#### 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, 2020

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

(State or Other Jurisdiction of Incorporation or Organization)

24 Carpenter Road, Chester, New York (Address of Principal Executive Offices)

(Zip Code)

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

Not Applicable

(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 [ ] Non-accelerated filer [X]

Accelerated filer [ ] 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 12, 2020, 43,942,888 shares of common stock, \$0.01 par value per share, were outstanding, which excludes 2,737,231 shares of treasury stock.

13-3044880 (I.R.S. Employer Identification No.)

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Item 1. Financial Statements (Unaudited)

# REPRO MED SYSTEMS, INC. BALANCE SHEETS (Unaudited)

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

See accompanying Notes to Financial Statements.

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

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

See accompanying Notes to Financial Statements.

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

		Nine Mon Septem		
		2020		2019
CASH FLOWS FROM OPERATING ACTIVITIES				
Net (Loss)/Income	\$	(377,435)	\$	644,606
Adjustments to reconcile net (loss)/income to net cash provided by/(used in) operating	æ	(377,435)	φ	044,000
activities:				
Stock-based compensation expense		1,191,146		897,300
Stock-based litigation settlement expense		1,285,102		—
Depreciation and amortization		297,801		252,594
Deferred capital gain - building lease		—		(3,763)
Deferred taxes		(161,368)		134,563
Gain on disposal of fixed assets		(16,591)		(49,740)
Changes in operating assets and liabilities:				
Increase in accounts receivable		(502,075)		(2, 120, 780)
Increase in inventory		(3,244,662)		(634,803)
Increase in prepaid expenses and other assets		(457,330)		(206,560)
Increase in accounts payable		790,414		421,479
Increase/(Decrease) in accrued payroll and related taxes		249,879		(310,355)
Increase in accrued expenses		1,754,970		490,053
Increase/(Decrease) in accrued tax liability		158,586		(16,608)
NET CASH PROVIDED BY/(USED IN) OPERATING ACTIVITIES		968.437		(502,014)
		,		
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of property and equipment		(908,323)		(158,193)
Purchases of patents		(124,216)		(188,274)
Proceeds from disposal of property and equipment		25,000		217,821
Proceeds from certificate of deposit		_		1,517,927
NET CASH (USED IN)/PROVIDED BY INVESTING ACTIVITIES		(1,007,539)		1,389,281
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from issuance of equity		26,606,486		508,900
Payments for cancelled shares				(2,820)
Borrowings from indebtedness		4,976,508		(2,020)
Payments on indebtedness		(4,976,508)		_
Payments on finance lease liability		(4,502)		(3,122)
NET CASH PROVIDED BY FINANCING ACTIVITIES		26,601,984		502,958
NET CASH FROVIDED BT FINANCING ACTIVITIES		20,001,984		302,938
NET INCREASE IN CASH AND CASH EQUIVALENTS		26,562,882		1,390,225
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		5,870,929		3,738,803
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	32,433,811	\$	5,129,028
Supplemental Information				
Cash paid during the periods for:				
	\$	27,698	\$	280
Interest		· · · ·	\$	
Income taxes	\$	318,983	\$	103,465

See accompanying Notes to Financial Statements.

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

	Common Stock			A	Additional Paid-in Retained				Treasury		Total ckholders'
	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

See accompanying Notes to Financial Statements.

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

	Commo Shares	on	Stock Amount	 Additional Paid-in Capital		Retained Earnings		Freasury Stock	Total Stockholders' Equity
Three and Nine Months Ended September 30, 2019									
BALANCE, DECEMBER 31, 2018	40,932,911	\$	409,329	\$ 4,595,214	\$	4,300,468	\$	(344,204)	\$ 8,960,807
Issuance of stock-based compensation	8,914		89	176,161		_		—	176,250
Compensation expense related to stock options	_		_	121,875		_			121,875
Repurchase of shares	(2,000)		(20)	(2,800)				_	(2,820)
Net loss						(85,390)		_	(85,390)
BALANCE, MARCH 31, 2019	40,939,825	\$	409,398	\$ 4,890,450	\$	4,215,078	\$	(344,204)	\$ 9,170,722
Issuance of stock-based compensation	116,386		1,164	35,484					36,648
Compensation expense related to stock options	_			194,765					194,765
Issuance upon options exercised	65.000		650	24,050				_	24.700
Net income						78,183			78,183
BALANCE, JUNE 30, 2019	41,121,211	\$	411,212	\$ 5,144,749	\$	4,293,261	\$	(344,204)	\$ 9,505,018
Issuance of stock-based compensation Compensation expense related to stock	12,447		124	43,502		—		_	43,626
options				324,135					324,135
Issuance upon warrants exercised	1,000,000		10,000	440,000		_		_	450,000
Issuance upon options exercised	95,000		950	33,250					34,200
Net income				 	_	651,813	_		651,813
BALANCE, SEPTEMBER 30, 2019	42,228,658	\$	422,286	\$ 5,985,636	\$	4,945,074	\$	(344,204)	\$ 11,008,792

See accompanying Notes to Financial Statements.

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#### REPRO MED SYSTEMS, INC. NOTES TO FINANCIAL STATEMENTS (Unaudited)

## NOTE 1 -- NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

## NATURE OF OPERATIONS

REPRO MED SYSTEMS, INC. (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, 2019 ("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.

#### CERTIFICATE OF DEPOSIT

The certificate of deposit was recorded at cost plus accrued interest. The certificate of deposit earned interest at a rate of 1.73% and matured in May 2019.

#### 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 2017 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.

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# 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.

### 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 Mon	ths Ende	d
	Septe	mber 30, 2020	Septe	ember 30, 2019
Net income	\$	249,175	\$	651,813
Weighted Average Outstanding Shares:				
Outstanding shares		43,914,542		39,022,298
Option shares includable		204,969		276,110
		44,119,511		39,298,408
Net income per share				
Basic	\$	0.01	\$	0.02
Diluted	\$	0.01	\$	0.02
		Nine Mont	hs Ended	l
	Septe	mber 30, 2020	Sonto	mh an 20 2010
			Septe	ember 30, 2019
Net (loss)/income	\$	(377,435)	<u>s</u>	644,606
Net (loss)/income Weighted Average Outstanding Shares:	<u>\$</u>			
	<u>\$</u>			
Weighted Average Outstanding Shares:	<u>\$</u>	(377,435) 41,326,815 —(a)		644,606
Weighted Average Outstanding Shares: Outstanding shares	<u>\$</u>	(377,435) 41,326,815		644,606 38,534,021
Weighted Average Outstanding Shares: Outstanding shares	<u>\$</u>	(377,435) 41,326,815 —(a)		644,606 38,534,021 200,062
Weighted Average Outstanding Shares: Outstanding shares Option shares includable	<u>\$</u>	(377,435) 41,326,815 —(a)		644,606 38,534,021 200,062

(a) Option shares of 203,121 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.

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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, 2020 and 2019:

	Th	ree Months En	ded Se	ptember 30,	Ν	ine Months End	ded September 30,			
		2020	2019		2020			2019		
Sales										
Domestic	\$	5,372,536	\$	5,856,203	\$	17,459,212	\$	14,308,994		
International		707,779		761,194		2,660,016		2,631,493		
Total	\$	6,080,315	\$	6,617,397	\$	20,119,228	\$	16,940,487		

#### 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 August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure for Fair Value Measurement.* The amendments in this ASU modify the disclosure requirements on fair value measurements in Topic 820 based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of this ASU. An entity is permitted to early adopt any removed or modified disclosures upon issuance of this ASU and delay adoption of the additional disclosures until their effective date. The Company adopted this standard on January 1, 2020 and it had no impact on our financial statement disclosures.

In August 2018, the FASB issued ASU No. 2018-15, Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this ASU align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this ASU. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption of the amendments in this ASU is permitted, including adoption in any interim period, for all entities. The amendments in this ASU should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company adopted this new accounting guidance on January 1, 2020, on a prospective basis. The implementation of this standard did not have a material impact on the Company's operating results, cash flows, financial condition or related disclosures.

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## 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, 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 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 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*, 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, 2020.

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## 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, 2020.

#### 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:

	Septe	mber 30, 2020	Dece	ember 31, 2019
Furniture, office equipment, and leasehold improvements	\$	1,291,985	\$	1,135,107
Manufacturing equipment and tooling		1,856,881		1,295,978
Total property and equipment		3,148,866		2,431,085
Less: accumulated depreciation		(1,888,191)		(1,819,239)
Property and equipment, net	\$	1,260,675	\$	611,846

Depreciation expense was \$99,071 and \$69,740 for the three months ended September 30, 2020 and 2019, respectively, and \$251,084 and \$218,328 for the nine months ended September 30, 2020 and 2019, 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. Except as described below, KORU Medical is not presently a party to any litigation or other legal proceeding that is believed to be material to its financial condition.

#### Litigation

Refer to Form 10-Q for the quarterly period ended June 30, 2020 regarding the dismissed case with our principal competitor, EMED Technologies Corporation ("EMED").

## NOTE 4 — STOCK-BASED COMPENSATION

On June 29, 2016, the Board of Directors amended the Company's 2015 Stock Option Plan (as amended, the "Plan") authorizing the Company to grant awards to certain executives, key employees, and consultants under the Plan, which was approved by shareholders at the Annual Meeting of Shareholders held on September 6, 2016. The total number of shares of Common Stock, with respect to which awards may be granted pursuant to the Plan, may not exceed 6,000,000 pursuant to an amendment to the Plan approved by shareholders on April 23, 2019, at the 2019 Annual Meeting of Shareholders.

On May 20, 2020, the Company entered into a Settlement Agreement related to its litigation with EMED as described above in "NOTE 3 — COMMITMENTS AND CONTINGENCIES." 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 vesting 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 can be settled in cash in lieu of common stock at the Company's sole discretion, provided that the number of shares of common stock and/or amount of cash paid by the Company upon exercise will be capped at a value of \$16.21 per share. The option was recorded at \$347,008, the estimated fair value of the option using the Black-Scholes option pricing model with a volatility rate of 52.68% and a risk-free rate of 0.17%. The Settlement Agreement includes mutual releases and covenants not to sue for any claim arising before May 20, 2020 and the Company products. This was a non-cash settlement from which we recognized expense in the amount of \$2.2 million in the second quarter of 2020.

