

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 11, 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 August 11, 2021, Repro Med Systems, Inc. dba KORU Medical Systems ("KORU Medical") issued a press release announcing its financial results for the second quarter ended June 30, 2021. A related conference call will be held on August 11, 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 (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 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, 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 11, 2021</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.

REPRO MED SYSTEMS, INC.  
(Registrant)

Date: August 11, 2021

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

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**KORU Medical Systems Announces 2021 Second Quarter Financial Results**

**CHESTER, NY – August 11, 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 second quarter ended June 30, 2021.

**Second Quarter 2021 Summary:**

- Solid net revenue of \$5.5 million; positive sequential quarterly growth
- Gross margin of 58.1%
- Net loss of \$1.1 million

"We are pleased with our performance and sequential revenue growth in the second quarter and look forward to continuing to build growth and momentum in the second half of 2021. We are beginning to see a rebound in growth in the subcutaneous immunoglobulin market, and we are well positioned to remain the category leader," said Linda Tharby, KORU Medical's CEO. "We are focused on executing on our strategy, driving growth in our core SCIg therapy franchise through commercial efforts to increase penetration of home subcutaneous delivery, building a pipeline of subcutaneous therapeutic candidates and introducing product and technology innovations to generate further topline growth."

**Second Quarter 2021 Financial Results**

Net sales were \$5.5 million, a decline of 28.3% compared to the second quarter of 2020, due to approximately \$2.3 million of COVID-related stocking orders and higher novel therapies sales from non-recurring clinical trials, each in the prior year. Sequential quarter net sales growth was 2%, driven by a 4% increase in domestic core business, and growth in novel therapies revenues. Both the overall domestic immunoglobulin market and our end-user sales to the specialty pharmacy channel grew mid-single digits through Q2 2021, which we believe indicates market recovery in new patient starts for SCIg therapy.

Gross margin was 58.1% for the second quarter of 2021, a decrease of 5.6 percentage points compared to the second quarter of 2020. Gross margin was negatively impacted by lower volumes, resulting in unfavorable absorption in the quarter.

Total operating expenses for the second quarter of 2021 were \$4.6 million, compared to \$5.9 million for the same period in 2020, which included \$2.3 million of litigation expenses. Excluding the impact of litigation expenses, operating expenses grew primarily due to new commercialization, research and development, and regulatory initiatives in support of our growth strategy, as well as CEO transition related costs.

Net loss for the second quarter of 2021 was \$1.1 million, or \$(0.03) per diluted share, unchanged from the same period in 2020. On a non-GAAP basis, adjusted diluted earnings per share was \$(0.02), \$0.04 lower than the same period in 2020.

Non-GAAP adjusted EBITDA for the second quarter of 2021 was \$(0.3) million, compared to \$1.8 million in the second quarter of 2020.

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**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<sup>®</sup> and FreedomEdge<sup>®</sup> Syringe Infusion Drivers, Precision Flow Rate Tubing<sup>™</sup> and HiGH-Flo Subcutaneous Safety Needle Sets<sup>™</sup>. 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).

**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 "believe", "look forward," "focused on" and "indicating". 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, 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](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 June 30, 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:**

Greg Chodaczek  
347-620-7010  
[investor@korumedical.com](mailto:investor@korumedical.com)

