

August 3, 2022



KORU Medical Systems Announces 2022 Second Quarter Financial Results

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, 2022.

Highlights:

- Year-over-year net sales growth of 18.4% to \$6.5 million, marking the third consecutive quarter of double-digit growth
- Expanded novel therapies pipeline with two new biopharmaceutical agreements
- Raising the revenue guidance to \$27.0 to 27.5 million
- Completed first phase of move to new corporate headquarters in Mahwah, New Jersey

"We delivered another strong quarter of revenue growth with contribution across all three of our businesses," said Linda Tharby, KORU Medical's President and CEO. "We continue to gain momentum on our strategic objectives with an expansion of our novel therapies pipeline and growth in our domestic and international core businesses. Despite facing some Q2 supply chain challenges, we continue to make meaningful progress towards building a stronger foundation. We are excited about our progress in driving long-term growth and value for patients, customers and shareholders as a leading provider of large volume drug delivery solutions."

2022 Second Quarter Financial Results

	Three Months Ended June 30,		Change from Prior Year	
	2022	2021	\$	%
Net Sales				
Domestic Core	\$4,996,791	\$4,597,797	\$ 398,994	8.7%
International Core	951,485	859,694	91,791	10.7%
Novel Therapies	598,352	70,683	527,669	746.6%
Total	<u>\$6,546,628</u>	<u>\$5,528,174</u>	<u>\$ 1,018,454</u>	<u>18.4%</u>

Total net sales increased \$1.0 million, or 18.4%, for the three months ended June 30, 2022, as compared with the same period last year. This increase was driven primarily by higher novel therapies sales related to a NRE development milestone for a large pharmaceutical customer, clinical product sales for an expanded pipeline, and increases in average selling prices for our products. Our domestic core business grew by 8.7%, and was impacted by

supply chain issues and labor shortages which created backorders estimated to be \$0.3 million that are not included in the reported net sales number. The increase in domestic core demand inclusive of backorders was attributed to volume growth driven by SCIG market growth and label expansions. We define backorders as any non-cancellable open order not shipped before promised delivery date net of rebates, discounts, and other fees. Backorders are expected to be cleared in the third quarter of 2022. International net sales were \$1.0 million for the three months ended June 30, 2022, up 10.7% compared with the same period last year due to volume growth in several European markets driven by key tender wins.

Gross profit increased \$0.14 million or 4.2% in the three months ended June 30, 2022, compared to the same period in 2021, while gross profit as a percentage of net sales decreased by 700 basis points to 51.1%. The decline in the gross profit percent was primarily caused by the accelerated amortization of manufacturing variances in the quarter, due to lower levels of finished goods inventory. This accounting treatment contributed 380 basis points to the reduction and we believe it is a non-recurring event. In addition, the gross profit percent was impacted by manufacturing variances due to supply chain issues in the first quarter of 2022, amortized in the current period. Further contributing to the lower gross profit percent were higher NRE revenues, which are lower gross margin, and a nominal impact from an increase in average selling prices, partially offsetting the aforementioned unfavorable impacts.

Total operating expenses for the second quarter of 2022 were \$7.0 million, compared to \$4.6 million for the same period in 2021. The increase in operating expenses is due to strategic investments in research and development, and new hires to support business development, commercialization, quality and regulatory capabilities.

Net loss for the second quarter of 2022 was \$2.9 million, or \$(0.07) per diluted share, compared to a net loss of \$1.1 million, or \$(0.03) per diluted share for the same period of 2021. Net loss included a tax benefit of \$0.7 million for the second quarter of 2022. On a non-GAAP basis, adjusted diluted earnings per share was \$(0.06) compared to \$(0.02) in the same period of 2021.

Cash and cash equivalents were \$18.3 million as of June 30, 2022.

Assumptions and Outlook for Full Year 2022

KORU Medical's outlook for full year 2022 reflects numerous assumptions that could affect its business, based on the information management has as of this date, which includes assumptions regarding the continued recovery from the COVID-19 pandemic related to new SCIG patient starts, SCIG market growth rate in the high single digits, plasma supply, clinical trial activity and expansion of the novel therapies pipeline, inflationary impact (including labor and supply price increases), supply chain and labor shortage impacts, timely receipt of equipment financing and credits and planned inventory reductions by year end 2022. Management will discuss its outlook and several of its assumptions on its second quarter 2022 earnings call.

KORU Medical now expects full year 2022 revenue to be in the range of \$27.0 to \$27.5 million (previously \$26.5 to \$27.0 million).