On February 20, 2019, the Board of Directors of the Company approved an increase in compensation for each non-employee director from \$25,000 to \$50,000 annually effective January 1, 2019, and an additional \$10,000 annually for the chair of each Board committee effective February 20, 2019, in each case to be paid quarterly half in cash and half in common stock at the end of each fiscal quarter. On September 30, 2019, the Board of Directors of the Company named R. John Fletcher, a current KORU Medical director, as Chairman, replacing Executive Chairman, Daniel S. Goldberger, who remains a non-executive member of KORU Medical's Board of Directors. In Mr. Fletcher's role as Chairman, he receives an additional \$50,000 in annual compensation, to be paid quarterly in shares of KORU Medical common stock based on the closing price of the stock on the last day of each quarter.

Pursuant to Daniel S. Goldberger's employment agreement dated October 12, 2018, on February 1, 2019, when Donald B. Pettigrew was appointed to President and Chief Executive Officer, Mr. Goldberger was awarded a performance bonus in the amount of \$270,000 to be paid half in cash and half in stock. The number of shares that were issued totaled 90,604 and was based upon the closing price of the Common Stock of the Company on February 1, 2019, as reported by the OTCQX. These shares were issued on April 3, 2019.

#### 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, 2020 and September 30, 2019 was \$6.53 and \$1.33, 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, 2020 and September 30, 2019. 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.

	Septembe	er 30,
	2020	2019
Dividend yield	0.00%	0.00%
Expected Volatility	62.11 - 62.18%	56.10 - 60.70%
Weighted-average volatility		_
Expected dividends		_
Expected term (in years)	10 Years	10 Years
Risk-free rate	0.63 - 0.64%	1.60 - 2.72%

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

	Nine Months Ended September 30,							
	2020							
	Weighted Average Exercise Shares Price			Shares		Veighted Average Exercise Price		
Outstanding at January 1	3.647.000	\$	1.32	2.419.000	\$	1.00		
Granted	360,000	\$	9.54	1,650,000	\$	1.92		
Exercised	747,006	\$	0.65	160,000	\$	0.37		
Forfeited	200,000	\$	2.09	12,000	\$	0.87		
Outstanding at September 30	3,059,994	\$	2.40	3,897,000	\$	1.41		
Options exercisable at September 30	1,009,629	\$	1.36	1,037,885	\$	0.81		
Weighted average fair value of options granted during the period	_	\$	6.53		\$	1.33		
Stock-based compensation expense	_	\$	572,775		\$	473,139		

Total stock-based compensation expense totaled \$572,775 and \$473,139 for the nine months ended September 30, 2020 and 2019, respectively. Cash received from option exercises for the nine months ended September 30, 2020 and 2019 was \$95,880 and \$58,900, respectively.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2020 and 2019 was \$6.53 and \$1.33, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2020 and 2019 was \$296,226 and \$30,022, respectively.

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The following table presents information pertaining to options outstanding at September 30, 2020:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Av Ex	eighted verage ercise Price	Number Exercisable	 Weighted Average Exercise Price
\$0.50 - 9.76	3,059,994	7.5 years	\$	2.40	1,009,629	\$ 1.36

As of September 30, 2020, there was \$3,679,084 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 48 months. The total fair value of shares vested as of September 30, 2020 and 2019, was \$874,041 and \$506,729, respectively.

## Performance Based Stock Options

The per share weighted average fair value of stock options granted during the nine months ended September 30, 2020 and 2019 was zero and \$1.16, 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, 2020 and September 30, 2019. 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.

	September	30,
	2020	2019
Dividend yield	—	0.00%
Expected Volatility	—	58.90%
Weighted-average volatility	_	—
Expected dividends		
Expected term (in years)	—	10 Years
Risk-free rate	_	2.07%

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

	Nine Months Ended September 30,						
	20	020	2	2019			
	Shares	A	Veighted Average Exercise Price	Shares	A	Veighted Average Exercise Price	
Outstanding at January 1	1,000,000	\$	1.70	_	\$	_	
Granted		\$	_	1,000,000	\$	1.70	
Exercised	—	\$	—	—	\$	—	
Forfeited	_	\$	_	_	\$	_	
Outstanding at September 30	1,000,000	\$	1.70	1,000,000	\$	1.70	
Options exercisable at September 30	333,333	\$	1.70	_	\$	_	
Weighted average fair value of options granted during the period	_	\$	_		\$	1.16	
Stock-based compensation expense	_	\$	438,365		\$	167,636	

Total performance stock-based compensation expense totaled \$438,365 and \$167,636 for the nine months ended September 30, 2020 and 2019, respectively.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2020 and 2019, was zero and \$1.16, respectively.

The following table presents information pertaining to performance based options outstanding at September 30, 2020.

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	 Weighted Average Exercise Price
\$1.70	1,000,000	8.7 years	\$ 1.70	333,333	\$ 1.70

As of September 30, 2020, there was \$430,833 of total unrecognized compensation cost related to non-vested performance share option based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 31 months. The total fair value of shares vested as of September 30, 2020 and 2019 was \$387,520 and zero, respectively.

## NOTE 5 — DEBT OBLIGATIONS

On February 8, 2018, the Company issued a promissory note (the "Original Note") to KeyBank National Association ("KeyBank") in the amount of \$1.5 million as a variable rate revolving line of credit loan due on demand with an interest rate of LIBOR plus 2.25%, collateralized with a certificate of deposit in the amount of \$1.5 million. On September 25, 2018, KeyBank released the certificate of deposit as collateral for the loan and the Company executed a Commercial Security Agreement as collateral for the loan.

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 current line of credit agreement and Original Note. The Company drew on the additional \$2.0 million on April 23, 2020. The Original Note was in the form of a variable rate revolving line of credit with an interest rate of LIBOR plus 2.25%. 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%. Interest is due monthly, and all principal and unpaid interest is due on June 1, 2021. The \$3.5 million Note may be prepaid at any 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, 2020.

On April 20, 2020, the Company entered into a Loan Agreement with the Bank (the "PPP Loan Agreement") pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), providing for a loan in the principal amount of \$1,476,508 (the "PPP Loan"). The PPP Loan was funded on April 27, 2020. On May 13, 2020, the Company returned the funds it received.

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 Ioan. 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, 2020, 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 1 to 3 years, some of which include options to extend the leases annually and some with options to terminate the leases within 1 year.

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# The components of lease expense were as follows:

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2020		2019		2020		2019	
Operating lease cost	\$	37,921	\$	37,922	\$	113,764	\$	111,672
Short-term lease cost		19,846		5,535		33,535		18,196
Total lease cost	\$	57,767	\$	43,457	\$	147,299	\$	129,868
Finance lease cost:								
Amortization of right-of-use assets	\$	791	\$	1,061	\$	4,502	\$	3,182
Interest on lease liabilities		47		47		199		178
Total finance lease cost	\$	838	\$	1,108	\$	4,701	\$	3,360

Supplemental cash flow information related to leases was as follows:

		Nine Mon Septem		
	2020 2019		2019	
Cash paid for amounts included in the measurement of lease liabilities:				
Operating cash flows from operating leases	\$	113,764	\$	111,672
Financing cash flows from finance leases		4,502		3,122

Supplemental balance sheet information related to leases was as follows:

	September 30, 2020		December 31, 2019	
Operating Leases				
Operating lease right-of-use assets	\$	271,679	\$	373,734
Operating lease current liabilities		140,450		136,888
Operating lease long term liabilities		131,229		236,846
Total operating lease liabilities	\$	271,679	\$	373,734
Finance Leases				
Property and equipment, at cost	\$	12,725	\$	12,725
Accumulated depreciation		(9,344)		(4,837)
Property and equipment, net	\$	3,381	\$	7,888
Finance lease current liabilities		3,026		5,296
Finance lease long term liabilities		414		2,646
Total finance lease liabilities	\$	3,440	\$	7,942
	Sep	September 30, 2020		cember 31, 2019
Weighted Average Remaining Lease Term				
Operating leases		1.6 Years		2.4 Years
Finance leases		1 Year		1.3 Years
Weighted Average Discount Rate				
Operating leases		4.75%		4.75%
Finance leases		4.75%		4.75%
		- 16	-	

Maturities of lease liabilities are as follows:

Year Ending December 31,	Oper	ating Leases	<b>Finance Leases</b>		
2020 (excluding the nine months ended September 30, 2020)	\$	37,922	\$	832	
2021		149,476		2,705	
2022		97,256		_	
2023				_	
2024				_	
2025					
Thereafter					
Total undiscounted lease payments		284,654		3,537	
Less: imputed interest		(12,975)		(97)	
Total lease liabilities	\$	271,679	\$	3,440	

#### NOTE 7 — RELATED PARTY TRANSACTIONS

#### BUILDING LEASE

Mark Pastreich, a former director through April 2019, is a principal in the entity that owns the building leased by us for our corporate headquarters and manufacturing facility at 24 Carpenter Road, Chester, New York 10918. On February 28, 2019, we completed year twenty of a twenty-year lease with monthly lease payments of \$11,042. On November 14, 2017, we executed a lease extension, which calls for six-month extensions beginning March 1, 2019 with the option to renew six times at a monthly lease amount of \$12,088. The Company exercised four of the six additional renewal options for September 1, 2019 through August 31, 2021.

The lease payments were \$36,264 for both three months ended September 30, 2020 and 2019, and \$108,792 and \$106,700 for the nine months ended September 30, 2020 and 2019, respectively. The Company also paid property taxes in the amount of \$12,546 and \$13,749 for three months ended September 30, 2020 and 2019, respectively and \$39,205 and \$39,165 for the nine months ended September 30, 2020 and 2019, respectively.

## NOTE 8 — 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 additional 468,750 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 \$26.5 million.

#### NOTE 9 — SUBSEQUENT EVENT

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 is expected to be made within the next ten days (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.

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# 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, future operating results, Food and Drug Administration regulations, introduction of competitive products, acceptance of and demand for new and existing products, ability to penetrate new markets, success in enforcing and obtaining patents, reimbursement related risks, government regulation of the home health care industry, success of the research and development effort, expanding the market of FREEDOM60<sup>®</sup> 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.

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.

The following discussion and analysis for the three and nine months ended September 30, 2020 should be read in conjunction with the financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and with our audited financial statements for the year ended December 31, 2019 included in our 2019 Annual Report on Form 10-K.

