

November 8, 2023



KORU Medical Systems, Inc. Announces 2023 Third 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 third quarter ended September 30, 2023 and updates full year 2023 outlook.

Highlights:

- Third quarter net revenue of \$7.0 million, a 10% decline versus prior year
- Novel Therapies net revenue decline of \$0.6 million was impacted primarily by a large clinical trial order in the prior year and timing of collaborations
- Domestic Core net revenue of \$5.8 million, a 2% decline, reflected a prior year backorder clearance of \$0.3 million
- Improved gross margin to 62.0%, an increase of 630 BPS versus prior year, driven by increased manufacturing efficiencies
- Continued strategic, operational expense discipline, ending the quarter with \$10.8 million in cash and cash equivalents
- Revised full year 2023 net revenue guidance to \$28.0 to \$28.5 million, reaffirmed gross margin guidance between 58%-60% for full-year and a planned Q4 exit between 60%-62%, and increased year-end cash balance guidance to greater than \$10.5 million
- Announced a new Novel Therapies innovation collaboration and brought the total closed collaborations to 15
- Received a 510(k) clearance for FREEDOM60[®] Infusion System as the first and only FDA-cleared device for use with Hizentra[®] 50 mL prefilled syringes
- Named Ken Miller, a 30-year healthcare and pharmaceutical executive, as Chief Commercial Officer

"Our third quarter revenues were impacted by our Novel Therapies business due to the timing of collaborations and by our Domestic Core business, which saw lower than anticipated growth in the underlying market. We progressed several initiatives in the quarter aimed at growing our top-line, including expanding our Novel Therapies collaborations, outperforming the U.S. subcutaneous immunoglobulin market, advancing our geographic expansion efforts, and gaining a new 510(k) clearance for a prefilled syringe indication," said Linda Tharby, KORU Medical's President and CEO. "We simultaneously advanced our efforts towards profitability and delivered on our gross margin goals despite revenue headwinds by exercising strategic operational expense discipline in light of our current

environment. We are confident we have the right plan in place to capitalize on upcoming catalysts, grow our position in our subcutaneous immunoglobulin business, and expand into the larger addressable Novel Therapies market."

2023 Third Quarter Financial Results

	Three Months Ended September 30,		Change from Prior Year	
	2023	2022	\$	%
Net Revenues				
Domestic Core	\$ 5,773,863	\$ 5,900,042	\$ (126,179)	(2.1%)
International Core	1,066,567	1,096,746	(30,179)	(2.8%)
Novel Therapies	162,768	763,610	(600,842)	(78.7%)
Total	\$ 7,003,198	\$ 7,760,398	\$ (757,200)	(9.8%)

Total net revenues decreased \$0.8 million, or 9.8%, for the three months ended September 30, 2023, as compared with the same period last year. Novel Therapies net revenues declined by 78.7%, primarily driven by a large clinical trial order of \$0.5 million in the prior period and the timing of collaboration revenue. Domestic Core net revenues declined by 2.1% driven by lower consumable volumes as compared to the prior year period, which included a clearing of a \$0.3 million consumable backorder. Partially offsetting this decline, was an increase in pump units sold. International Core net revenues declined by 2.8%, driven largely by a tender order in the prior year period, partially offset by growth in several countries.

Gross profit was mostly flat compared to the prior year, with revenue declines offset by a decrease in manufacturing costs. Gross margin increased to 62.0% compared to 55.7% in the third quarter of 2022. The increase was primarily driven by production efficiencies from the outsourced manufacturing initiative and Chester site exit when compared to the prior year.

Operating expenses for the three months ended September 30, 2023, were \$6.1 million, up from \$5.9 million for the same period last year, driven primarily by an increase of \$0.4 million in research and development expense mostly offset by a reduction of \$0.2 million in selling, general and administrative expenses.

Net loss for the third quarter of 2023 was \$1.4 million, or \$(0.03) per diluted share, compared to a net loss of \$1.2 million, or \$(0.03) per diluted share for the same period of 2022. Net loss included a tax benefit of \$0.3 million for the third quarter of 2023.

Assumptions and Outlook for Full Year 2023

For the full year 2023, the Company's guidance has been revised to reflect the slower anticipated growth in the underlying U.S. subcutaneous immunoglobulin market and the timing of Novel Therapies collaboration wins and expected milestone completion. KORU Medical is updating its 2023 growth outlook on the underlying U.S. subcutaneous immunoglobulin drug market Q4 growth of 3-4% from a prior full year expectation of 5%.

