

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) March 23, 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 23, 2021, Repro Med Systems, Inc. dba KORU Medical Systems (“KORU”) issued a press release announcing its operating and financial results for the three and twelve months ended December 31, 2020 and first quarter 2021 guidance. A related conference will be held on March 23, 2021 at 4:30 am Eastern Time.

KORU is making reference to non-GAAP financial information in both the press release and the conference call. A reconciliation of GAAP to non-GAAP results is provided in the attached Exhibit 99.1 press release.

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 March 23, 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: March 23, 2021

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



KORU Medical Systems Reports Fourth Quarter and Full Year 2020 Financial Results

CHESTER, NY – March 23, 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 fourth quarter and full year ended December 31, 2020.

2020 Full Year Financial Highlights:

- Net revenue of \$24.2 million
- Gross margin of 62%
- Net loss of \$1.2 million
- Ended the year with \$27.3 million in cash and cash equivalents

Q4 2020 Financial Highlights:

- Net revenue of \$4.1 million
- Gross margin of 57%
- Net loss of \$0.8 million

“Like many companies in the healthcare sector, 2020 was a challenging year for KORU Medical,” said Jim Beck, Interim Chief Executive Officer. “Despite these challenges, we made progress on many fronts and our employees have remained steadfast in their commitment to improving patients’ lives through the use of our specialty infusion solutions. As we move into 2021, our Company remains focused on executing our long-term strategies to drive growth and expand the market for subcutaneous infusions for life-saving therapies. We are excited about our new CEO and are confident that under Linda Tharby’s direction, KORU Medical is well positioned for our next phase of growth.”

2020 Full Year Financial Results

Net sales were \$24.2 million for 2020, a 4.4% increase from \$23.2 million in 2019. Growth was primarily driven by an increase in product sales volume and higher novel therapies sales of \$0.9 million, offset by higher allowances which include (i) rebates resulting from the net impact of pricing increases at our largest distributor in the second half of 2019, and (ii) pricing decreases and growth rebates to secure our contractual position with several large customers in 2020. Further increasing allowances were payment discounts and distribution fees at our largest distributor under new contract terms entered into the fourth quarter of 2019.

Gross margin was 62% in 2020 compared to 64% in 2019. The decrease was primarily driven by the higher allowances as described above.

Total operating expenses increased 13% to \$16.2 million in 2020 compared to \$14.3 million in 2019. The increase was primarily driven by salary and related benefits and consulting fees related to marketing, regulatory and strategic initiatives, partially offset by lower trade show and travel expenses due to COVID-19 related travel restrictions and lower legal fees.

Net loss was \$1.2 million in 2020, which includes the non-cash settlement expense of \$2.2 million, compared to net income of \$0.6 million in 2019.

Adjusted EBITDA for 2020 was \$3.7 million compared to \$6.2 million in 2019.

Our inventory position grew from \$2.4 million at December 31, 2019 to \$6.8 million at December 31, 2020 mostly to ensure timely order fulfillment as we transition manufacturing of our needle sets and tubing products for supply continuity to Command Medical Products, Inc. As the transition is completed this inventory is expected to convert to a source of cash in the future.

Cash and cash equivalents were \$27.3 million as of December 31, 2020.

Q4 2020 Financial Results

Net sales were \$4.1 million for Q4 2020, a 34.8% decrease from \$6.2 million in Q4 2019. Net sales were down primarily due to inventory in the channel from the precautionary buying related to COVID-19 in the first half of the year and the large early order placed in the third quarter of 2020, as well as lower international sales and novel therapies sales, which currently includes clinical trial sales. Higher allowances also contributed to lower net sales in the quarter.

Gross margin was 57% in Q4 2020 compared to 63% in Q4 2019, primarily driven by lower net sales for reasons described above.

Total operating expenses decreased 15.7% to \$3.5 million in Q4 2020 compared to \$4.1 million in Q4 2019. The decrease was primarily due to lower litigation expense and lower bonus accrual, partially offset by consulting for sustainability and strategic initiatives.

Net loss was \$0.8 million in Q4 2020, compared to a net loss of \$0.1 million in Q4 2019.

Adjusted EBITDA for Q4 2020 was (\$0.3) million compared to \$1.5 million in Q4 2019.