KORU Medical continues to monitor its operations and government recommendations and has made modifications to its normal operations because of the COVID-19 outbreak, including requiring most of its non-production related team members to work remotely or on a staggered work shift. The Company has continued to maintain a manufacturing operational capacity at its manufacturing facility located in Chester, New York, and has instituted heightened cleaning and sanitization standards and several health and safety protocols and procedures to safeguard its team members who do continue to report in person. Until the ultimate extent and duration of the pandemic is known, we cannot predict the ultimate 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 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 the pandemic. Refer to "PART II – OTHER INFORMATION, ITEM 1A. RISK FACTORS" of this Quarterly Report on Form 10-Q for further discussion of the potential impact of the COVID-19 pandemic on our business.

We ended the third quarter of 2020 with net sales of \$6.1 million, down 8.1% versus the prior year's third quarter. Our net sales were negatively impacted principally by reduced U.S. clinical trial activity and higher allowances consisting of pricing and growth rebates related to certain customers and payment discounts and distribution fees at our largest distributor under new contract terms. The third quarter of 2019 included two unusually large orders, and the third quarter of 2020 included a significant order from our largest distributor placed early in exchange for a nominal discount, which may impact our net sales for the fourth quarter of 2020.

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# **RESULTS OF OPERATIONS**

#### Three months ended September 30, 2020 compared to September 30, 2019

#### Net Sales

The following table summarizes our net sales for the three months ended September 30, 2020 and 2019:

	Th	ee Months En	ded Se	ptember 30,	C	hange from Prio	r Year	% of Sales		
		2020		2019	19 \$		%	2020	2019	
Sales										
Domestic	\$	5,372,536	\$	5,856,203	\$	(483,667)	(8.3%)	88.4%	88.5%	
International		707,779		761,194		(53,415)	(7.0%)	11.6%	11.5%	
Total	\$	6,080,315	\$	6,617,397	\$	(537,082)	(8.1%)			

Total net sales decreased \$0.5 million or 8.1% to \$6.1 million for the three months ended September 30, 2020 compared with the same period last year. Net sales decreased primarily due to reduced U.S. clinical trial activity (\$0.4 million). Higher allowances consisting of pricing and growth rebates related to certain customers and payment discounts and distribution fees at our largest distributor under new contract terms and lower international sales also contributed to lower net sales in the three months ended September 30, 2020. There were two unusually large orders in the third quarter of 2019, one domestic from our largest distributor and one international. Sales in the third quarter of 2020 included a \$1.0 million order from our largest distributor placed early in exchange for a nominal discount, which may impact our net sales for the fourth quarter of 2020.

## Gross Profit

Our gross profit for the three months ended September 30, 2020 and 2019 is as follows:

	Th	ree Months End	led Sep	Change from Prior Year			
	2020		2019			\$	%
Gross Profit	\$	3,940,723	\$	4,382,908	\$	(442,185)	(10.1%)
Stated as a Percentage of Net Sales		64.8%		66.2%			

Gross profit decreased \$0.4 million or 10.1% in the three months ended September 30, 2020, compared to the same period in 2019, driven by lower net sales as described above, partially offset by favorable production variances.

#### Selling, general and administrative, Litigation and Research and development

Our selling, general and administrative expenses, litigation and research and development costs for the three months ended September 30, 2020 and 2019 are as follows:

	Three Months Ended September 30,					Change from Prior Year			
	2020		2019		\$		%		
Selling, general and administrative	\$	3,075,169	\$	2,441,381	\$	633,788	26.0%		
Litigation		675		864,009		(863,334)	(99.9%)		
Research and development		390,416		170,260		220,156	129.3%		
·	\$	3,466,260	\$	3,475,650	\$	(9,390)	(0.3%)		
Stated as a Percentage of Net Sales		57.0%		52.5%					

Selling, general and administrative expenses increased \$0.6 million, or 26.0%, during the three months ended September 30, 2020 compared to the same period last year, mostly due to higher salary, related benefits and recruiting fees of \$0.4 million resulting from new hires in the 2020 period. Higher consulting fees related to marketing and regulatory initiatives of \$0.1 million also added to the increase, as well as higher directors and officer's insurance premiums and other miscellaneous expenses totaling \$0.2 million. Offsetting these increases were lower trade show and travel expenses of \$0.1 million as a result of COVID-19 related travel restrictions.

Litigation fees decreased \$0.9 million during the three months ended September 30, 2020 compared to the same period last year primarily due to the negotiation of and entry into a litigation settlement agreement with EMED in May 2020.

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Research and development expenses increased \$0.2 million during the three months ended September 30, 2020 compared with the same period last year mostly due to higher consulting services and additional testing related to development initiatives.

#### Depreciation and amortization

Depreciation and amortization expense increased by 39.7% to \$115,637 in the three months ended September 30, 2020 compared with \$82,774 in the three months ended September 30, 2019. We continue to invest in capital assets, mostly related to manufacturing and computer equipment.

#### Net Income

	Th	ree Months End	led Sept	Change from Prior Year			
	2020			2019		\$	%
Net Income	\$	249,175	\$	651,813	\$	(402,638)	(61.8%)
Stated as a Percentage of Net Sales		4.1%		9.9%			

Our net income for the three months ended September 30, 2020 was \$0.2 million, compared to net income of \$0.7 million for the three months ended September 30, 2019, primarily due to lower net sales of \$0.5 million with total operating expenses remaining flat for the same periods.

## Nine months ended September 30, 2020 compared to September 30, 2019

#### Net Sales

The following table summarizes our net sales for the nine months ended September 30, 2020 and 2019:

	Ni	Nine Months Ended September 30,				Change from Pri	or Year	% of Sales		
		2020		2019		\$	%	2020	2019	
Sales										
Domestic	\$	17,459,212	\$	14,308,994	\$	3,150,218	22.0%	86.8%	84.5%	
International		2,660,016		2,631,493		28,523	1.1%	13.2%	15.5%	
Total	\$	20,119,228	\$	16,940,487	\$	3,178,741	18.8%			

Total net sales increased \$3.2 million or 18.8% for the nine months ended September 30, 2020 as compared to the prior year period. The increase was due principally to an increase in product sales volume, as well as higher U.S. clinical trial activity (\$1.0 million). We believe the increase in product sales volume reflects an increase in continued growth in diagnosis of PIDD and CIDP. Also contributing to the increase in product sales volume was a \$1.0 million order from our largest distributor placed early in exchange for a nominal discount, which may impact our net sales for the fourth quarter of 2020. Partially offsetting net sales were higher allowances consisting of pricing and growth rebates related to certain customers and payment discounts at our largest distributor under new contract terms.

#### Gross Profit

Our gross profit for the nine months ended September 30, 2020 and 2019 is as follows:

	Ν	Nine Months Ended September 30,				Change from Pri	or Year
		2020		2019		\$	%
Gross Profit	\$	12,638,813	\$	10,906,526	\$	1,732,287	15.9%
Stated as a Percentage of Net Sales		62.8%		64.4%			

Gross profit increased \$1.7 million or 15.9% in the nine months ended September 30, 2020, compared to the same period last year, reflecting net sales growth described above as well as favorable production variances in the third quarter of 2020. Gross profit for the nine months was negatively impacted by overtime costs related to COVID-19 absenteeism and an obsolescence reserve resulting from a discontinued product line, partially offset by favorable production variances in the third quarter of 2020.

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#### 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, 2020 and 2019 are as follows:

	Nine Months Ended September 30,			Change from Prior Year		
		2020		2019	 \$	%
Selling, general and administrative	\$	9,039,980	\$	6,976,684	\$ 2,063,296	29.6%
Litigation		2,446,747		2,481,471	(34,724)	(1.4%)
Research and development		944,637		450,454	494,183	109.7%
×	\$	12,431,364	\$	9,908,609	\$ 2,522,755	25.5%
Stated as a Percentage of Net Sales		61.8%		58.5%		

Selling, general and administrative expenses increased \$2.1 million, or 29.6%, during the nine months ended September 30, 2020 compared to the same period last year, mostly due to higher salary and related benefits, severance, bonus and recruiting fees in aggregate totaling \$1.4 million. Also contributing to the increase were consulting fees of \$0.5 million related to marketing, regulatory and strategic initiatives, as well as increased director fees and higher insurance premiums related to our directors and officers' insurance policy in aggregate totaling \$0.3 million, and miscellaneous expenses of \$0.3 million. Offsetting the increase were lower trade show and travel expenses of \$0.4 million as a result of COVID-19 related travel restrictions.

Litigation fees decreased \$34,724 compared to the same period last year due primarily to the negotiation of and entry into a litigation settlement agreement reached with EMED in May 2020 resulting in a non-cash expense of \$2.2 million.

Research and development expenses increased \$0.5 million during the nine months ended September 30, 2020 compared with the same period last year mostly due to increased salary and related benefits due to higher headcount and additional testing as we continue our development initiatives.

#### Depreciation and amortization

Depreciation and amortization expense increased by 17.9% to \$297,801 in the nine months ended September 30, 2020 compared with \$252,594 in the nine months ended September 30, 2019. We continued to invest in capital assets, mostly related to manufacturing and computer equipment.

#### Net (Loss)/Income

	Nine Months Ended September 30,				 Change from Prior Year		
		2020		2019	 \$	%	
Net (Loss)/Income	\$	(377,435)	\$	644,606	\$ (1,022,041)	(158.6%)	
Stated as a Percentage of Net Sales		(1.9%)		3.8%			

Our net loss for the nine months ended September 30, 2020 was \$0.4 million compared to net income of \$0.6 million for the nine months ended September 30, 2019, driven by the EMED settlement charge and higher selling, general and administrative expenses, partially offset by higher sales as described above.

## LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of \$32.4 million as of September 30, 2020, which includes the net proceeds from the recent capital raise totaling \$26.5 million. In response to concerns about the potential impact of COVID-19, the Company elected to draw \$3.5 million during the three months ended June 30, 2020, the full amount available on its line of credit, and paid it back during the three months ended September 30, 2020. 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, selling, general and administrative expenses.

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## Cash Flows

The following table summarizes our cash flows:

	Nine Months Ended September 30, 2020		Nine Months Ended September 30, 2019		
Net cash provided by/(used in) operating activities	\$	968,437	\$	(502,014)	
Net cash (used in)/provided by investing activities	\$	(1,007,539)	\$	1,389,281	
Net cash provided by financing activities	\$	26,601,984	\$	502,958	

#### Operating Activities

Net cash provided by operating activities of \$1.0 million for the nine months ended September 30, 2020 was mostly attributable to noncash 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.

