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 March 31, 2019

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)

<u>13-3044880</u> (I.R.S. Employer Identification No.)

24 Carpenter Road, Chester, New York (Address of Principal Executive Offices) <u>10918</u> (Zip Code)

<u>(845) 469-2042</u>

(Registrant's telephone number, including area code)

<u>N/A</u>

(Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report)

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 ($\S232.405$ of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [X] 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 [] 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

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	REPR	OTCQX

As of May 7, 2019, 38,316,634 shares of common stock, \$0.01 par value per share, were outstanding, which excludes 2,737,231 shares of treasury stock.

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Item 1. Financial Statements

REPRO MED SYSTEMS, INC. BALANCE SHEETS

		Iarch 31, 2019 Inaudited)	De	ecember 31, 2018
ASSETS		, , ,		
CURRENT ASSETS				
Corrent ASSETS Cash and cash equivalents	\$	2,592,889	\$	3,738,803
Certificates of deposit	Э	1,524,416	Ф	1,517,927
Accounts receivable less allowance for doubtful accounts of \$37,500 at March 31,		1,524,410		1,317,927
2019 and December 31, 2018		2,655,273		1,425,854
Inventory		2,508,684		2,103,879
Prepaid expenses		2,508,604		246,591
TOTAL CURRENT ASSETS		9,567,877		9,033,054
Property and equipment, net		833,015		858,781
Patents, net of accumulated amortization of \$249,716 and \$239,581 at March 31, 2019		855,015		050,701
and December 31, 2018, respectively		670,738		632,156
Right of use assets, net		472,224		052,150
Deferred tax asset				1,466
Other assets		19,582		19,582
	\$	11,563,436	\$	10,545,039
TOTAL ASSETS	ş	11,505,450	¢	10,545,059
LIABILITIES AND STOCKHOLDERS' EQUITY				
LIADILITIES AND STOCKHOLDERS EQUIT				
CURRENT LIABILITIES				
Deferred capital gain - current	\$	_	\$	3,763
Accounts payable		943,091		453,498
Accrued expenses		699,887		688,649
Accrued payroll and related taxes		248,049		421,714
Accrued tax liability		_		16,608
Finance lease liability - current		4,241		
Operating lease liability - current		131,845		_
TOTAL CURRENT LIABILITIES		2,027,113		1,584,232
Deferred tax liability		24,128		_
Finance lease liability, net of current portion		1,094		_
Operating lease liability, net of current portion		340,379		_
		2,392,714		1,584,232
TOTAL LIABILITIES		· · · ·		
STOCKHOLDERS' EQUITY				
Common stock, \$0.01 par value; 75,000,000 shares authorized, 40,939,825 and				
40,932,911 shares issued, 38,202,594 and 38,195,680 shares outstanding at				
March 31, 2019 and December 31, 2018, respectively		409.398		409.329
Additional paid-in capital		4,890,450		4,595,214
Retained earnings		4,890,430		4,395,214
Ketamet carnings		9,514,926		9,305,011
Less: Treasury stock, 2,737,231 shares at March 31, 2019 and December 31, 2018,		9,514,920		9,505,011
respectively, at cost		(344,204)		(344,204)
TOTAL STOCKHOLDERS' EQUITY		9,170,722		8,960,807
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$	11,563,436	\$	10,545,039
TOTAL LIADILITIES AND STOCKHOLDERS EQUILI	Ŷ	11,000,100	Ψ	10,010,009

The accompanying notes are an integral part of these financial statements

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REPRO MED SYSTEMS, INC. STATEMENTS OF OPERATIONS

(UNAUDITED)

		For the Three Months Ended March 31,		
		2019		2018
NET SALES	\$	4,974,278	\$	4,033,224
Cost of goods sold		1,926,324		1,567,400
Gross Profit		3,047,954	-	2,465,824
OPERATING EXPENSES				
Selling, general and administrative		2,977,383		1,880,269
Research and development		101,959		9,848
Depreciation and amortization		83,651		74,578
Total Operating Expenses		3,162,993		1,964,695
Net Operating (Loss)/Profit		(115,039)		501,129
Non-Operating Income				
(Loss)/Gain on currency exchange		(9,690)		9,424
(Loss) on disposal of fixed asset		(240)		
Interest, net and other income		17,480		615
TOTAL OTHER INCOME		7,550	_	10,039
(LOSS)/INCOME BEFORE TAXES		(107,489)		511,168
Income Tax Benefit/(Expense)		22,099		(107,741)
NET (LOSS)/INCOME	\$	(85,390)	\$	403,427
NET (LOSS)/INCOME PER SHARE				
Basic	<u>\$</u>	0.00	\$	0.01
Diluted	\$	0.00	\$ \$	0.01
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING				
Basic		38,203,606		38,016,498
Diluted		39,033,623		38,781,445

The accompanying notes are an integral part of these financial statements

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

	For the Three Months Ended March 31,			nded
	2019			2018
CASH FLOWS FROM OPERATING ACTIVITIES				
Net (Loss)/Income	\$	(85,390)	\$	403,427
Adjustments to reconcile net (loss)/income to net cash used in operating activities:	φ	(05,570)	Ψ	405,427
Stock based compensation expense		298,125		45,933
Depreciation and amortization		83,651		74,578
Deferred capital gain - building lease		(3,763)		(5,620)
Deferred taxes		25,594		2,329
Loss on disposal of fixed asset		240		
Changes in operating assets and liabilities:				
(Increase)/Decrease in accounts receivable		(1,229,419)		7,307
Increase in inventory		(404,805)		(141,868)
Increase in prepaid expense and other assets		(40,024)		(32,563)
Increase in accounts payable		489,593		95,366
Decrease in accrued payroll and related taxes		(173,665)		(138,275)
Increase/(Decrease) in accrued expense		11,238		(319,139)
Decrease in accrued tax liability		(16,608)		(4,589)
NET CASH USED IN OPERATING ACTIVITIES		(1,045,233)		(13,114)
CASH FLOWS FROM INVESTING ACTIVITIES				
Payments for capital expenditures		(41,626)		(4,145)
(Purchase)/proceeds from certificate of deposit		(6,489)		104,360
Payments for patents		(48,718)		(28,482)
NET CASH (USED IN)/PROVIDED BY INVESTING ACTIVITIES		(96,833)		71,733
CASH FLOWS FROM FINANCING ACTIVITIES				
Payment for cancelled shares		(2,820)		_
Finance lease		(1,028)		
NET CASH USED IN FINANCING ACTIVITIES		(3,848)		
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS		(1,145,914)		58,619
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD		3,738,803		3,974,536
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$	2,592,889	\$	4,033,155
Supplemental Information				
Cash paid during the periods for:	<i>ф</i>	1.5.1	¢	
Interest	\$	174	\$	
Taxes	\$		\$	110,000
NON-CASH FINANCING AND INVESTING ACTIVITIES				
Issuance of common stock as compensation	\$	176,250	\$	33,750

