

KORU Medical Systems, Inc. Announces 2023 First Quarter Financial Results

Strong Start to 2023 With 18% Revenue Growth

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 first quarter ended March 31, 2023.

Highlights:

- First quarter net revenue growth versus prior year of 18% to \$7.4 million, marking the sixth consecutive quarter of double-digit growth with strength in all three businesses
- U.S. Core business growth of 15% outpacing the subcutaneous immunoglobulin drug market growth
- International Core business growth of 23%, driven by growth in several markets and increases in SCIg global drug availability
- Novel Therapies business growth of 62%, increasing the total number of pharmaceutical collaborations to 15
- Sequential quarterly gross margin improvement to 56.1%, and completion of the manufacturing transition paving the way to exit the year with 60%-62% gross margin
- Reaffirming 2023 net revenues expected to be between \$32.5 and \$33.5 million, representing growth in the range of 17-20%

"The first quarter represents continued momentum towards our Vision 26 strategy, as our team delivered strong double-digit growth across all three of our businesses," said Linda Tharby, KORU Medical's President and CEO. "In our US core business, we continue to increase our leadership position in a growing home subcutaneous drug delivery market. We are seeing impact from our geographic expansion strategy with strong results in our international core business. Our efforts in the novel therapies business to bring new drugs and patients to our Freedom System is accelerating with increased numbers of total collaborations and pipeline opportunities. We are excited by a strong start to our year, and by the value we are creating for our patients, customers, and shareholders."

2023 First Quarter Financial Results

	Ended March 31,				Change from Prior Year			
	 2023		2022		\$		%	
Net Revenues								
Domestic Core	\$ 5,719,135	\$	4,993,536	\$	725,599	\$	14.5%	
International Core	1,097,490		894,942		202,548		22.6%	
Novel Therapies	575,980		355,852		220,128		61.9%	
Total	\$ 7,392,605	\$	6,244,330	\$	1,148,275	\$	18.4%	

Three Months

Total net revenues increased \$1.1 million, or 18%, for the three months ended March 31, 2023, as compared with the same period last year, with double-digit growth across all businesses. Domestic Core growth of 15% was primarily driven by increased growth in pumps and consumables from a growing SCIg market, new account wins, increased prefilled syringe adoption, and increases in average selling prices. International Core growth of 23%, was driven by strength across several EU markets, expanded distribution, and growing global Immunoglobulin drug volume availability. Novel Therapies net revenues grew by 62% primarily related to services performed on an NRE innovation development agreement for a pharmaceutical customer.

Gross profit increased \$0.5 million or 15% in the three months ended March 31, 2023, compared to the same period in 2022. The 2023 first quarter gross profits increase was driven by the increase in net revenues of \$1.1 million as described above. Gross profit as a percentage of revenues decreased to 56.1% compared to 58.0% from the first quarter of 2022. The decline in the gross profit as a percentage of revenues was primarily caused by higher manufacturing costs associated with labor and materials in connection with our transition from Chester, partially offset by an increase in average selling prices.

Total operating expenses for the first quarter of 2023, were \$7.2 million, compared to \$6.7 million for the same period in 2022. The increase in operating expenses was primarily due to investments in research and development.

Net loss for the first quarter of 2023 was \$2.4 million, or \$(0.05) per diluted share, compared to a net loss of \$2.5 million, or (\$0.06) per diluted share for the same period of 2022. Net loss included a tax benefit of \$0.6 million for the first quarter of 2023.

Assumptions and Outlook for Full Year 2023

KORU Medical reaffirms all prior guidance for 2023. The Company's guidance for full year 2023 reflects numerous assumptions that could affect its business, based on the information management has as of this date, which includes, SCIg market growth rate of ~10%, prefilled syringe penetration of 15-20%, plasma supply, clinical trial activity and expansion of the novel therapies pipeline, inflationary impact (including labor and supply price increases), third party contract manufacturing execution, supply chain and labor shortage impacts, and timely receipt of other receivable credits. Management will discuss its outlook and several of its assumptions on its first quarter 2023 earnings call.

KORU Medical reaffirms:

- Full year 2023 net revenues between \$32.5 and \$33.5 million, representing growth in the range of 17%-20%
- Gross margin between 58% and 60% on a full year, with first half margin expected between 55% to 57% and a planned exit between 60% and 62%

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 Thursday, May 4, 2023, at 4:30 PM ET.

To participate in the call, please dial (800)-734-8507 (domestic) or (212)-231-2925 (international) and provide conference ID: 22026692. 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 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

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 quarter ended March 31, 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 May 4,2023. 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.

KORU MEDICAL SYSTEMS, INC. BALANCE SHEETS (UNAUDITED)