Net cash used in operating activities of \$0.5 million for the nine months ended September 30, 2019 was mostly attributable to increased accounts receivable of \$2.1 million as one of our major customer's payment terms changed on January 1, 2019 from net 30 to net 60 days, increased inventory of \$0.6 million as we build stock to keep pace with sales growth, as well as severance payments and payments for insurance renewals. Partially offsetting these were our non-cash charges for stock based compensation of \$0.9 million and depreciation and amortization of long lived tangible and intangible asset of \$0.3 million, as well as increases in accounts payable of \$0.4 million primarily for major supplier invoices and accrued expenses of \$0.5 million primarily due to legal fees and bonus accruals.

## Investing Activities

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. Our net cash provided by investing activities of \$1.4 million for the nine months ended September 30, 2019 was mostly the result of the maturation of a certificate of deposit for \$1.5 million and the sale of the house the Company owned for \$0.2 million, offset by capital expenditures of \$0.2 million, and patent applications and maintenance of existing applications of \$0.2 million.

#### Financing Activities

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. The \$0.5 million provided by financing activities for the nine months ended September 30, 2019 is a result of warrants and options exercised during the period.

See "NOTE 5 — DEBT OBLIGATIONS" for further detail regarding the promissory note and loan agreement, and "NOTE 8 — EQUITY" regarding the equity offering.

We believe that as of September 30, 2020, cash on hand and cash expected to be generated from future operating activities will be sufficient to fund our operations, including further research and development and capital expenditures, for the next 12 months, as well as accelerate execution of our strategic initiatives. We believe KORU Medical's home infusion products continue to find a solid following in the subcutaneous immunoglobulin ("SCIg") market, as well as into new markets like neurology where Hizentra® received an expanded indication for CIDP.

#### NON-GAAP FINANCIAL MEASURES

Management of the Company believes that investors' understanding of the Company's performance is enhanced by disclosing non-GAAP financial measures as a reasonable basis for comparison of the Company's ongoing results of operations. These non-GAAP measures should not be considered a substitute for GAAP-basis measures and results. Our non-GAAP measures may not be comparable to non-GAAP measures of other companies. The table below provides a disclosure of these non-GAAP financial measures to the most closely analogous measure determined in accordance with GAAP. Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. They are limited in value because they exclude charges that have a material effect on our reported results and, therefore, should not be relied upon as the sole financial measures to evaluate our financial results. The non-GAAP financial measures are meant to supplement, and to be viewed in conjunction with, GAAP financial results.

We disclose and discuss Adjusted EBITDA as a non-GAAP financial measure in our public releases, including quarterly earnings releases, and other filings with the Securities and Exchange Commission. We define Adjusted EBITDA as earnings (net income/(loss)) before interest, income tax expense, depreciation and amortization, discontinued product expense, reorganization charges, litigation expenses including stock-based settlement expense, manufacturing initiative and stock option expenses. Prior to January 1, 2020, discontinued product expense and manufacturing initiative expenses were not included in our definition of Adjusted EBITDA. We believe that Adjusted EBITDA is used by investors and other users of our financial statements as a supplemental financial measure that, when viewed with our GAAP results and the accompanying reconciliation, we believe the disclosure of Adjusted EBITDA helps investors meaningfully evaluate and compare our cash flow generating capacity from quarter to quarter and year to year. Adjusted EBITDA is used by management as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations. Because management uses Adjusted EBITDA for such purposes, the Company uses Adjusted EBITDA as a significant criterion for determining the amount of annual cash incentive compensation paid to our executive officers and employees. We have historically found that Adjusted EBITDA is superior to other metrics for our company-wide cash incentive program, as it is more easily explained and understood by our typical employee.

A reconciliation of our non-GAAP measures is below:

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

*Discontinued Product Expense.* We have excluded the effect of expenses related to a discontinued product line in calculating our non-GAAP Adjusted EBITDA measure. We expected to retire our Res-Q-Vac product line towards the end of 2020, but due to the failure of equipment used to manufacture the product, the discontinuation and resulting expense was accelerated into the first quarter of 2020 which we would not otherwise incur in periods presented as part of our continuing operations. Subsequently, in the second and third quarter of 2020, we sold off a portion of the discontinued inventory previously reserved. We do not expect to incur any significant related expenses in the future.

*Reorganization Charges.* We have excluded the effect of reorganization charges in calculating our non-GAAP Adjusted EBITDA measure. We incurred significant expenses in connection with the termination and replacement of C-suite executives and senior management which we would not otherwise incur in periods presented as part of our continuing operations. Reorganization charges include costs related to the replacement of C-suite executives including a transition bonus and recruiting fees, prior to March 31, 2019.

*Litigation.* We have excluded litigation expenses in calculating our non-GAAP Adjusted EBITDA measure. Litigation expenses include stock-based litigation settlement expense of \$2.2 million related to the settlement agreement entered into with EMED on May 20, 2020. We continue to evaluate our business performance excluding litigation fees; however, we expect these expenses related to the EMED litigation to discontinue soon because of the settlement.

Manufacturing Initiative Expenses. We have excluded the effect of expenses related to the implementation of those portions of our strategic plan related to creating manufacturing efficiencies, in calculating our non-GAAP Adjusted EBITDA measure. We incurred expenses in connection with executing on these initiatives which we would not otherwise incur in periods presented as part of our continuing operations. We expect to incur related expenses for the next twelve to eighteen months as we continue to execute on our strategic plan.

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Stock Option Expense. We have excluded the effect of stock option expenses in calculating our non-GAAP Adjusted EBITDA measure. Although stock option compensation is a key incentive offered to our employees, we continue to evaluate our business performance excluding stock option compensation expenses. We record non-cash compensation expense related to grants of options and 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.

# 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, 2020, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

## PART II - OTHER INFORMATION

On November 11, 2020, Repro Med Systems, Inc. d/b/a KORU Medical Systems (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 is expected to be made within the next ten days (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.

The foregoing description of the Manufacturing and Supply Agreement is not complete and is qualified in its entirety by reference to the full text of the Manufacturing and Supply Agreement, a copy of which is attached as an exhibit to this Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020.

## **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. Except as described below, KORU Medical is not presently a party to any litigation or other legal proceeding that is believed to be material to its financial condition.

#### Litigation

Refer to Form 10-Q for the quarterly period ended June 30, 2020 regarding the dismissed case with our principal competitor, EMED Technologies Corporation ("EMED").

## 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, 2019, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common stock. The following are material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2019:

#### Our business has been and could continue to be adversely affected by the COVID-19 pandemic.

The COVID-19 pandemic has and will continue affecting economies and businesses around the world. We are closely monitoring the impact of COVID-19 on all aspects of our business, including how it may impact our employees and business operations. While we did not incur significant manufacturing disruptions during the quarter ended September 30, 2020 from the COVID-19 pandemic, customer purchasing patterns and clinical trial activity have been less predictable as a result of the pandemic. We may experience disruptions that could severely impact our results of operations and financial condition. We are unable to predict the impact that COVID-19 will have on our future operating results and financial condition due to numerous uncertainties. These uncertainties include the geographic spread of the pandemic, the severity of the virus, the impact of the virus directly on our employees or those of our suppliers, the duration of the outbreak, governmental actions, travel restrictions and social distancing, business closures or business disruptions (including those impacting our supply chain), delays in clinical trials, the effectiveness of actions taken in the United States and other countries to contain and treat the disease, the availability of plasma and drugs that are administered by our products, the number of new prescriptions for PIDD and CIDP, purchasing patterns of customers in response to the pandemic, changes to our operations, or whether the United States and additional countries are required to move to complete lock-down status, among others. Our sales representatives are unable to hold in-person meetings with customers and health care providers to discuss our products, which may further impact our sales. As local jurisdictions continue to put restrictions in place, our ability to continue to manufacture our products may also be limited. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The health of our workforce and our ability to meet staffing needs at our facility cannot be predicted and is vital to our operations. We will continue to monitor the COVID-19 situation closely and intend to follow health and safety guidelines as they evolve. Further, the spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, it has resulted in significant disruption of global financial markets, which could reduce our ability to access capital, negatively affecting our liquidity. In addition, the recession resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. The ultimate long-term impact of COVID-19 is highly uncertain and cannot be predicted with confidence.

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

Each non-employee director of the Company is eligible to receive of \$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 and pro-rated for partial service. The Chairman of the Board is eligible to receive an additional \$50,000 annually (effective October 1, 2019), all to be paid in common stock. The Company issued an aggregate of 6,681 and 23,869 shares of common stock to its non-employee directors for the three and nine months ended September 30, 2020, respectively.

On January 7, 2020, Manuel Marques, the Company's Chief Operating Officer, exercised options held by him for an aggregate 175,000 shares of common stock for an aggregate exercise price of \$85,500.

On May 9, 2020, Karen Fisher, the Company's Chief Financial Officer, exercised options held by her for an aggregate 535,000 shares of common stock through delivery of previously owned shares having an aggregate fair market value of \$322,294.

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 (the "Claims"). 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 vesting 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 can be settled in cash in lieu of common stock at the Company's sole discretion, provided that the number of shares of common stock and/or amount of cash paid by the Company upon exercise will be capped at a value of \$16.21 per share. The Settlement Agreement includes mutual releases and covenants not to sue for any claim arising before May 20, 2020 and the Company covenants not to challenge any EMED patents that were the subject of the Claims unless EMED asserts them in the future against Company products.

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.

#### ITEM 6. EXHIBITS.

- 10.1 Manufacturing and Supply Agreement dated as of November 11, 2020 between Repro Med Systems, Inc. and Command Medical Products. Certain information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.
- 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\* Interactive Data Files of Financial Statements and Notes.

\* In accordance with Regulation S-T, the Interactive Data Files in Exhibit 101 to the Quarterly Report on Form 10-Q shall be deemed "furnished" and not "filed".

