UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

[X] QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Quarterly Period Ended September 30, 2021

or

[_] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____.

Commission File Number: **0-12305**

REPRO MED SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

New York	**13-3044880**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
24 Carpenter Road, Chester, New York	**10918**
(Address of principal executive offices)	(Zip Code)

(845) 469-2042
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.01 par value	**KRMD**	**The Nasdaq Stock Market**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. **[X]** Yes [_] No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). **[X]** Yes [_] No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer [_]	Accelerated filer [_]
Non-accelerated filer **[X]**	Smaller reporting company **[X]**
	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. [_]

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). [_] Yes **[X]** No

As of November 10, 2021, 44,561,160 shares of common stock, $0.01 par value per share, were outstanding, which excludes 3,420,502 shares of treasury stock.

REPRO MED SYSTEMS, INC.
FORM 10-Q
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2021
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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

REPRO MED SYSTEMS, INC.
BALANCE SHEETS
(UNAUDITED)

	September 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	$ 39,918,934
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	—	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	466,801
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
TOTAL STOCKHOLDERS' EQUITY	36,798,241	36,156,979
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 41,358,091	$ 39,918,934

The accompanying notes are an integral part of these financial statements.

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

	Three Months Ended	Nine Months Ended

	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 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

The accompanying notes are an integral part of these financial statements.

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
NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES	(3,602,378)	968,437
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		
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

The accompanying notes are an integral part of these financial statements.

REPRO MED SYSTEMS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Common Stock		Additional Paid-in	Retained	Treasury	Total Stockholders'
	Shares	Amount	Capital	Earnings	Stock	Equity
Three and Nine Months Ended September 30, 2021						
BALANCE, DECEMBER 31, 2020	46,680,119	$ 466,801	$ 35,880,986	$ 3,652,754	$ (3,843,562)	$ 36,156,979
Issuance of stock-based compensation	10,124	101	56,149	—	—	56,250
Compensation expense related to stock options	—	—	677,934	—	—	677,934
Litigation settlement share issuance	95,238	952	937,142	—	—	938,094
Issuance upon options exercised	1,110,580	11,106	1,218,894	—	—	1,230,000
Net loss	—	—	—	(1,276,138)	—	(1,276,138)
BALANCE, MARCH 31, 2021	47,896,061	$ 478,960	$ 38,771,105	$ 2,376,616	$ (3,843,562)	$ 37,783,119
Issuance of stock-based compensation	14,615	146	97,050	—	—	97,196
Compensation expense related to stock options	—	—	441,841	—	—	441,841
Compensation expense related to restricted stock awards	—	—	66,135	—	—	66,135
Net loss	—	—	—	(1,124,549)	—	(1,124,549)
BALANCE, JUNE 30, 2021	47,910,676	$ 479,106	$ 39,376,131	$ 1,252,067	$ (3,843,562)	$ 37,263,742
Issuance of stock-based compensation	20,988	211	142,290	—	—	142,501
Compensation expense related to stock options	—	—	406,414	—	—	406,414
Compensation expense related to restricted stock awards	—	—	79,362	—	—	79,362
Net loss	—	—	—	(1,093,778)	—	(1,093,778)
BALANCE, SEPTEMBER 30, 2021	47,931,664	$ 479,317	$ 40,004,197	$ 158,289	$ (3,843,562)	$ 36,798,241

The accompanying notes are an integral part of these financial statements.

REPRO MED SYSTEMS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)

	Common Stock		Additional Paid-in	Retained	Treasury	Total Stockholders'
	Shares	Amount	Capital	Earnings	Stock	Equity
Three and Nine Months Ended September 30, 2020						
BALANCE, DECEMBER 31, 2019	42,239,788	$ 422,398	$ 6,293,069	$ 4,864,817	$ (344,204)	$ 11,236,080
Issuance of stock-based compensation	9,189	92	59,910	—	—	60,002
Compensation expense related to stock options	—	—	300,966	—	—	300,966
Cancellation of common stock	—	—	—	—	—	—

Issuance upon options exercised	175,000	1,750	83,750	—	—	85,500
Net income	—	—	—	449,428	—	449,428
BALANCE, MARCH 31, 2020	42,423,977	$ 424,240	$ 6,737,695	$ 5,314,245	$ (344,204)	$ 12,131,976
Issuance of stock-based compensation	7,999	80	59,922	—	—	60,002
Compensation expense related to stock options	—	—	363,851	—	—	363,851
Litigation settlement options	—	—	347,008	—	—	347,008
Litigation settlement share issuance	95,238	952	937,142	—	—	938,094
Issuance upon options exercised	519,156	5,192	5,189	—	—	10,381
Capital raise	3,593,750	35,937	26,436,043	—	—	26,471,980
Net loss	—	—	—	(1,076,038)	—	(1,076,038)
BALANCE, JUNE 30, 2020	46,640,120	$ 466,401	$ 34,886,850	$ 4,238,207	$ (344,204)	$ 39,247,254
Issuance of stock-based compensation	6,681	67	59,935	—	—	60,002
Compensation expense related to stock options	—	—	346,323	—	—	346,323
Issuance upon options exercised	25,006	250	(250)	—	—	—
Capital raise	—	—	38,625	—	—	38,625
Net income	—	—	—	249,175	—	249,175
BALANCE, SEPTEMBER 30, 2020	46,671,807	$ 466,718	$ 35,331,483	$ 4,487,382	$ (344,204)	$ 39,941,379

The accompanying notes are an integral part of these financial statements.

REPRO MED SYSTEMS, INC.
NOTES TO THE UNAUDITED FINANCIAL STATEMENTS

NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF OPERATIONS

REPRO MED SYSTEMS, INC. d/b/a KORU Medical Systems (the "Company," "KORU Medical," "we," "us" or "our") designs, manufactures and markets proprietary portable and innovative medical devices primarily for the ambulatory infusion market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international standards for quality system management. The Company operates as one segment.

