

KORU Medical Systems Announces 2021 Third Quarter Financial Results

CHESTER, N.Y.--(BUSINESS WIRE)-- 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 guarter 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.

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 and on the SEC website at 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.

REPRO MED SYSTEMS, INC. BALANCE SHEETS (UNAUDITED)

(5.0.105.1125)					
	Se	eptember 30, 2021	December 31, 2020		
ASSETS					
CURRENT ASSETS					
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	
TOTAL CURRENT ASSETS		37,660,827		37,525,792	
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	
TOTAL ASSETS	\$	41,358,091	\$	39,918,93	
LIABILITIES AND STOCKHOLDERS' EQUITY					
CURRENT LIABILITIES					
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		_	
TOTAL CURRENT LIABILITIES		4,559,850		3,666,402	
Operating lease liability, net of current portion		<u></u> _		95,553	
TOTAL LIABILITIES		4,559,850		3,761,955	
Commitments and contingencies (Refer to Note 3)					
STOCKHOLDERS' EQUITY					
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		466,80	
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	
TOTAL STOCKHOLDERS' EQUITY		36,798,241		36,156,979	
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	41,358,091	\$	39,918,934	

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

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	Three Months Ended September 30,					Nine Months Ended 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	Ξ	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	\$	(80.0)	\$	(0.01)			
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING											
Basic		44,322,335		43,914,542		44,510,021		41,326,815			
	_	44,322,335	_	44,119,511	_	44,510,021		41,326,815			
Diluted	_	11,022,000	_	17,110,011	_	14,010,021	_	11,020,010			

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

For the

	For the Nine Months Septembe			Ended		
	_	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:	•	(-, - , ,	•	(- ,)		
		1,967,632		1,191,146		
Stock-based compensation expense				4 005 400		
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		
NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES		(3,602,378)		968.437		
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CASH FLOWS FROM INVESTING ACTIVITIES						
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)		
NET CASH USED IN INVESTING ACTIVITIES		(318,493)		(1,007,539)		
	_			,		
CASH FLOWS FROM FINANCING ACTIVITIES						
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)		
NET CASH PROVIDED BY FINANCING ACTIVITIES		2,838,996		26,601,984		
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS		(1,081,875)		26,562,882		
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD						
	_	27,315,286		5,870,929		
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	26,233,411	\$	32,433,811		
Supplemental Information						
Supplemental Information Cash paid during the periods for:						
	\$	6,194	\$	27,698		
Interest	_		Ė			
Income Taxes	\$	850	\$	318,983		
Schedule of Non-Cash Operating, Investing and Financing Activities:						
Issuance of common stock as compensation	\$	295,947	\$	180,006		
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REPRO MED SYSTEMS, INC.

Issuance of common stock as settlement for litigation

\$

938,094

938,094

SUPPLEMENTAL INFORMATION

(UNAUDITED)

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

	Three M Ended Sept	 	Nine Months Ended September 30,						
	2021	2020	2021	2020					
Net Sales			 						
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					
Total	\$ 6,040,544	\$ 6,080,315	\$ 16,999,669	\$ 20,119,228					

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

Reconciliation of Reported Net Sales to Non-GAAP Net Sales		Three Mon Septem		Change from Prior Year			
		2021		2020	_	\$	%
Reported Net Sales	\$	6,040,544	\$	6,080,315	\$	(39,771)	(0.7%)
Early Order/Inventory Stocking		_		(552,000)		552,000	(100.0%)
Non-GAAP Adjusted Net Sales	\$	6.040,544	\$	5,528,315	\$	512,229	9.3%

Reconciliation of Reported Net Sales to Non-GAAP Net Sales		Nine Mont Septem		Change from Prior Year				
		2021	2020		\$	%		
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%)		
Non-GAAP Adjusted Net Sales	\$	16,999,669	\$ 18,784,228	\$	(1,784,559)	(9.5%)		

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.

REPRO MED SYSTEMS, INC. SUPPLEMENTAL INFORMATION (UNAUDITED)

A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net (Loss)/Income	Three Month Septemb			Nine Months Ended September 30,																																																																						
to Non-GAAP Adjusted EBITDA:	 2021	2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2020		2021 2020		2021		2020
GAAP Net Loss	\$ (1,093,778)	\$	249,175	\$ (3,494,465)	\$	(377,435)																																																																				
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																																																																				

Reconciliation of Reported Diluted EPS		i hree Mont Septemi		Nine Months Ended September 30,				
to Non-GAAP Adjusted Diluted EPS*:	2021 2020		- :	2021	2020			
Reported Diluted Earnings Per Share	\$	(0.02)	\$	0.01	\$	(80.0)	\$ (0.01)	
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	

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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.

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^{*}Numbers presented are rounded to the nearest whole cent

Source: KORU Medical Systems