

# KORU Medical Systems, Inc. Announces 2023 Second Quarter Financial Results and Updates Full Year 2023 Outlook

MAHWAH, N.J.--(BUSINESS WIRE)-- **KORU Medical Systems, Inc. (NASDAQ: KRMD)** ("**KORU Medical" or the "Company"),** a leading medical technology company focused on the development, manufacturing, and commercialization of innovative and easy-to-use specialty infusion solutions that improve quality of life for patients, today reported financial results for the second quarter ended June 30, 2023 and updates full year 2023 outlook.

# **Highlights:**

- Second quarter net revenue growth versus prior year of 6% to \$6.9 million
- Domestic Core business growth of 8%, outperforming a second quarter U.S. script decline in subcutaneous immunoglobulin (SCIg) market, driven by strong volumes in consumables and pumps
- International Core business growth of 17%, driven by growth in several markets and increases in SCIg global drug availability
- Announced a new Novel Therapies collaboration for a Phase III study
- Submitted a 510(k) for FREEDOM60<sup>®</sup> Infusion System with Hizentra<sup>®</sup> 50 mL prefilled syringes
- Reduced 2023 net revenues guidance to \$31.0 \$32.5 million, representing growth in the range of 11-17% from prior guidance of \$32.5 \$33.5 million representing growth in the range of 17-20%
- Named Tom Adams as Chief Financial Officer

"I am pleased with our second quarter progress, as our growth exceeded the overall SCIg market in both the U.S. and Internationally," said Linda Tharby, KORU Medical's President and CEO. "The foundation of our business remains sound, and we are diligently focused on delivering above-market revenue performance, advancing our portfolio with our innovation efforts, and increasing the number of drugs on our Freedom Infusion System. We are excited to welcome Tom Adams as our Chief Financial Officer and look forward to his continued leadership contributions. We remain committed and on track to attain our Vision 2026 strategic goals, and deliver added value to patients, customers and shareholders."

# 2023 Second Quarter Financial Results

Three Months Ended June 30,			Change from Prior Year			
2023		2022		\$	%	
\$ 5,388,172	\$	4,996,791	\$	391,381	7.8%	
1,117,004		951,485		165,519	17.4%	
430,754		598,352		(167,598)	(28.0)%	
\$ 6,935,930	\$	6,546,628	\$	389,302	5.9%	
\$     \$	\$ 5,388,172 1,117,004 430,754	\$ 5,388,172 \$ 1,117,004 430,754	\$ 5,388,172 \$ 4,996,791 1,117,004 951,485 430,754 598,352	\$ 5,388,172 \$ 4,996,791 \$ 1,117,004 951,485 430,754 598,352	\$ 5,388,172 \$ 4,996,791 \$ 391,381 1,117,004 951,485 165,519 430,754 598,352 (167,598)	

Total net revenue increased \$0.4 million, or 6%, for the three months ending June 30, 2023, compared to last year. Domestic Core growth of 8% was primarily driven by increased growth in consumables and pumps, new accounts, and increased prefilled syringe adoption. International Core growth of 17% was driven by strength across several EU markets, and growing global immunoglobulin drug volume availability. Novel Therapies net revenue declined by 28% in primarily related to strong non-recurring engineering revenues in the comparable quarter last year as well as the timing of 2023 pipeline wins.

Gross profit increased \$0.5 million or 16% in the three months ended June 30, 2023, compared to the same period in 2022. The gross profit increase was driven by the rise in net revenue of \$0.4 million, as described above. Gross profit as a percentage of revenue increased to 56.1% compared to 51.1% in the second quarter of 2022. The increase in the gross profit as a percentage of revenue was primarily driven by increased production efficiencies compared to the prior year.

Total operating expenses for the second quarter of 2023 were \$7.1 million, compared to \$7.0 million for the same period in 2022. The increase in operating expenses was primarily due to the impact of research and development costs in support of our innovation efforts.

Net loss for the second quarter of 2023 was \$2.5 million, or \$(0.05) per diluted share, compared to a net loss of \$2.9 million, or (\$0.07) per diluted share for the same period of 2022. Net loss included a tax benefit of \$0.6 million for the second quarter of 2023.

# **Assumptions and Outlook for Full Year 2023**

KORU Medical updates prior guidance for 2023. The Company's guidance for full year 2023 has been updated to reflect a contraction in the underlying U.S. subcutaneous immunoglobulin market. KORU Medical is updating its 2023 growth outlook on the underlying U.S. subcutaneous immunoglobulin market to 5% from 10%. In addition, the Company's guidance reflects a change in the timing of 2023 Novel Therapy deal signings.