Financial Guidance

While KORU Medical Systems does not intend to provide quarterly guidance in the future, and given the timing of its release in the quarter, the Company expects net sales for the first quarter of 2021 to be at least \$5.0 million.

Stock Repurchase Plan

As announced on November 16, 2020, the Board of Directors authorized a stock repurchase program under which the Company may purchase up to \$10.0 million of its outstanding common stock through December 31, 2021. Through December 31, 2020, the Company had acquired 683,271 shares of its outstanding common stock for a total purchase price of \$3.5 million.

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 that involve risks and uncertainties. Forward-looking statements can be identified by words such as “may,” “believe” and “enables.” 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 COVID-19, future operating results, availability of investment opportunities, market fluctuations, 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 23, 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

	<u>December 31,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 27,315,286	\$ 5,870,929
Accounts receivable less allowance for doubtful accounts of \$24,469 and \$32,645 for December 31, 2020, and December 31, 2019, respectively	2,572,954	3,234,521
Inventory	6,829,772	2,388,477
Prepaid expenses	807,780	387,396
TOTAL CURRENT ASSETS	37,525,792	11,881,323
Property and equipment, net	1,167,623	611,846
Intangible assets, net of accumulated amortization of \$199,899 and \$288,967 at December 31, 2020 and December 31, 2019, respectively	843,587	807,135
Operating lease right-of-use assets	236,846	373,734
Deferred income tax assets, net	125,274	188,241
Other assets	19,812	19,582
TOTAL ASSETS	\$ 39,918,934	\$ 13,881,861
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 624,920	\$ 572,656
Accrued expenses	2,610,413	1,296,612
Accrued payroll and related taxes	287,130	190,265
Accrued tax liability	—	204,572
Finance lease liability – current	2,646	5,296
Operating lease liability – current	141,293	136,888
TOTAL CURRENT LIABILITIES	3,666,402	2,406,289
Finance lease liability, net of current portion	—	2,646
Operating lease liability, net of current portion	95,553	236,846
TOTAL LIABILITIES	3,761,955	2,645,781
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 46,680,119 and 42,239,788 shares issued; 43,259,617 and 39,502,557 shares outstanding at December 31, 2020, and December 31, 2019, respectively	466,801	422,398
Additional paid-in capital	35,880,986	6,293,069
Treasury stock, 3,420,502 shares and 2,737,231 shares at December 31, 2020 and December 31, 2019, respectively, at cost	(3,843,562)	(344,204)
Retained earnings	3,652,754	4,864,817
TOTAL STOCKHOLDERS' EQUITY	36,156,979	11,236,080
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 39,918,934	\$ 13,881,861

REPRO MED SYSTEMS, INC.
STATEMENTS OF OPERATIONS

	For the Three Months Ended December 31,		For the Years Ended December 31,	
	2020	2019	2020	2019
NET SALES	\$ 4,057,220	\$ 6,222,134	\$ 24,176,448	\$ 23,162,621
Cost of goods sold	1,759,947	2,274,850	9,240,362	8,308,811
Gross Profit	2,297,273	3,947,284	14,936,086	14,853,810
OPERATING EXPENSES				
Selling, general and administrative	2,988,330	2,794,861	12,028,310	9,771,744
Litigation	466	934,412	2,447,213	3,415,683
Research and development	352,116	290,020	1,296,753	740,475
Depreciation and amortization	120,794	87,635	418,595	340,229
Total Operating Expenses	3,461,706	4,106,928	16,190,871	14,268,131
Net Operating (Loss)/Profit	(1,164,433)	(159,644)	(1,254,785)	585,679
Non-Operating Income				
Gain/(Loss) on currency exchange	12,700	2,529	1,536	(17,754)
(Loss)/Gain on disposal of fixed assets, net	—	(1,910)	16,591	47,830
Interest income, net	18,705	21,572	42,395	80,663
TOTAL OTHER INCOME	31,405	22,191	60,522	110,739
(LOSS)/INCOME BEFORE INCOME TAXES	(1,133,028)	(137,453)	(1,194,263)	696,418
Income Tax Benefit/(Expense)	298,400	57,197	(17,800)	(132,069)
NET (LOSS)/INCOME	<u>\$ (834,628)</u>	<u>\$ (80,256)</u>	<u>\$ (1,212,063)</u>	<u>\$ 564,349</u>
NET (LOSS)/INCOME PER SHARE				
Basic	<u>\$ (0.02)</u>	<u>\$ 0.00</u>	<u>\$ (0.03)</u>	<u>\$ 0.01</u>
Diluted	<u>\$ (0.02)</u>	<u>\$ 0.00</u>	<u>\$ (0.03)</u>	<u>\$ 0.01</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	<u>43,732,728</u>	<u>39,502,152</u>	<u>41,929,736</u>	<u>38,778,074</u>
Diluted	<u>43,732,728</u>	<u>39,502,152</u>	<u>41,929,736</u>	<u>39,061,310</u>