BASIS OF PRESENTATION

The accompanying financial statements should be read in conjunction with the Company's annual report on Form 10-K for the year ended December 31, 2020 ("Annual Report"). Certain information and footnote disclosures normally included in annual financial statements prepared in accordance with United States generally accepted accounting principles ("GAAP") have been condensed or omitted from the accompanying financial statements. The accompanying year-end balance sheet was derived from the audited financial statements included in the Annual Report. The accompanying interim financial statements are unaudited and reflect all adjustments which are in the opinion of management necessary for a fair statement of the Company's financial position, results of operations, and cash flows for the periods presented. All such adjustments are of a normal, recurring nature. The Company's results of operations and cash flows for the interim periods are not necessarily indicative of the results of operations and cash flows that it may achieve in future periods.

CASH AND CASH EQUIVALENTS

For purposes of the statement of cash flows, the Company considers all short-term investments with an original maturity of three months or less to be cash equivalents. The Company holds cash in excess of $250,000 at its depository, which exceeds the FDIC insurance limits and is, therefore, uninsured.

INVENTORY

Inventories of raw materials are stated at the lower of standard cost, which approximates average cost, or market value including allocable overhead. Work-in-process and finished goods are stated at the lower of standard cost or market value and include direct labor and allocable overhead.

PATENTS

Costs incurred in obtaining patents have been capitalized and are being amortized over the legal life of the patents.

INCOME TAXES

Deferred income taxes are provided using the liability method whereby deferred tax assets are recognized for deductible temporary differences and operating loss and tax credit carry forwards and deferred tax liabilities are recognized for taxable temporary differences.

The Company believes that it has no uncertain tax positions requiring disclosure or adjustment. Generally, tax years starting with 2018 are subject to examination by income tax authorities.

PROPERTY, EQUIPMENT, AND DEPRECIATION

Property and equipment is stated at cost and is depreciated using the straight-line method over the estimated useful lives of the respective assets.

STOCK-BASED COMPENSATION

The Company maintains a stock option plan under which it grants stock options to certain executives, key employees and consultants.

The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. All options are charged against income at their fair value. The entire compensation expense of the award is recognized over the vesting period. Shares of stock granted for director fees are recorded at the fair value of the shares at the grant date.

The Company also maintains an omnibus equity incentive plan. To date the Company has only granted shares of stock for director fees under this plan and those shares of stock granted are recorded at the fair value of the shares at the grant date.

The Company issues restricted stock awards. Restricted stock awards are equity classified and measured at the fair market value of the underlying stock at the grant date. The fair value of restricted stock awards vesting at certain market capitalization thresholds were estimated on the date of grant using the Brownian Motion Monte Carlo lattice model. The fair value of restricted stock awards with time-based vesting were estimated on the date of grant at the current stock price. We recognize restricted stock expense using the straight-line attribution method over the requisite service period and account for forfeitures as they occur.

NET INCOME PER COMMON SHARE

Basic earnings per share are computed on the weighted average of common shares outstanding during each year. Diluted earnings per share include only an increase in the weighted average shares by the common shares issuable upon exercise of employee and consultant stock options. See "NOTE 4 — STOCK-BASED COMPENSATION" for further detail.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net (loss)/income	$ (1,093,778)	$ 249,175	$ (3,494,465)	$ (377,435)
Weighted Average Outstanding Shares:				
Outstanding shares	44,322,335	43,914,542	44,510,021	41,326,815
Option shares includable	—[a]	204,969[a]	—[a]	—[a]
	44,322,335	44,119,511	44,510,021	41,326,815
Net (loss)/income per share				
Basic	$ (0.02)	$ 0.01	$ (0.08)	$ (0.01)
Diluted	$ (0.02)	$ 0.01	$ (0.08)	$ (0.01)

(a) For the three months ended September 30, 2021, option shares of296,504 were not included as the impact is anti-dilutive. For the nine months ended September 30, 2021, and 2020, option shares of 244,422 and 203,121 respectively, were not included as the impact is anti-dilutive. For the three and nine months ended September 30, 2021 and 2020, restricted shares of 1,000,000 and zero respectively, were not included as the impact is anti-dilutive.

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Important estimates include but are not limited to asset lives, valuation allowances, inventory valuation, and accruals.

REVENUE RECOGNITION

The Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2014-09,*Revenue from Contracts with Customers*, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers. We adopted this ASU effective January 1, 2018, on a full retrospective basis. Adoption of this standard did not result in significant changes to our accounting policies, business processes, systems or controls, or have a material impact on our financial position, results of operations and cash flows or related disclosures. As such, prior period financial statements were not recast.

The Company's revenues result from the sale of assembled products. We recognize revenues when shipment occurs, and at which point the customer obtains control and ownership of the goods. Shipping costs generally are billed to customers and are included in sales.

The Company generally does not accept return of goods shipped unless it is a Company error. The only credits provided to customers are for defective merchandise. The Company warrants the syringe driver from defects in materials and workmanship under normal use and the warranty does not include a performance obligation. The costs under the warranty are expensed as incurred.

Provisions for distributor pricing and annual customer growth rebates are variable consideration and are recorded as a reduction of revenue in the same period the related sales are recorded or when it is probable the annual growth target will be achieved. Rebates are provided to distributors for the difference in selling price to distributor and pricing specified to select customers.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Sales				
Domestic	$ 5,254,336	$ 5,372,536	$ 14,346,895	$ 17,459,212
International	786,208	707,779	2,652,774	2,660,016
Total	$ 6,040,544	$ 6,080,315	$ 16,999,669	$ 20,119,228

LEASES

In February 2016, the FASB issued a standard related to leases to increase transparency and comparability among organizations by

requiring the recognition of right-of-use ("ROU") assets and lease liabilities on the balance sheet. Most prominent among the changes in the standard is the recognition of ROU assets and lease liabilities by the Company for those leases classified as operating leases under current GAAP, while our accounting for capital leases remains substantially unchanged. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard became effective for us on January 1, 2019. The standard had a material impact on our balance sheets but did not have a material impact on our statements of operations. See "NOTE 6 — LEASES" for further detail.

