

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) August 9, 2023

**KORU Medical Systems, Inc.**

(Exact name of registrant as specified in its charter)

<b><u>Delaware</u></b> (State or other jurisdiction of incorporation)	<b><u>0-12305</u></b> (Commission File Number)	<b><u>13-3044880</u></b> (IRS Employer Identification No.)
<b><u>100 Corporate Drive, Mahwah, NJ</u></b> (Address of principal executive offices)	<b><u>07430</u></b> (Zip Code)	

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

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(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>
<b>common stock, \$0.01 par value</b>	<b>KRMD</b>	<b>The Nasdaq Stock Market</b>

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.

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**ITEM 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION.**

On August 9, 2023, KORU Medical Systems, Inc. ("KORU Medical" or "we") issued a press release announcing its financial results for the second quarter ended June 30, 2023 and updates to full year financial outlook for the fiscal year ended December 31, 2023. A related conference call will be held on August 9, 2023 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	<a href="#">Press release dated August 9, 2023</a>
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: August 9, 2023

By: /s/ Thomas Adams  
Thomas Adams

Chief Financial Officer

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**EXHIBIT 99.1**



**KORU MEDICAL SYSTEMS, INC. ANNOUNCES 2023 SECOND QUARTER FINANCIAL RESULTS AND UPDATES FULL YEAR 2023 OUTLOOK**

MAHWAH, NJ – August 9, 2023 – 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	\$	%
<b>Net Revenues</b>				
Domestic Core	\$ 5,388,172	\$ 4,996,791	\$ 391,381	7.8%
International Core	1,117,004	951,485	165,519	17.4%
Novel Therapies	430,754	598,352	(167,598)	(28.0)%
<b>Total</b>	<b>\$ 6,935,930</b>	<b>\$ 6,546,628</b>	<b>\$ 389,302</b>	<b>5.9%</b>

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 and \$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 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](http://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 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 March 31, 2023, which are on file with the SEC and available on our website at [www.korumedical.com/investors](http://www.korumedical.com/investors) and on the SEC website at [www.sec.gov](http://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.

**Investor Contact:**  
**Greg Chodaczek**  
347-620-7010  
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## KORU MEDICAL SYSTEMS, INC. BALANCE SHEETS (UNAUDITED)

	<u>June 30,</u> <u>2023</u>	<u>December 31,</u> <u>2022</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
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
<b>TOTAL CURRENT ASSETS</b>	<b>22,541,392</b>	<b>29,801,636</b>
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
<b>TOTAL ASSETS</b>	<b>\$ 35,995,972</b>	<b>\$ 42,332,443</b>

## LIABILITIES AND STOCKHOLDERS' EQUITY

### CURRENT LIABILITIES

Accounts payable	\$ 1,574,630	\$ 2,391,799
Accrued expenses	1,362,293	2,889,941
Note payable	—	433,295
Other liabilities	263,253	257,337
Accrued payroll and related taxes	422,623	542,399
Financing lease liability – current	101,072	98,335
Operating lease liability – current	352,809	345,834
<b>TOTAL CURRENT LIABILITIES</b>	<b>4,076,680</b>	<b>6,958,940</b>
Financing lease liability, net of current portion	343,053	394,283
Operating lease liability, net of current portion	3,475,092	3,653,257
<b>TOTAL LIABILITIES</b>	<b>7,894,825</b>	<b>11,006,480</b>

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	44,252,117
Treasury stock, 3,420,502 shares as of June 30, 2023 and December 31, 2022, at cost	(3,843,562)	(3,843,562)
Accumulated deficit	(14,477,982)	(9,571,211)
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>28,101,147</b>	<b>31,325,963</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 35,995,972</b>	<b>\$ 42,332,443</b>

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

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

	Three Months Ended June 30,		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

Basic	\$ (0.05)	\$ (0.07)	\$ (0.11)	\$ (0.12)
Diluted	\$ (0.05)	\$ (0.07)	\$ (0.11)	\$ (0.12)

## WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING

Basic	45,606,603	44,921,870	45,547,427	44,795,625
Diluted	45,606,603	44,921,870	45,547,427	44,795,625

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

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

	<b>For the Six Months Ended June 30,</b>	
	<b>2023</b>	<b>2022</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net Loss	\$ (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)
Decrease / (Increase) in Inventory	1,126,643	(665,176)
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	(119,776)	535,438
Decrease in Accrued expenses	(1,527,648)	(735,508)
<b>NET CASH USED IN OPERATING ACTIVITIES</b>	<b>(4,814,520)</b>	<b>(4,625,314)</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(375,246)	(1,915,289)
Purchases of intangible assets	(17,298)	(13,540)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(392,544)</b>	<b>(1,928,829)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Payments on indebtedness	(433,295)	(508,583)
Payments on finance lease liability	(48,493)	(6,611)
<b>NET CASH USED IN FINANCING ACTIVITIES</b>	<b>(481,788)</b>	<b>(515,194)</b>
<b>NET DECREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(5,688,852)</b>	<b>(7,069,337)</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>17,408,257</b>	<b>25,334,889</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 11,719,405</b>	<b>\$ 18,265,552</b>
<b>Supplemental Information</b>		
<b>Cash paid during the periods for:</b>		
Interest	\$ 20,165	\$ 6,204
Income taxes	\$ 3,160	\$ —
<b>Schedule of Non-Cash Operating, Investing and Financing Activities:</b>		
Issuance of common stock as compensation	\$ 266,023	\$ 258,005

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

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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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
	GAAP Net Loss	\$ (2,495,886)	\$ (2,921,341)	\$ (4,906,771)
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	<u>\$ (2,207,088)</u>	<u>\$ (2,366,995)</u>	<u>\$ (4,177,482)</u>	<u>\$ (4,220,831)</u>

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