The Company expects to exit the year with a 55-60% gross margin updated from prior

guidance of 60%. Supply chain disruptions and labor shortages resulted in unfavorable manufacturing variances in the second quarter of 2022, but are expected to improve in the second half of the year. Transfer of finished goods manufacturing to our third party contract manufacturing source is now expected in Q1 2023 (previously Q4 2022).

The Company is updating its guidance to include a minimum cash balance of \$16.0 million for year end 2022.

The Company has no further updates to prior guidance.

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 3, 2022, at 4:30 PM ET.

To participate in the call, please dial (877)-407-0784 (domestic) or (201)-689-8560 (international) and provide conference ID 13730791. 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 specialty infusion solutions 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, growth of novel

therapies pipeline, amortization of manufacturing variances, and market growth. 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, COVID-19, innovation and competition, labor and supply price increases, inflationary impacts, labor supply, and 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, 2021 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, 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 3, 2022. 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>June 30,</u> <u>2022</u>	<u>December</u> <u>31,</u> <u>2021</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 18,265,552	\$ 25,334,889
Accounts receivable less allowance for doubtful accounts of \$24,471 for June 30, 2022, and December 31, 2021	4,084,762	3,592,886
Inventory	6,771,514	6,106,338
Other Receivables	680,796	718,220
Prepaid expenses	1,165,668	1,568,821
TOTAL CURRENT ASSETS	30,968,292	37,321,154
Property and equipment, net	2,823,090	1,106,445
Intangible assets, net of accumulated amortization of \$294,301 and \$263,729 at June 30, 2022 and December 31, 2021, respectively	791,781	808,813
Operating lease right-of-use assets	4,190,931	95,553
Finance lease right-of-use, net of accumulated depreciation of \$5,918	349,153	—
Deferred income tax assets, net	3,249,323	1,941,254
Other assets	88,772	19,812
TOTAL ASSETS	\$42,461,342	\$ 41,293,031
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 2,389,862	\$ 1,227,533
Accrued expenses	1,974,196	2,709,704
Notes Payable	—	508,583
Other Liabilities	240,501	90,000
Accrued payroll and related taxes	696,042	160,603
Finance lease liability - current	66,503	—
Operating lease liability – current	363,030	95,553
TOTAL CURRENT LIABILITIES	5,730,134	4,791,976
Finance lease liability, net of current portion	281,958	—
Operating lease liability, net of current portion	3,827,900	—
TOTAL LIABILITIES	9,839,992	4,791,976
Commitments and contingencies (Refer to Note 3)		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 48,407,619 and 48,044,162 shares issued 44,987,117 and 44,623,660 shares outstanding at June 30, 2022, and December 31, 2021, respectively	484,076	480,441
Additional paid-in capital	42,349,760	40,774,245
Treasury stock, 3,420,502 shares at June 30, 2022 and December 31, 2021, respectively, at cost	(3,843,562)	(3,843,562)
Retained deficit	(6,368,924)	(910,069)
TOTAL STOCKHOLDERS' EQUITY	32,621,350	36,501,055
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$42,461,342	\$ 41,293,031

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
NET SALES	\$ 6,546,628	\$ 5,528,174	\$ 12,790,958	\$ 10,959,125
Cost of goods sold	3,200,455	2,317,990	5,822,480	4,517,087
Gross Profit	3,346,173	3,210,184	6,968,478	6,442,038
OPERATING EXPENSES				
Selling, general and administrative	5,530,022	4,085,945	11,021,235	9,078,774
Research and development	1,303,731	386,878	2,452,086	723,719
Depreciation and amortization	125,882	118,415	235,134	233,888
Total Operating Expenses	6,959,635	4,591,238	13,708,455	10,036,381
Net Operating Loss	(3,613,462)	(1,381,054)	(6,739,977)	(3,594,343)
Non-Operating Income/(Expense)				
(Loss)/Gain on currency exchange	(21,705)	1,239	(28,840)	(14,478)
Gain on disposal of fixed assets, net	—	—	—	736
Interest income, net	3,566	9,950	2,103	19,721
TOTAL OTHER INCOME/(EXPENSE)	(18,139)	11,189	(26,737)	5,979
LOSS BEFORE INCOME TAXES	(3,631,601)	(1,369,865)	(6,766,714)	(3,588,364)
Income Tax Benefit	710,260	245,316	1,307,859	1,187,677
NET LOSS	<u>\$ (2,921,341)</u>	<u>\$ (1,124,549)</u>	<u>\$ (5,458,855)</u>	<u>\$ (2,400,687)</u>
NET LOSS PER SHARE				
Basic	\$ (0.07)	\$ (0.03)	\$ (0.12)	\$ (0.05)
Diluted	\$ (0.07)	\$ (0.03)	\$ (0.12)	\$ (0.05)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	44,921,870	44,489,853	44,795,625	44,226,936
Diluted	44,921,870	44,489,853	44,795,625	44,226,936