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

In December 2019, the FASB issued ASU No. 2019-12,*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* The amendments in this ASU simplify the accounting for income taxes by removing several exceptions including the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company adopted this standard on January 1, 2021, and it had no impact on our financial statement disclosures.

ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

In June 2016, the FASB issued ASU No. 2016-13,*Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current GAAP and, instead, requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. This ASU affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in this update are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In March 2020, the FASB issued ASU No. 2020-04,*Reference Rate Reform (Topic 848)*, which provided elective amendments for entities that have contracts, hedging relationships and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. The amendments may be applied to impacted contracts and hedges prospectively through December 31, 2022. The Company is currently evaluating the impact this guidance will have on its financial statements.

The Company considers the applicability and impact of all recently issued accounting pronouncements. Recent accounting pronouncements not specifically identified in our disclosures are either not applicable to the Company or are not expected to have a material effect on our financial condition or results of operations.

FAIR VALUE MEASUREMENTS

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement that should be determined using assumptions that market participants would use in pricing an asset or liability. Valuation techniques used to measure fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. To measure fair value, the Company uses the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data by correlation or other means.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Value is determined using pricing models, discounted cash flow methodologies, or similar techniques and includes instruments for which the determination of fair value requires significant judgment or estimation.

The carrying amounts of cash and cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued expenses are considered to be representative of their fair values because of the short-term nature of those instruments. There were no transfers between levels in the fair value hierarchy during the nine months ended September 30, 2021.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. No impairment losses have been recorded through September 30, 2021.

RECLASSIFICATION

Certain reclassifications have been made to conform prior period data to the current presentation. These reclassifications had no effect on reported net income.

NOTE 2 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	September 30, 2021	December 31, 2020
Furniture and office equipment	$ 799,761	$ 753,536
Leasehold improvements	556,907	542,796
Manufacturing equipment and tooling	2,028,807	1,856,909
Total property and equipment	3,385,475	3,153,241
Less: accumulated depreciation and amortization	(2,225,656)	(1,985,618)
Property and equipment, net	$ 1,159,819	$ 1,167,623

Depreciation expense was $100,502 and $99,071 for the three months ended September 30, 2021, and 2020, respectively, and $301,469 and $251,084 for the nine months ended September 30, 2021, and 2020, respectively.

NOTE 3 — COMMITMENTS AND CONTINGENCIES

LEGAL PROCEEDINGS

The Company has been and may again become involved in legal proceedings, claims and litigation arising in the ordinary course of business. KORU Medical is not presently a party to any litigation or other legal proceeding that is believed to be material to its financial condition.

OTHER

On November 11, 2020, the Company entered into a Manufacturing and Supply Agreement with Command Medical Products, Inc. ("Command"), pursuant to which Command has agreed to manufacture and supply the Company's subassemblies, needle sets and tubing products pursuant to the Company's specifications and purchase orders. The first binding purchase order pursuant to the Manufacturing and Supply Agreement was made on November 17, 2020 (the "Effective Date").

The Manufacturing and Supply Agreement provides for a term of five years from the Effective Date. Either party may terminate the Manufacturing and Supply Agreement upon a material breach by the other Party that has not been cured within 90 days, upon the bankruptcy or insolvency of the other Party or as expressly set forth elsewhere in the Agreement. If the Company terminates the Manufacturing and Supply Agreement other than for those reasons within the first three years from the Effective Date, the Company is obligated to pay an early termination fee to Command.

The Manufacturing and Supply Agreement also includes customary provisions relating to, among other things, delivery, inspection procedures, warranties, quality management, business continuity plans, handling and transport, intellectual property, confidentiality and indemnification.

NOTE 4 — STOCK-BASED COMPENSATION

The Company has two equity incentive plans: the 2015 Stock Option Plan, as amended (the "2015 Plan") and the 2021 Omnibus Equity Incentive Plan (the "2021 Plan"). As of September 30, 2021, there were options to purchase 3,385,000 shares of the Company's common stock outstanding to certain executives, key employees and consultants under the 2015 Plan, of which 1,650,000 were issued during the nine months ended September 30, 2021. Additional options may be issued under the 2015 Plan as outstanding options are forfeited, subject to a maximum 6,000,000 available for issuance under the 2015 Plan. The 2021 Plan provides for the grant of up to 1,000,000 incentive stock options, nonqualified stock options, stock awards, restricted stock awards, restricted stock units and/or stock appreciation rights to employees, consultants and directors. As of September 30, 2021, there had been issued 20,988 shares of common stock as directors fees under the 2021 Plan.

Prior to January 1, 2021, each non-employee director of the Company was eligible to receive $50,000 annually (effective January 1, 2019), plus $10,000 for chairing a Board committee (effective February 20, 2019), all to be paid quarterly half in cash and half in common stock. The Chairman of the Board was eligible to receive an additional $50,000 annually (effective October 1, 2019), all to be paid in common stock.

Effective January 1, 2021, each non-employee director of the Company (other than the Chairman of the Board) and Board advisor were eligible to receive of $75,000 annually, to be paid quarterly $12,500 in cash and $6,250 in common stock. The Chairman of the Board is eligible to receive $100,000 annually, to be paid quarterly $12,500 in cash and $12,500 in common stock. Effective May 18, 2021, each non-employee director of the Company (other than the Chairman of the Board) and Board advisor are eligible to receive of $110,000 annually, to be paid quarterly $12,500 in cash and $15,000 in common stock. The Chairman of the Board is eligible to receive $140,000 annually, to be paid quarterly $12,500 in cash and $22,500 in common stock. All payments were and are pro-rated for partial service.

