

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) **November 10, 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>
<b>common stock, \$0.01 par value</b>	<b>KRMD</b>	<b>The Nasdaq Stock Market</b>

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 November 10, 2021, Repro Med Systems, Inc. dba KORU Medical Systems ("KORU Medical") issued a press release announcing its financial results for the third quarter ended September 30, 2021. A related conference call will be held on November 10, 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, Adjusted EPS and Adjusted Net Sales (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. 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.

We present net sales after adjusting for net sales that we believe would have been made during periods other than those in which they were made, due to the pandemic and an early order (“Adjusted Net Sales”). We believe adjustments for these items allow investors to better understand our underlying net sales results and facilitate comparisons between the periods shown. Management uses Adjusted Net Sales 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 November 10, 2021</a>
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.

REPRO MED SYSTEMS, INC.  
(Registrant)

Date: November 10, 2021

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

- 3 -

---



## **KORU MEDICAL SYSTEMS ANNOUNCES 2021 THIRD QUARTER FINANCIAL RESULTS**

**CHESTER, NY – November 10, 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 third quarter ended September 30, 2021.

### **Recent Highlights:**

- Achieved net revenue of \$6.0 million, a 9% increase versus Q2 2021, marking the third consecutive quarter of positive sequential growth
- Received FDA 510(k) clearance for CSL Hizentra® 20 ml prefilled syringe with the Freedom Edge® Syringe Infusion System
- Appointed three leadership team hires and announced an external innovation collaboration
- Scheduled strategic plan update presentation on December 2, 2021

“Our strong third quarter top-line results reflect continued momentum in all areas of our business – core US and international, as well as our novel therapies pipeline,” said Linda Tharby, KORU Medical’s CEO. “I’m proud of the team’s progress this quarter as we strengthen our foundation, continue to build the KORU Medical team, and increase our investment in innovation. We remain focused on continued execution of our strategy, which drives incremental growth and market expansion building on our leadership position in large volume subcutaneous home infusion and extending that position into new drug therapies.”

### **Third Quarter 2021 Financial Results**

Net revenue was \$6.0 million, (0.7)% lower compared with \$6.1 million in the prior-year period. Adjusting for net inventory stocking of \$0.6 million last year, adjusted net revenue grew 9%, with growth in all areas of our business; domestic core driven by pumps, international driven by consumables and increased novel therapies revenues. Sequential quarterly net revenue growth was 9%, with domestic core growth of 10% driven by pumps and needle sets and growth in novel therapies revenue.

Gross margin was 57.9% for the third quarter of 2021, a decline from prior year of 64.8%. The majority of the decline was driven by delays in the transition to our secondary manufacturing source. We also recorded a reserve for in-process material scrap. This was partially offset by favorability in product mix. We are confident in our path to accelerate margin improvement in 2022.

---

Total operating expenses for the third quarter of 2021 were \$4.8 million, compared to \$3.6 million for the same period in 2020. The increase in operating expenses is due to increased spend in support of strategic initiatives including commercialization, regulatory filings, and research and development.

Net loss for the third quarter of 2021 was \$1.1 million, or \$(0.02) per diluted share, compared with net income of \$0.2 million, or \$0.01 per diluted share for the same period in 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](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 “scheduled”, “our path”, and “look forward”. 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 November 10, 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)

- 2 -

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

	<u>September 30,</u>	<u>December 31,</u>
	<u>2021</u>	<u>2020</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 26,233,411	\$ 27,315,286
Accounts receivable less allowance for doubtful accounts of \$24,469 for September 30, 2021 and December 31, 2020	3,122,665	2,572,954
Inventory	6,967,932	6,829,772
Prepaid expenses	1,336,819	807,780
<b>TOTAL CURRENT ASSETS</b>	<b>37,660,827</b>	<b>37,525,792</b>
Property and equipment, net	1,159,819	1,167,623
Intangible assets, net of accumulated amortization of \$248,252 and \$199,899 at September 30, 2021 and December 31, 2020, respectively	821,071	843,587
Operating lease right-of-use assets	131,228	236,846
Deferred income tax assets, net	1,565,334	125,274
Other assets	19,812	19,812
<b>TOTAL ASSETS</b>	<b>\$ 41,358,091</b>	<b>\$ 39,918,934</b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,385,413	\$ 624,920
Accrued expenses	2,036,848	2,610,413
Accrued payroll and related taxes	332,814	287,130
Finance lease liability – current	414	2,646
Operating lease liability – current	131,228	141,293
Note Payable	673,133	—
<b>TOTAL CURRENT LIABILITIES</b>	<b>4,559,850</b>	<b>3,666,402</b>
Operating lease liability, net of current portion	—	95,553
<b>TOTAL LIABILITIES</b>	<b>4,559,850</b>	<b>3,761,955</b>
Commitments and contingencies (Refer to Note 3)		
<b>STOCKHOLDERS' EQUITY</b>		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 47,931,664 and 46,680,119 shares issued 44,511,162 and 43,259,617 shares outstanding at September 30, 2021 and December 31, 2020, respectively	479,317	466,801
Additional paid-in capital	40,004,197	35,880,986
Treasury stock, 3,420,502 shares at September 30, 2021 and December 31, 2020, at cost	(3,843,562)	(3,843,562)
Retained earnings	158,289	3,652,754
<b>TOTAL STOCKHOLDERS' EQUITY</b>	<b>36,798,241</b>	<b>36,156,979</b>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY</b>	<b>\$ 41,358,091</b>	<b>\$ 39,918,934</b>

