

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) April 8, 2024

KORU Medical Systems, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(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**

(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 8.01 OTHER INFORMATION.

As previously reported, in March 2024, KORU Medical Systems, Inc. (the “Company”) received an assessment report from its notified body in the European Union, BSI, stating that, following BSI’s review of technical documentation submitted by the Company in connection with a prior audit nonconformance, a recommendation for continued certification cannot be made. The Company filed an appeal to that determination. On April 8, 2024, the Company’s appeal was upheld. The Company intends to address the identified nonconformance through the routine BSI assessment process.

Forward-Looking Statements

This Current Report on Form 8-K contains “forward-looking” statements regarding the nonconformance and BSI assessment process and that are based on the Company’s beliefs and assumptions and on information currently available to the Company on the date of this Current Report on Form 8-K. These forward-looking statements may involve known and unknown risks, uncertainties and other factors that may cause the Company’s actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Except as required by law, the Company assumes no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in the forward-looking statements, even if new information becomes available in the future. Further information on factors that could cause the Company’s actual results to differ materially from the results anticipated by the Company’s forward-looking statements is included in the reports the Company has filed with the U.S. Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2023.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated April 11, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: April 11, 2024

By: /s/ Linda Tharby
Linda Tharby

President and Chief Executive Officer



KORU Medical Systems Announces Successful Appeal in EU Notified Body Review

MAHWAH, NJ – April 11, 2024 – KORU Medical Systems, Inc. (NASDAQ: KRMD) (“KORU Medical” or the “Company”), a leading medical technology company focused on development, manufacturing, and commercialization of innovative and patient-centric large volume subcutaneous infusion solutions, today announced a successful appeal related to an ongoing audit by its notified body in the EU, The British Standards Institute (BSI).

The Company’s appeal of an assessment report from BSI regarding a recommendation against continued certification in connection with prior audit nonconformance, was upheld. As a result, the Company will proceed through the routine BSI assessment process without suspension or interruption of the Company’s sale of products in the EU.

“We are pleased by our successful appeal to BSI’s assessment report. Our team’s swift response and positive interaction with BSI, resulted in no interruption of sales of KORU Medical’s products to the market and our patients,” said Linda Tharby, KORU Medical’s President and CEO. “Our products remain certified, marketed and sold in the EU, and we are excited by the continued expansion of our international business.”

About KORU Medical Systems

KORU Medical Systems develops, manufactures, and commercializes innovative and patient-centric large volume subcutaneous infusion solutions that improve quality of life for patients around the world. The FREEDOM Syringe Infusion System (the “Freedom 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, including but not limited to sales expansion into new regions. Actual results may differ materially from these statements due to potential risks and uncertainties such as those risks and uncertainties included under the captions "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 which is 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 April 11, 2024. 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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