

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 12, 2021

REPRO MED 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.)

24 Carpenter Road, Chester, New York
(Address of principal executive offices)

10918
(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 March 12, 2021, Repro Med Systems, Inc. dba KORU Medical Systems (“KORU Medical”) issued a press release announcing its operating and financial results for the first quarter ended March 31, 2021. A related conference will be held on March 12, 2021 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 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 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. Because management uses Adjusted EBITDA for such purposes, KORU Medical uses Adjusted EBITDA as a significant criterion for determining the amount of annual cash incentive compensation paid to our executive officers and employees. We have historically found that Adjusted EBITDA is superior to other metrics for our company-wide cash incentive program, as it is more easily explained and understood by our typical employee.

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, reorganization stock-based compensation expense, and tax (expense) adjustment.

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 12, 2021

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)

Date: May 12, 2021

By: /s/ Karen Fisher
Karen Fisher
Chief Financial Officer

KORU MEDICAL SYSTEMS ANNOUNCES 2021 FIRST QUARTER FINANCIAL RESULTS

CHESTER, NY – May 12, 2021 – 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, 2021.

First Quarter 2021 Summary:

- Announced Linda Tharby, med-tech veteran, as President and CEO, effective April 12, 2021
- Recorded solid net revenue of \$5.4 million; robust sequential quarterly growth
- Gross margin of 59.5%
- Recorded a net loss of \$1.3 million, including leadership change expenses totaling \$1.3 million

“I am very excited and grateful for the opportunity to lead KORU Medical in its mission to improve the quality of life of home infusion patients around the globe,” said Linda Tharby, KORU Medical’s new CEO. “KORU Medical has built a leading market position in a growing home infusion space with its Freedom Integrated Infusion System. I look forward to working with our team in accelerating our growth potential, delivering innovation to our customers, and creating value for shareholders.”

“In the first quarter of 2021, we faced difficult year-over-year quarterly revenue comparisons, which included several one-time purchases and a current year COVID-19 impact on new patient starts. I am encouraged by our strong sequential quarterly growth and increasing new pump placements, indicating newly diagnosed SCIG patients returning to pre-COVID levels.”

First Quarter 2021 Financial Results

Net sales were \$5.4 million for the three months ending March 31, 2021, a 14% decrease from \$6.3 million in the same period of 2020, with strong sequential quarterly growth. The decrease was due principally to lower novel therapies sales compared to last year due to a non-recurring clinical trial, lower domestic core pump volume primarily due to ordering patterns and a one-time pharmaceutical customer pump purchase in the prior year. Domestic core business also reflected a slowdown in the growth of new patient starts for SCIG therapy, as the COVID-19 pandemic continued to delay provider visits and new diagnoses.

International revenues were \$1.0 million, flat with prior year.

Gross margin was 59.5% for the first quarter of 2021, roughly equivalent to the same period in 2020.

Total operating expenses for the first quarter of 2021 were \$5.4 million, compared to \$3.2 million for the same period in 2020. The \$2.2 million increase was due principally to expenses of \$1.3 million related to leadership changes, which included non-cash equity charges, as well as costs of \$0.6 million associated with new hires in the second half of last year to support commercialization, business development and medical affairs for the Company's novel therapies initiatives.

Net loss for the first quarter of 2021 was \$1.3 million, or \$(0.03) per diluted share, compared to a net gain of \$0.4 million, or \$0.01 per diluted share for the same period of 2020. Net loss for the first quarter of 2021 included \$1.3 million of recent leadership change expenses, as noted above. On a non-GAAP basis, adjusted diluted earnings per share was \$0.00 compared to \$0.02 in the same period of 2020.

Non-GAAP adjusted EBITDA for the first quarter of 2021 was \$(0.4) million, compared to \$1.3 million in the first quarter of 2020.

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.

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. Forward-looking statements can be identified by words such as “may,” “look forward” and “confidence.” 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 and COVID-19, 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, 2020, 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 March 31, 2021. 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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REPRO MED SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

	March 31, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 26,774,720	\$ 27,315,286
Accounts receivable less allowance for doubtful accounts of \$24,469 for March 31, 2021, and December 31, 2020, respectively	3,561,341	2,572,954
Inventory	8,058,824	6,829,772
Prepaid expenses	690,325	807,780
TOTAL CURRENT ASSETS	39,085,210	37,525,792
Property and equipment, net	1,154,368	1,167,623
Intangible assets, net of accumulated amortization of \$214,969 and \$199,899 at March 31, 2021 and December 31, 2020, respectively	844,309	843,587
Operating lease right-of-use assets	201,598	236,846
Deferred income tax assets, net	1,068,485	125,274
Other assets	19,812	19,812
TOTAL ASSETS	\$ 42,373,782	\$ 39,918,934
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 1,915,523	\$ 624,920
Accrued expenses	1,755,800	2,610,413
Accrued payroll and related taxes	715,899	287,130
Finance lease liability – current	1,843	2,646
Operating lease liability – current	141,869	141,293
TOTAL CURRENT LIABILITIES	4,530,934	3,666,402
Operating lease liability, net of current portion	59,729	95,553
TOTAL LIABILITIES	4,590,663	3,761,955
Commitments and contingencies (Refer to Note 3)		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 47,896,061 and 46,680,119 shares issued; 44,475,559 and 43,259,617 shares outstanding at March 31, 2021, and December 31, 2020, respectively	478,960	466,801
Additional paid-in capital	38,771,105	35,880,986
Treasury stock, 3,420,502 shares and 3,420,502 shares at March 31, 2021 and December 31, 2020, respectively, at cost	(3,843,562)	(3,843,562)
Retained earnings	2,376,616	3,652,754
TOTAL STOCKHOLDERS' EQUITY	37,783,119	36,156,979
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 42,373,782	\$ 39,918,934

