.6%	59.6%	55.1%

**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 2022 and 2023 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 fourth quarter ended 2023 in the amount of \$6.0 million to illustrate the impact on net loss and earnings per share.

Product Discontinuation. We have excluded the effect of disposing of a non-launched inventoried product that has no value in our core business product portfolio.

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