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**REPRO MED SYSTEMS, INC.  
BALANCE SHEETS  
(UNAUDITED)**

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 26,538,478	\$ 27,315,286
Accounts receivable less allowance for doubtful accounts of \$24,469 for June 30, 2021, and December 31, 2020	2,577,400	2,572,954
Inventory	7,562,750	6,829,772
Prepaid expenses	461,553	807,780
<b>TOTAL CURRENT ASSETS</b>	<u>37,140,181</u>	<u>37,525,792</u>
Property and equipment, net	1,110,550	1,167,623
Intangible assets, net of accumulated amortization of \$232,820 and \$199,899 at June 30, 2021 and December 31, 2020, respectively	834,644	843,587
Operating lease right-of-use assets	166,483	236,846
Deferred income tax assets, net	1,327,230	125,274
Other assets	19,812	19,812
<b>TOTAL ASSETS</b>	<u>\$ 40,598,900</u>	<u>\$ 39,918,934</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,005,653	\$ 624,920
Accrued expenses	1,771,666	2,610,413
Accrued payroll and related taxes	390,326	287,130
Finance lease liability – current	1,030	2,646
Operating lease liability – current	142,450	141,293
<b>TOTAL CURRENT LIABILITIES</b>	<u>3,311,125</u>	<u>3,666,402</u>
Operating lease liability, net of current portion	24,033	95,553
<b>TOTAL LIABILITIES</b>	<u>3,335,158</u>	<u>3,761,955</u>
Commitments and contingencies (Refer to Note 3)		
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 47,910,676 and 46,680,119 shares issued 44,490,174 and 43,259,617 shares outstanding at June 30, 2021, and December 31, 2020, respectively	479,106	466,801
Additional paid-in capital	39,376,131	35,880,986
Treasury stock, 3,420,502 shares at June 30, 2021 and December 31, 2020, respectively, at cost	(3,843,562)	(3,843,562)
Retained earnings	1,252,067	3,652,754
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<u>37,263,742</u>	<u>36,156,979</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<u>\$ 40,598,900</u>	<u>\$ 39,918,934</u>

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**REPRO MED SYSTEMS, INC.  
STATEMENTS OF OPERATIONS  
(Unaudited)**

<b>Three Months Ended June 30,</b>		<b>Six Months Ended June 30,</b>	
<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>

NET SALES	\$ 5,528,174	\$ 7,708,904	\$ 10,959,125	\$ 14,038,913
Cost of goods sold	2,317,990	2,799,024	4,517,087	5,340,823
Gross Profit	3,210,184	4,909,880	6,442,038	8,698,090
OPERATING EXPENSES				
Selling, general and administrative	4,085,945	3,201,831	9,078,774	5,964,811
Litigation	—	2,346,914	—	2,446,072
Research and development	386,878	298,196	723,719	554,221
Depreciation and amortization	118,415	94,940	233,888	182,164
Total Operating Expenses	4,591,238	5,941,881	10,036,381	9,147,268
Net Operating Loss	(1,381,054)	(1,032,001)	(3,594,343)	(449,178)
Non-Operating Income/(Expense)				
Gain/(Loss) on currency exchange	1,239	(2,594)	(14,478)	(13,091)
(Loss)/Gain on disposal of fixed assets, net	—	(5,522)	736	(5,522)
Interest income, net	9,950	(5,002)	19,721	14,028
TOTAL OTHER INCOME/(EXPENSE)	11,189	(13,118)	5,979	(4,585)
LOSS BEFORE INCOME TAXES	(1,369,865)	(1,045,119)	(3,588,364)	(453,763)
Income Tax Benefit/(Expense)	245,316	(30,919)	1,187,677	(172,847)
NET LOSS	\$ (1,124,549)	\$ (1,076,038)	\$ (2,400,687)	\$ (626,610)
NET LOSS PER SHARE				
Basic	\$ (0.03)	\$ (0.03)	\$ (0.05)	\$ (0.02)
Diluted	\$ (0.03)	\$ (0.03)	\$ (0.05)	\$ (0.02)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	44,489,853	40,361,924	44,226,936	40,018,559
Diluted	44,489,853	40,361,924	44,226,936	40,018,559

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

	For the Six Months Ended June 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (2,400,687)	\$ (626,610)
Adjustments to reconcile net loss to net cash (used in)/provided by operating activities:		
Stock-based compensation expense	1,339,356	784,821
Stock-based litigation settlement expense	—	1,285,102
Depreciation and amortization	233,888	182,164
Deferred income taxes	(1,201,956)	(145,770)
(Gain)/Loss on disposal of fixed assets	(736)	5,522
Changes in operating assets and liabilities:		
(Increase)/Decrease in accounts receivable	(4,446)	268,619
Increase in inventory	(732,978)	(1,278,811)
Decrease/(Increase) in prepaid expenses and other assets	346,227	(156,316)
Increase in accounts payable	380,733	347,350
Increase in accrued payroll and related taxes	103,196	333,272
(Decrease)/Increase in accrued expenses	(838,747)	1,389,588
Increase in accrued tax liability	—	318,618
NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES	(2,776,150)	2,707,549
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(152,223)	(363,750)
Proceeds from disposal of property and equipment	9,065	—
Purchases of intangible assets	(23,978)	(149,523)
NET CASH USED IN INVESTING ACTIVITIES	(167,136)	(513,273)
CASH FLOWS FROM FINANCING ACTIVITIES		
Borrowings from indebtedness	—	3,500,000
Proceeds from issuance of equity	1,230,000	26,567,861
Common stock issuance as settlement for litigation	938,094	—
Payments on finance lease liability	(1,616)	(3,717)
NET CASH PROVIDED BY FINANCING ACTIVITIES	2,166,478	30,064,144
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	(776,808)	32,258,420
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	27,315,286	5,870,929

CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 26,538,478</u>	<u>\$ 38,129,349</u>
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Supplemental Information

Cash paid during the periods for:

Interest	<u>\$ 47</u>	<u>\$ 13,554</u>
Income Taxes	<u>\$ 850</u>	<u>\$ —</u>

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

Issuance of common stock as compensation	<u>\$ 153,446</u>	<u>\$ 120,004</u>
Issuance of common stock as settlement for litigation	<u>\$ 938,094</u>	<u>\$ 938,094</u>

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

The following table summarizes our net sales for the three and six months ended June 30, 2021 and 2020:

	<b>Three Months</b>		<b>Six Months</b>	
	<b>Ended June 30,</b>		<b>Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
<b>Net Sales</b>				
Domestic	\$ 4,597,797	\$ 5,557,577	\$ 9,010,214	\$ 10,430,343
International	859,694	853,043	1,838,600	1,837,910
Novel Therapies	70,683	1,298,284	110,311	1,770,660
<b>Total</b>	<u>\$ 5,528,174</u>	<u>\$ 7,708,904</u>	<u>\$ 10,959,125</u>	<u>\$ 14,038,913</u>

A reconciliation of our non-GAAP measures is below:

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
<b>Reconciliation of GAAP Net (Loss)</b>				
<b>to Non-GAAP Adjusted EBITDA:</b>				
GAAP Net Loss	\$ (1,124,549)	\$ (1,076,038)	\$ (2,400,687)	\$ (626,610)
Tax (Benefit)/Expense	(245,316)	30,919	(1,187,677)	172,847
Depreciation and Amortization	118,415	94,940	233,888	182,164
Interest Income, Net	(9,950)	5,002	(19,721)	(14,028)
Reorganization Charges	224,605	—	1,193,880	—
Discontinued Product Expense	—	(31,581)	—	77,977
Litigation Expenses	—	2,346,914	—	2,446,071
Manufacturing Initiative Expenses	149,718	25,957	201,441	135,759
Stock-based Compensation Expense	605,172	423,853	1,339,356	784,821
Non-GAAP Adjusted EBITDA	<u>\$ (281,905)</u>	<u>\$ 1,819,966</u>	<u>\$ (639,520)</u>	<u>\$ 3,159,001</u>

	<b>Three Months Ended</b>		<b>Six Months Ended</b>	
	<b>June 30,</b>		<b>June 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
<b>Reconciliation of Reported Diluted EPS</b>				
<b>to Non-GAAP Adjusted Diluted EPS:</b>				
Reported Diluted Earnings Per Share	\$ (0.03)	\$ (0.02)	\$ (0.05)	\$ (0.01)
Reorganization Charges	0.01	—	0.03	—
Discontinued Product Expense	—	—	—	—
Litigation Expenses	—	0.06	—	0.06
Manufacturing Initiative Expenses	—	—	—	—
Stock-based Compensation Expense	—	—	0.01	—
Tax (Expense) Adjustment	—	(0.02)	(0.01)	(0.01)
Non-GAAP Adjusted Diluted Earnings Per Share	<u>\$ (0.02)</u>	<u>\$ 0.02</u>	<u>\$ (0.02)</u>	<u>\$ 0.04</u>

*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 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 six to nine 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 common stock to our board of directors and our CEO. 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 six months ended June 30, 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 Stock-based Compensation Expense in calculating Adjusted Diluted EPS.

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