

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, 2022

REPRO MED 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>24 Carpenter Road, Chester, New York</u> (Address of principal executive offices)	<u>10918</u> (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 May 4, 2022, Rebro Med Systems, Inc. dba KORU Medical Systems ("KORU Medical") issued a press release announcing its financial results for the first quarter ended March 31, 2022 and an update to its financial outlook for the fiscal year ended December 31, 2022. A related conference call will be held on May 4, 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 May 4, 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.

REPRO MED SYSTEMS, INC.

(Registrant)

By: /s/ Karen Fisher
Karen Fisher

Chief Financial Officer

Date: May 4, 2022

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KORU MEDICAL SYSTEMS ANNOUNCES 2022 FIRST QUARTER FINANCIAL RESULTS

CHESTER, NY – May 4, 2022 – Repro Med Systems, Inc. dba KORU Medical Systems (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, 2022.

Highlights:

- Year-over-year net sales growth of 15% to \$6.2 million, marking the second consecutive quarter of double-digit growth
- Received 4th FDA clearance in 5 months, a 510(k) clearance for use of the FreedomEdge® infusion pump to deliver EMPAVELI® and Aspaveli®, a prescription medicine used to treat adults with a rare disease called paroxysmal nocturnal hemoglobinuria (PNH)
- Expanded novel therapies pipeline in new drug categories, including a Phase II clinical trial, and expanded an innovation development agreement with a large SCIg customer
- Signed distribution agreement in Germany, with an increased focus on international markets
- Announced Brian Case, 20+ year experienced R&D veteran, as Chief Technology Officer

"I am extremely proud of our team in delivering strong first quarter results as we continue to execute our strategic growth plan to become a broader drug delivery provider. A rebounding U.S. immunoglobulin market is encouraging, and we are successfully driving a dual focus on increasing revenues in our core subcutaneous Ig business through expanded label indications and a growing prefill market, while expanding the Freedom platform into new drug areas," said Linda Tharby, KORU Medical's President and CEO. "We also continue to build the team's capability with the hiring of Brian Case as our Chief Technology Officer, a proven experienced leader. I am very excited for the future of the company as we drive long-term growth, create value for customers and shareholders, and increasingly progress our strategic plan."

2022 First Quarter Financial Results

	Three Months Ended March 31,		Change from Prior Year	
	2022	2021	\$	%
Net Sales				
Domestic Core	\$ 4,993,536	\$ 4,412,417	\$ 581,119	13.2%
International Core	894,942	978,906	(83,964)	(8.6%)
Novel Therapies	355,852	39,628	316,224	798.0%
Total	\$ 6,244,330	\$ 5,430,951	\$ 813,379	15.0%

Net sales for the first quarter of 2022 were \$6.2 million, compared to \$5.4 million in the prior year period, a 15% increase. Domestic core was up 13.2% due to growth in pumps and consumables driven by an overall increase in the subcutaneous immunoglobulin market, as well as our key growth initiatives including prefills and label expansions. Novel Therapies sales were \$0.4 million for the quarter, including recognition of initial non-recurring engineering service ("NRE") revenues from a pre-commercialization innovation development agreement with a large subcutaneous immunoglobulin (SCIg) customer, which is expected to continue to generate revenue through 2022. International core was down by 8.6% year-over-year, due to quarterly buying pattern changes of a few smaller customers.

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Gross profit increased by \$0.4 million, or 12.1%, in the first quarter of 2022, while gross margin decreased by 150 basis points to 58.0%. The decline in gross margin was largely due to higher NRE revenues from the innovation effort described above. Also contributing to lower margins was higher manufacturing costs in our core business from increasing raw material and labor costs, partially offset by increased price and mix.

Total operating expenses for the first quarter of 2022 were \$6.7 million, compared to \$5.4 million for the same period in 2021. The increase in operating expenses is due to strategic investments in research and development, new hires to support business development and commercialization, and quality and regulatory.