On May 20, 2020, the Company entered into a Settlement Agreement with EMED Technologies Corporation ("EMED") to settle all claims in connection with all pending litigation matters between them. Pursuant to the Settlement Agreement, the Company issued to EMED (i) 95,238 restricted stock units, which vested on May 21, 2020, and 95,238 restricted stock units, which vested on January 1, 2021, and (ii) an option to purchase up to 400,000 shares of the Company's common stock at an exercise price of $11.21 per share prior to February 1, 2021, which was not exercised.

On April 12, 2021, pursuant to an employment agreement entered into on March 15, 2021, with Linda Tharby, the Company's President and Chief Executive Officer, the Company issued three restricted stock awards for an aggregate 1,000,000 shares of common stock for an aggregate stock price of $3,310,000 and each vesting subject to employment on the respective vesting date. These awards were issued as an inducement employment.

2015 STOCK OPTION PLAN, as amended

Time Based Stock Options

The per share weighted average fair value of stock options granted during the nine months ended September 30, 2021 and September 30, 2020 was $2.93 and $6.53, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the nine months ended September 30, 2021 and September 30, 2020. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued. We have recognized tax benefits associated with stock-based compensation of $56,102 and $150,566 for the nine months ended September 30, 2021 and 2020, respectively.

	September 30,	
	2021	2020
Dividend yield	0.00%	0.00%
Expected Volatility	74.01 – 76.77%	62.11 – 62.18%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10	10
Risk-free rate	1.20 – 1.62%	0.63 – 0.64%

The following table summarizes the status of the Plan with respect to time based stock options:

	Nine Months Ended September 30,			
	2021		2020	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	2,922,494	$ 2.46	3,647,000	$ 1.32
Granted	1,650,000	$ 3.75	360,000	$ 9.54
Exercised	1,000,000	$ 1.23	747,006	$ 0.65
Forfeited	187,494	$ 3.36	200,000	$ 2.09
Outstanding at September 30	3,385,000	$ 3.39	3,059,994	$ 2.40
Options exercisable at September 30	1,005,625	$ 2.65	1,009,629	$ 1.36
Weighted average fair value of options granted during the period	—	$ 2.93	—	$ 6.53
Stock-based compensation expense	—	$ 1,934,935	—	$ 572,775

Total stock-based compensation expense was $1,934,935 and $572,775 for the nine months ended September 30, 2021, and 2020, respectively. Cash received from option exercises for the nine months ended September 30, 2021, and 2020 was $1,230,000 and $95,880, respectively.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2021, and 2020 was $4.8 million and $2.4 million, respectively. There were 1.0 million options exercised during the nine months ended September 30, 2021, and 747,006 during the nine months ended September 30, 2020.

The following table presents information pertaining to options outstanding at September 30, 2021:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.50-$9.76	3,385,000	7.8 years	$ 3.39	1,005,625	$ 2.65

As of September 30, 2021, there was $5.8 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 46 months. The total fair value of shares vested as of September 30, 2021, and September 30, 2020, was $1,909,141 and $874,041, respectively.

Performance Based Stock Options

There were no stock options granted during the nine months ended September 30, 2021, and 2020.

The following table summarizes the status of the Plan with respect to performance-based stock options

	Nine Months Ended September 30,			
	2021		2020	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	1,000,000	$ 1.70	1,000,000	$ 1.70
Granted	—	$ —	—	$ —
Exercised	—	$ —	—	$ —
Forfeited	1,000,000	$ 1.70	—	$ —
Outstanding at September 30	—	$ —	1,000,000	$ 1.70
Options exercisable at September 30	—	$ —	333,333	$ 1.70
Weighted average fair value of options granted during the period	—	$ —	—	$ —
Stock-based compensation expense	—	$ (408,747)	—	$ 438,365

Total performance stock-based compensation expense totaled ($408,747) and $438,365 for the nine months ended September 30, 2021, and 2020, respectively. All performance-based stock options were forfeited as of September 30, 2021, and there was no unrecognized compensation cost remaining.

RESTRICTED STOCK AWARDS

On April 12, 2021, pursuant to an employment agreement entered into on March 15, 2021, with Linda Tharby, the Company's President and Chief Executive Officer and as an inducement to her employment, the Company issued three restricted stock awards for an aggregate 1,000,000 shares of common stock for an aggregate stock price of $3,310,000 and each vesting subject to employment on the respective vesting date. The following table summarizes the activities for our unvested restricted stock awards for the nine months ended September 30, 2021, and 2020.

	Nine Months Ended September 30,			
	2021		2020	
	Shares	Weighted Average Grant-Date Fair Value	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	—	$ —	—	$ —
Granted	1,000,000	$ 3.01	—	$ —
Vested	—	$ —	—	$ —
Forfeited/canceled	—	$ —	—	$ —
Unvested at September 30	1,000,000	$ 3.01	—	$ —

As of September 30, 2021, there was $2,379,089 of unrecognized compensation cost related to unvested employee restricted shares. This amount is expected to be recognized over a weighted-average period of 39 months. We have recognized tax benefits associated with restricted stock award compensation of $30,554 and zero for the nine months ended September 30, 2021 and 2020, respectively.

NOTE 5 — DEBT OBLIGATIONS

On July 26, 2021, the Company entered into a commercial insurance premium finance and security agreement with AON Premium Finance, LLC in the aggregate principal amount of $0.9 million bearing an annual percentage rate of4.17%, to finance its insurance premiums. Monthly payments are due on the first of each month beginning August 1, 2021 through June 1, 2022.

On April 14, 2020, the Company issued a promissory note to KeyBank in the aggregate principal amount of $3.5 million (the "Note") as an extension of its line of credit, replacing its then current line of credit agreement. The $3.5 million Note is in the form of a variable rate non-disclosable revolving line of credit with an interest rate of Prime Rate announced by the Bank minus 0.75%. The Note was renewed on June 24, 2021, in the same form with an interest rate of Prime Rate announced by the Bank minus 1.50%. Interest is due monthly, and all principal and unpaid interest is due on June 1, 2022. The $3.5 million Note may be prepaid atany time prior to maturity with no prepayment penalties. The $3.5 million Note contains events of default and other provisions customary for a loan of this type.

