

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 3, 2020

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 November 3, 2020, Rebro Med Systems, Inc. dba KORU Medical Systems (“KORU”) issued a press release announcing its operating and financial results for the third quarter ended September 30, 2020. A related conference will be held on November 4, 2020 at 9:00 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	<u>Press release dated November 3, 2020</u>

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 3, 2020

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



FOR IMMEDIATE RELEASE

KORU MEDICAL SYSTEMS ANNOUNCES FINANCIAL RESULTS FOR THIRD QUARTER 2020

CHESTER, NY – November 3, 2020 – **Repro Med Systems, Inc. dba KORU Medical Systems (NASDAQ: KRMD)** (“**KORU Medical**” or the “**Company**”) today announced financial results for the third quarter ended September 30, 2020 (“**Q3 2020**”).

Q3 2020 Overview

“The strength and resiliency of our core business, which provides our Freedom Integrated Infusion System to individuals with Primary Immune Deficiency Disease and Chronic Inflammatory Demyelinating Polyneuropathy, is helping us navigate the challenges of the COVID-19 pandemic. Our total net sales declined in Q3 2020 primarily attributable to lower clinical trial activity and allowances associated with U.S. sales. Net sales for the first nine months of 2020 rose 19% from the same period last year and volume growth continued within our business.”

Mr. Pettigrew continued, “We are continuing to manage our operations to deliver growth by capitalizing on multiple, sustainable long-term growth drivers. We remain confident in the strength of our core business, which is predominantly comprised of recurring revenues and excludes clinical trials. Our core business is likely to continue to grow given the heightened awareness of PIDD and CIDP diseases, proven and effective immunoglobulin therapy, the benefits of at home treatment, growing addressable patient populations, and an increasing focus by pharmaceutical manufacturers to develop subcutaneous drugs that allow individuals to self-administer these therapies at home. We believe we remain well-positioned to further capture clinical trials sales, support expanded drug indications for existing therapies, and pursue international expansion as the effects of the pandemic subside. Our business fundamentals and cash position remain strong.”

Update on Strategic Growth Initiatives

Hematology Drug Launch and Additional Clinical Trial Participation

The Freedom System was utilized in a recently completed Phase III clinical trial for a subcutaneous hematology drug. This drug is aimed at treating paroxysmal nocturnal hemoglobinuria (PNH), a rare, chronic blood disorder that affects over 15,000 patients worldwide. KORU Medical expects that this new drug will launch in 2021 and that the Freedom System will be the preferred delivery method. The Company also believes that the Freedom System will be utilized in several additional upcoming clinical trials with this same drug focused on expanding indications and disease states for larger patient populations.

“The new PNH drug is progressing towards its planned launch in 2021 and is currently being trialed in other indications using the Freedom System. Relationships such as this are an essential part of our strategic plan as this PNH indication alone has the potential to significantly expand our core business,” said Mr. Pettigrew.

Q3 2020 Financial Results Summary

Net sales were \$6.1 million in Q3 2020 compared to \$6.6 million in last year’s third quarter.

Gross profit in Q3 2020 was \$3.9 million, or 64.8% of net sales, compared to \$4.4 million, or 66.2% of net sales, in Q3 2019, reflecting lower net sales.

Total operating expenses in Q3 2020 remained stable at \$3.6 million from Q3 2019.

Net income for Q3 2020 was \$0.2 million, or \$0.01 per share, compared to net income in Q3 2019 of \$0.7 million, or \$0.02 per share.

Q3 2020 Adjusted EBITDA was \$0.9 million compared to Adjusted EBITDA of \$2.2 million in Q3 2019. Adjusted EBITDA excludes from net income / (loss): income tax expense, depreciation and amortization, interest income, net, discontinued product expense, litigation expenses including stock-based settlement expense, manufacturing initiative expenses, and stock option expense.

Balance Sheet Summary

Cash and cash equivalents as of September 30, 2020 totaled \$32.4 million, with the increase from December 31, 2019 reflecting \$26.5 million of net proceeds from the capital raise completed in Q2 2020.