The accompanying notes are an integral part of these financial statements

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

NOTE 1 NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF OPERATIONS

REPRO MED SYSTEMS, INC. (the "Company", "RMS" or "we") 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.

FISCAL YEAR END

The Company's fiscal year end is December 31.

BASIS OF PRESENTATION

The accompanying unaudited financial statements as of March 31, 2019, have been prepared in accordance with generally accepted accounting principles and with instructions to SEC regulation S-X for interim financial statements.

In the opinion of the Company's management, the financial statements contain all adjustments consisting of normal recurring accruals necessary to present fairly the Company's financial position as of March 31, 2019, and the results of operations and cash flow for the three months periods ended March 31, 2019, and 2018.

The results of operations for the three months ended March 31, 2019 and 2018 are not necessarily indicative of the results to be expected for the full year. These interim financial statements should be read in conjunction with the financial statements and notes thereto of the Company and management's discussion and analysis of financial condition and results of operations included in the Company's Annual Report for the twelve months ended December 31, 2018, as filed with the Securities and Exchange Commission on Form 10-K.

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.

CERTIFICATES OF DEPOSIT

The certificate of deposit is recorded at cost plus accrued interest. The certificate of deposit earns interest at a rate of 1.73% and matures 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 2016 are subject to examination by income tax authorities.

PROPERTY, EQUIPMENT, AND DEPRECIATION

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

STOCK-BASED COMPENSATION

The Company maintains a stock option plan under which it grants stock options and has issued stock 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 are recorded at the fair value of the shares at the grant date.

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("U.S. 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, and accruals.

REVENUE RECOGNITION

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

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

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

Provisions for distributor pricing and annual customer volume rebates are variable consideration and are recorded as a reduction of revenue in the same period the related sales are recorded or when it's 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.

LEASES

In February 2016, the FASB issued a new 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 U.S. 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 January 1, 2019. The standard had a material impact on our balance sheets, but did not have a material impact on our income statements. See NOTE 7 LEASES.

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RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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, 2019, 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 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 is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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 is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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 OF FINANCIAL INSTRUMENTS

The carrying amounts reported in the balance sheet for cash, trade receivables, accounts payable and accrued expenses approximate fair value based on the short-term maturity of these instruments.

ACCOUNTING FOR LONG-LIVED ASSETS

The Company reviews its long-lived assets for impairment at least annually or whenever the circumstances and situations change such that there is an indication that the carrying amounts may not be recoverable. As of March 31, 2019, the Company does not believe that any of its assets are impaired.

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 RELATED PARTY TRANSACTIONS

LEASED AIRCRAFT

From 1992 to 2018, we leased an aircraft from AMI Aviation, Inc., of which our former President and Chief Executive Officer, Andrew Sealfon, was a majority shareholder. The lease payments were \$0 and \$3,876 for the three months ended March 31, 2019 and 2018, respectively. Upon the termination of Mr. Sealfon as President and Chief Executive Officer on July 25, 2018, the Company ceased leasing this aircraft.

BUILDING LEASE

Mr. Pastreich, our former board of director, 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 lease payments were \$34,172 for the three months ended March 31, 2019, and \$33,126 for the three months ended March 31, 2018. The Company also paid property taxes for the three months ended March 31, 2019 in the amount of \$12,427 and \$12,712 for the three months ended March 31, 2019.

NOTE 3 PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	March 31, 2019		Dece	ember 31, 2018
Land	\$	54,030	\$	54,030
Building		171,094		171,094
Furniture, office equipment, and leasehold improvements		1,085,234		1,058,507
Manufacturing equipment and tooling		1,282,303		1,279,865
		2,592,661		2,563,496
Less: accumulated depreciation		(1,759,646)		(1,704,715)
Property and equipment, net	\$	833,015	\$	858,781

Depreciation expense was \$73,515 and \$66,480 for the three months ended March 31, 2019 and March 31, 2018, respectively.

NOTE 4 LEGAL PROCEEDINGS

We are involved in several lawsuits with our principal competitor, EMED Technologies Corporation ("EMED"). EMED has alleged that our needle sets infringe various patents controlled by EMED. Certain of these lawsuits also allege antitrust violations, unfair business practices, and various other claims. We are vigorously defending against all of the lawsuits brought by EMED. Although no assurances can be given, we believe we have meritorious defenses to all of EMED's claims.

The initial case involving EMED was filed by us in the United States District Court for the Eastern District of California on September 20, 2013 (the "California case"), in response to a letter from EMED claiming patent infringement by us, and seeking a declaratory judgment establishing the invalidity of the patent referenced in the letter – EMED's US patent 8,500,703 – "703." EMED answered the complaint and asserted patent infringement of the '703 patent and several counterclaims relating generally to claims of unfair business practices against us. We responded by adding several claims against EMED, generally relating to claims of unfair business practices on EMED's part. Both parties have requested injunctive relief and monetary damages in unspecified amounts.