In connection with the Note, the Company entered into a Commercial Security Agreement with the Bank dated April 14, 2020 (the "Security Agreement"), pursuant to which the Company granted a security interest in substantially all assets of the Company to secure the obligations of the Company under the Note. The Security Agreement contains terms and conditions typical for the granting of security interests of this kind.

The Company had no amount outstanding against the line of credit as of September 30, 2021.

On April 27, 2020, the Company entered into a Progress Payment Loan and Security Agreement ("PPLSA") and a Master Security Agreement (the "MSA"), each dated as of April 20, 2020, with Key Equipment Finance, a division of the Bank ("KEF"), to provide up to $2.5 million in financing for equipment purchases from third party vendors. The PPLSA allows the Company to make draws with KEF to make certain payments to the equipment suppliers prior to the commencement of periodic payments under a term loan. Each draw under the PPLSA will bear interest at a variable rate equal to the then-current Prime Rate and will be secured by the financed equipment under the MSA. At the end of each calendar quarter or year, the advances made under the PPLSA will be converted to term loans, subject to KEF's approval of the equipment and certain other closing conditions being met. Once the draws under the PPLSA are converted into a term loan, each promissory note will bear interest at a fixed rate of 4.07% per annum, subject to adjustment based on KEF's cost of funds, with principal and interest payable in 84 equal consecutive monthly installments. Each fixed rate installment promissory note may be prepaid, subject to a penalty if prepaid before the fifth anniversary of its issuance. As of September 30, 2021, the Company had no amount outstanding against the PPLSA.

NOTE 6 — LEASES

We have finance and operating leases for our corporate office and certain office and computer equipment. Our leases have remaining lease terms of one year, some of which include options to extend the leases monthly and annually and some with options to terminate the leases within 1 year.

The components of lease expense were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease cost	$ 37,093	$ 37,921	$ 112,383	$ 113,764
Short-term lease cost	35,960	19,846	104,396	33,535
Total lease cost	$ 73,053	$ 57,767	$ 216,779	$ 147,299
Finance lease cost:				
Amortization of right-of-use assets	$ 597	$ 791	$ 2,188	$ 4,502
Interest on lease liabilities	10	47	57	199

Total finance lease cost	$ 607	$ 838	$ 2,245	$ 4,701

Supplemental cash flow information related to leases was as follows:

	Nine Months Ended September 30,	
	2021	2020
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 105,618	$ 113,764
Financing cash flows from finance leases	2,232	4,502

Supplemental balance sheet information related to leases was as follows:

	September 30, 2021	December 31, 2020
Operating Leases		
Operating lease right-of-use assets	$ 131,228	$ 236,846
Operating lease current liabilities	131,228	141,293
Operating lease long term liabilities	—	95,553
Total operating lease liabilities	$ 131,228	$ 236,846
Finance Leases		
Property and equipment, at cost	$ 12,725	$ 12,725
Accumulated depreciation	(12,327)	(10,139)
Property and equipment, net	$ 398	$ 2,586
Finance lease current liabilities	414	2,646
Finance lease long term liabilities	—	—
Total finance lease liabilities	$ 414	$ 2,646

	September 30, 2021	December 31, 2020
Weighted Average Remaining Lease Term		
Operating leases	0.9 Years	1.4 Years
Finance leases	0.2 Years	0.7 Years
Weighted Average Discount Rate		
Operating leases	4.75%	4.75%
Finance leases	4.75%	4.75%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
2021 (excluding the nine months ended September 30, 2021)	$ 37,092	$ 417
2022	97,257	—
2023	—	—
2024	—	—
2025	—	—
Thereafter	—	—
Total undiscounted lease payments	134,349	417
Less: imputed interest	(3,121)	(3)
Total lease liabilities	$ 131,228	$ 414

NOTE 7 — EQUITY

On June 18, 2020, the Company entered into a Purchase Agreement with Piper Sandler & Co. and Canaccord Genuity LLC, as representatives of the several underwriters named therein (the "Underwriters"), pursuant to which the Company agreed to issue and sell 3,125,000 shares of its common stock. Under the terms of the Purchase Agreement, the Company granted to the Underwriters an option, exercisable for a period of 30 days, to purchase up to an additional468,750 shares of the Company's common stock, which the Underwriters exercised in full on June 19, 2020. The Underwriters purchased the shares pursuant to the Purchase Agreement, including the shares subject to the option, at a price of $7.52 per share. Proceeds to the Company, net of discounts, commissions, fees and expenses, were $26.6 million.

On November 16, 2020, the Company announced that its Board of Directors had 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. As of September 30, 2021, the Company had purchased 683,271 shares for an aggregate $3,499,358 pursuant to this program. Management does not intend to make any further purchases before the end of the year.

PART I — ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

This Quarterly Report on Form 10-Q contains certain "forward-looking" statements (as such term is defined in the Private Securities Litigation Reform Act of 1995) and information relating to us that are based on the beliefs of the management, as well as assumptions made and information currently available.

Our actual results may vary materially from the forward-looking statements made in this report due to important factors such as uncertainties associated with COVID-19, customer ordering patterns, availability and costs of raw materials and labor and our ability to recover such costs, our ability to convert inventory to a source of cash, future operating results, growth of new patient starts, Food and Drug Administration and foreign authority regulations and the outcome of regulatory audits, 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 our 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. When used in this report, the words "estimate," "project," "believe," "may," "will," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. Such statements reflect current views with respect to future events based on currently available information and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to release publicly any revision to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Throughout this report, the "Company," "KORU Medical," "we," "us" or "our" refers to Repro Med Systems, Inc.