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# 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 12, 2020	<u>/s/ Donald B. Pettigrew</u> Donald B. Pettigrew, President and Chief Executive Officer (Principal Executive Officer)
November 12, 2020	<u>/s/ Karen Fisher</u> Karen Fisher, Chief Financial Officer and Treasurer (Principal Financial Officer)
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#### Exhibit 10.1

#### CERTAIN IDENTIFIED INFORMATION HAS BEEN EXCLUDED FROM THE EXHIBIT BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) WOULD BE COMPETITIVELY HARMFUL IF PUBLICLY DISCLOSED, AND THE EXCLUDED TERMS HAVE BEEN MARKED AT THE APPROPRIATE PLACE WITH THREE ASTERISKS [\*\*\*].

# MANUFACTURING AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement (this "Agreement") is entered into as of November 11, 2020 (the "Execution Date") by and between (1) Repro Med Systems, Inc. d/b/a KORU Medical Systems having offices at 24 Carpenter Road, Chester, NY 10918 ("KORU"), and (2) Command Medical Products, Inc. having corporate offices at 15 Signal Avenue, Ormond Beach, Florida 32174, U.S.A. ("Command"). KORU and Command shall hereinafter be individually referred to as a "Party" and collectively as the "Parties."

## RECITALS

- A. KORU is engaged in the research and development, manufacture, distribution, and marketing of certain medical devices.
- B. Command is engaged in the contract manufacturing and sale of certain disposable medical device products.
- C. KORU desires that Command manufacture and supply the Product (defined below) to KORU.
- D. KORU and Command desire to enter into this Agreement governing the supply of the Product to KORU under the conditions contained herein.

# AGREEMENT

NOW THEREFORE, in consideration of the covenants contained herein, the above recitals, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto agree as follows:

# 1. **DEFINITIONS**

**1.1** "Affiliate" of a Party shall mean any corporation or other business entity controlling, controlled by, or under common control with such Party.

**1.2** "Certificate of Conformance" or "COC" shall mean a document prepared by Command containing at a minimum: Product name, Lot (defined below) number, lot quantity and a statement indicating compliance to all Specifications. Each COC shall be signature approved by Command's Quality Assurance department.

**1.3 "Control"** (including "controlling", "controlled by" and "under common control with" of any party, corporation, or other business entity) shall mean the direct or indirect ownership of at least fifty percent (50%) of the voting or income interest in such party, corporation, or other business entity, respectively.

**1.4** "Current Good Manufacturing Practices" (abbreviated "GMPs" or "cGMPs") shall mean the standards established by the United States Food and Drug Administration (the "FDA") for current Good Manufacturing Practices, as specified in FDA 21 C.F.R. §820 Quality Systems Regulations (or its successor provisions; ISO 13485 Medical Devices – Quality Management Systems and other sections so designated by the title "Good Manufacturing Practices"; as applicable to each respective Product to be manufactured and/or supplied by Command.

**1.5** "Effective Date" shall mean the date of the first binding Purchase Order under this Agreement.

**1.6** "Execution Date" shall have the meaning first set forth above.

**1.7 "Facilities"** shall mean Command's manufacturing facilities at 15 Signal Avenue, Ormond Beach, Florida 32174, U.S.A. and Kilómetro Carretera Norte, Corporación de Zona Franca, Managua Edificios, Nicaragua 16 and 17.

**1.8 "Lead Time"** shall mean the time period that begins on the day Command receives a Purchase Order (defined below) for Product from KORU and ends on the day Command is required to ship the Product from Ormond Beach, Florida to KORU.

**1.9 "Lot"** shall mean a defined quantity of starting material, packaging material or product processed in one process or series of processes so that it could be expected to be homogeneous.

**1.10** "NRE Agreement" shall mean that certain Non-Recurring Engineering Agreement dated as of the Effective Date between the Parties.

**1.11 "Product"** shall mean the product(s) to be manufactured and supplied by Command to KORU under Purchase Order(s) issued under this Agreement and as more specifically detailed in Exhibit A attached hereto.

**1.12 "Purchase Order"** shall mean a written binding purchase order issued to Command by KORU for the purchase of Product under this Agreement.

**1.13 "Specifications"** shall mean the Product specifications attached hereto as Exhibit B. The Specifications shall also include all necessary test protocols, packaging and labeling specifications, bills of material and other documentation required to describe, control, and assure the quality of the manufacture of the Product, regardless of whether the foregoing is included as a part of Exhibit B.

**1.14** "Technology" means all methods, processes, designs, data, software, apparatus, devices, techniques, formulations, flow charts, block diagrams, reports, systems, sketches, compositions of matter, discoveries and inventions (whether or not patentable), works of authorship (whether or not copyrightable), information, algorithms, procedures, notes, summaries, results and conclusions.

# 2. <u>TERM AND TERMINATION</u>

**2.1** <u>Term</u>. This Agreement shall commence on the Execution Date; provided that, prior to the Effective Date, if any, the Parties hereto shall have no obligations pursuant to this Agreement except as set forth in Sections 9, 7.10 and 10.11. This Agreement shall terminate on the fifth (5<sup>th</sup>) anniversary of the Effective Date, unless earlier terminated as provided in Section 2.2 (the "Expiration Date").

# 2.2 <u>Termination</u>.

(a) Either Party may terminate this Agreement without any early termination fee prior to the Expiration Date (i) for material breach by the other Party of this Agreement or the NRE Agreement upon written notice specifying the nature of the breach, provided the breaching Party shall have ninety (90) days to cure such breach for any breach that is curable, (ii) upon written notice to the other Party if the other Party shall

formally declare bankruptcy, insolvency, liquidation, or receivership; or shall have instigated against it bankruptcy, insolvency, liquidation, or receivership proceedings, and shall fail to remove itself from such proceedings within ten (10) days from the date of institution of such proceedings, and (iii) as expressly set forth elsewhere in this Agreement. For the avoidance of doubt, KORU may terminate this Agreement without any early termination fee upon notice to Command in the event any of the completion dates set forth in Section 5 of the NRE Agreement are not met as specified in Section 3.4 of the NRE Agreement.

( b ) In the event this Agreement is terminated for any reason, Command shall continue performing any work reasonably requested by KORU for the orderly close out of the affected Purchase Order(s) and for the fulfillment of regulatory requirements.

(c) Without limiting Command's obligations under the NRE Agreement, within [\*\*\*] days following the termination of this Agreement, Command shall deliver to KORU all data, materials, equipment and other property owned by KORU and/or provided by KORU to Command for the manufacturing and supply activities under the impacted Purchase Order(s).

(**d**) Termination of this Agreement, for any reason, shall not release either Party from liability which at said time has already incurred, nor affect in any way the survival of any rights, duties or obligations of either Party which are expressly stated elsewhere in this Agreement to survive termination. Without limiting the generality of the foregoing, the Parties agree that Sections 2.2 and 3.2 and Articles 6, 7, 8, 9, and 10 shall survive termination of this Agreement for any reason.

(e) Termination of this Agreement prior to the Expiration Date by KORU for any reason(s) other than as set forth in Section 2.2.(a), will result in an early termination fee set forth below, which fee shall be as liquidated damages and not as a penalty.

Contract Year	Early Termination Fee
Year 1	\$[***]
Year 2	\$[***]
Year 3	\$[***]

(f) Payment terms for this Section 2.2 are Net [\*\*\*] days.

(g) Termination of this Agreement, for whatever reason except for material breach by the other Party, shall not affect the obligation of any Party to make any payments for which that Party may be liable prior to such termination.

# 3. <u>MANUFACTURE AND SUPPLY OF PRODUCT</u>

**3.1** <u>Performance Standards</u>. Command shall manufacture the Product in accordance with the Specifications and this Agreement, and shall comply with all applicable cGMPs and all other applicable Federal, state, local laws, standards, requirements, and regulations (and their foreign counterparts) in connection with the manufacture, testing, packaging, labeling, shipping, and handling of the Product.

(a) Command shall be responsible for normal and daily maintenance of all consigned equipment provided by KORU. KORU will be responsible for all other repair and/or replacement costs relating to consigned equipment, except to the extent resulting from Command's negligence. This equipment will be

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insured by KORU, while located in Command's manufacturing plant(s).

3.2 <u>Command Representations</u>. Command makes the following representations to KORU:

(a) Command is duly organized, validly existing and in good standing under the laws of Florida. Command has all requisite power and authority to own, operate and lease its properties and to carry on its business as now conducted. Command has full corporate power and authority to execute, deliver and perform this Agreement; all corporate actions of Command necessary for such execution, delivery and performance have been duly taken; and this Agreement is a valid and binding obligation of Command.

(**b**) Command shall perform all manufacturing, storage, handling, and testing of the Product(s) at the Facilities. Command warrants that the Facilities have been inspected by the FDA and/or any other required government agency and are in good standing with said governmental agencies, are fully compliant with cGMPs and that all employees working on the Product whose responsibilities involve work, which must be performed under cGMP standards have been properly trained in the requirements of those standards. Command additionally warrants that the Facilities hold all necessary licenses and permits from local, state, and federal, governmental authorities required for the manufacture and testing of the Product and that all such licenses and permits are in full force and effect. Command is not aware of the existence of any outstanding violations of any such licenses or permits and warrants that no proceeding is pending or, to the knowledge of Command, threatened, seeking the revocation or limitation of any such licenses or permits.

**3.3** <u>Suppliers</u>. Command shall use raw materials sourced only by those suppliers approved in writing by KORU. Command assumes the responsibility for interacting with all raw material suppliers as required to deliver the Product in accordance with the KORU applicable Purchase Order(s), including the Specifications, and this Agreement. Command shall not change its raw material or packaging materials without the prior written consent of KORU, which may be withheld in KORU's sole discretion.

**3.4** Intellectual Property. KORU is the sole and exclusive owner of all Technology relating to, concerning or incorporated in the Products, including such Technology developed by Command, together with all molds (whether provided by KORU or Command) and intellectual property relating thereto. All intellectual property which has arisen prior to the date of this Agreement or arises hereafter as a result of work that Command performed or performs in connection with the Products that is specific to the Products, including, without limitation, conceptions, innovations, developments, processes, formulations, improvements or methods, whether or not patentable or susceptible to any other form of protection, shall be the sole and exclusive property of KORU. Command shall not take, omit to take or cause any action that is inconsistent with or tends to diminish or impair KORU's rights as set forth in this Section 3.4, and Command agrees to assist in every proper and legal way to obtain, maintain and protect KORU's rights in such property in the United States and all foreign countries. Command hereby assigns, and agrees to assign, to KORU all right, title and interest in the United States and all foreign countries in and to KORU's rights set forth in this Section 3.4, including any and all patents, patent applications, copyright registrations, trade secrets, rights under international treaties or any other protection available in any country.