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

For the
Six Months Ended
June 30,

	<u>2022</u>	<u>2021</u>
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (5,458,855)	\$ (2,400,687)
Adjustments to reconcile net loss to net cash (used in) operating activities:		
Stock-based compensation expense	1,579,151	1,339,356
Depreciation and amortization	235,134	233,888
Deferred income taxes	(1,308,069)	(1,201,956)
(Gain) on disposal of fixed assets	—	(736)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(454,452)	(4,446)
Increase in inventory	(665,176)	(732,978)
Decrease in prepaid expenses and other assets	334,193	346,227
Increase in other liabilities	150,501	—
Increase in accounts payable	1,162,329	380,733
Increase in accrued payroll and related taxes	535,438	103,196
Decrease in accrued expenses	(735,508)	(838,747)
NET CASH (USED IN) OPERATING ACTIVITIES	<u>(4,625,314)</u>	<u>(2,776,150)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(1,915,289)	(152,223)
Proceeds from disposal of property and equipment	—	9,065
Purchases of intangible assets	(13,540)	(23,978)
NET CASH (USED IN) INVESTING ACTIVITIES	<u>(1,928,829)</u>	<u>(167,136)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Payment on indebtedness	(508,583)	—
Proceeds from issuance of equity	—	1,230,000
Common stock issuance as settlement for litigation	—	938,094
Payments on finance lease liability	(6,611)	(1,616)
NET CASH (USED IN)/ PROVIDED BY FINANCING ACTIVITIES	<u>(515,194)</u>	<u>2,166,478</u>
NET (DECREASE) IN CASH AND CASH EQUIVALENTS	<u>(7,069,337)</u>	<u>(776,808)</u>
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>25,334,889</u>	<u>27,315,286</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$18,265,552</u>	<u>\$26,538,478</u>
Supplemental Information		
Cash paid during the periods for:		
Interest	<u>\$ 6,204</u>	<u>\$ 47</u>
Income Taxes	<u>\$ —</u>	<u>\$ 850</u>
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	<u>\$ 258,005</u>	<u>\$ 153,446</u>
Issuance of common stock as settlement for litigation	<u>\$ —</u>	<u>\$ 938,094</u>

KORU MEDICAL SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)

The following table summarizes our net sales for the three and six months ended June 30, 2022 and 2021:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net Sales				
Domestic	\$ 4,996,791	\$ 4,597,797	\$ 9,990,327	\$ 9,010,214
International	951,485	859,694	1,846,427	1,838,600
Novel Therapies	598,352	70,683	954,204	110,311
Total	\$ 6,546,628	\$ 5,528,174	\$ 12,790,958	\$ 10,959,125

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
GAAP Net Loss	\$(2,921,341)	(1,124,549)	\$(5,458,855)	\$(2,400,687)
Tax (Benefit)/Expense	(710,260)	(245,316)	(1,307,859)	(1,187,677)
Depreciation and Amortization	125,882	118,415	235,134	233,888
Interest (Income)/Expense, Net	(3,566)	(9,950)	(2,103)	(19,721)
Reorganization Charges	270,433	224,605	565,433	1,193,880
Discontinued Product Expense	—	—	—	—
Litigation Expenses	—	—	—	—
Manufacturing Initiative Expenses	50,344	149,718	88,349	201,441
Stock-based Compensation Expense	821,513	605,172	1,659,070	1,339,356
Non-GAAP Adjusted EBITDA	\$(2,366,995)	\$(281,905)	\$(4,220,831)	\$(639,520)

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Reported Diluted Earnings Per Share	\$ (0.07)	\$ (0.03)	\$ (0.12)	\$ (0.05)
Reorganization Charges	0.01	0.01	0.01	0.03
Discontinued Product Expense	—	—	—	—
Litigation Expenses	—	—	—	—
Manufacturing Initiative Expenses	—	—	—	—
Stock-based Compensation Expense	—	—	—	0.01
Tax (Expense) Adjustment	—	—	—	(0.01)
Non-GAAP Adjusted Diluted Earnings Per Share	\$(0.06)	\$(0.02)	\$(0.11)	\$(0.02)

Reorganization Charges. We have excluded the effect of reorganization charges in calculating our non-GAAP measures. In 2021 we incurred significant expenses in connection with the departure and replacement of our chief executive officer and the recruiting of two new board members, which we would not have otherwise incurred in periods presented as part of our continuing operations. In 2022 we incurred further severance expense related to the reorganization of the leadership team and the departure of our chief financial officer, 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 six to nine 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 expense related to grants of options for executives, employees and consultants, and grants of restricted 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.