### **KORU Medical Outlook:**

- Reducing full year 2023 net revenue guidance to \$31.0 \$32.5 million, representing growth in the range of 11%-17% from prior guidance of \$32.5 - \$33.5 million, representing growth in the range of 17-20%
- Reaffirming 2023 gross margin between 58%-60% and a planned 2023 exit between 60%-62%
- Reaffirming cash balance at year-end 2023 greater than \$10.0 million

#### **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 9, 2023, 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: 10180800. The live webcast will be available on the IR Calendar on the <a href="News/Events">News/Events</a> page of the Investors section of KORU Medical's website.

#### **Non-GAAP Measures**

This press release includes the non-GAAP financial measures "Adjusted EBITDA" and "Adjusted Diluted Earnings Per Share" 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 Systems develops, manufactures, and commercializes innovative and easy-to-use subcutaneous drug delivery systems that improve quality of life for patients around the world. The FREEDOM Syringe Infusion 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, expected financial outlook and operating performance for fiscal 2022. 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 "outlook", "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 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, 2022 and our Quarterly Report on Form 10-Q for the guarter ended June 30, 2023, which are 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 9, 2023. 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.

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

#### KORU MEDICAL SYSTEMS, INC. BALANCE SHEETS (UNAUDITED)

	June 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 11,719,405	\$17,408,257
Accounts receivable less allowance for doubtful accounts of \$21,459 as of June 30, 2023 and	, , , , , ,	, , , , , ,
December 31, 2022	3,639,755	3,558,884
Inventory	5,278,224	6,404,867
Other receivables	1,131,115	972,396
Prepaid expenses	772,893	1,457,232
TOTAL CURRENT ASSETS	22,541,392	29,801,636
Property and equipment, net	3,811,843	3,886,975
Intangible assets, net of accumulated amortization of \$357,809 and \$325,872 as of June 30, 2023 and		
December 31, 2022, respectively	772,543	787,182
Operating lease right-of-use assets	3,626,348	3,786,545
Deferred income tax assets, net	5,144,876	3,967,480
Other assets	98,970	102,625
TOTAL ASSETS	\$ 35,995,972	\$42,332,443
CURRENT LIABILITIES Accounts payable	\$ 1.574.630	\$ 2,391,799
Accrued expenses	1,362,293	2,889,941
Note payable	202.252	433,295
Other liabilities	263,253	257,337
Accrued payroll and related taxes	422,623	542,399
Financing lease liability – current	101,072 352,809	98,335
Operating lease liability – current		345,834
TOTAL CURRENT LIABILITIES	4,076,680	6,958,940
Financing lease liability, net of current portion	343,053	394,283
Operating lease liability, net of current portion	3,475,092	3,653,257
TOTAL LIABILITIES	7,894,825	11,006,480
Commitments and Contingencies (Note 7)		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 49,033,652 and 48,861,891 shares issued 45,613,150 and 45,441,389 shares outstanding as of June 30, 2023, and December 31, 2022, respectively	490,337	488,619
Additional paid-in capital	45,932,354	
Treasury stock, 3,420,502 shares as of June 30, 2023 and December 31, 2022, at cost	(3,843,562)	
Accumulated deficit	, , ,	(9,571,211)
TOTAL STOCKHOLDERS' EQUITY	28,101,147	
	\$ 35,995,972	
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	ψ 55,335,372	Ψ+2,002,440

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

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

	Three Mon		Six Months Ended June 30,		
	2023	2022	2023	2022	
NET REVENUES	\$ 6,935,931	\$ 6,546,628	\$14,328,536	\$12,790,958	
Cost of goods sold	3,047,807	3,200,455	6,293,377	5,822,480	
Gross Profit	3,888,124	3,346,173	8,035,159	6,968,478	
OPERATING EXPENSES					
Selling, general and administrative	5,303,167	5,530,022	10,729,044	11,021,235	
Research and development	1,596,614	1,303,731	3,161,483	2,452,086	
Depreciation and amortization	212,919	125,882	426,036	235,134	
Total Operating Expenses	7,112,700	6,959,635	14,316,563	13,708,455	
Net Operating Loss	(3,224,576)	(3,613,462)	(6,281,404)	(6,739,977)	
Non-Operating Income/(Expense)					
Loss on currency exchange	(2,472)	(21,705)	(3,152)	(28,840)	
Loss on disposal of fixed assets, net	_	_	(56,279)	_	
Interest income, net	131,167	3,566	256,669	2,103	
TOTAL OTHER INCOME/(EXPENSE)	128,695	(18,139)	197,238	(26,737)	
LOSS BEFORE INCOME TAXES	(3,095,881)	(3,631,601)	(6,084,166)	(6,766,714)	
Income Tax Benefit	599,995	710,260	1,177,395	1,307,859	
NET LOSS	\$ (2,495,886)	\$ (2,921,341)	\$ (4,906,771)	\$ (5,458,855)	
NET LOSS PER SHARE					
Peril	\$ (0.05)	\$ (0.07)	\$ (0.11)	\$ (0.12)	
Basic	\$ (0.05)	, ,	,	·	
Diluted	ψ (0.03)	ψ (0.07)	ψ (0.11)	ψ (0.12)	
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING	i				
Basic	45,606,603	44,921,870	45,547,427	44,795,625	
Diluted	<u>45,606,603</u>	44,921,870	45,547,427	44,795,625	

