

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) November 9, 2022

KORU Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

New York
(State or other jurisdiction
of incorporation)

0-12305
(Commission
File Number)

13-3044880
(IRS Employer
Identification No.)

100 Corporate Drive, Mahwah, NJ
(Address of principal executive offices)

07430
(Zip Code)

Registrant's telephone number, including area code (845) 469-2042

not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
common stock, \$0.01 par value	KRMD	The Nasdaq Stock Market

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

On November 9, 2022, KORU Medical Systems, Inc. ("KORU Medical" or "we") issued a press release announcing its financial results for the third quarter ended September 30, 2022 and an update to its financial outlook for the fiscal year ended December 31, 2022. A related conference call will be held on November 9, 2022 at 4:30 pm Eastern Time.

KORU Medical is making reference to non-GAAP financial measures in both the press release and the conference call. Our management believes that investors' understanding of KORU Medical's performance is enhanced by disclosing the non-GAAP financial measures of Adjusted EBITDA and Adjusted EPS (each as defined below) as a reasonable basis for comparison of our ongoing results of operations. KORU Medical strongly encourages investors to review its consolidated financial statements and publicly filed reports in their entirety and cautions investors that the non-GAAP measures used by KORU Medical may differ from similar measures used by other companies, even when similar terms are used to identify such measures. Non-GAAP measures should not be considered replacements for, and should be read together with, the most comparable GAAP financial measures. A reconciliation of GAAP to non-GAAP results is provided in the attached Exhibit 99.1 press release.

We define Adjusted EBITDA as earnings (net (loss)/income) before interest expense/(income), net, income tax (benefit)/expense, depreciation and amortization, reorganization charges, discontinued product expense, litigation expenses, manufacturing initiative expenses and stock-based compensation expense. We believe that Adjusted EBITDA is used by investors and other users of our financial statements as a supplemental financial measure that, when viewed with our GAAP results and the accompanying reconciliation, we believe provides additional information that is useful to gain an understanding of the factors and trends affecting our business. We also believe the disclosure of Adjusted EBITDA helps investors meaningfully evaluate and compare our cash flow generating capacity from quarter to quarter and year to year. Adjusted EBITDA is used by management as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

We present diluted earnings per share after eliminating items that we believe are not part of our ordinary operations and affect the comparability of the periods presented (“Adjusted EPS”). Adjusted EPS includes adjustments for reorganization charges, discontinued product expense, litigation expenses, manufacturing initiative expenses, stock-based compensation expense, and tax (expense). We believe adjustments for these items allow investors to better understand our underlying operating results and facilitate comparisons between the periods shown. Management uses Adjusted EPS as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

The information in Item 2.02 of this Current Report on Form 8-K, including Exhibit 99.1, is furnished and shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release dated November 9, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KORU Medical Systems, Inc.

(Registrant)

Date: November 9, 2022

By: /s/ Thomas Adams
Thomas Adams

Interim Chief Financial Officer

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KORU MEDICAL SYSTEMS ANNOUNCES 2022 THIRD QUARTER FINANCIAL RESULTS

MAHWAH, NJ – November 9, 2022 –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 subcutaneous drug delivery systems that improve quality of life for patients, today reported financial results for the third quarter ended September 30, 2022.

Highlights:

- Year-over-year net sales growth of 28.5% to \$7.8 million (inclusive of \$0.3 million backorder clearance), marking the fourth consecutive quarter of double-digit growth
- Expanded Novel Therapies business with four new Phase II clinical drug trials, and one drug progressed to Phase III bringing the total number of collaborations to fourteen
- Improved sequential gross margin profile to 55.7% in Q3 2022 from 51.1% in Q2 2022
- Raising 2022 full year revenue guidance to \$27.5 to \$28.0 million

"The third quarter marks another successful quarter for the Company with strong revenue growth across each of our businesses," said Linda Tharby, KORU Medical's President and CEO. "Delivering on our strategic objectives remains a primary focus, and the progress made this quarter is representative of continued solid execution by the team. We are excited by the momentum in our novel therapies business with multiple new collaborations this quarter and by the double digit growth performance in both our domestic and international core business."

2022 Third Quarter Financial Results

	Three Months		Change from Prior Year	
	Ended September 30,		\$	%
	2022	2021		
Net Sales				
Domestic Core	\$ 5,900,042	\$ 5,076,294	\$ 823,748	16.2%
International Core	1,096,746	747,281	349,465	46.8%
Novel Therapies	763,610	216,969	546,641	251.9%
Total	<u>\$ 7,760,398</u>	<u>\$ 6,040,544</u>	<u>\$ 1,719,854</u>	<u>28.5%</u>

Total net sales increased \$1.7 million, or 28.5%, for the three months ended September 30, 2022, as compared with the same period last year as we saw double digit growth across all businesses. Domestic core growth was primarily driven by increased volume attributed to SCIg market growth and label expansions including prefill syringes. Domestic core included the clearing of \$0.3 million in backorders from the second quarter of 2022. Novel therapies sales grew by 251.9% in the third quarter of 2022 related to services performed for a non-recurring engineering (NRE) innovation development agreement for a pharmaceutical customer and increases in clinical trial product sales to several pharmaceutical customers. Sales growth in our international core business was driven by volume growth in several EU markets compared with prior year.