On September 11, 2015, we requested an exparte reexamination of the '703 patent by the US Patent and Trademark Office ("USPTO"). The exparte reexamination resulted in a Final Office Action dated July 19, 2017 rejecting all of EMED's claims in the patent. On January 25, 2018 EMED filed an Appeal Brief with a Petition for Revival, which was accepted. On April 9, 2018, the USPTO denied EMED's request for reconsideration of the order rejecting all claims in the '703 patent. Both the California case and EMED's appeal of the USPTO rejections are pending.

The second court case was filed by EMED in the United States District Court for the Eastern District of Texas on June 25, 2015, claiming patent infringement on another of its patents (US 8,961,476 – "476"), by our needle sets, and seeking unspecified monetary damages ("ED Texas '476 matter"). This '476 patent is related to the now rejected EMED '703 patent.

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On September 17, 2015, we requested an inter partes review ("IPR") of the '476 patent, and in response to our request, the Court entered an order staying the ED Texas '476 matter until after the Patent Trial and Appeal Board ("PTAB") of the USPTO made a decision regarding the validity of the patent. On January 12, 2017, the PTAB issued its Final Written Decision in our favor, invalidating all but one ("dependent Claim 9") of the claims in the '476 patent. EMED appealed the PTAB's ruling to the United States Court of Appeals for the Federal Circuit, which affirmed the PTAB's Final Written Decision in our favor on April 3, 2018. On April 18, 2018, EMED filed a petition for en banc rehearing, which was denied. On August 16, 2018, EMED petitioned the United States Supreme Court for a Writ of Certiorari to review the Federal Circuit's upholding the PTAB's Final Written Decision. On October 29, 2018 the United States Supreme Court denied EMED's Petition for a Writ of Certiorari, thus finally affirming the PTAB's invalidation of '476, save for one dependent claim.

Following the PTAB's Final Written Decision in the IPR regarding the '476 patent, EMED filed a new patent application claiming priority back to the application that issued as '703, which is the patent at issue in the California case. Submitted for accelerated examination, this new application issued as US 9,808,576 – "576" on November 7, 2017. On this same date, EMED filed a new case (the "third case") in the United States District Court for the Eastern District of Texas claiming patent infringement of '576, also directed to our needle sets, and seeking unspecified damages and a preliminary injunction against our marketing of its needle sets. We filed a Motion to Dismiss or Transfer Venue to the United States District Court for the Southern District of New York ("SDNY"), which has resulted in the transfer of the third case to SDNY ("SDNY '576 matter").

The SDNY '576 matter is proceeding with preliminary matters and although neither a discovery schedule nor a fixed trial date has not been set, a trial is expected to be scheduled sometime in 2020.

On April 23, 2018, EMED filed a new civil case (the "fourth case") against us in the United States District Court for the Eastern District of Texas asserting antitrust, defamation and unfair business practice claims, and seeking unspecified damages, similar to those previously presented in the California case, described above. As the result of a hearing on November 14, 2018, on December 7, 2018 the Court entered an order transferring the fourth case to the United States District Court for the Eastern District of California (the "California Court"). The fourth case is expected to be consolidated with the California case, or dismissed, as the California Court sees fit.

At the same hearing on November 14, 2018, the Texas Court granted EMED leave to amend its infringement contentions, following the IPR decision invalidating all but one claim of the '476 patent, in order to assert infringement of that sole remaining claim, namely dependent Claim 9. The Texas Court's order allowing EMED's amendment of its infringement contentions against us was entered on December 7, 2018.

The ED Texas '476 matter is now proceeding under EMED's amended infringement contention to incorporate the surviving dependent Claim 9, which incorporates Claims 1 and 8 of the '476 patent, meaning that, to prove infringement on the part of us, EMED must prove more elements of infringement than it originally charged against us. The Texas Court has set a trial date of August 19, 2019 for the trial of the ED Texas '476 matter.

As is required by the respective Courts in both the SDNY '576 matter and the ED Texas '476 matter, the parties are engaging in settlement discussions and have conducted a court-sponsored mediation session, which did not result in settlement.

Although we believe RMS has meritorious claims and defenses in all of the above-described actions and proceedings, their outcomes cannot be predicted with any certainty. If any of these actions against us are successful, they could have a material adverse effect on our business, results of operations, financial condition and cash flows.

NOTE 5 STOCK-BASED COMPENSATION

On June 29, 2016, the Board of Directors amended the 2015 Stock Option Plan (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 held on September 6, 2016. Currently, the total number of shares of Common Stock, with respect to which awards may be granted pursuant to the Plan, may not exceed 4,000,000. On February 20, 2019, our Board of Directors approved an increase to the number of shares authorized under the Plan to 6,000,000, subject to shareholder approval at the 2019 Annual Meeting of Shareholders.

As of March 31, 2019, the Company had 3,469,000 options outstanding to certain executives, key employees and consultants under the Plan, of which 1,050,000 were issued during the three months ended March 31, 2019.

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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.

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 on April 1, 2019. The number of shares to be issued is based upon the closing price of the Common Stock of the Company on February 1, 2019 as reported by the OTCQX.

The per share weighted average fair value of stock options granted during the three months ended March 31, 2019 and March 31, 2018 was \$1.10 and zero, 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 three months ended March 31, 2019 and March 31, 2018. 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.

	March 31,		
	2019	2018	
Dividend yield	0.00%	—	
Expected Volatility	59.4-60.3%		
Weighted-average volatility	—	_	
Expected dividends	_		
Expected term (in years)	10	_	
Risk-free rate	2.64-2.72%	_	

The following table summarizes the status of the Plan:

	Three Months Ended March 31,						
	2019 201)18		
	Shares	A	Veighted Average Exercise Price	Shares	A E	eighted verage xercise Price	
Outstanding at January 1	2,419,000	\$	1.00	1,038,000	\$	0.41	
Granted	1,050,000	\$	1.57	_	\$	_	
Exercised		\$	_		\$		
Forfeited		\$	_	_	\$	_	
Outstanding at March 31	3,469,000	\$	1.17	1,038,000	\$	0.41	
Options exercisable at March 31	828,219	\$	0.58	756,385	\$	0.39	
Weighted average fair value of options granted during the							
period		\$	1.10		\$		
Stock-based compensation expense		\$	121,875		\$	12,183	

Total stock-based compensation expense was \$121,875 and \$12,183 for the three months ended March 31, 2019 and March 31, 2018, respectively.