KORU Medical Outlook:

- Reducing full year 2023 net revenue guidance to \$28.0 - \$28.5 million, from prior guidance of \$31.0 - \$32.5 million

- Reaffirming 2023 gross margin guidance between 58%-60% and a planned 2023 exit between 60%-62%
- Increasing cash balance guidance at year-end 2023 to greater than \$10.5 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, November 8, 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:10182999. 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 2023. 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 quarter 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 November 8, 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)

	<u>September 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 10,772,178	\$ 17,408,257
Accounts receivable less allowance for doubtful accounts of \$24,777 as of September 30, 2023 and \$21,459 as of December 31, 2022	4,050,756	3,558,884
Inventory	4,676,913	6,404,867
Other receivables	813,499	972,396
Prepaid expenses	1,373,348	1,457,232
TOTAL CURRENT ASSETS	<u>21,686,694</u>	<u>29,801,636</u>
Property and equipment, net	3,820,087	3,886,975
Intangible assets, net of accumulated amortization of \$373,943 and \$325,872 as of September 30, 2023 and December 31, 2022, respectively	758,423	787,182
Operating lease right-of-use assets	3,544,959	3,786,545
Deferred income tax assets, net	5,445,123	3,967,480
Other assets	98,969	102,625
TOTAL ASSETS	<u>\$ 35,354,255</u>	<u>\$ 42,332,443</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 945,619	\$ 2,391,799
Accrued expenses	1,458,529	2,889,941
Note payable	466,026	433,295
Other liabilities	500,620	257,337
Accrued payroll and related taxes	392,527	542,399
Financing lease liability – current	102,470	98,335
Operating lease liability – current	356,349	345,834
TOTAL CURRENT LIABILITIES	<u>4,222,140</u>	<u>6,958,940</u>
Financing lease liability, net of current portion	316,906	394,283
Operating lease liability, net of current portion	3,384,666	3,653,257
TOTAL LIABILITIES	<u>7,923,712</u>	<u>11,006,480</u>
Commitments and Contingencies (Note 7)		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 49,059,583 and 48,861,891 shares issued 45,639,081 and 45,441,389 shares outstanding as of September 30, 2023, and December 31, 2022, respectively	490,596	488,619
Additional paid-in capital	46,629,753	44,252,117
Treasury stock, 3,420,502 shares as of September 30, 2023 and December 31, 2022, at cost	(3,843,562)	(3,843,562)
Accumulated deficit	(15,846,244)	(9,571,211)
TOTAL STOCKHOLDERS' EQUITY	<u>27,430,543</u>	<u>31,325,963</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 35,354,255</u>	<u>\$ 42,332,443</u>

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
NET REVENUES	\$ 7,003,198	\$ 7,760,398	\$ 21,331,734	\$ 20,551,356
Cost of goods sold	2,661,021	3,438,036	8,954,398	9,260,516
Gross Profit	<u>4,342,177</u>	<u>4,322,362</u>	<u>12,377,336</u>	<u>11,290,840</u>
OPERATING EXPENSES				
Selling, general and administrative	4,623,928	4,825,349	15,352,972	15,846,584
Research and development	1,293,256	862,148	4,454,739	3,314,233
Depreciation and amortization	216,014	164,344	642,050	399,479
Total Operating Expenses	<u>6,133,198</u>	<u>5,851,841</u>	<u>20,449,761</u>	<u>19,560,296</u>
Net Operating Loss	(1,791,021)	(1,529,479)	(8,072,425)	(8,269,456)
Non-Operating Income/(Expense)				
Loss on currency exchange	(9,390)	(10,057)	(12,542)	(38,897)
Loss on disposal of fixed assets, net	(3,527)	—	(59,806)	—
Interest income, net	135,429	42,476	392,098	44,579
TOTAL OTHER INCOME/(EXPENSE)	<u>122,512</u>	<u>32,419</u>	<u>319,750</u>	<u>5,682</u>
LOSS BEFORE INCOME TAXES	(1,668,509)	(1,497,060)	(7,752,675)	(8,263,774)
Income Tax Benefit	300,247	271,500	1,477,642	1,579,359
NET LOSS	<u>\$ (1,368,262)</u>	<u>\$ (1,225,560)</u>	<u>\$ (6,275,033)</u>	<u>\$ (6,684,415)</u>
NET LOSS PER SHARE				
Basic	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.14)</u>	<u>\$ (0.15)</u>
Diluted	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.14)</u>	<u>\$ (0.15)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	45,639,081	45,038,181	45,578,314	44,877,366
Diluted	<u>45,639,081</u>	<u>45,038,181</u>	<u>45,578,314</u>	<u>44,877,366</u>