# 4. <u>PRICING AND PAYMENT</u>

**4.1** <u>Product Prices</u>. Pricing for the Product ordered is set forth in Exhibit A attached hereto. Subsequent modifications to pricing shall be subject to mutual agreement by the Parties and captured in a revised Exhibit A signed by both Parties. Modifications to pricing may be related to but not limited to changes in raw material pricing, production processes or design changes. Any increase in pricing must be substantiated and presented in writing to KORU for review and shall be subject to KORU's written approval prior to implementation. Command shall make all reasonable efforts to incorporate any efficiency gains and/or reduced

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raw material pricing and to reflect resulting price reductions negotiated in good faith in an updated Exhibit A signed by both Parties.

**4.2** Payment KORU. Unless otherwise agreed to by Command in writing, Command shall invoice KORU for Product ordered at the time of shipment and, except for any amounts disputed by KORU in good faith, KORU shall pay each invoice within [\*\*\*] days of KORU's receipt of Product Each invoice shall set forth, in U.S. Dollars, the applicable price for the shipment properly determined in accordance with the provisions of this Agreement and the calculation thereof, as well as a reference to the Purchase Order, carrier name, bill of lading number, tracking information, and any other information necessary for identification and control of the shipment. If KORU disputes any portion of an invoice received from Command, then KORU shall so notify Command in writing of the disputed amounts, and the Parties shall use good faith efforts to reconcile the disputed amounts as soon as practicable. Invoices should be sent to the address as specified in writing by KORU in the applicable Purchase Order. KORU's failure to dispute an invoiced amount shall not relieve Parties of any obligations or warranties under this Agreement.

**4.3** <u>Cost Saving Methods</u>. Both KORU and Command shall meet, at a minimum once annually, to review cost savings opportunities for the manufacture of the Product. All such cost saving efforts shall be agreed upon by the Parties in writing prior to the commencement of any changes required to implement the savings. From the time the cost savings referenced in this Section 4.3 are implemented to the termination of this Agreement, the cost savings shall be allocated as agreed upon by the Parties depending upon origin of cost savings method.

# 5. FORECASTS, PURCHASE ORDERS AND DELIVERY

**5.1** <u>Forecasts</u>. Together with the blanket Purchase Orders referenced in Section 5.2, KORU shall provide Command with a [\*\*\*] month non-binding forecast of the estimated quantities of Product believed to be required by KORU.

5.2 Purchase Orders. KORU shall provide Command blanket Purchase Orders for product demands with a minimum balance of [\*\*\*] month demands to ensure raw materials and capacity planning is in place to support demands. All Product ordered by KORU shall be in the form of a firm written Purchase Order. Each Purchase Order shall contain at a minimum, the following information: description of the Product and quantity ordered, price, freight carrier information, requested ship date, and Purchase Order number for billing purposes. Command shall accept or reject KORU's Purchase Order in writing within five (5) business days. If otherwise compliant with the terms of this Agreement, Purchase Orders may be rejected by Command only if the requested Lead Time is less than [\*\*\*] weeks from the date of the Purchase Order or if the quantity of the Product ordered exceeds [\*\*\*]% of the quantity set forth in the forecast provided pursuant to Section 5.1. At Command's request, KORU shall provide Command with such raw materials as reasonably necessary for Command to meet the requested production delivery schedule in the first Purchase Order(s) for bulk packed Products provided under this Agreement, the cost of which will be credited to KORU on the invoice for such Purchase Order. In the event Command does not notify KORU of acceptance within five (5) business days after receipt of such Purchase Order, the Purchase Order shall be deemed accepted by Command. Such accepted Purchase Order shall be binding, except that ship dates may be moved ahead or back by mutual written agreement of Command and KORU.

**5.3** <u>Delivery</u>. Unless expressly provided otherwise in the applicable Purchase Order, shipping to KORU for the Product shall be [\*\*\*]. The Product will be packaged and shipped non- sterile per the Specifications, and each delivery shall be accompanied by COC with respect to the Product contained therein. Title to such Product shall pass to KORU upon Command's receipt of a bill of lading from the carrier per the Specifications. In the event that any delivery of the Product is anticipated to be late, Command will promptly

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notify KORU Executive Team of the circumstances for the delay and propose a revised ship plan. Command will make all reasonable efforts to minimize the delay. KORU is entitled to terminate this Agreement upon notice to Command without any early termination fee in the case delivery within the reasonable control of Command is delayed by more than [\*\*\*] days.

# 6. <u>WARRANTIES</u>

**6.1** <u>Product Warranty</u>. Command warrants that all Product supplied under this Agreement shall, when it leaves Command's possession and control, conform with the Specifications and with all applicable laws and regulations, and shall be free from defects in workmanship. Command further warrants that the Product shall be manufactured in accordance with applicable cGMPs and with all applicable laws and regulations.

**6.2** <u>Acceptance, Rejection, and Claims</u>. KORU may inspect any or all shipments of Product for proper labeling, packaging and count within [\*\*\*] days of KORU's receipt of each shipment; however, any such inspection shall not relieve Command of any obligations or warranties under this Agreement. KORU has the right to reject, via written notification to Command within this [\*\*\*] day period, any or all of a shipment of Product that fails to satisfy any warranty in this Agreement and may reject all of a given Lot of Product if a statistical sample does not meet the Specifications. Upon confirmation of defective condition by Command, KORU shall be entitled to the immediate replacement, free of charge (including shipping charges), of any Product supplied by Command in breach of any warranty under this Agreement.

**6.3** Spoilage Due to Change or Obsolescence. KORU shall not be liable to Command for any printed packaging components, work in progress or finished Product which is damaged, destroyed or which become obsolete or otherwise spoiled and cannot be sold or distributed, other than due to the acts or omissions of KORU. KORU shall be liable to Command for any printed packaging components, purchased raw materials, work in progress or finished Product which becomes obsolete as a result of a specification or drawing change.

**6.4** <u>Third Party Claims</u>. Command represents and warrants that it has, and will have during the term of this Agreement, all rights necessary for the manufacture of Product, without interfering with or infringing upon any patents, copyrights, trademarks, or other intellectual property rights of any third party.

# 7. <u>REGULATORY AND QUALITY</u>

7.1 <u>Compliance</u>. Command agrees that its work under this Agreement will be conducted in compliance with all applicable laws, rules and regulations, and with the standard of care customary in the industry. If requested by KORU, Command shall provide KORU with a certificate evidencing its accreditation by the appropriate accrediting body. Such accreditation shall remain in force during the term of this Agreement. Command agrees that all Product shipments to KORU shall be in accordance with KORU's instructions and all applicable laws and regulations governing the shipment, labeling, and packaging of the Product.

**7.2** <u>Product Complaints/Reports</u>. Except as otherwise noted below, in the event that Command receives any complaint, claim or adverse reaction report regarding any Product, including, but not limited to, notices from the FDA regarding any regulatory non-compliance of Product, Command shall provide KORU with all information contained in such complaint, report, or notice and such additional information regarding the Product as may be reasonably requested. Command shall comply with FDA requirements for complaint handling. If Product contains a defect which could or did cause death or serious bodily injury, Command shall immediately provide KORU with a complete description of all relevant details known to Command concerning any such incident, including but not limited to, a description of any defect and such other information which may be necessary to report the incident to the FDA or any other Ministry of Health. KORU is responsible for filing any/all MDR Reports as required by the FDA.

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**7.3** <u>Recalls</u>. KORU shall have the right to reasonably declare any recall of, or field corrective action to, any Product supplied to KORU under this Agreement. Command agrees to cooperate with KORU in connection with any such recall. Command shall bear rework and/or replacement expenses (including shipping charges for returned and replacements) of Product(s) associated with the recall if non-conformity was a result of Command's non-compliant workmanship to the product Specifications.

7.4 <u>Government Inquiries</u>. Without limiting the generality of Section 7.2, Command shall use its best efforts to:

(a) Respond fully and accurately to all inquiries directed to it by the FDA or any government agency with respect to the manufacture and testing of the Product.

(**b**) Assist KORU in responding to inquiries directed to KORU by the FDA or any government agency with respect to the manufacture and testing of the Product.

(c) Promptly inform KORU of the existence and substance of any inquiry, investigation or inspection initiated by the FDA or any government agency, department or body relating to the Product or its manufacture. The existence of any such inquiry, investigation or inspection shall not alone constitute a breach of this Agreement or excuse any performance due under this Agreement, except as set forth in Section 7.6. Command shall immediately provide KORU with copies of any and all inspection reports, letters, documents or similar instruments submitted or received from the FDA or other government agency related to the Product or its manufacture, testing or use.

7.5 <u>Inspection of Manufacturing Facilities</u>.

(a) Command shall permit KORU and its agents, during business hours and upon notice to Command, to inspect the Facilities where the Product is manufactured, handled, stored or tested, as well as all processes relating to the manufacture, handling, storage, or testing of the Product, as well as all test records regarding the Product.

(b) Command shall extend the same inspection privileges set forth above to agents of the FDA as required, and shall promptly notify KORU of any such inspection. Command shall provide KORU with copies of any and all inspection reports from the FDA regarding that specifically detail any non-conformance relating to the manufacture of the Product within [\*\*\*] working days of receipt of such reports.

**7.6** Command warrants and agrees that it will correct within a reasonable amount of time from the date of notification, all deficiencies and/or non-conformances found during a KORU or FDA audit at its own expense. For the avoidance of doubt, failure by Command to adequately respond and satisfactorily close out an FDA "warning letter" shall constitute a material breach of this agreement.

7.7 <u>Control Testing</u>. Command shall perform quality control testing in accordance with the Specifications for release of each Lot of Product to KORU. Quality control testing shall include testing associated with the production of the Product, including, but not limited to, incoming component and raw material testing, in process testing, and final release testing as agreed upon between KORU and Command.

7.8 <u>Specifications and Change Control</u>.

(a) The Specifications may not be changed without prior written approval by KORU.

(b) Command shall not make any changes to any validated manufacturing process, Facilities, or equipment used in the manufacture that affects the form, fit or function of the Product without KORU's prior

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written approval, which may be withheld in KORU's sole discretion.