The weighted-average grant-date fair value of options granted during the three months ended March 31, 2019 and March 31, 2018, was \$1.2 million and zero, respectively. There were no options exercised during the three months ended March 31, 2019 and March 31, 2018.

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The following table presents information pertaining to options outstanding at March 31, 2019:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Veighted Average Exercise Price	Number Exercisable	 Weighted Average Exercise Price
\$0.36-\$1.57	3,469,000	5.5 years	\$ 1.17	828,219	\$ 0.58

As of March 31, 2019, there was \$2.1 million of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 38 months. The total fair value of shares vested as of March 31, 2019 and March 31, 2018, was \$293,373 and \$156,425, respectively.

NOTE 6 DEBT OBLIGATIONS

On February 8, 2018, the Company executed a Promissory Note with 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. The Company entered into this arrangement to establish a credit lending history and, in the event needed, to have additional cash on hand for future expansion. 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. As of March 31, 2019, the Company has no outstanding amounts against the line of credit.

NOTE 7 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.

The components of lease expense were as follows:

	 Ionths Ended ch 31, 2019
Operating lease cost	\$ 35,829
Finance lease cost:	
Amortization of right-of-use assets	\$ 1,060
Interest on lease liabilities	72
Total finance lease cost	\$ 1,132

Supplemental cash flow information related to leases was as follows:

	Three Months Ended March 31, 2019		
Cash paid for amounts included in the measurement of lease liabilities:			
Finance cash flows from finance leases	\$	1,028	
Finance lease cost:			
Amortization of right-of-use assets	\$	1,060	
Interest on lease liabilities		72	
Total finance lease cost	\$	1,132	

Supplemental balance sheet information related to leases was as follows:

	Three Months End March 31, 2019		
Operating Leases			
Operating lease right-of-use assets	\$	472,224	
Operating lease current liabilities		131,845	
Operating lease long term liabilities		340,379	
Total operating lease liabilities	\$	472,224	
Finance Leases	<u>_</u>	() ()	
Property and equipment, at cost	\$	6,363	
Accumulated depreciation		1,060	
Property and equipment, net	\$	5,303	
Finance lease current liabilities		4,241	
Finance lease long term liabilities		1,094	
Total finance lease liabilities	\$	5,335	

	Three Months Ended March 31, 2019
Weighted Average Remaining Lease Term	
Operating leases	3 Years
Finance leases	1 Year
Weighted Average Discount Rate	
Operating leases	4.75%
Finance leases	4.75%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Ope	rating Leases	Fir	ance Leases
2019	\$	113,764	\$	3,300
2020		151,685		2,206
2021		149,476		
2022		97,256		
Total lease payments		512,181		5,506
Less imputed interest		(39,957)		(171)
Total	\$	472,224	\$	5,335
			- 13	-

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 future operating results, unpredictability related to Food and Drug Administration regulations, introduction of competitive products, acceptance of and demand for new and existing products, ability to penetrate new markets, success in enforcing and obtaining patents, reimbursement related risks, government regulation of the home health care industry, success of the research and development effort, expanding the market of FREEDOM60[®] demand in the SCIg market, availability of sufficient capital if or when needed, dependence on key personnel and the outcome of litigation. When used in this report, the words "estimate," "project," "believe," "may," "will," "anticipate," "intend," "expect" and similar expressions are intended to identify forward-looking statements. Such statements reflect current views with respect to future events based on currently available information and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to release publicly any revision to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Throughout this report, "RMS," the "Company," "we," "us" and "our" refer to Repro Med Systems, Inc.

OVERVIEW

We ended the first quarter of 2019 with record net sales results of \$5.0 million, an increase of 23% compared with the same period last year, driven by needle sales and the fulfillment of open orders from December 31, 2018 totaling \$0.2 million. We believe the growth was a result of our national account focus, growth in diagnosis of primary immunodeficiency diseases ("PIDD") and expansion into the neurology market with expanded Hizentra® indication for chronic inflammatory demyelinating polyneuropathy ("CIDP"). Our gross margin percentage was the same for both periods. We had a net loss for the period ended March 31, 2019, compared with net income for the previous year mostly due to increased legal fees for litigation activity and for the resale registration statement and previously announced executive management changes, higher salary and related expenses resulting from the executive management changes, as well as a performance bonus payment to our former interim Chief Executive Officer.

RESULTS OF OPERATIONS

Three months ended March 31, 2019 compared to March 31, 2018

Net Sales

The following table summarizes our net sales for the three months ended March 31, 2019 and 2018:

	Т	hree Months E	s Ended March 31,			hange from Pri	or Year	% of Sales	
		2019	2018			\$	%	2019	2018
Sales									
Domestic	\$	3,883,565	\$	3,375,208	\$	508,357	15.1%	78.1%	83.7%
International		1,090,713		658,016		432,697	65.8%	21.9%	16.3%
Total	\$	4,974,278	\$	4,033,224	\$	941,054	23.3%		

Total net sales increased \$0.9 million or 23.3% for the three months ended March 31, 2019 compared with the same period last year. This growth was driven mostly by increased volume in needle sales and the fulfillment of open orders from December 31, 2018 totaling \$0.2 million. We believe the growth was a result of our national account focus, growth in the diagnosis of PIDD and expansion into the neurology market with expanded Hizentra® indication for CIDP.

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Gross Profit

Our gross profit for the three months ended March 31, 2019 and 2018 is as follows:

	Three Months Ended March 31,				Change from Pri	ior Year
		2019		2018	 \$	%
Gross Profit	\$	3,047,954	\$	2,465,824	\$ 582,130	23.6%
Stated as a Percentage of Net Sales		61.3%		61.1%		

Gross profit increased \$0.6 million or 23.6% in the three months ended March 31, 2019, compared to the same period in 2018. This increase in the quarter was mostly driven by the increase in net sales of \$0.9 million.