Net loss for the first quarter of 2022 was \$2.5 million, or \$(0.06) per diluted share, compared to a net loss of \$1.3 million, or \$(0.03) per diluted share for the same period of 2021. Net loss included a tax benefit of \$0.6 million for the first quarter of 2022. On a non-GAAP basis, adjusted diluted earnings per share was \$(0.05) compared to \$0.00 in the same period of 2021.

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, plasma supply, clinical trial activity, labor and supply price increases, and supply chain impacts. Management will discuss its outlook and several of its assumptions on its first quarter 2022 earnings call.

For full year 2022, KORU Medical reaffirms expectations that the SCIG market will recover to a high single digit rate. Assuming this market growth holds, the Company expects full year 2022 revenue to be in the range of \$26.5 to \$27.0 million (previously \$26.0 to \$27.0 million).

The Company reiterates its guidance to exit the year at a 60% gross margin run rate. Additionally, Q1 2022 supply chain disruption impacts, which are not expected to recur, have resulted in unfavorable manufacturing variances, which will be recognized in the second quarter of 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, May 4, 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 13728821. The live webcast will be available on the Events & Presentations 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 EPS" 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.

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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, and expected 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, 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, which is on file with the SEC and is 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, 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.

Investor Contact:
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347-620-7010
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REPRO MED SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

March 31,
2022

December 31,
2021

ASSETS

CURRENT ASSETS		
Cash and cash equivalents	\$ 22,577,247	\$ 25,334,889
Accounts receivable less allowance for doubtful accounts of \$24,271 for March 31, 2022 and December 31, 2021	3,145,397	3,592,886
Inventory	6,017,737	6,106,338
Other Receivables	680,075	718,220
Prepaid expenses	1,510,851	1,568,821
TOTAL CURRENT ASSETS	33,931,307	37,321,154
Property and equipment, net	1,763,269	1,106,445
Intangible assets, net of accumulated amortization of \$278,897 and \$263,729 at March 31, 2022 and December 31, 2021, respectively	795,339	808,813
Operating lease right-of-use assets	4,309,282	95,553
Deferred income tax assets, net	2,538,853	1,941,254
Other assets	89,587	19,812
TOTAL ASSETS	\$ 43,427,637	\$ 41,293,031

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES		
Accounts payable	\$ 1,267,980	\$ 1,227,533
Accrued expenses	2,171,724	2,709,704
Note Payable	255,614	508,583
Other Liabilities	115,625	90,000
Accrued payroll and related taxes	506,315	160,603
Operating lease liability – current	395,359	95,553
TOTAL CURRENT LIABILITIES	4,712,617	4,791,976
Operating lease liability, net of current portion	3,913,923	—
TOTAL LIABILITIES	8,626,540	4,791,976
Commitments and contingencies (Refer to Note 3)		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 48,121,289 and 48,044,162 shares issued; 44,700,787 and 44,623,660 shares outstanding at March 31, 2022, and December 31, 2021, respectively	481,212	480,441
Additional paid-in capital	41,611,030	40,774,245
Treasury stock, 3,420,502 shares at March 31, 2022 and December 31, 2021, respectively, at cost	(3,843,562)	(3,843,562)
Retained deficit	(3,447,583)	(910,069)
TOTAL STOCKHOLDERS' EQUITY	34,801,097	36,501,055
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 43,427,637	\$ 41,293,031

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REPRO MED SYSTEMS, INC. STATEMENTS OF OPERATIONS (UNAUDITED)

	For the Three Months Ended March 31,	
	2022	2021
NET SALES	\$ 6,244,330	\$ 5,430,951
Cost of goods sold	2,622,025	2,199,097
Gross Profit	3,622,305	3,231,854
OPERATING EXPENSES		
Selling, general and administrative	5,491,213	4,992,829
Research and development	1,148,355	336,841
Depreciation and amortization	109,252	115,473
Total Operating Expenses	6,748,820	5,445,143
Net Operating Loss	(3,126,515)	(2,213,289)
Non-Operating Expense		
Loss on currency exchange	(7,135)	(15,717)
Gain on disposal of fixed asset	—	736
Interest (Expense)/Income, net	(1,463)	9,771
TOTAL OTHER EXPENSE	(8,598)	(5,210)
LOSS BEFORE INCOME TAXES	(3,135,113)	(2,218,499)
Income Tax Benefit	597,599	942,361
NET LOSS	\$ (2,537,514)	\$ (1,276,138)