(c) KORU shall use commercially reasonable efforts to provide Command with sufficient written notice of any instructions or requirements of a government regulatory agency that may require a change of the Specifications. Command shall immediately notify KORU if any such changes in the Specifications shall render Command unable to supply the Product in accordance with the term and conditions of this Agreement.

**7.9** <u>Technical Assistance</u>. Command shall provide KORU with certain technical support regarding the Product as reasonably requested by KORU, including, but not limited to, analytical test methods, manufacturing process development, and validation support. Command may assess charges for such requests and will provide a formal written quote prior to execution of requested tasks for approval by KORU.

**7.10** <u>Quality Agreement</u>. Within 30 days following the Execution Date, Command and KORU shall review and update as necessary to reflect the Products, the existing written Quality Agreement between the Parties (the "Quality Agreement"). Upon review and update, the Quality Agreement shall be executed by the Parties and attached hereto as Exhibit C and shall be incorporated herein. The Quality Agreement may be updated from time to time upon the mutual written agreement of the Parties.

# 8. INDEMNIFICATION, LIMITATION OF LIABILITY AND INSURANCE

**8.1** Indemnification by KORU. KORU agrees to indemnify, defend and hold harmless Command, its officers, agents, and employees from any and all liability, loss (including reasonable attorneys' fees) or damage they may suffer as the result of claims, demands, costs or judgments against them arising out of the negligence, recklessness or willful misconduct on the part of KORU, its officers, agents, employees, contractors or consultants in connection with this Agreement.

**8.2** <u>Indemnification by Command</u>. Command agrees to indemnify, defend and hold harmless KORU, its officers, agents, and employees from any and all liability, loss (including reasonable attorneys' fees), or damage they may suffer as the result of claims, demands, costs or judgments against them arising out of:

(a) a failure by Command, its officers, agents, employees, contractors or consultants to adhere to this Agreement or the KORU Purchase Order received from KORU;

(**b**) negligence, recklessness or willful misconduct on the part of Command, its officers, agents, employees, contractors or consultants; or

(c) a breach of any applicable Federal, state or local law or of this Agreement by Command, its officers, agents, employees, contractors or consultants.

**8.3** General Conditions of Indemnification. Each Party's agreement to indemnify, defend and hold the other harmless is conditioned on the indemnified Party (i) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified activities within thirty (30) days after the indemnified Party has knowledge of such claim, demand or action; (ii) permitting the indemnifying Party to assume full responsibility to investigate, prepare for and defend against any such claim or demand; (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defense of any such claim or demand; and (iv) not compromising or settling such claim or demand without the indemnifying Party's written consent; provided, however, that the failure of the indemnified Party to undertake any of the foregoing actions shall not relieve the indemnifying Party of any obligation it may have under this Article 8, except to the extent that the indemnifying Party's ability to fulfill such obligation has been materially prejudiced thereby.

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**8.4** <u>Limitation of Liability</u>. EXCEPT FOR BREACHES OR VIOLATIONS OF ARTICLE 9, OR INDEMNITY LIABILITIES ARISING UNDER THIS ARTICLE 8, OR CASES OF GROSS NEGLIGENCE, MATERIAL BREACH OR WILLFUL MISCONDUCT, IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY CONSEQUENTIAL, INDIRECT, SPECIAL, INCIDENTAL OR PUNITIVE DAMAGES INCLUDING LOSS OF USE, REVENUES OR PROFITS, INTERRUPTION OF BUSINESS OR CLAIMS AGAINST EITHER PARTY OR ITS CUSTOMERS BY ANY THIRD PARTY, WHETHER SUCH CLAIM IS BASED IN CONTRACT, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR OTHERWISE, EVEN IF THE PARTY IS ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

**8**. 5 Insurance. Command, at its sole cost and expense, will maintain appropriate insurance including, but not limited to, Commercial General Liability Insurance with Broad Form Contractual Liability; premises, operations coverage including products and completed operations and Personal Injury/Property Damage Coverage, with limits of not less than \$[\*\*\*] per occurrence. A Certificate of Insurance indicating such coverage will be delivered to KORU upon request. The Certificate will (a) indicate that the policy will not change or terminate without at least fifteen (15) days prior written notice to KORU, (b) KORU shall be listed as an additional insured on the commercial general liability policy.

# 9. <u>CONFIDENTIALITY AND NON-COMPETITION</u>

**9.1** Confidential Information. For purposes of this Agreement, "Confidential Information" shall mean all information (i) identified in written or oral format by the disclosing Party as confidential, trade secret or proprietary information and, if disclosed orally, summarized in written format within thirty (30) days of disclosure, or (ii) the receiving Party knows or should reasonably be expected to know is confidential, trade secret or proprietary information of the disclosing Party, including but not limited to the Specifications and information set forth on Exhibits A and A-1. Notwithstanding the foregoing, "Confidential Information" shall not include any information which the receiving Party can show: (i) is now or subsequently becomes legally and publicly available without breach of this Agreement by the receiving Party, (ii) was rightfully in the possession of the receiving Party without any obligation of confidentiality prior to receiving it from the disclosing Party, without any obligation of confidentiality, (iv) was developed by or for the receiving Party independently and without reference to such information as shown by documentary evidence, or (v) is required to be disclosed by applicable law (including but not limited to securities laws applicable to public companies).

9.2 Nondisclosure. Each Party agrees not to use the Confidential Information of the other Party for any purpose, including trading in the financial instruments of the other Party, except in its performance under this Agreement. In addition, the receiving Party shall treat and protect such Confidential Information in the same manner as it treats its own information of like character, but with not less than reasonable care. The receiving Party agrees to take appropriate measures by instruction and/or written agreement prior to disclosure of Confidential Information to its employees and contractors to prevent unauthorized use or disclosure, and shall be responsible for any such unauthorized use or disclosure by its employees and contractors. Confidential Information may be disclosed to the extent necessary to comply with an order of an administrative agency or court of competent jurisdiction provided, however, that the Party so required to disclose Confidential Information shall provide prior written notice thereof to the other Party in sufficient time to enable that Party to seek a protective order or otherwise prevent such disclosure. The receiving Party's confidentiality obligations under this Article 9 shall survive the termination of this Agreement and shall remain binding on the Parties hereto until the Confidential Information falls within one of the exceptions stated in Section 9.1. Previously executed non-disclosure agreements between the Parties will remain in effect in conjunction with the Agreement until the termination dates specified in those agreements. Disclosure of Confidential Information under this Agreement will create no license, right, interest, or ownership in any such information in a receiving

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**9.3** <u>Injunctive Relief</u>. In the event of a breach of any of the foregoing provisions, the receiving Party agrees that the harm suffered by the disclosing Party would not be compensable by monetary damages alone and, accordingly, that the disclosing Party shall, in addition to other available legal or equitable remedies, be entitled to an injunction against any unauthorized use or disclosure of its Confidential Information.

**9.4** <u>Return of Confidential Information</u>. Upon the termination of this Agreement, or at any time the disclosing Party so requests, the receiving Party shall return to the disclosing Party any written, printed or other materials embodying the disclosing Party's Confidential Information, including all copies or excerpts thereof, or shall destroy such information pursuant to the disclosing Party's request.

**9.5** Export Controls. Command hereby acknowledges and agrees that all of KORU's Confidential Information, including materials, disclosed hereunder is subject to United States export controls, under the export administration regulations, 15 C.F.R. parts 730-774. Command shall strictly comply with all such United States export controls applicable to KORU's Confidential Information or materials, and, without limiting the generality of this Article 9, Command shall not (i) utilize any of such Confidential Information or materials for any purpose whatsoever, except as specifically authorized in this Agreement; or (ii) export, transfer, divert or disclose any of such Confidential Information or materials. Koru is responsible for supporting Command with necessary Product details and classifications to support Import/Export of devices between Facilities.

**9**. 6 <u>Non-Competition</u>. From and after the Execution Date through the expiration or earlier termination of this Agreement, Command shall not accept a new sizeable customer without KORU's written consent to develop, manufacture, supply, distribute or market any subcutaneous mechanical pump delivery system or products that directly compete with KORU's Products covered in this Agreement. For the avoidance of doubt, sizable is defined as equal to or more than [\*\*\*]% of Command's annual sales revenues. Command shall not use any equipment or other materials provided by KORU for such competitor.

### 10. GENERAL PROVISIONS

**10.1** <u>Export Control</u>. Command shall comply with all applicable export and import control laws and regulations.

**10.2** Integration / Modification. This Agreement, together with all Exhibits attached hereto, and Purchase Orders issued hereunder, the Business Continuity Plan and the NRE Agreement (together, the "Ancillary Documents"), contain the entire understandings of the Parties with respect to the subject matter herein, and supersedes all prior and contemporaneous agreements (other than any confidential disclosure agreement entered into between the Parties) and communications, whether oral, written or otherwise, concerning any and all matters contained herein. In the event of a conflict between this Agreement and any Ancillary Document, the terms of this Agreement shall prevail.

**10.3** <u>Relationship Between the Parties</u>. In fulfilling its obligations pursuant to this Agreement, each Party shall be acting as an independent contractor. Neither Party is granted any right or authority to assume or to create any obligation or responsibility, express or implied, on behalf of or in the name of the other Party.

**10.4** <u>Assignment</u>: This Agreement is binding upon and inures to the benefit of the Parties to it, and to their successors and assigns. Neither Party shall have the right to assign or subcontract this Agreement or any of its rights or obligations hereunder without the prior written consent of the other Party; provided, however, that KORU shall have the right to assign this Agreement to any Affiliate.

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### Party.

**10.5** <u>Non-Waiver</u>. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance.

**10.6** <u>No Third-Party Beneficiaries.</u> This Agreement is neither expressly nor impliedly made for the benefit of any party other than those executing it.

**10.7** <u>Severability</u>. If, for any reason, any part of this Agreement or any Purchase Order is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, such provision will be changed and interpreted to accomplish the objectives of such provision to the greatest extent possible under applicable law and the remaining provisions of this Agreement or Purchase Order (as the case may be) will continue in full force and effect.

**10.8** Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by (i) any method of mail (postage prepaid) requiring return receipt, or by overnight courier, or (ii) by email, in each case to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice shall be presumptively deemed to be sufficiently given for all purposes upon the earlier of: (x) in the case of mail or overnight courier, (a) the date of actual receipt; (b) if mailed, three (3) calendar days after the date of postmark; or (c) if delivered by overnight courier, the next business day the overnight courier regularly makes deliveries.