Selling, general and administrative and Research and development

Our selling, general and administrative expenses and research and development costs for the three months ended March 31, 2019 and 2018 are as follows:

	Three Months Ended March 31				Change from Pri	or Year
		2019		2018	 \$	%
Selling, general and administrative	\$	2,977,383	\$	1,880,269	\$ 1,097,114	58.3%
Research and development		101,959		9,848	92,111	935.3%
	\$	3,079,342	\$	1,890,117	\$ 1,189,225	62.9%
Stated as a Percentage of Net Sales		61.9%		46.9%		

Selling, general and administrative expenses increased \$1.1 million, or 58.3%, during the three months ended March 31, 2019 compared to the same period last year partially due to increased litigation activity including the engagement of new counsel and legal support for the filing of the resale registration statement and executive management changes matters totaling \$0.5 million. Executive salary and related benefits increased \$0.5 million due to the addition of the Executive Chairman of the Board, our new President and Chief Executive Officer and other executive changes, including a performance bonus payment to our former interim Chief Executive Officer in the amount of \$0.3 million. We also added a Vice President of Medical Affairs to the team, adding \$0.1 million year over year. Higher investor related benefit expenses and director fees also contributed \$0.1 million to the increase. Offsetting these increases was attrition in regulatory salary and related benefit expense in the amount of \$0.1 million.

Research and development expenses increased \$0.1 million during the three months ended March 31, 2019 compared with the same period last year due to increased headcount and expanded product development initiatives compared to last year.

Depreciation and amortization

Depreciation and amortization expense increased by 12.2 % to \$83,651 in the three months ended March 31, 2019 compared with \$74,578 in the three months ended March 31, 2018. We continued to invest in capital assets, mostly related to computer equipment and leasehold improvements, and in patent applications and their maintenance.

Net Income

	Three Months Ended March 31,				Change from Pr	ior Year
		2019		2018	\$	%
Net Income	\$	(85,390)	\$	403,427	\$ (488,817)	-121.2%
Stated as a Percentage of Net Sales		-1.7%		10.0%		

Our net loss for the three months ended March 31, 2019 was \$0.1 million compared to \$0.4 million in net income for the three months ended March 31, 2018, driven by increased selling, general and administrative expenses, as described above.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash of \$2.6 million as of March 31, 2019. Additionally, we have a \$1.5 million certificate of deposit that matures in May 2019 and a \$1.5 million line of credit with no outstanding amounts against it. 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 and professional fees.

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We believe that as of March 31, 2019, 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. We believe RMS'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.

We continue to be in litigation with a competitor, EMED Technologies Corp. ("EMED") and have incurred a significant amount of legal fees in connection with that process. Although the Company believes it has meritorious claims and defenses in the actions and proceedings, their outcomes cannot be predicted with any certainty. If any of these actions against the Company are successful, they could have a material adverse effect on the Company's business, results of operations, financial condition and cash flows.

Cash Flows

The following table summarizes our cash flows:

	Months Ended rch 31, 2019	Months Ended rch 31, 2018
Net cash used in operating activities	\$ (1,045,233)	\$ (13,114)
Net cash (used in)/ provided by investing activities	\$ (96,833)	\$ 71,733
Net cash used in financing activities	\$ (3,848)	\$ _

Operating Activities

Net cash used in operating activities of \$1.0 million for the three months ended March 31, 2019 was mostly attributable to increased accounts receivable of \$1.2 million as one of our major customer's payment terms changed on January 1, 2019 from net 30 to net 60 days and increased inventory of \$0.4 million as we look to build stock to keep pace with sales growth. Partially offsetting these was an increase in accounts payable of \$0.5 million and non-cash charges for stock based compensation of \$0.3 million.

Net cash used in operating activities of \$13,114 for the three months ended March 31, 2018 was primarily the result of increased inventory of \$0.1 million, and the pay out of bonuses, commissions and severance accrued for at December 31, 2017 totaling \$0.6 million in aggregate. Mostly offsetting these decreases were higher net income of \$0.4 million and non-cash charges of \$0.1 million for depreciation and amortization of long lived tangible and intangible assets, stock based compensation of \$45,933, as well as an increase in accounts payable of \$0.1 million.

Investing Activities

Net cash used in investing activities of \$0.1 million for the three months ending March 31, 2019 was for capital expenditures for computer equipment and leasehold improvements, as well as continued investment in patents. Net cash provided by investing activities of \$0.1 million for the three months ended March 31, 2018 was mostly the result of the maturity of a certificate of deposit.

Financing Activities

The \$3,848 used in financing activities for the three months ended March 31, 2019 is related to payments for cancelled shares and leased office equipment. There were no financing activities for the three months ended March 31, 2018.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In June 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2016-13— Financial Instruments – Credit Losses (Topic 326); Measurement of Credit Losses on Financial Instruments, which amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current GAAP and, instead, requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. This ASU affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in this update are effective for fiscal years beginning after December 15, 2019, 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.

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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 is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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 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 is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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.

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) before interest, income taxes, depreciation and amortization, reorganization charges, litigation and stock compensation expenses. 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 provides additional information that is useful to gain an understanding of the factors and trends affecting our business. We also 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.

We also include the use of non-GAAP normalized net income in our earnings releases. RMS management evaluates its business and makes certain operating decisions (e.g., budgeting, forecasting, employee compensation, asset management and resource allocation) using normalized net income. Management believes that because this measure provides it with useful supplemental information for evaluating and operating the business, investors would find it beneficial to have the opportunity to view the business in the same manner. Normalized net income is a measure that focuses on the Company's operations and facilitates comparison from period to period on a consistent basis.