REPRO MED SYSTEMS, INC.
STATEMENTS OF CASH FLOWS

For the Years Ended
December 31,

	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (Loss)/Income	\$ (1,212,063)	\$ 564,349
Adjustments to reconcile net (loss)/income to net cash (used in)/provided by operating activities:		
Stock-based compensation expense	1,618,732	1,204,844
Stock-based litigation settlement expense	1,285,102	—
Depreciation and amortization	418,595	340,229
Gain on disposal of fixed assets	(16,591)	(47,830)
Deferred capital gain – building lease	—	(3,763)
Deferred income taxes	62,967	(186,775)
Provision for doubtful accounts	(8,176)	(4,855)
Abandonment of intangible assets	41,919	—
Changes in operating assets and liabilities:		
Decrease/(Increase) in accounts receivable	669,743	(1,803,812)
Increase in inventory	(4,441,295)	(284,598)
Increase in prepaid expenses and other assets	(420,614)	(140,805)
Increase in accounts payable	52,264	119,158
Increase/(Decrease) in accrued payroll and related taxes	96,865	(231,449)
Increase in accrued expenses	1,313,801	607,963
(Decrease)/Increase in accrued tax liability	(204,572)	187,964
NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES	(743,323)	320,620
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(920,604)	(201,174)
Purchases of intangible assets	(140,548)	(224,365)
Proceeds from certificates of deposit	—	1,517,927
Proceeds from disposal of property and equipment	25,000	217,821
NET CASH (USED IN)/PROVIDED BY INVESTING ACTIVITIES	(1,036,152)	1,310,209
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of equity	26,728,486	508,900
Purchase of treasury stock	(3,499,358)	—
Borrowings from indebtedness	4,976,508	—
Payments on indebtedness	(4,976,508)	—
Payments on finance lease liability	(5,296)	(4,783)
Payment for cancelled shares	—	(2,820)
NET CASH PROVIDED BY FINANCING ACTIVITIES	23,223,832	501,297
NET INCREASE IN CASH AND CASH EQUIVALENTS	21,444,357	2,132,126
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	5,870,929	3,738,803
CASH AND CASH EQUIVALENTS, END OF YEAR	\$ 27,315,286	\$ 5,870,929

Supplemental Information

Cash paid during the years for:

Interest	\$ 27,736	\$ 342
Income taxes	\$ 321,983	\$ 130,879

Schedule of Non-Cash Investing and Financing Activities:

Non-cash equity issuance for the EMED Settlement	\$ 938,094	\$ —
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A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net (Loss)/Income to Non-GAAP Adjusted EBITDA:	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
GAAP Net (Loss)/Income	\$ (834,628)	\$ (80,256)	\$ (1,212,063)	\$ 564,349
Income Tax (Benefit)/Expense	(298,400)	(57,197)	17,800	132,069
Depreciation and Amortization	120,794	87,635	418,595	340,229
Interest Income, Net	(18,705)	(21,572)	(42,395)	(80,663)
Reorganization Charges	95,700	—	95,700	354,926
Discontinued Product (Income)/Expense	(459)	—	70,859	—
Litigation	466	934,212	2,447,213	3,415,683
Manufacturing Initiative Expenses	51,723	110,282	246,527	230,668
Stock-based Compensation Expense	607,592	564,069	1,618,732	1,204,844
Non-GAAP Adjusted EBITDA	<u>\$ (275,917)</u>	<u>\$ 1,537,173</u>	<u>\$ 3,660,968</u>	<u>\$ 6,162,105</u>