NET LOSS PER SHARE		
Basic	\$ (0.06)	\$ (0.03)
Diluted	\$ (0.06)	\$ (0.03)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic	44,667,977	43,960,936
Diluted	44,667,977	43,960,936

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**REPRO MED SYSTEMS, INC.
STATEMENTS OF CASH FLOWS
(UNAUDITED)**

	For the Three Months Ended March 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (2,537,514)	\$ (1,276,138)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	837,556	734,184
Depreciation and amortization	109,252	115,473
Deferred income taxes	(597,599)	(943,211)
Gain on disposal of fixed assets	—	(736)
Changes in operating assets and liabilities:		
Decrease/(Increase) in accounts receivable	447,489	(988,387)
Decrease in other receivables	38,145	—
Decrease/(Increase) in inventory	88,601	(1,229,052)
(Increase)/Decrease in prepaid expenses and other assets	(11,805)	117,455
Increase in accounts payable	40,447	1,290,603
Increase in accrued payroll and related taxes	345,712	428,769
Decrease in accrued expenses	(537,981)	(854,613)
Increase in other liabilities	25,625	—
NET CASH USED IN OPERATING ACTIVITIES	(1,752,072)	(2,605,653)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(750,908)	(95,477)
Proceeds from disposal of property and equipment	—	9,065
Purchases of intangible assets	(1,694)	(15,792)
NET CASH USED IN INVESTING ACTIVITIES	(752,602)	(102,204)
CASH FLOWS FROM FINANCING ACTIVITIES		
Payments on indebtedness	(252,968)	—
Proceeds from issuance of equity	—	1,230,000
Common stock issuance as settlement for litigation	—	938,094
Payments on finance lease liability	—	(803)
NET CASH (USED IN)/PROVIDED BY FINANCING ACTIVITIES	(252,968)	2,167,291
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,757,642)	(540,566)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	25,334,889	27,315,286
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 22,577,247	\$ 26,774,720
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 4,425	\$ 28
Income Taxes	\$ —	\$ 850
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	\$ 142,500	\$ 56,250
Issuance of common stock as settlement for litigation	\$ —	\$ 938,094

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**REPRO MED SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)**

**Reconciliation of Reported Diluted EPS to
Three Months Ended
March 31,**

Non-GAAP Adjusted Diluted EPS:	<u>2022</u> <u>2021</u>	
Reported Diluted Earnings Per Share	\$ (0.06)	\$ (0.03)
Reorganization Charges	0.01	0.02
Manufacturing Initiative Expenses	—	—
Reorganization Stock-based Compensation Expense	—	0.01
Tax (Expense) adjustment	—	—
Non-GAAP Adjusted Diluted Earnings Per Share	<u>\$ (0.05)</u>	<u>\$ 0.00</u>

Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA:	Three Months Ended	
	March 31,	
	<u>2022</u>	<u>2021</u>
GAAP Net Loss	\$ (2,537,514)	\$ (1,276,138)
Tax Benefit	(597,599)	(942,361)
Depreciation/Amortization	109,252	115,473
Interest Income, Net	1,463	(9,771)
Reorganization Charges	295,000	969,274
Manufacturing Initiative Expenses	38,005	51,723
Stock-based Compensation Expense	837,556	734,184
Non-GAAP Adjusted EBITDA	<u>\$ (1,853,837)</u>	<u>\$ (357,616)</u>

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, 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 nine to fifteen 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. Adjusted EBITDA for the three months ended March 31, 2021 included stock-based compensation expense of \$0.4 million related to the departure and replacement of our chief executive officer. This expense is included in Reorganization Stock-based Compensation Expense in calculating Adjusted Diluted EPS.