- 3 -

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

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2021	2020	2021	2020
NET SALES	\$ 6,040,544	\$ 6,080,315	\$ 16,999,669	\$ 20,119,228
Cost of goods sold	2,544,794	2,139,592	7,061,881	7,480,415
Gross Profit	3,495,750	3,940,723	9,937,788	12,638,813
OPERATING EXPENSES				
Selling, general and administrative	3,901,830	3,075,169	12,980,604	9,039,980
Litigation	—	675	—	2,446,747
Research and development	800,020	390,416	1,523,739	944,637
Depreciation and amortization	115,934	115,637	349,822	297,801
Total Operating Expenses	4,817,784	3,581,897	14,854,165	12,729,165
Net Operating (Loss)/Profit	(1,322,034)	358,826	(4,916,377)	(90,352)
Non-Operating (Expense)/Income				
(Loss)/Gain on currency exchange	(7,283)	1,927	(21,761)	(11,164)
Gain on disposal of fixed assets, net	273	22,113	1,009	16,591
Interest (expense)/income, net	(2,838)	9,662	16,883	23,690
TOTAL OTHER (EXPENSE)/INCOME	(9,848)	33,702	(3,869)	29,117
(LOSS)/INCOME BEFORE INCOME TAXES	(1,331,882)	392,528	(4,920,246)	(61,235)
Income Tax Benefit/(Expense)	238,104	(143,353)	1,425,781	(316,200)
NET (LOSS)/INCOME	\$ (1,093,778)	\$ 249,175	\$ (3,494,465)	\$ (377,435)
NET (LOSS)/INCOME PER SHARE				
Basic	\$ (0.02)	\$ 0.01	\$ (0.08)	\$ (0.01)
Diluted	\$ (0.02)	\$ 0.01	\$ (0.08)	\$ (0.01)
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	44,322,335	43,914,542	44,510,021	41,326,815
Diluted	44,322,335	44,119,511	44,510,021	41,326,815

- 4 -

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

	For the	
	Nine Months Ended	
	September 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (3,494,465)	\$ (377,435)
Adjustments to reconcile net loss to net cash (used in)/provided by operating activities:		
Stock-based compensation expense	1,967,632	1,191,146
Stock-based litigation settlement expense	—	1,285,102
Depreciation and amortization	349,822	297,801
Deferred income taxes	(1,440,060)	(161,368)
Gain on disposal of fixed assets	(1,009)	(16,591)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(549,711)	(502,075)
Increase in inventory	(138,160)	(3,244,662)
Increase in prepaid expenses and other assets	(529,039)	(457,330)
Increase in accounts payable	760,493	790,414

Increase in accrued payroll and related taxes	45,684	249,879
(Decrease)/Increase in accrued expenses	(573,565)	1,754,970
Increase in accrued tax liability	—	158,586
<b>NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES</b>	<b>(3,602,378)</b>	<b>968,437</b>
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property and equipment	(301,720)	(908,323)
Proceeds from disposal of property and equipment	9,065	25,000
Purchases of intangible assets	(25,838)	(124,216)
<b>NET CASH USED IN INVESTING ACTIVITIES</b>	<b>(318,493)</b>	<b>(1,007,539)</b>
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Borrowings from indebtedness	924,389	4,976,508
Payments on indebtedness	(251,255)	(4,976,508)
Proceeds from issuance of equity	1,230,000	26,606,486
Common stock issuance as settlement for litigation	938,094	—
Payments on finance lease liability	(2,232)	(4,502)
<b>NET CASH PROVIDED BY FINANCING ACTIVITIES</b>	<b>2,838,996</b>	<b>26,601,984</b>
<b>NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS</b>	<b>(1,081,875)</b>	<b>26,562,882</b>
<b>CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD</b>	<b>27,315,286</b>	<b>5,870,929</b>
<b>CASH AND CASH EQUIVALENTS, END OF PERIOD</b>	<b>\$ 26,233,411</b>	<b>\$ 32,433,811</b>