If to Command: Command Medical Products, Inc. 15 Signal Ave Ormond Beach, FL 32174 <u>Attention:</u> Jim Carnall <u>Email: [\*\*\*]</u>

If to KORU: Repro Med Systems, Inc. d/b/a KORU Medical Systems 24 Carpenter Road Chester, NY 10918 <u>Attention</u>: Chief Financial Officer <u>Email:</u> [\*\*\*]

**10.9** <u>Legal Fees</u>. The prevailing Party in any litigation between the Parties relating to this Agreement will be entitled to recover its reasonable attorneys' fees and court costs, in addition to any other relief that it may be awarded.

**10.10** Governing Law and Venue. Notwithstanding its place of execution or performance, this Agreement shall be governed by and construed in accordance with the laws of the State of Delaware, USA, irrespective of its laws regarding choice or conflict of laws. Prior to filing a lawsuit, the Parties agree to attempt to resolve the dispute in good faith through discussions among their respective executives within sixty (60) days following notice of the dispute by one Party to the other. Any dispute arising under or relating to this Agreement that is not resolved through such discussions shall be submitted for resolution to a state or federal court of competent jurisdiction in Delaware, USA, and the Parties hereby agree to submit to the jurisdiction and venue of such court.

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**10.11** <u>Crisis Management and Business Continuity Planning</u>. Throughout the term of this Agreement, Command will maintain and follow a written disaster recovery plan (the **"KORU's Business Continuity Plan"**) in order to ensure the supply of Products and Services to KORU in the event of a business disruption including but not limited to: hurricanes, tornadoes, flooding, pandemic and facility downtime. An outline of all material terms of KORU's Business Continuity Plan shall be attached as Exhibit D to this Agreement and incorporated herein. A final copy of the KORU's Business Continuity Plan detailing the terms of the outline and addressing customary business continuity plan elements as set forth in Exhibit E will be submitted to KORU within thirty (30) days after the Execution Date of this Agreement. An annual review of this plan may be incorporated into scheduled Business Reviews as desired by either Party. For the avoidance of doubt, failure to comply with the Business Continuity Plan shall constitute a material breach of this Agreement.

10.12 Interpretation.

(**a**) <u>Captions & Headings</u>. The captions and headings of clauses contained in this Agreement preceding the text of the articles, sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference and shall not constitute any part of this Agreement, or have any effect on its interpretation or construction.

(**b**) <u>Capitalized Terms</u>. Capitalized terms not specifically outlined in Article 1 shall have the respective meanings ascribed to them in this Agreement.

(c) <u>Singular & Plural</u>. All references in this Agreement to the singular shall include the plural where applicable, and all references to gender shall include both genders and the neuter.

(**d**) <u>Articles, Sections & Subsections</u>. Unless otherwise specified, references in this Agreement to any article shall include all sections, subsections, and paragraphs in such article; references in this Agreement to any section shall include all subsections and paragraphs in such sections; and references in this Agreement to any subsection shall include all paragraphs in such subsection.

(e) <u>Days</u>. All references to days in this Agreement shall mean calendar days, unless otherwise specified.

(f) <u>Ambiguities</u>. Ambiguities and uncertainties in this Agreement, if any, shall not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

**10.13** <u>Counterparts; Facsimile and Electronic Signatures</u>. This Agreement may be executed by exchange of signature pages by facsimile and/or or other "electronic signature" (as defined in the Electronic Signatures in Global and National Commerce Act of 2000) in a manner agreed upon by the Parties hereto; and/or in any number of counterparts, each of which shall be an original as against any Party whose signature appears thereon and all of which together shall constitute one and the same instrument.

**10.14** <u>No Drafter</u>. Neither Party shall be deemed to be the drafter of this Agreement, or of any particular provision or provisions, and no part of this Agreement shall be construed against a Party on the basis that the particular Party is the drafter of any part of this Agreement.

**10.15** <u>Further Assurances</u>. Each Party to this Agreement shall, at its own expense, furnish, execute, and deliver all documents and take all actions as may reasonably be required to effect the purposes of this Agreement.

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# **IN WITNESS WHEREOF,** the Parties hereto have executed this Agreement as of the Execution Date.

Repro Med Systems, Inc.	Command Medical Products, Inc.	
d/b/a KORU Medical Systems		
By: <u>/s/ Karen Fisher</u>	By: <u>/s/ James D. Carnall</u>	
Name: <u>Karen Fisher</u>	Name: James D. Carnall	
Title: Chief Financial Officer	Title: President & COO	
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## EXHIBIT A Page 1 of 2

# KORU PRODUCT PRICING – BULK PACKED

KORU Product	<b>Bulk Price</b>
[***]	[***]

### EXHIBIT A Page 2 of 2

## KORU PRODUCT PRICING – FINAL PACKED

### Non-Sterile Finished Good Pricing

KORU Product	Year 1 Qty	Year 1	Year 2	Year 3	Year 4
					and 5
[***]	[***]	[***]	[***]	[***]	[***]

Contract Pricing Details:

- Pricing shall be subject to increase in the event raw material pricing exceeds costs outlined on attached matrix Exhibit A-1.
- If the aggregate dollar amount of Purchase Orders placed in Year 1 is less than \$[\*\*\*], Command reserves the right to assess a price penalty of [\*\*\*]% increase on piece price for units shipped in that year.
- Years 2, 3, 4&5 prices set forth above are based on [\*\*\*]% year over year increases in the aggregate dollar amount of Purchase Orders. If such [\*\*\*]% year over year increase in not met, Command reserves the right to prior year tier pricing.
- Year 1 means from the Effective Date to the first anniversary of the Effective Date; Year 2 means from the first anniversary of the Effective Date to the second anniversary of the Effective Date; etc.

# EXHIBIT A-1

## KORU RAW

KORU Product	<b>Costed Raw Material BOM</b>
[***]	[***]

## RAW Pricing Details:

• Pricing does not reflect [\*\*\*]% cost reduction for new KORU [\*\*\*].

## EXHIBIT B

# PRODUCT SPECIFICATIONS MATRIX

## (ATTACHED HERETO)

[\*\*\*]

### EXHIBIT C

## **QUALITY AGREEMENT**

(TO BE ATTACHED)

# BUSINESS CONTINUITY PLAN - OUTLINE Command Medical Products, Inc. & KORU



The purpose of this document is to provide an outline for the specific risk management approach for sustaining/reinstating operations of KORU's manufacturing lines located at Command Medical Products Nicaragua manufacturing facility in the event of a business interruption. As contemplated by the Manufacturing and Supply Agreement to which this document is attached as an exhibit (MSA), a detailed final Business Continuity Plan materially consistent with this document will be established by both Command and KORU.

Command Medical – Florida 15 Signal Avenue, Ormond Beach, FL 32174 U.S.A Phone: 386-672-8116

Kilometro 12.5 Carretera Norte Corporacion de Zona Franca, Edificio 16 Managua, Nicaragua **Phone: [\*\*\*]** 

Command will maintain [\*\*\*] months of raw materials on-hand and a [\*\*\*]-month minimum of finished devices on-hand at Command's [\*\*\*] facility.

KORU will maintain [\*\*\*] months of finished devices at KORU's warehouse(s).

Based on the above, this strategy provides [\*\*\*] months of finished devices inventory stock to draw from during a business interruption without impact to supply chain.

The finished devices and raw material inventory levels in the Business Continuity Plan will be reviewed periodically and adjusted based on mutual agreement between KORU and Command; if necessary, to mitigate perceived risks.

#### **Raw Material**

 Subject to the requirements set forth above, raw material inventory may be maintained in two sites (US and Nicaragua) at varying levels depending on environmental conditions. Material concentration may be shifted or adjusted based on order surges, suspected risk and/or impending obsolescence as agreed to by both parties.

#### **Finished Devices**

• Command will maintain designated stock of finished devices products in their US [\*\*\*] warehouse and all orders will be fulfilled from that facility and replenished with production units manufactured in Nicaragua. This inventory will supplement any on -hand inventory maintained at KORU.

#### Second Site Manufacturing

 In the event of a significant business interruption in Command's Nicaragua facility not within the reasonable control of Command that necessitates cease of manufacturing for at least [\*\*\*] months, and if requested by KORU, manufacturing of KORU's Products will promptly be transferred from Nicaragua to Command's [\*\*\*] facility to ensure supply chain is intact and KORU's inventory is replenished. Upon any such transfer, (i) pricing for Products shall be as set forth on Schedule I to this document in lieu of as set forth on Exhibit A to the MSA, and (ii) KORU may terminate the MSA thereafter without early termination penalty.

# BUSINESS CONTINUITY PLAN - OUTLINE Command Medical Products, Inc. & KORU



SCHEDULE 1

### KORU PRODUCT PRICING – FINAL PACKED @ [\*\*\*]

KORU Product	Unit Price
[***]	[***]

### EXHIBIT E

## **BUSINESS CONTINUITY PLAN ELEMENTS**

- 1. Risk Assessment
- 2. Business Impact Analysis (BIA)
- 3. Business Continuity Plan
  - a. Initial Response
  - b. Relocation
  - c. Recovery
  - d. Restoration
- 4. Strategy and Plan Development
  - a. Purpose and Scope
  - b. Goals and Objectives
  - c. Assumptions
  - d. Key Roles and Responsibilities
  - e. Business Impact Analysis (BIA) Results
  - f. Risk Mitigation Plans
  - g. Business Recovery (BR) & Continuity Strategies
- 5. Plan Testing & Maintenance

#### EXHIBIT 31.1

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

I, Donald B. Pettigrew, Principal Executive Officer, certify that:

- 1) I have reviewed this Quarterly Report on Form 10-Q of Repro Med Systems, Inc. (the "Report");
- 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;
- 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 12, 2020

<u>/s/ Donald B. Pettigrew</u> Donald B. Pettigrew 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");
- 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;
- 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 12, 2020

<u>/s/ Karen Fisher</u> 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, 2020 as filed with the Securities and Exchange Commission, I, Donald B. Pettigrew, 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 12, 2020

<u>/s/ Donald B. Pettigrew</u> Donald B. Pettigrew 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, 2020 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 12, 2020

<u>/s/ Karen Fisher</u> Karen Fisher Chief Financial Officer and Treasurer