A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net (Loss)/Income	Three Months March 31	
to Non-GAAP Adjusted EBITDA:	 2019	2018
GAAP Net (Loss)/Income	\$ (85,390) \$	403,427
Tax (Benefit)/Expense	(22,099)	107,741
Depreciation/Amortization	83,651	74,578
Interest Income, Net	(17,480)	(615)
Reorganization Charges	354,926	72,551
Litigation	492,515	155,800
Stock Compensation Expense	121,875	27,183
Non-GAAP Adjusted EBITDA	\$ 927,998 \$	840,665

		Three Month	1s Ended	
Reconciliation of GAAP Net (Loss)/Income	March 31,			
To Non-GAAP Normalized Net Income:	2019 2018			
GAAP Net (Loss)/Income	\$	(85,390) \$	6 403,427	
Reorganization Charges		354,926	72,551	
Litigation		492,515	155,800	
Stock Compensation Expense		121,875	27,183	
Tax (Expense) adjustment		(203,556)	(53,662)	
Non-GAAP Normalized Net Income	\$	680,370 \$	605,299	

Reorganization Charges. We have excluded the effect of Reorganization Charges in calculating our non-GAAP Adjusted EBITDA and non-GAAP Normalized Net Income measures. We incurred significant expenses in connection with the recent 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.

Litigation. We have excluded litigation expenses in calculating our non-GAAP Adjusted EBITDA and non-GAAP Normalized Net Income measures. We continue to evaluate our business performance excluding litigation fees and we expect them to continue and/or increase in future periods.

Stock Compensation Expense. We have excluded the effect of stock-based compensation expenses in calculating our non-GAAP Adjusted EBITDA and non-GAAP Normalized Net Income measures. Although stock based compensation is a key incentive offered to our employees, we continue to evaluate our business performance excluding stock-based 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.

PART I – ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not Applicable.

PART I – 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.

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There have been no changes in the Company's internal control over financial reporting during the quarter ended March 31, 2019, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are involved in several lawsuits with our principal competitor, EMED Technologies Corporation ("EMED"). EMED has alleged that our needle sets infringe various patents controlled by EMED. Certain of these lawsuits also allege antitrust violations, unfair business practices, and various other claims. We are vigorously defending against all of the lawsuits brought by EMED. Although no assurances can be given, we believe we have meritorious defenses to all of EMED's claims.

The initial case involving EMED was filed by us in the United States District Court for the Eastern District of California on September 20, 2013 (the "California case"), in response to a letter from EMED claiming patent infringement by us, and seeking a declaratory judgment establishing the invalidity of the patent referenced in the letter – EMED's US patent 8,500,703 – "703." EMED answered the complaint and asserted patent infringement of the '703 patent and several counterclaims relating generally to claims of unfair business practices against us. We responded by adding several claims against EMED, generally relating to claims of unfair business practices on EMED's part. Both parties have requested injunctive relief and monetary damages in unspecified amounts.

On September 11, 2015, we requested an exparte reexamination of the '703 patent by the US Patent and Trademark Office ("USPTO"). The exparte reexamination resulted in a Final Office Action dated July 19, 2017 rejecting all of EMED's claims in the patent. On January 25, 2018 EMED filed an Appeal Brief with a Petition for Revival, which was accepted. On April 9, 2018, the USPTO denied EMED's request for reconsideration of the order rejecting all claims in the '703 patent. Both the California case and EMED's appeal of the USPTO rejections are pending.

The second court case was filed by EMED in the United States District Court for the Eastern District of Texas on June 25, 2015, claiming patent infringement on another of its patents (US 8,961,476 – "476"), by our needle sets, and seeking unspecified monetary damages ("ED Texas '476 matter"). This '476 patent is related to the now rejected EMED '703 patent.

On September 17, 2015, we requested an inter partes review ("IPR") of the '476 patent, and in response to our request, the Court entered an order staying the ED Texas '476 matter until after the Patent Trial and Appeal Board ("PTAB") of the USPTO made a decision regarding the validity of the patent. On January 12, 2017, the PTAB issued its Final Written Decision in our favor, invalidating all but one ("dependent Claim 9") of the claims in the '476 patent. EMED appealed the PTAB's ruling to the United States Court of Appeals for the Federal Circuit, which affirmed the PTAB's Final Written Decision in our favor on April 3, 2018. On April 18, 2018, EMED filed a petition for en banc rehearing, which was denied. On August 16, 2018, EMED petitioned the United States Supreme Court for a Writ of Certiorari to review the Federal Circuit's upholding the PTAB's Final Written Decision. On October 29, 2018 the United States Supreme Court denied EMED's Petition for a Writ of Certiorari, thus finally affirming the PTAB's invalidation of '476, save for one dependent claim.

Following the PTAB's Final Written Decision in the IPR regarding the '476 patent, EMED filed a new patent application claiming priority back to the application that issued as '703, which is the patent at issue in the California case. Submitted for accelerated examination, this new application issued as US 9,808,576 – "'576" on November 7, 2017. On this same date, EMED filed a new case (the "third case") in the United States District Court for the Eastern District of Texas claiming patent infringement of '576, also directed to our needle sets, and seeking unspecified damages and a preliminary injunction against our marketing of its needle sets. We filed a Motion to Dismiss or Transfer Venue to the United States District Court for the Southern District of New York ("SDNY"), which has resulted in the transfer of the third case to SDNY ("SDNY '576 matter").

The SDNY '576 matter is proceeding with preliminary matters and although neither a discovery schedule nor a fixed trial date has not been set, a trial is expected to be scheduled sometime in 2020.

On April 23, 2018, EMED filed a new civil case (the "fourth case") against us in the United States District Court for the Eastern District of Texas asserting antitrust, defamation and unfair business practice claims, and seeking unspecified damages, similar to those previously presented in the California case, described above. As the result of a hearing on November 14, 2018, on December 7, 2018 the Court entered an order transferring the fourth case to the United States District Court for the Eastern District of California (the "California Court"). The fourth case is expected to be consolidated with the California case, or dismissed, as the California Court sees fit.