Non-GAAP Measures

This press release includes the non-GAAP financial measure of “Adjusted EBITDA” that is not in accordance with, nor an alternate to, generally accepted accounting principles and may be different from non-GAAP measures used by other companies. In addition, this non-GAAP measure is 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 our reported results and, therefore, should not be relied upon as the sole financial measures to evaluate our financial results. The non-GAAP financial measure is meant to supplement, and to be viewed in conjunction with, GAAP financial results. A reconciliation of our non-GAAP measure is included in an attachment to this press release.

Conference Call

Management will host a conference call on Wednesday, November 4, 2020 at 9:00 am ET to discuss the results and business activities. Interested parties may participate in the call by dialing:

- (877) 407-9753 (*Domestic*) or
- (201) 493-6739 (*International*)

Webcast registration: [Click Here](#)

Following the live call, a replay will be available for six months on the Company’s website, www.korumedical.com under “Investor Relations.”

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 “will,” “expects,” “likely,” “look forward,” “planned,” “potential,” and “believe.” 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, such as uncertainties associated with COVID-19, future operating results, Food and Drug Administration regulations, introduction of competitive products, acceptance of and demand for new and existing products, ability to penetrate new markets, success in enforcing and obtaining patents, reimbursement related risks, government regulation of the home health care industry, success of the research and development effort, expanding the market of FREEDOM60[®] demand in the SCIG market, availability of sufficient capital if or when needed, dependence on key personnel, and the impact of recent accounting pronouncements; 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, 2019, and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2020, which are on file with the SEC and are 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 November 3, 2020. 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.

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REPRO MED SYSTEMS, INC.
BALANCE SHEETS
(Unaudited)

ASSETS	September 30, 2020	December 31, 2019
CURRENT ASSETS		
Cash and cash equivalents	\$ 32,433,811	\$ 5,870,929
Accounts receivable less allowance for doubtful accounts of \$24,676 and \$32,645 at September 30, 2020 and December 31, 2019, respectively	3,736,596	3,234,521
Inventory	5,633,139	2,388,477
Prepaid expenses	844,496	387,396
TOTAL CURRENT ASSETS	42,648,042	11,881,323
Property and equipment, net	1,260,675	611,846
Patents, net of accumulated amortization of \$335,686 and \$288,967 at September 30, 2020 and December 31, 2019, respectively	884,635	807,135
Right of use assets, net	271,679	373,734
Deferred tax asset	349,609	188,241
Other assets	19,812	19,582
TOTAL ASSETS	\$ 45,434,452	\$ 13,881,861
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	1,363,070	572,656
Accrued expenses	3,051,582	1,296,612
Accrued payroll and related taxes	440,144	190,265
Accrued tax liability	363,158	204,572
Finance lease liability – current	3,026	5,296
Operating lease liability – current	140,450	136,888
TOTAL CURRENT LIABILITIES	5,361,430	2,406,289
Finance lease liability, net of current portion	414	2,646
Operating lease liability, net of current portion	131,229	236,846
TOTAL LIABILITIES	5,493,073	2,645,781
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value; 75,000,000 shares authorized, 46,671,807 and 42,239,788 shares issued, 43,934,576 and 39,502,557 shares outstanding at September 30, 2020 and December 31, 2019, respectively	466,718	422,398
Additional paid-in capital	35,331,483	6,293,069
Treasury stock, 2,737,231 shares at September 30, 2020 and December 31, 2019, respectively, at cost	(344,204)	(344,204)
Retained earnings	4,487,382	4,864,817
TOTAL STOCKHOLDERS' EQUITY	39,941,379	11,236,080
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 45,434,452	\$ 13,881,861