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

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

For the Six Months Ended June 30, 2023 2022 CASH FLOWS FROM OPERATING ACTIVITIES (4,906,771)\$ (5,458,855)Adjustments to reconcile net loss to net cash used in operating activities: Stock-based compensation expense 1,681,955 1,579,151 Depreciation and amortization 426,036 235,134 Deferred income taxes (1,177,395)(1,308,069)Loss on disposal of fixed assets 56,279 ROU landlord credit (10,994)Changes in operating assets and liabilities: (Increase) in Accounts receivable (239,590)(454,452)1,126,643 (665, 176)Decrease / (Increase) in Inventory Decrease in Prepaid expenses and other assets 687,994 334,193 Increase in Other liabilities 5,916 150,501 (Decrease) / Increase in Accounts payable (817, 169)1,162,329 (Decrease) / Increase in Accrued payroll and related taxes 535,438 (119,776)(735,508)Decrease in Accrued expenses (1,527,648)(4,625,314)NET CASH USED IN OPERATING ACTIVITIES (4,814,520)CASH FLOWS FROM INVESTING ACTIVITIES Purchases of property and equipment (375, 246)(1,915,289) (17,298)(13,540)Purchases of intangible assets (392,544)(1,928,829)NET CASH USED IN INVESTING ACTIVITIES CASH FLOWS FROM FINANCING ACTIVITIES Payments on indebtedness (433, 295)(508,583)(48,493)(6,611)Payments on finance lease liability (481,788)(515, 194)NET CASH USED IN FINANCING ACTIVITIES NET DECREASE IN CASH AND CASH EQUIVALENTS (5,688,852)(7,069,337)17,408,257 25,334,889 CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD 11,719,405 18,265,552 CASH AND CASH EQUIVALENTS, END OF PERIOD Supplemental Information Cash paid during the periods for: 6,204 \$ 20,165 \$ Interest 3,160 \$ Income taxes Schedule of Non-Cash Operating, Investing and Financing Activities:

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

258,005

266,023 \$

A reconciliation of our non-GAAP measures is below:

Issuance of common stock as compensation

#### KORU MEDICAL SYSTEMS, INC. SUPPLEMENTAL INFORMATION (UNAUDITED)

	Three Months	Six Months Ended		
Reconciliation of GAAP Net (Loss)	June 30,	June 30,		
to Non-GAAP Adjusted EBITDA:	 2023	2022	2023	2022
GAAP Net Loss	\$ (2,495,886) \$	(2,921,341) \$	(4,906,771) \$	(5,458,855)
Tax (Benefit)/Expense	(599,995)	(710,260)	(1,177,395)	(1,307,859)
Depreciation and Amortization	212,919	125,882	426,036	235,134
Interest (Income)/Expense, Net	(131,168)	(3,566)	(256,669)	(2,103)
Reorganization Charges	_	270,433	_	565,433
Manufacturing Initiative Expenses	6,308	50,344	55,361	88,349
Stock-based Compensation Expense	800,734	821,513	1,681,956	1,659,070
Non-GAAP Adjusted EBITDA	\$ (2,207,088) \$	(2,366,995) \$	(4,177,482) \$	(4,220,831)

Reconciliation of Reported Diluted EPS	Three Months Ended June 30,				Six Months Ended June 30,	
to Non-GAAP Adjusted Diluted EPS:	 2023		2022	2023	2022	
Reported Diluted Earnings Per Share	\$ (0.05)	\$	(0.07) \$	(0.11) \$	(0.12)	
Reorganization Charges	_		0.01	_	0.01	
Manufacturing Initiative Expenses	_		_	_	_	
Stock-based Compensation Expense	_		_	_	_	
Tax (Expense) Adjustment	 					
Non-GAAP Adjusted Diluted Earnings Per Share	\$ (0.05)	\$	(0.06) \$	(0.11) \$	(0.11)	

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

Reorganization Charges. We have excluded the effect of reorganization charges in calculating our non-GAAP measures. In 2022 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.

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