OVERVIEW

The Company designs, manufactures and markets proprietary portable and innovative medical devices primarily for the ambulatory infusion market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international standards for quality system management.

KORU Medical continues to monitor its operations and government recommendations as they relate to the COVID-19 pandemic. We cannot predict the effects the pandemic may have on our business, in particular with respect to demand for our products, our strategy, and our prospects, the effects on our customers, or the impact on our financial results. For example, our future net sales growth may continue to be impacted due to fewer new prescriptions for individuals with Primary Immune Deficiency Disease ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP") as a result of patients not seeking care during the pandemic. We believe that the pandemic has precipitated limited availability and rising costs of raw materials and labor, which may impact our financial results if current trends continue.

Our revenues derive from three business sources: (i) domestic core, (ii) international core, and (iii) novel therapies. Our core revenues consist of sales of our products for the delivery of SCIg to treat PIDD, CIDP, and other disease states that are FDA cleared for use with the KORU Medical syringe driver. Novel therapies consist of revenues from clinical trials, which consist of sales of syringe drivers, tubing and needles, as well as non-recurring engineering services.

Total net sales were $6.0 million for the third quarter of 2021, nearly even with the same period last year, which included inventory stocking of $0.6 million last year. Sequential quarter net sales from the three months ended June 30, 2021, grew 9%, driven by domestic core growth of 10%.

Our gross margin, which is our gross profit, stated as a percentage of net sales, for the period was 57.9%, a decline from prior year of 64.8%. The majority of the decline, or (9.2) percentage points, was driven by delays in the transition to our secondary manufacturing source. We also recorded a reserve for in-process material scrap, or (3.6) percentage points. This was partially offset by 5.7 percentage points of favorability mostly due to price/mix as we sold more pumps and needles when compared to last year.

RESULTS OF OPERATIONS

Three months ended September 30, 2021, compared to September 30, 2020

Net Sales

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

	Three Months Ended September 30,		Change from Prior Year		% of Net Sales	
	2021	2020	$	%	2021	2020
Net Sales						
Domestic Core	$ 5,076,294	$ 5,289,076	$ (212,782)	(4.0%)	84.0%	87.0%
Novel Therapies	178,042	83,460	94,582	113.3%	2.9%	1.4%
Total Domestic	5,254,336	5,372,536	(118,200)	(2.2%)	87.0%	88.4%
International Core	747,281	702,034	45,247	6.4%	12.4%	11.5%
Novel Therapies	38,927	5,745	33,182	577.6%	0.6%	0.1%
Total International	786,208	707,779	78,429	11.1%	13.0%	11.6%
Total	$ 6,040,544	$ 6,080,315	$ (39,771)	(0.7%)		

Total net sales decreased $39,771, or 0.7%, for the three months ended September 30, 2021, as compared with the same period last year, which included approximately $0.6 million of inventory stocking related net sales. International core net sales for the three months ended September 30, 2021, grew 6.4% as compared with the same period last year driven by increased consumables sales. Novel therapies sales also increased for the three months ended September 30, 2021, as compared with the same period last year, as we

continue to expand our pharmaceutical pipeline.

Gross Profit

Our gross profit for the three months ended September 30, 2021, and 2020 is as follows:

	Three Months Ended September 30,		Change from Prior Year	
	2021	2020	$	%
Gross Profit	$ 3,495,750	$ 3,940,723	$ (444,973)	(11.3%)
Stated as a Percentage of Net Sales	57.9%	64.8%		

Gross profit decreased $0.4 million or 11.3% in the three months ended September 30, 2021, as compared to the same period in 2020.

Gross profit, stated as a percentage of sales, which is referred to as gross margin, declined (6.9) percentage points. The majority of the decline, (9.2) percentage points, was driven by delays in the transition to our secondary manufacturing source. We also recorded a reserve for in-process material scrap of (3.6) percentage points. This was partially offset by 5.7 percentage points of favorability due to price/mix.

Selling, general and administrative, Litigation and Research and development

Our selling, general and administrative, litigation and research and development costs for the three months ended September 30, 2021, and 2020 are as follows:

	Three Months Ended September 30,		Change from Prior Year	
	2021	2020	$	%
Selling, general and administrative	$ 3,901,830	$ 3,075,169	$ 826,661	26.9%
Litigation	—	675	(675)	(100.0%)
Research and development	800,020	390,416	409,604	104.9%
	$ 4,701,850	$ 3,466,260	$ 1,235,590	35.6%
Stated as a Percentage of Net Sales	77.8%	57.0%		

Selling, general and administrative expenses increased $0.8 million, or 26.9%, during the three months ended September 30, 2021 compared to the same period last year, due primarily to higher salary and related benefits as we build our executive team, as well as consulting fees for our 510K filings and commercialization efforts, in aggregate $0.6 million. The remaining amount was related to higher board of director fees and related liability insurance in aggregate $0.2 million.

Research and development expenses increased $0.4 million during the three months ended September 30, 2021, compared with the same period last year as we have higher salary and related expenses due to building our internal research and development team and consulting fees to support product development for novel therapies, as well as the disposal of expired samples of $0.2 million.

Depreciation and amortization

Depreciation and amortization expense increased by 0.3 % to $115,934 in the three months ended September 30, 2021, compared with $115,637 in the three months ended September 30, 2020. We continue to invest in capital assets, mostly related to manufacturing and computer equipment, offset by assets reaching their remaining useful life.

Net (Loss)/Income

	Three Months Ended September 30,		Change from Prior Year	
	2021	2020	$	%
Net (Loss)/Income	$ (1,093,778)	$ 249,175	$ (1,342,953)	(539.0%)
Stated as a Percentage of Net Sales	(18.1%)	4.1%		

Our net loss was $1.1 million in the three months ended September 30, 2021, compared with net income of $0.2 million in same period last year mostly driven by lower gross profit, higher selling, general and administrative expenses and higher research and development expenses, all as described above. A favorable tax benefit for the period resulting from the loss was also recognized during the three months ended September 30, 2021.