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

	For the Three Months Ended March 31,	
	2021	2020
NET SALES	\$ 5,430,951	\$ 6,330,009
Cost of goods sold	2,199,097	2,541,799
Gross Profit	<u>3,231,854</u>	<u>3,788,210</u>
OPERATING EXPENSES		
Selling, general and administrative	4,992,829	2,862,138
Research and development	336,841	256,025
Depreciation and amortization	115,473	87,224
Total Operating Expenses	<u>5,445,143</u>	<u>3,205,387</u>
Net Operating (Loss)/Profit	(2,213,289)	582,823
Non-Operating (Expense)/Income		
Loss on currency exchange	(15,717)	(10,497)
Gain on disposal of fixed asset	736	—
Interest income, net	9,771	19,030
TOTAL OTHER (EXPENSE)/INCOME	<u>(5,210)</u>	<u>8,533</u>
(LOSS)/INCOME BEFORE TAXES	(2,218,499)	591,356
Income Tax Benefit/(Expense)	942,361	(141,928)
NET (LOSS)/INCOME	<u>\$ (1,276,138)</u>	<u>\$ 449,428</u>
NET (LOSS)/INCOME PER SHARE		
Basic	<u>\$ (0.03)</u>	<u>\$ 0.01</u>
Diluted	<u>\$ (0.03)</u>	<u>\$ 0.01</u>
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic	<u>43,960,936</u>	<u>39,675,107</u>
Diluted	<u>43,960,936</u>	<u>39,874,989</u>

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

For the
Three Months Ended
March 31,

	<u>2021</u>	<u>2020</u>
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (Loss)/Income	\$ (1,276,138)	\$ 449,428
Adjustments to reconcile net (loss)/income to net cash (used in)/provided by operating activities:		
Stock-based compensation expense	734,184	360,968
Depreciation and amortization	115,473	87,224
Deferred income taxes	(943,211)	(63,203)
Gain on disposal of fixed assets	(736)	—
Changes in operating assets and liabilities:		
Increase in accounts receivable	(988,387)	(185,160)
Increase in inventory	(1,229,052)	(700,539)
Decrease/(Increase) in prepaid expenses and other assets	117,455	(156,288)
Increase in accounts payable	1,290,603	524,398
Increase in accrued payroll and related taxes	428,769	39,571
Decrease in accrued expenses	(854,613)	(408,294)
Increase in accrued tax liability	—	205,131
NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES	<u>(2,605,653)</u>	<u>153,236</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(95,477)	(99,591)
Proceeds from disposal of property and equipment	9,065	—
Purchases of intangible assets	(15,792)	(80,547)
NET CASH USED IN INVESTING ACTIVITIES	<u>(102,204)</u>	<u>(180,138)</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Borrowings from indebtedness	—	1,500,000
Proceeds from issuance of equity	1,230,000	85,500
Common stock issuance as settlement for litigation	938,094	—
Payments on finance lease liability	(803)	(1,848)
NET CASH PROVIDED BY FINANCING ACTIVITIES	<u>2,167,291</u>	<u>1,583,652</u>
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	<u>(540,566)</u>	<u>1,556,750</u>
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	<u>27,315,286</u>	<u>5,870,929</u>
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 26,774,720</u>	<u>\$ 7,427,679</u>
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 28	\$ 87
Income Taxes	\$ 850	\$ —
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	\$ 56,250	\$ 60,002
Issuance of common stock as settlement for litigation	\$ 938,094	\$ —

REPRO MED SYSTEMS, INC.
SUPPLEMENTAL INFORMATION
(UNAUDITED)

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS:	Three Months Ended	
	March 31,	
	2021	2020
Reported Diluted Earnings Per Share	\$ (0.03)	\$ 0.01
Reorganization Charges	0.02	—
Discontinued Product Expense	—	—
Litigation Expenses	—	—
Manufacturing Initiative Expenses	—	0.01
Reorganization Stock-based Compensation Expense	0.01	—
Tax (Expense) adjustment	—	—
Non-GAAP Adjusted Diluted Earnings Per Share	\$ 0.00	\$ 0.02

Reconciliation of GAAP Net (Loss)/Income to Non-GAAP Adjusted EBITDA:	Three Months Ended	
	March 31,	
	2021	2020
GAAP Net (Loss)/Income	\$ (1,276,138)	\$ 449,428
Tax (Benefit)/Expense	(942,361)	141,928
Depreciation/Amortization	115,473	87,224
Interest Income, Net	(9,771)	(19,030)
Reorganization Charges	969,274	—
Discontinued Product Expense	—	109,558
Litigation Expenses	—	99,158
Manufacturing Initiative Expenses	51,723	109,803
Stock-based Compensation Expense	734,184	360,968
Non-GAAP Adjusted EBITDA	\$ (357,616)	\$ 1,339,037

Reorganization Charges. We have excluded the effect of reorganization charges in calculating our non-GAAP measures. 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.

Discontinued Product Expense. We have excluded the effect of expenses related to a discontinued product line in calculating our non-GAAP measures. We expected to retire our Res-Q-Vac product line towards the end of 2020, but due to the failure of equipment used to manufacture the product, the discontinuation and resulting expense was accelerated into the first quarter of 2020 which we would not have otherwise incurred in periods presented as part of our continuing operations. We did not incur any related expense in 2021.

Litigation. We have excluded litigation expenses in calculating our non-GAAP measures. Litigation expenses in 2020 included professional fees associated with our litigation with EMED, which discontinued as a result of the settlement on May 20, 2020.

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.