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

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

For the
Nine Months Ended
September 30,

	2023	2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (6,275,033)	\$ (6,684,415)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,379,613	2,361,085
Depreciation and amortization	642,050	399,479
Deferred income taxes	(1,477,643)	(1,579,569)
Loss on disposal of fixed assets	59,806	—
ROU landlord credit	(16,489)	218,044
Changes in operating assets and liabilities:		
Increase in Accounts receivable	(332,975)	(1,445,079)
Decrease / (Increase) in Inventory	1,727,954	(777,818)
Increase in Prepaid expenses and other assets	87,540	(160,794)
Increase in Other liabilities	243,282	267,491
(Decrease) / Increase in Accounts payable	(1,446,180)	138,077
(Decrease) / Increase in Accrued payroll and related taxes	(149,872)	663,444
Decrease in Accrued expenses	(1,431,412)	(140,958)
NET CASH USED IN OPERATING ACTIVITIES	(5,989,358)	(6,741,013)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(586,897)	(2,541,693)
Purchases of intangible assets	(19,312)	(36,003)
NET CASH USED IN INVESTING ACTIVITIES	(606,209)	(2,577,696)
CASH FLOWS FROM FINANCING ACTIVITIES		
Borrowings from indebtedness	565,172	644,733
Payments on indebtedness	(532,441)	(508,583)
Proceeds from issuance of equity		314,000
Payments on finance lease liability	(73,243)	(25,062)
NET CASH USED IN PROVIDED BY FINANCING ACTIVITIES	(40,512)	425,088
NET DECREASE IN CASH AND CASH EQUIVALENTS	(6,636,079)	(8,893,621)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	17,408,257	25,334,889
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 10,772,178	\$ 16,441,268
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 34,773	\$ 15,700
Income taxes	\$ 3,160	\$ —
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	\$ 348,849	\$ 355,505

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

KORU MEDICAL SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)

The following table summarizes our net sales for the three and nine months ended September 30, 2023 and 2022:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net Sales				
Domestic	\$ 5,773,863	\$ 5,900,042	\$ 16,881,170	\$ 15,890,369
International	1,066,567	1,096,746	3,281,061	2,943,173
Novel Therapies	162,768	763,610	1,169,503	1,717,814
Total	<u>\$ 7,003,198</u>	<u>\$ 7,760,398</u>	<u>\$ 21,331,734</u>	<u>\$ 20,551,356</u>

KORU MEDICAL SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)

A reconciliation of our non-GAAP measures is below:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Reconciliation of GAAP Net (Loss) to Non-GAAP Adjusted EBITDA:				
GAAP Net Loss	\$ (1,368,262)	(1,225,559)	\$ (6,275,033)	\$ (6,684,415)
Tax (Benefit)/Expense	(300,247)	(271,500)	(1,477,642)	(1,579,359)
Depreciation and Amortization	216,014	164,344	642,050	399,479
Interest (Income)/Expense, Net	(135,429)	(42,476)	(392,098)	(44,579)
Reorganization Charges	—	200,000	—	765,433
Manufacturing Initiative Expenses	—	20,537	55,361	108,886
Stock-based Compensation Expense	697,658	779,510	2,379,613	2,429,999
Non-GAAP Adjusted EBITDA	<u>\$ (890,266)</u>	<u>\$ (375,144)</u>	<u>\$ (5,067,749)</u>	<u>\$ (4,604,556)</u>

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:				
Reported Diluted Earnings Per Share	\$ (0.03)	\$ (0.03)	\$ (0.14)	\$ (0.15)
Reorganization Charges	—	—	—	0.02
Non-GAAP Adjusted Diluted Earnings Per Share	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>	<u>\$ (0.14)</u>	<u>\$ (0.13)</u>

**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.

View source version on businesswire.com:

<https://www.businesswire.com/news/home/20231108988140/en/>

Investor Contact:

Greg Chodaczek

347-620-7010

investor@korumedical.com

Source: KORU Medical Systems, Inc.