Gross profit increased \$0.8 million or 23.7% in the three months ended September 30, 2022, compared to the same period in 2021. This increase in gross profit was driven by volume increase in net sales of \$1.7 million as described above. Gross profit as a percentage of net sales decreased to 55.7% compared to 57.9% from the third quarter of 2021. The decline in the gross profit percent was primarily due to higher manufacturing costs associated with labor and materials. The growth of the novel therapies business, and associated NRE service revenue also contributed to the lower gross margin. Unfavorable product mix was offset by a nominal increase in average selling prices.

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Total operating expenses for the third quarter of 2022 were \$5.9 million, compared to \$4.8 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 third quarter of 2022 was \$1.2 million, or \$(0.03) per diluted share, compared to a net loss of \$1.1 million, or \$(0.02) per diluted share for the same period of 2021. Net loss included a tax benefit of \$0.3 million for the third quarter of 2022.

Cash and cash equivalents were \$16.4 million as of September 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 other receivable credits and planned inventory reductions by year end 2022. Management will discuss its outlook and several of its assumptions on its third quarter 2022 earnings call.

KORU Medical now expects full year 2022 revenue to be in the range of \$27.5 to \$28.0 million (previously \$27.0 to \$27.5 million).

The Company is confirming to exit the year with a 55.0% to 60.0% gross margin.

The Company is lowering its operating expenses guidance to \$26.5 to \$27.0 million (previously \$27.0 to \$28.0 million).

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

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 9, 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: 13732861. 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.

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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, 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 November 9. 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.

Investor Contact:
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KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

	September 30,	December 31,
	2022	2021

ASSETS

CURRENT ASSETS

Cash and cash equivalents	\$ 16,441,268	\$ 25,334,889
Accounts receivable less allowance for doubtful accounts of \$24,471 for September 30, 2022, and December 31, 2021	5,070,077	3,592,886
Inventory	6,884,156	6,106,338
Other Receivables	686,108	718,220
Prepaid expenses	1,660,655	1,568,821
TOTAL CURRENT ASSETS	30,742,264	37,321,154
Property and equipment, net	3,318,612	1,106,445
Intangible assets, net of accumulated amortization of \$310,011 and \$263,729 at September 30, 2022 and December 31, 2021, respectively	798,534	808,813
Operating lease right-of-use assets	3,865,370	95,553
Finance lease right-of-use, net of accumulated depreciation of \$23,671 at September 30, 2022	331,400	—
Deferred income tax assets, net	3,520,823	1,941,254
Other assets	88,772	19,812
TOTAL ASSETS	\$ 42,665,775	\$ 41,293,031

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES

Accounts payable	\$ 1,365,610	\$ 1,227,533
Accrued expenses	2,568,746	2,709,704
Notes Payable	644,733	508,583
Other Liabilities	357,491	90,000
Accrued payroll and related taxes	824,047	160,603
Finance lease liability - current	64,467	—
Operating lease liability – current	342,399	95,553
TOTAL CURRENT LIABILITIES	6,167,493	4,791,976
Finance lease liability, net of current portion	265,542	—
Operating lease liability, net of current portion	3,741,015	—
TOTAL LIABILITIES	10,174,050	4,791,976

Commitments and contingencies (Refer to Note 3)

STOCKHOLDERS' EQUITY

Common stock, \$0.01 par value, 75,000,000 shares authorized, 48,657,023 and 48,044,162 shares issued 45,236,521 and 44,623,660 shares outstanding at September 30, 2022, and December 31, 2021, respectively	486,570	480,441
Additional paid-in capital	43,443,201	40,774,245
Treasury stock, 3,420,502 shares at September 30, 2022 and December 31, 2021, respectively, at cost	(3,843,562)	(3,843,562)
Retained deficit	(7,594,484)	(910,069)
TOTAL STOCKHOLDERS' EQUITY	32,491,725	36,501,055
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 42,665,775	\$ 41,293,031