Supplemental Information

Cash paid during the periods for:

Interest	\$ 6,194	\$ 27,698
Income Taxes	\$ 850	\$ 318,983

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

Issuance of common stock as compensation	\$ 295,947	\$ 180,006
Issuance of common stock as settlement for litigation	\$ 938,094	\$ 938,094

- 5 -

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

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

	<b>Three Months</b>		<b>Nine Months</b>	
	<b>Ended September 30,</b>		<b>Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
<b>Net Sales</b>				
Domestic	\$ 5,076,294	\$ 5,289,076	\$ 14,084,552	\$ 15,719,419
International	747,281	702,034	2,585,881	2,539,944
Novel Therapies	216,969	89,205	329,236	1,859,865
<b>Total</b>	<b>\$ 6,040,544</b>	<b>\$ 6,080,315</b>	<b>\$ 16,999,669</b>	<b>\$ 20,119,228</b>

A reconciliation of one of our non-GAAP measures is below:

<b>Reconciliation of Reported Net Sales to Non-GAAP Net Sales</b>	<b>Three Months</b>		<b>Change from Prior Year</b>	
	<b>Ended September 30,</b>		<b>Change from Prior Year</b>	
	<b>2021</b>	<b>2020</b>	<b>\$</b>	<b>%</b>
Reported Net Sales	\$ 6,040,544	\$ 6,080,315	\$ (39,771)	(0.7%)
Early Order/Inventory Stocking	—	(552,000)	552,000	(100.0%)
<b>Non-GAAP Adjusted Net Sales</b>	<b>\$ 6,040,544</b>	<b>\$ 5,528,315</b>	<b>\$ 512,229</b>	<b>9.3%</b>

<b>Reconciliation of Reported Net Sales to Non-GAAP Net Sales</b>	<b>Nine Months</b>		<b>Change from Prior Year</b>	
	<b>Ended September 30,</b>		<b>Change from Prior Year</b>	
	<b>2021</b>	<b>2020</b>	<b>\$</b>	<b>%</b>
Reported Net Sales	\$ 16,999,669	\$ 20,119,228	\$ (3,119,559)	(15.5%)
Early Order/Inventory Stocking	—	(1,335,000)	1,335,000	(100.0%)
<b>Non-GAAP Adjusted Net Sales</b>	<b>\$ 16,999,669</b>	<b>\$ 18,784,228</b>	<b>\$ (1,784,559)</b>	<b>(9.5%)</b>

*Early Order/Inventory Stocking.* We have excluded the effect of an early order and covid related inventory stocking in calculating our non-GAAP measure. We had an early order from our largest distributor in the three months ended September 30, 2020, which would have otherwise been placed in the three months ended December 31, 2020, as well as higher purchases in the six months ended June 30, 2020, that we believe would have normally been made in the second half of 2020, had it not been for the pandemic.

- 6 -

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

A reconciliation of our non-GAAP measures is below:

<b>Reconciliation of GAAP Net (Loss)/Income to Non-GAAP Adjusted EBITDA:</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
	GAAP Net Loss	\$ (1,093,778)	\$ 249,175	\$ (3,494,465)
Tax (Benefit)/Expense	(238,104)	143,353	(1,425,781)	316,200
Depreciation and Amortization	115,934	115,637	349,822	297,801
Interest Expense/(Income), Net	2,838	(9,662)	(16,883)	(23,690)
Reorganization Charges	(1,262)	—	1,192,618	—
Discontinued Product Expenses	—	(6,659)	—	71,318
Litigation Expenses	—	675	—	2,446,747
Manufacturing Initiative Expenses	35,892	59,045	237,333	194,804
Stock-based Compensation Expense	628,276	406,325	1,967,632	1,191,146
Non-GAAP Adjusted EBITDA	\$ (550,204)	\$ 957,889	\$ (1,189,724)	\$ 4,116,891

<b>Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS*:</b>	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>	<b>2021</b>	<b>2020</b>
	Reported Diluted Earnings Per Share	\$ (0.02)	\$ 0.01	\$ (0.08)
Reorganization Charges	—	—	0.03	—
Discontinued Product Expense	—	—	—	—
Litigation Expenses	—	—	—	0.06
Manufacturing Initiative Expenses	—	—	0.01	—
Stock-based Compensation Expense	—	—	0.01	—
Tax (Expense) Adjustment	—	—	(0.01)	(0.01)
Non-GAAP Adjusted Diluted Earnings Per Share	\$ (0.02)	\$ 0.01	\$ (0.04)	\$ 0.04

\*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. 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 nine months ended September 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 the only amount included in Stock-based Compensation Expense in calculating Adjusted Diluted EPS.