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
NET SALES	\$ 6,080,315	\$ 6,617,397	\$ 20,119,228	\$ 16,940,487
Cost of goods sold	2,139,592	2,234,489	7,480,415	6,033,961
Gross Profit	3,940,723	4,382,908	12,638,813	10,906,526
OPERATING EXPENSES				
Selling, general and administrative	3,075,169	2,441,381	9,039,980	6,976,684
Litigation	675	864,009	2,446,747	2,481,471
Research and development	390,416	170,260	944,637	450,454
Depreciation and amortization	115,637	82,774	297,801	252,594
Total Operating Expenses	3,581,897	3,558,424	12,729,165	10,161,203
Net Operating Profit/(Loss)	358,826	824,484	(90,352)	745,323
Non-Operating Income/(Expense)				
Gain/(Loss) on currency exchange	1,927	(9,358)	(11,164)	(20,283)
Gain on disposal of fixed assets, net	22,113	—	16,591	49,740
Interest income, net	9,662	23,368	23,690	59,091
TOTAL OTHER INCOME/(EXPENSE)	33,702	14,010	29,117	88,548
INCOME/(LOSS) BEFORE INCOME TAXES	392,528	838,494	(61,235)	833,871
Income Tax Expense	(143,353)	(186,681)	(316,200)	(189,265)
NET INCOME/(LOSS)	<u>\$ 249,175</u>	<u>\$ 651,813</u>	<u>\$ (377,435)</u>	<u>\$ 644,606</u>
NET INCOME/(LOSS) PER SHARE				
Basic	<u>\$ 0.01</u>	<u>\$ 0.02</u>	<u>\$ (0.01)</u>	<u>\$ 0.02</u>
Diluted	<u>\$ 0.01</u>	<u>\$ 0.02</u>	<u>\$ (0.01)</u>	<u>\$ 0.02</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	<u>43,914,542</u>	<u>39,022,298</u>	<u>41,326,815</u>	<u>38,534,021</u>
Diluted	<u>44,119,511</u>	<u>39,298,408</u>	<u>41,326,815</u>	<u>38,734,083</u>

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

	Nine Months Ended September 30,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (Loss)/Income	\$ (377,435)	\$ 644,606
Adjustments to reconcile net (loss)/income to net cash provided by/(used in) operating activities:		
Stock-based compensation expense	1,191,146	897,300
Stock-based litigation settlement expense	1,285,102	—
Depreciation and amortization	297,801	252,594
Deferred capital gain - building lease	—	(3,763)
Deferred taxes	(161,368)	134,563
Gain on disposal of fixed assets	(16,591)	(49,740)
Changes in operating assets and liabilities:		
Increase in accounts receivable	(502,075)	(2,120,780)
Increase in inventory	(3,244,662)	(634,803)
Increase in prepaid expenses and other assets	(457,330)	(206,560)
Increase in accounts payable	790,414	421,479
Increase/(Decrease) in accrued payroll and related taxes	249,879	(310,355)
Increase in accrued expenses	1,754,970	490,053
Increase/(Decrease) in accrued tax liability	158,586	(16,608)
NET CASH PROVIDED BY/(USED IN) OPERATING ACTIVITIES	968,437	(502,014)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(908,323)	(158,193)
Purchases of patents	(124,216)	(188,274)
Proceeds from disposal of property and equipment	25,000	217,821
Proceeds from certificate of deposit	—	1,517,927
NET CASH (USED IN)/PROVIDED BY INVESTING ACTIVITIES	(1,007,539)	1,389,281
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of equity	26,606,486	508,900
Payments for cancelled shares	—	(2,820)
Borrowings from indebtedness	4,976,508	—
Payments on indebtedness	(4,976,508)	—
Payments on finance lease liability	(4,502)	(3,122)
NET CASH PROVIDED BY FINANCING ACTIVITIES	26,601,984	502,958
NET INCREASE IN CASH AND CASH EQUIVALENTS	26,562,882	1,390,225
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	5,870,929	3,738,803
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 32,433,811	\$ 5,129,028
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 27,698	\$ 280
Income taxes	\$ 318,983	\$ 103,465

Reconciliation of GAAP Net Income/(Loss) to Non-GAAP Adjusted EBITDA:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
GAAP Net Income/(Loss)	\$ 249,175	\$ 651,813	\$ (377,435)	\$ 644,606
Income Tax Expense	143,353	186,681	316,200	189,265
Depreciation and Amortization	115,637	82,774	297,801	252,594
Interest Income, Net	(9,662)	(23,368)	(23,690)	(59,091)
Reorganization Charges	—	—	—	354,926
Discontinued Product Expense	(6,659)	—	71,318	—
Litigation*	675	864,009	2,446,747	2,481,471
Manufacturing Initiative Expenses	59,045	120,386	194,804	120,386
Stock Option Expense	346,323	324,135	1,011,140	640,775
Non-GAAP Adjusted EBITDA	<u>\$ 897,887</u>	<u>\$ 2,206,430</u>	<u>\$ 3,936,885</u>	<u>\$ 4,624,932</u>

* For the nine months ended September 30, 2020, litigation consisted of a \$2.2 million non-cash, stock-based settlement expense.