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
NET SALES	\$ 7,760,398	\$ 6,040,544	\$ 20,551,356	\$ 16,999,669
Cost of goods sold	3,438,036	2,544,794	9,260,516	7,061,881
Gross Profit	4,322,362	3,495,750	11,290,840	9,937,788
OPERATING EXPENSES				
Selling, general and administrative	4,825,349	3,901,830	15,846,584	12,980,604
Research and development	862,148	800,020	3,314,233	1,523,739
Depreciation and amortization	164,344	115,934	399,479	349,822
Total Operating Expenses	5,851,841	4,817,784	19,560,296	14,854,165
Net Operating Loss	(1,529,479)	(1,322,034)	(8,269,456)	(4,916,377)
Non-Operating Income/(Expense)				
Loss on currency exchange	(10,057)	(7,283)	(38,897)	(21,761)
Gain on disposal of fixed assets, net	—	273	—	1,009
Interest income (expense), net	42,476	(2,838)	44,579	16,883
TOTAL OTHER INCOME/(EXPENSE)	32,419	(9,848)	5,682	(3,869)
LOSS BEFORE INCOME TAXES	(1,497,060)	(1,331,882)	(8,263,774)	(4,920,246)
Income Tax Benefit	271,500	238,104	1,579,359	1,425,781

NET LOSS	\$ (1,225,560)	\$ (1,093,778)	\$ (6,684,415)	\$ (3,494,465)
NET LOSS PER SHARE				
Basic	\$ (0.03)	\$ (0.02)	\$ (0.15)	\$ (0.08)
Diluted	\$ (0.03)	\$ (0.02)	\$ (0.15)	\$ (0.08)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	45,038,181	44,322,335	44,877,366	44,510,021
Diluted	45,038,181	44,322,335	44,877,366	44,510,021

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

	For the Nine Months Ended September 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (6,684,415)	\$ (3,494,465)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,361,085	1,967,632
Depreciation and amortization	399,479	349,822
Deferred income taxes	(1,579,569)	(1,440,060)
Loss on disposal of fixed assets	—	(1,009)
ROU landlord credit	218,044	—
Changes in operating assets and liabilities:		
Increase in accounts receivable	(1,445,079)	(549,711)
Increase in inventory	(777,818)	(138,160)
Increase in prepaid expenses and other assets	(160,794)	(529,039)
Increase in other liabilities	267,491	—
Increase in accounts payable	138,077	760,493
Increase in accrued payroll and related taxes	663,444	45,684
Decrease in accrued expenses	(140,958)	(573,565)
NET CASH USED IN OPERATING ACTIVITIES	(6,741,013)	(3,602,378)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(2,541,693)	(301,720)
Proceeds from disposal of property and equipment	—	9,065
Purchases of intangible assets	(36,003)	(25,838)
NET CASH USED IN INVESTING ACTIVITIES	(2,577,696)	(318,493)
CASH FLOWS FROM FINANCING ACTIVITIES		
Borrowings from indebtedness	644,733	924,389
Payment on indebtedness	(508,583)	(251,255)
Proceeds from issuance of equity	314,000	1,230,000
Common stock issuance as settlement for litigation	—	938,094
Payments on finance lease liability	(25,062)	(2,232)
NET CASH PROVIDED BY FINANCING ACTIVITIES	425,088	2,838,996
NET DECREASE IN CASH AND CASH EQUIVALENTS	(8,893,621)	(1,081,875)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	25,334,889	27,315,286
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 16,441,268	\$ 26,233,411
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 15,700	\$ 6,194
Income Taxes	\$ —	\$ 850
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	\$ 355,505	\$ 295,947
Issuance of common stock as settlement for litigation	\$ —	\$ 938,094

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KORU MEDICAL SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)

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

	Three Months		Nine Months	
	Ended September 30,		Ended September 30,	
	2022	2021	2022	2021
Net Sales				
Domestic	\$ 5,900,042	\$ 5,076,294	\$ 15,890,369	\$ 14,084,552
International	1,096,746	747,281	2,943,173	2,585,881
Novel Therapies	763,610	216,969	1,717,814	329,236
Total	\$ 7,760,398	\$ 6,040,544	\$ 20,551,356	\$ 16,999,669

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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		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
GAAP Net Loss	\$ (1,225,559)	\$ (1,093,778)	\$ (6,684,415)	\$ (3,494,465)
Tax (Benefit)/Expense	(271,500)	(238,104)	(1,579,359)	(1,425,781)
Depreciation and Amortization	164,344	115,934	399,479	349,822
Interest (Income)/Expense, Net	(42,476)	2,838	(44,579)	(16,883)
Reorganization Charges	200,000	(1,262)	765,433	1,192,618
Manufacturing Initiative Expenses	20,537	35,892	108,886	237,333
Stock-based Compensation Expense	779,510	628,276	2,429,999	1,967,632
Non-GAAP Adjusted EBITDA	\$ (375,144)	\$ (556,204)	\$ (4,604,556)	\$ (1,189,724)

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Reported Diluted Earnings Per Share	\$ (0.03)	\$ (0.02)	\$ (0.15)	\$ (0.08)
Reorganization Charges	—	—	0.02	0.03
Manufacturing Initiative Expenses	—	—	—	0.01
Stock-based Compensation Expense	—	—	—	0.01
Tax (Expense) Adjustment	—	—	—	(0.01)
Non-GAAP Adjusted Diluted Earnings Per Share	\$ (0.03)	\$ (0.02)	\$ (0.13)	\$ (0.04)

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 three to six 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 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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