		March 31, 2023	De	cember 31, 2022
ASSETS				
OLIDDENIT ACCETO				
CURRENT ASSETS	Φ.	40.004.005	Φ	47 400 057
Cash and cash equivalents	\$	12,224,865	\$	17,408,257
Accounts receivable less allowance for doubtful accounts of \$21,459 for March 31, 2023, and for December 31, 2022		4,164,513		3,558,884
Inventory		6,638,418		6,404,867
Other Receivables		1,014,761		972,396
Prepaid expenses		1,172,101		1,457,232
TOTAL CURRENT ASSETS	_	25,214,658		29,801,636
Property and equipment, net		3.906.067		3,886,975
Intangible assets, net of accumulated amortization of \$341,755 and \$325,872 at March 31, 2023 and		0,000,00.		0,000,0.0
December 31, 2022, respectively		782,531		787,182
Operating lease right-of-use assets		3,706,874		3,786,545
Deferred income tax assets, net		4,544,880		3,967,480
Other assets		98,970		102,625
TOTAL ASSETS	\$	38,253,980	\$	42,332,443
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES	Φ.	4 500 400	Φ	0.004.700
Accounts payable	\$	1,503,120	Ф	2,391,799
Accrued expenses		1,591,737		2,889,941
Note Payable		218,403		433,295
Other Liabilities		261,544		257,337
Accrued payroll and related taxes		500,415		542,399
Financing lease liability – current		99,694		98,335
Operating lease liability – current	_	349,304	_	345,834
TOTAL CURRENT LIABILITIES		4,524,217		6,958,940
Financing lease liability, net of current portion		368,844		394,283
Operating lease liability, net of current portion	_	3,564,619	_	3,653,257
TOTAL LIABILITIES	_	8,457,680	_	11,006,480
STOCKHOLDERS' EQUITY				
Common stock, \$0.01 par value, 75,000,000 shares authorized, 48,960,766 and 48,861,891 shares issued 45,540,264 and 45,441,389 shares outstanding at March 31, 2023, and December				
31, 2022, respectively		489,608		488,619
Additional paid-in capital		45,132,350		44,252,117
Treasury stock, 3,420,502 shares at March 31, 2023 and December 31, 2022, at cost		(3,843,562)		(3,843,562
Retained deficit		(11,982,096)	_	(9,571,211
		00 700 000		31,325,963
TOTAL STOCKHOLDERS' EQUITY		29,796,300	_	31,323,303

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

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

	Three Months Ended March 31,		
	 2023	_	2022
NET SALES	\$ 7,392,605	\$	6,244,330
Cost of goods sold	3,245,570		2,622,025
Gross Profit	4,147,035		3,622,305
OPERATING EXPENSES			
Selling, general and administrative	5,425,877		5,491,213
Research and development	1,564,869		1,148,355
Depreciation and amortization	213,117		109,252
Total Operating Expenses	7,203,863		6,748,820
Net Operating Loss	(3,056,828)		(3,126,515)
Non-Operating Income/(Expense)			
Loss on currency exchange	(680)		(7,135)
Loss on disposal of fixed assets, net	(56,279)		_
Interest income (expense), net	125,502		(1,463)
TOTAL OTHER INCOME/(EXPENSE)	68,543		(8,598)
LOSS BEFORE INCOME TAXES	(2,988,285)		(3,135,113)
Income Tax Benefit	 577,400		597,599
NET LOSS	\$ (2,410,885)	\$	(2,537,514)
NET LOSS PER SHARE			
D :	\$ (0.05)	\$	(0.06)
Basic			, ,
Diluted	 (0.05)	Ф	(0.06)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING			
Basic	 45,487,593		44,667,977
Diluted	 45,487,593		44,667,977

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

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

For the

Three Months Ended March 31, 2023 2022 CASH FLOWS FROM OPERATING ACTIVITIES Net Loss (2,410,885) \$ (2,537,514)Adjustments to reconcile net loss to net cash used in operating activities: Stock-based compensation expense 881,222 837,556 Depreciation and amortization 213,117 109,252 Deferred income taxes (577,400)(597,599)Loss on disposal of fixed assets 56,279 ROU landlord credit (5,497)Changes in operating assets and liabilities: (Increase)/Decrease in accounts receivable (647,994)447.489 Decrease in other receivables 38.145 (Increase)/Decrease in inventory (233,551)88,601 Decrease/(Increase) in prepaid expenses and other assets 288,786 (11,805)Increase in other Liabilities 4,207 25,625 (Decrease)/Increase in accounts payable (888,679)40,447 (Decrease)/Increase in accrued payroll and related taxes (41,984)345,712 Decrease in accrued expenses (1,298,204)(537,981)NET CASH USED IN OPERATING ACTIVITIES (4,660,583)(1,752,072)CASH FLOWS FROM INVESTING ACTIVITIES Purchases of property and equipment (272,605)(750,908)Purchases of intangible assets (11,232)(1,694)(283,837)(752,602)NET CASH USED IN INVESTING ACTIVITIES CASH FLOWS FROM FINANCING ACTIVITIES Payments on indebtedness (214,892)(252,968)Payments on finance lease liability (24,080)(238,972)(252,968)NET CASH USED IN FINANCING ACTIVITIES NET DECREASE IN CASH AND CASH EQUIVALENTS (5,183,392)(2,757,642)17,408,257 25,334,889 CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD 12,224,865 22,577,247 CASH AND CASH EQUIVALENTS, END OF PERIOD Supplemental Information Cash paid during the periods for:

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

Interest Income Taxes

Schedule of Non-Cash Operating, Investing and Financing Activities:

Issuance of common stock as compensation

\$

12,326

175,776

4,425

142.500

KORU MEDICAL SYSTEMS, INC. SUPPLEMENTAL INFORMATION (UNAUDITED)

Three Months Ended Reconciliation of GAAP Net Loss March 31, to Non-GAAP Adjusted EBITDA: 2023 2022 **GAAP Net Loss** (2,410,885)(2,537,514)Tax Benefit (577.400)(597.599)109,252 Depreciation/Amortization 213,117 (125,502)Interest Income, Net 1,463 Reorganization Charges 295.000 Manufacturing Initiative Expenses 49.053 38.005 881,222 837,556 Stock-based Compensation Expense (1,970,395)(1,853,837)Non-GAAP Adjusted EBITDA

		,	I free Months Ended March 31,				
2023		2022					
\$	(0.05)	\$	(0.06)				
	<u> </u>		0.01				
	_		_				
	_		_				
	_		_				
\$	(0.05)	\$	(0.05)				
	\$	\$ (0.05) — — — —	\$ (0.05) \$				

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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. We expect to incur related expenses for the next three months.

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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Source: KORU Medical Systems, Inc.

^{*}Numbers presented are rounded to the nearest whole cent