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At the same hearing on November 14, 2018, the Texas Court granted EMED leave to amend its infringement contentions, following the IPR decision invalidating all but one claim of the '476 patent, in order to assert infringement of that sole remaining claim, namely dependent Claim 9. The Texas Court's order allowing EMED's amendment of its infringement contentions against us was entered on December 7, 2018.

The ED Texas '476 matter is now proceeding under EMED's amended infringement contention to incorporate the surviving dependent Claim 9, which incorporates Claims 1 and 8 of the '476 patent, meaning that, to prove infringement on the part of us, EMED must prove more elements of infringement than it originally charged against us. The Texas Court has set a trial date of August 19, 2019 for the trial of the ED Texas '476 matter.

As is required by the respective Courts in both the SDNY '576 matter and the ED Texas '476 matter, the parties are engaging in settlement discussions and have conducted a court-sponsored mediation session, which did not result in settlement.

Although we believe RMS has meritorious claims and defenses in all of the above-described actions and proceedings, their outcomes cannot be predicted with any certainty. If any of these actions against us are successful, they could have a material adverse effect on our business, results of operations, financial condition and cash flows.

ITEM 1A. RISK FACTORS

Our operations and financial results are subject to various risks and uncertainties, including those described in Part I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2018, which could adversely affect our business, financial condition, results of operations, cash flows, and the trading price of our common and capital stock. There have been no material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2018.

PART II - ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

On October 21, 2015, the Board of Directors of the Company approved non-employee director compensation of \$25,000 each annually, to be paid quarterly half in cash and half in common stock, beginning September 1, 2015. 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. The Company issued 25,782 and 25,962 shares of common stock to its non-employee directors during the three month period ended March 31, 2019 and March 31, 2018, respectively.

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 on April 1, 2019. The number of shares issued was 90,604 based upon the closing price of the Common Stock of the Company on February 1, 2019 as reported by the OTCQX.

On June 29, 2016, the Board of Directors amended the 2015 Stock Option Plan authorizing the Company to grant awards to certain employees under the plan, which was approved by shareholders at the Annual Meeting 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, shall not exceed 4,000,000 shares. On February 20, 2019, our Board of Directors approved an increase to the number of shares authorized under the plan to 6,000,000, subject to stockholder approval at the 2019 Annual Meeting of Stockholders. As of March 31, 2019, the Company had 3,469,000 options outstanding to certain executives, key employees and consultants under the plan, of which 1,050,000 were issued during the three months ended March 31, 2019.

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.

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PART II – ITEM 6. EXHIBITS.

- 4.1 Form of Incentive Stock Option Award Agreement pursuant to the Company's 2015 Stock Option Plan, as amended.
- 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.
May 7, 2019	<u>/s/ Donald B. Pettigrew</u> Donald B. Pettigrew, President and Chief Executive Officer
May 7, 2019	<u>/s/ Karen Fisher</u> Karen Fisher, Chief Financial Officer and Treasurer
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EXHIBIT 4.1

INCENTIVE STOCK OPTION AGREEMENT

This **INCENTIVE STOCK OPTION AGREEMENT** ("*Agreement*"), dated as of [DATE] (the "*Date of Grant*"), is by and between Repro Med Systems, Inc., a New York corporation (the "*Company*"), and [EMPLOYEE NAME] (the "*Employee*"), residing at [EMPLOYEE ADDRESS].

WHEREAS, the Company has duly adopted, and its shareholders approved, the 2015 Stock Option Plan of Repro Med Systems, Inc. (as amended, the "*Plan*"), and the committee appointed to administer the Plan ("*Committee*") has determined that it is in furtherance of the objectives of the Plan to grant an Option (the "*Option*") to the Employee to purchase the number of shares of common stock ("*Shares*"), par value \$.01 per Share of the Company ("*Common Stock*") hereinafter set forth; and

WHEREAS, it is the intention of the Committee that said Option qualify to the fullest extent possible as an incentive stock option entitled to special tax treatment for qualified stock options under Section 421(a) of the Internal Revenue Code;

NOW, THEREFORE, in consideration of the foregoing and of the mutual covenants hereinafter set forth, and other good and valuable consideration, the parties hereto agree as follows:

1. The Company hereby grants to the Employee, as a matter of incentive and to encourage stock ownership in the Company, and not in lieu of, or to provide an increase in, any salary or other compensation for his services, the right and option to purchase, on the terms and conditions hereinafter set forth, up to [] Shares of Common Stock, at the purchase price of \$[] per Share. The Option shall vest and become exercisable as follows: [INSERT VESTING] (each such [], a "Vesting Date"), provided the Employee is employed by the Company on the respective Vesting Date. No fewer than 100 Shares may be purchased at any one time unless the number purchased is the total number at the time purchasable under the Option, and provided further that this Option may not be exercised in whole or in any part while there is "outstanding" any other "qualified stock option" or "restricted stock option" (as those terms are defined in the Internal Revenue Code) which was granted, before the date of this Agreement, to the Employee to purchase stock in the Company at a price (determined as of the Date of Grant of this Option) higher than the option price of this Option. This Option shall terminate on the tenth anniversary of the Date of Grant or on such earlier date as may be provided herein or fixed pursuant hereto, and shall not be exercisable thereafter either by the Employee or his legal representatives.

2. (a) This Option, and any part thereof, may be exercised only by the giving of written notice of exercise to the Chief Financial Officer of the Company, specifying the number of whole Shares to be purchased and accompanied by payment in cash of the aggregate purchase price of the number of Shares purchased; such exercise shall be effective upon the receipt of such written notice and payment by the Company. The Option shall be so exercised during the Employee's lifetime only by the Employee and after his death only by his legal representatives, and not otherwise.

