

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) May 4, 2023

KORU Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

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

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

(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 May 4, 2023, KORU Medical Systems, Inc. ("KORU Medical" or "we") issued a press release announcing its financial results for the first quarter ended March 31, 2023 and reaffirming financial guidance for the fiscal year ended December 31, 2023. A related conference call will be held on May 4, 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	Press release dated May 4, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

- 2 -

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: May 4, 2023

By: /s/ Thomas Adams
Thomas Adams

Interim Chief Financial Officer

- 3 -

EXHIBIT 99.1



KORU MEDICAL SYSTEMS, INC. ANNOUNCES 2023 FIRST QUARTER FINANCIAL RESULTS
STRONG START TO 2023 WITH 18% REVENUE GROWTH

MAHWAH, NJ – May 4, 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 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

	Three Months 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%

- 1 -

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.

- 2 -

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 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 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.

Investor Contact:
Greg Chodaczek

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

	March 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
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 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		
Accounts payable	\$ 1,503,120	\$ 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)
TOTAL STOCKHOLDERS' EQUITY	29,796,300	31,325,963
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 38,253,980	\$ 42,332,443

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	<u>7,203,863</u>	<u>6,748,820</u>
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)	<u>68,543</u>	<u>(8,598)</u>
LOSS BEFORE INCOME TAXES	(2,988,285)	(3,135,113)
Income Tax Benefit	<u>577,400</u>	<u>597,599</u>
NET LOSS	<u>\$ (2,410,885)</u>	<u>\$ (2,537,514)</u>
NET LOSS PER SHARE		
Basic	<u>\$ (0.05)</u>	<u>\$ (0.06)</u>
Diluted	<u>\$ (0.05)</u>	<u>\$ (0.06)</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING		
Basic	<u>45,487,593</u>	<u>44,667,977</u>
Diluted	<u>45,487,593</u>	<u>44,667,977</u>

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

- 5 -

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

	For the Three Months Ended March 31,	
	<u>2023</u>	<u>2022</u>
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	<u>(4,660,583)</u>	<u>(1,752,072)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(272,605)	(750,908)
Purchases of intangible assets	(11,232)	(1,694)
NET CASH USED IN INVESTING ACTIVITIES	<u>(283,837)</u>	<u>(752,602)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on indebtedness	(214,892)	(252,968)
Payments on finance lease liability	(24,080)	—
NET CASH USED IN FINANCING ACTIVITIES	<u>(238,972)</u>	<u>(252,968)</u>
NET DECREASE IN CASH AND CASH EQUIVALENTS	(5,183,392)	(2,757,642)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	17,408,257	25,334,889
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 12,224,865</u>	<u>\$ 22,577,247</u>
Supplemental Information		
Cash paid during the periods for:		
Interest	<u>\$ 12,326</u>	<u>\$ 4,425</u>

Income Taxes	\$ —	\$ —
--------------	------	------

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

Issuance of common stock as compensation	\$ 175,776	\$ 142,500
--	------------	------------

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

- 6 -

KORU MEDICAL SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)

Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA:	Three Months Ended	
	March 31,	
	2023	2022
GAAP Net Loss	\$ (2,410,885)	\$ (2,537,514)
Tax Benefit	(577,400)	(597,599)
Depreciation/Amortization	213,117	109,252
Interest Income, Net	(125,502)	1,463
Reorganization Charges	—	295,000
Manufacturing Initiative Expenses	49,053	38,005
Stock-based Compensation Expense	881,222	837,556
Non-GAAP Adjusted EBITDA	<u>\$ (1,970,395)</u>	<u>\$ (1,853,837)</u>

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS*:	Three Months Ended	
	March 31,	
	2023	2022
Reported Diluted Earnings Per Share	\$ (0.05)	\$ (0.06)
Reorganization Charges	—	0.01
Manufacturing Initiative Expenses	—	—
Reorganization Stock-based Compensation Expense	—	—
Tax (Expense) adjustment	—	—
Non-GAAP Adjusted Diluted Earnings Per Share	<u>\$ (0.05)</u>	<u>\$ (0.05)</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. 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.

- 7 -