Nine months ended September 30, 2021, compared to September 30, 2020

Net Sales

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

	Nine Months Ended September 30,		Change from Prior Year		% of Net Sales	
	2021	2020	$	%	2021	2020
Net Sales						
Domestic Core	$ 14,084,552	$ 15,719,419	$ (1,634,867)	(10.4%)	82.9%	78.1%
Novel Therapies	262,343	1,739,793	(1,477,450)	(84.9%)	1.5%	8.6%
Total Domestic	14,346,895	17,459,212	(3,112,317)	(17.8%)	84.4%	86.8%
International Core	2,585,881	2,539,944	45,937	1.8%	15.2%	12.6%
Novel Therapies	66,893	120,072	(53,179)	(44.3%)	0.4%	0.6%
Total International	2,652,774	2,660,016	(7,242)	(0.3%)	15.6%	13.2%
Total	$ 16,999,669	$ 20,119,228	$ (3,119,559)	(15.5%)		

Total net sales decreased $3.1 million or 15.5% for the nine months ended September 30, 2021, as compared to the prior year period, driven primarily by lower novel therapies sales of $1.5 million compared with last year mostly due to a non-recurring clinical trial last year and lower domestic core net sales driven by what we believe to be inventory stocking and an early order $1.3 million last year at

our largest distributor. International core net sales were $2.6 million, 1.8% higher than with the same period last year, driven by our European expansion activity.

Gross Profit

Our gross profit for the nine months ended September 30, 2021, and 2020 is as follows:

	Nine Months Ended September 30,		Change from Prior Year	
	2021	2020	$	%
Gross Profit	$ 9,937,788	$ 12,638,813	$ (2,701,025)	(21.4%)
Stated as a Percentage of Net Sales	58.5%	62.8%		

Gross profit decreased $2.7 million or 21.4% in the nine months ended September 30, 2021, as compared to the same period last year. Gross margin declined (4.3) percentage points. The majority of the decline, (2.8) percentage points, was driven by a delay in the transition to our secondary manufacturing source and unfavorable mix impact of (2.1) percentage points driven by lower pump sales compared to last year due what we believe to be covid related stocking last year.

Selling, general and administrative, Litigation and Research and development

Our selling, general and administrative expenses, litigation and research and development costs for the nine months ended September 30, 2021, and 2020 are as follows:

	Nine Months Ended September 30,		Change from Prior Year	
	2021	2020	$	%
Selling, general and administrative	$ 12,980,604	$ 9,039,980	$ 3,940,624	43.6%
Litigation	—	2,446,747	(2,446,747)	(100.0%)
Research and development	1,523,739	944,637	579,102	61.3%
	$ 14,504,343	$ 12,431,364	$ 2,072,979	16.7%
Stated as a Percentage of Net Sales	85.3%	61.8%		

Selling, general and administrative expenses increased $3.9 million, or 43.6%, during the nine months ended September 30, 2021, compared to the same period last year, due primarily to $1.6 million in costs associated with the departure and replacement of the former chief executive officer and the recruitment of two new Board members, which includes non-cash equity expense of $0.4 million. Further contributing to the increase was higher salary and related benefits of $1.0 million from new hires in the second half of last year to support commercialization, business development and medical affairs for our novel therapies initiatives, as well as infrastructure. Market research, testing and consulting fees to support commercialization and regulatory filings of $0.9 million and higher director fees and director and officer liability insurance of $0.6 million also contributed. Offsetting these expenses were the Covid-related heroes bonus paid last year and lower other miscellaneous expenses, in aggregate $0.2 million.

Litigation expense was lower by $2.4 million as a result of the settlement agreement entered into last year.

Research and development expenses increased $0.6 million during the nine months ended September 30, 2021, compared with the same period last year mostly due to increases to support product development for novel therapies as well as the write-off of expired samples.

Depreciation and amortization

Depreciation and amortization expense increased by 17.5% to $349,822 in the nine months ended September 30, 2021, compared with $297,801 in the nine months ended September 30, 2020. We continue to invest in capital assets, mostly related to manufacturing and computer equipment.

Net (Loss)/Income

	Nine Months Ended September 30,		Change from Prior Year	
	2021	2020	$	%
Net Loss	$ (3,494,465)	$ (377,435)	$ (3,117,030)	825.8%
Stated as a Percentage of Net Sales	(20.6%)	(1.9%)		

Our net loss for the nine months ended September 30, 2021, was $3.5 million compared to net loss of $0.4 million for the nine months ended September 30, 2020, driven by lower gross profit, higher selling, general and administrative expenses and research and development expenses, offset by litigation expenses incurred last year, all as described above. Offsetting the loss was a tax benefit of $0.5 million resulting from book to tax differences related to stock option expense.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of $26.2 million as of September 30, 2021. Our principal source of operating cash inflows is from sales of our products to customers. Our principal cash outflows relate to the purchase and production of inventory and related costs, and selling, general and administrative expenses.

Cash Flows

The following table summarizes our cash flows:

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net cash (used in)/provided by operating activities	$ (3,602,378)	$ 968,437
Net cash used in investing activities	$ (318,493)	$ (1,007,539)
Net cash provided by financing activities	$ 2,838,996	$ 26,601,984

Operating Activities

Net cash used in operating activities of $3.6 million for the nine months ended September 30, 2021 was primarily due to the net loss of $3.5 million, working capital changes which included an increase in accounts receivable of $0.5 million due to timing, an increase in prepaids of $0.5 million due to insurance renewals, and a decrease in accrued expenses of $0.6 million most of which was non-cash activity related to the issuance of common stock in settlement of litigation. Further contributing were deferred tax assets of $1.4 million mostly increased for book to tax differences related to stock option expense. Offsetting these were an increase in accounts payable of $0.8 million, non-cash charges for stock-based compensation of $2.0 million, and depreciation and amortization of $0.3 million.