(b) With the consent of the Committee, as an alternative to cash, payment upon exercise may be made by delivery of Shares of Common Stock of the Company acquired prior to the Option exercise date, and/or surrender of the right to receive Shares of Common Stock that are being offered for purchase under the Option (as contemplated by section 1.422-5 (b) of the treasury regulations), and in each case such Shares having a Fair Market Value (as defined in the

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Plan and determined as of the exercise date) equal to all or part of the Option exercise price and a certified or official bank check (or the equivalent thereof acceptable to the Company) for any remaining portion of the full Option exercise price.

3. Neither the Employee nor his legal representatives shall be or have any rights or privileges of a shareholder of the Company in respect of any of the Shares issuable upon exercise of this Option unless and until a certificate or certificates for such Shares shall have been issued upon the exercise of the Option.

Except in the event of the death of the Employee, this Option may only be exercised 4. while the Employee is in the employ of the Company, or within the ninety (90) day period following termination of employment; provided, however, that if the Company terminates Employee's employment at any time for "Cause" (as hereinafter defined) all remaining Shares subject to this Option shall expire on the date of such termination, and no portion of this Option shall be exercisable on or after the date of such termination. In the event that the employment of the Employee is terminated during his employment due to death, his legal representatives shall have the privilege, for a period of the lesser of 12 months from such termination, or the date this Option expires by its terms, to purchase the vested portion of the Option. In the event the Employee's death occurs after his employment termination without Cause but during the 90 day period following such termination, the vested portion of the Option shall continue to be exercisable by his legal representatives until the earlier of the date the Option expires by its terms, or the first anniversary of the Employee's death. "Cause" means (i) conviction of, or the entry of a plea of guilty or no contest to, a felony; or involvement in any other criminal offence that causes the Company public disrepute, or adversely affects the Company's operations or financial performance or the relationship the Company has with its customers, (ii) gross negligence or willful misconduct with respect to the Company, including, without limitation dishonesty in the course of employment; (iii) alcohol abuse or use of controlled drugs other than in accordance with a physician's prescription; (iv) refusal to perform any lawful, material obligation or fulfill any duty to the Company; or (vi) any breach of any obligation or duty to the Company (whether arising by statute, common law or agreement) relating to confidentiality. noncompetition, nonsolicitation or proprietary rights. Notwithstanding the foregoing, if the Employee and the Company have entered into an employment agreement or other similar agreement that specifically defines "cause," then with respect to such Employee, "Cause" shall have the meaning defined in such agreement.

5. Except as herein otherwise provided, the Option, rights, and privileges conferred by this Option agreement shall not be transferred, assigned, pledged, or hypothecated in any way (whether by operation of law or otherwise) and shall not be subject to execution, attachment, or similar process. Upon any attempt so to transfer, assign, pledge, hypothecate, or otherwise dispose of the Option, or of any right or privilege conferred hereby, contrary to the provisions hereof, or upon the levy of an attachment or similar process upon the rights and privileges conferred hereby shall immediately become null and void.

6. If there is any change in the outstanding Shares of Common Stock by reason of a stock dividend or distribution, stock split-up, recapitalization, combination or exchange of Shares, or by reason of any merger, consolidation, spinoff or other corporate reorganization in which the Company is the surviving corporation, the number of Shares subject to this Option, and the purchase price per share, shall be equitably adjusted by the Committee, whose determination shall be final, binding and conclusive.

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7. The Company shall not be required to issue or deliver any certificate or certificates for Shares of its Common Stock purchased upon the exercise of any part of the Option granted hereby prior to (a) the admission of such Shares to listing on any stock exchange on which the Common Stock may then be listed, (b) the completion of any registration or any other qualification of such Shares under any State or Federal law or rules or regulations of any governmental regulatory body that the Committee shall, in its sole discretion, determine to be necessary or advisable, and (c) the obtaining of any approval or other clearance from any governmental regulatory body that the Committee shall, in its sole discretion, determine to be necessary or advisable. The Company shall make reasonable efforts to take all such steps as may be required by law and applicable regulations, including rules and regulations of the Securities and Exchange Commission, and any stock exchange on which the Shares may then be listed, in connection with the issuance or sale of any Shares purchased upon the exercise of such Option or the listing of such Shares on said exchange.

8. At the time of exercise, the Employee or his legal representatives may be required, upon the exercise of any portion of the Option, to represent that any and all Shares of Common Stock purchased upon the exercise of the Option granted hereby shall be acquired for investment and not with a view to, or for sale in connection with, any distribution thereof, and, if so required, each notice of the exercise of any portion of the Option shall be accompanied by a representation in writing signed by him or his legal representatives, as the case may be, that such Shares are being acquired in good faith for investment and not with a view to, or for sale in connection with, any distribution thereof (except in the case of the Employee's legal representatives, legatees, or other testamentary beneficiaries).

9. Any notice to be given to the Company shall be addressed to the Chief Financial Officer of the Company at its executive offices, and any notice addressed to the Employee shall be addressed to the Employee at his address set forth above, or such other address as either party may hereafter designate in writing to the above. Any such notice shall be given by first class, postage prepaid mail.

10. Nothing herein contained shall confer on the Employee any right to continue in the employ of the Company or any of its subsidiaries or shall interfere in any way with the right of the Company and/or its subsidiaries to terminate the Employee's employment or change his responsibilities, duties, or compensation at any time.

11. This Option is granted pursuant to the Plan and is subject to the terms and provisions thereof. In the event of any inconsistency between the provisions of this Agreement and the Plan, the provisions of the Plan shall control.

12. This Agreement shall be binding upon and inure to the benefit of the parties hereto and any successors to the business of the Company, but neither this Agreement nor any rights hereunder shall be assignable by the Employee.

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IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

REPRO MED SYSTEMS, INC.

By: _____ Name: Title:

ACCEPTED BY:

[EMPLOYEE NAME], Employee

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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 Form 10-Q of Repro Med Systems, Inc.;
- 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:
 - (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: May 7, 2019

<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 Form 10-Q of Repro Med Systems, Inc.;
- 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:
 - (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: May 7, 2019

<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 period ending March 31, 2019 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: May 7, 2019

<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 period ending March 31, 2019 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: May 7, 2019

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