Net cash provided by operating activities of $1.0 million for the nine months ended September 30, 2020, was mostly attributable to non-cash charges for stock-based compensation and litigation settlement expense of $2.5 million, an increase in accounts payable, accrued expenses and accrued payroll of $2.8 million, driven by the litigation settlement with EMED, the capital raise and customer rebates. Further adding to the increase was an increase in depreciation and amortization of $0.3 million and an increase in the accrued tax liability of $0.2 million, resulting from book to tax differences related to stock option expense. Offsetting these were primarily working capital changes which include an increase in inventory of $3.2 million as we built inventory to keep pace with sales growth and to insure timely order fulfillment, an increase in accounts receivable of $0.5 million due to timing of collections, and an increase in prepaid expenses and other assets of $0.5 million relating to increased insurance premiums.

Investing Activities

Net cash used in investing activities of $0.3 million for the nine months ending September 30, 2021, was for capital expenditures for manufacturing and office equipment.

Net cash used in investing activities of $1.0 million for the nine months ended September 30, 2020, was primarily for capital expenditures for research and development and strategic initiatives.

Financing Activities

The $2.8 million provided by financing activities for the nine months ended September 30, 2021, is from options exercised, the non-cash activity related to the issuance of common stock in settlement of litigation and a note payable for insurance premium financing.

Net cash provided by financing activities for the nine months ended September 30, 2020, of $26.6 million is from the $26.5 million capital raise, net of expenses and $0.1 million from options exercised.

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

Refer to “NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES” in the accompanying financial statements, which is incorporated herein by reference.

ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

Refer to “NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES” in the accompanying financial statements, which is incorporated herein by reference.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 4. CONTROLS AND PROCEDURES

The Company’s management, including the Company’s Principal Executive Officer and Principal Financial Officer, has evaluated the effectiveness of the Company’s disclosure controls and procedures as such is defined in Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Based upon their evaluations, the Principal Executive Officer and Principal Financial Officer concluded that, as of the end of the period covered by this report, the Company’s disclosure controls and procedures were effective for the purpose of ensuring that the information required to be disclosed in the reports that the Company files or submits under the Exchange Act with the Securities and Exchange Commission (the “SEC”) (1) is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and (2) is accumulated and communicated to the Company’s management, including its Principal Executive Officer and Principal Financial Officer, as appropriate to allow timely decisions regarding required disclosure.

There have been no changes in the Company’s internal control over financial reporting during the three months ended September 30, 2021, that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

The Company has been and may again become involved in legal proceedings, claims and litigation arising in the ordinary course of business. KORU Medical is not presently a party to any litigation or other legal proceeding that is believed to be material to its financial condition.

ITEM 1A. RISK FACTORS

Our operations and financial results are subject to various risks and uncertainties, including those described in “PART 1, ITEM 1A. RISK FACTORS” in our Annual Report on Form 10-K for the year ended December 31, 2020, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common stock. There have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2020.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

The Company issued an aggregate 20,988 shares of common stock to its non-employee directors during the three months ended September 30, 2021 under its 2021 Omnibus Equity Incentive Plan.

During the three months ended September 30, 2021, we issued 400,000 options at a weighted average exercise price of $3.17 to two new employees under the 2015 Stock Option Plan.

All of the securities issued by the Company as described in this Item were issued in reliance on the exemption from registration under Section 4(2) under the Securities Act of 1933, as amended.

Issuer Purchases of Equity Securities

On November 16, 2020, the Company announced that its Board of Directors had authorized a stock repurchase program under which the Company may choose to purchase up to $10.0 million of its outstanding common stock through December 31, 2021. As of December 31, 2020, the Company had purchased 683,271 shares for an aggregate $3,499,358 pursuant to this program. No purchases have been made since that time, as we continue to evaluate our cash needs in connection with strategic planning under the leadership of our new Chief Executive Officer.

PART II – ITEM 6. EXHIBITS.

31.1	Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002
32.2	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002
101.INS	Inline XBRL Instance Document - the XBRL Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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 thereunto duly authorized.

REPRO MED SYSTEMS, INC.

November 10, 2021 — /s/ Linda Tharby
Linda Tharby, President and Chief Executive Officer
(Principal Executive Officer)

November 10, 2021 — /s/ Karen Fisher
Karen Fisher, Chief Financial Officer and Treasurer
(Principal Financial Officer)

EXHIBIT 31.1

RULE 13A-14(A) / 15D-14(A) CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER

I, Linda Tharby, Principal Executive Officer, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Repro Med Systems, Inc. (the "Report");

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing this equivalent function):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2021

/s/ Linda Tharby
Linda Tharby
President and Chief Executive Officer

EXHIBIT 31.2

RULE 13A-14(A) / 15D-14(A) CERTIFICATION OF
PRINCIPAL FINANCIAL OFFICER

I, Karen Fisher, Principal Financial Officer, certify that:

1) I have reviewed this Quarterly Report on Form 10-Q of Repro Med Systems, Inc. (the "Report");

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing this equivalent function):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2021

/s/ Karen Fisher
Karen Fisher
Chief Financial Officer and Treasurer

EXHIBIT 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADDED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Repro Med Systems, Inc. (the "Company") on Form 10-Q (the "Report") for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission, I, Linda Tharby, Principal Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2021

/s/ Linda Tharby
Linda Tharby
President and Chief Executive Officer

EXHIBIT 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350
AS ADDED BY SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report of Repro Med Systems, Inc. (the "Company") on Form 10-Q (the "Report") for the quarter ended September 30, 2021 as filed with the Securities and Exchange Commission, I, Karen Fisher, Principal Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 10, 2021

/s/ Karen Fisher
Karen Fisher
Chief Financial Officer and Treasurer