

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

FORM 10-Q

(Mark One)

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

For the Quarterly Period Ended September 30, 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)

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

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

10918
(Zip Code)

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

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

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

<u>Title of each class</u>	<u>Trading symbol(s)</u>	<u>Name of each exchange on which registered</u>
common stock, \$0.01 par value	KRMD	The Nasdaq Stock Market

Indicate by check mark whether the registrant (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. 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 and post such files). 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

Accelerated filer
Smaller reporting company
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 No

As of November 6, 2019, 39,501,870 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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PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

REPRO MED SYSTEMS, INC.
BALANCE SHEETS

	September 30, 2019 (Unaudited)	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 5,129,028	\$ 3,738,803
Certificates of deposit	—	1,517,927
Accounts receivable less allowance for doubtful accounts of \$36,609 at September 30, 2019 and \$37,500 at December 31, 2018	3,546,634	1,425,854
Inventory	2,738,682	2,103,879
Prepaid expenses	453,151	246,591
TOTAL CURRENT ASSETS	11,867,495	9,033,054
Property and equipment, net	636,928	858,781
Patents, net of accumulated amortization of \$273,846 and \$239,581 at September 30, 2019 and December 31, 2018, respectively	786,164	632,156
Right of use assets, net	406,954	—
Deferred tax asset	—	1,466
Other assets	19,582	19,582
TOTAL ASSETS	\$ 13,717,123	\$ 10,545,039
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Deferred capital gain - current	\$ —	\$ 3,763
Accounts payable	874,977	453,498
Accrued expenses	1,178,702	688,649
Accrued payroll and related taxes	111,359	421,714
Accrued tax liability	—	16,608
Finance lease liability - current	3,242	—
Operating lease liability - current	135,275	—
TOTAL CURRENT LIABILITIES	2,303,555	1,584,232
Deferred tax liability	133,097	—
	271,679	—
Operating lease liability, net of current portion	—	—
TOTAL LIABILITIES	2,708,331	1,584,232
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value; 75,000,000 shares authorized, 42,228,658 and 40,932,911 shares issued, 39,491,427 and 38,195,680 shares outstanding at September 30, 2019 and December 31, 2018, respectively	422,286	409,329
Additional paid-in capital	5,985,636	4,595,214
Retained earnings	4,945,074	4,300,468
	11,352,996	9,305,011
Less: Treasury stock, 2,737,231 shares at September 30, 2019 and December 31, 2018, respectively, at cost	(344,204)	(344,204)
TOTAL STOCKHOLDERS' EQUITY	11,008,792	8,960,807
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 13,717,123	\$ 10,545,039

The accompanying notes are an integral part of these financial statements

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
NET SALES	\$ 6,617,397	\$ 4,547,187	\$ 16,940,487	\$ 13,082,737
Cost of goods sold	2,234,489	1,655,619	6,033,961	4,985,761
Gross Profit	4,382,908	2,891,568	10,906,526	8,096,976
OPERATING EXPENSES				
Selling, general and administrative	2,441,381	1,917,127	6,976,684	5,513,727
Litigation	864,009	286,487	2,481,471	592,787
Research and development	170,260	126,923	450,454	160,735
Depreciation and amortization	82,774	78,345	252,594	228,900
Total Operating Expenses	3,558,424	2,408,882	10,161,203	6,496,149
Net Operating Profit	824,484	482,686	745,323	1,600,827
Non-Operating Income/(Expense)				
Loss on currency exchange	(9,358)	(5,842)	(20,283)	(16,256)
Gain on disposal of fixed asset, net	—	6,000	49,740	6,000
Interest, net and other income, net	23,368	6,972	59,091	13,088
TOTAL OTHER INCOME	14,010	7,130	88,548	2,832
INCOME BEFORE TAXES	838,494	489,816	833,871	1,603,659
Income Tax Expense	(186,681)	(103,263)	(189,265)	(337,956)
NET INCOME	<u>\$ 651,813</u>	<u>\$ 386,553</u>	<u>\$ 644,606</u>	<u>\$ 1,265,703</u>
NET INCOME PER SHARE				
Basic	<u>\$ 0.02</u>	<u>\$ 0.01</u>	<u>\$ 0.02</u>	<u>\$ 0.03</u>
Diluted	<u>\$ 0.02</u>	<u>\$ 0.01</u>	<u>\$ 0.02</u>	<u>\$ 0.03</u>
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	<u>39,022,298</u>	<u>38,194,682</u>	<u>38,534,021</u>	<u>38,104,393</u>
Diluted	<u>39,298,408</u>	<u>38,985,684</u>	<u>38,734,083</u>	<u>38,875,737</u>

The accompanying notes are an integral part of these financial statements

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

	For the Nine Months Ended	
	September 30,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income	\$ 644,606	\$ 1,265,703
Adjustments to reconcile net income to net cash (used in)/provided by operating activities:		
Stock based compensation expense	897,300	154,925
Depreciation and amortization	252,594	228,900
Deferred capital gain - building lease	(3,763)	(16,860)
Deferred taxes	134,563	10,834
Gain on disposal of fixed asset	(49,740)	(6,000)
Changes in operating assets and liabilities:		
(Increase)/Decrease in accounts receivable	(2,120,780)	351,319
Increase in inventory	(634,803)	(290,722)
Increase in prepaid expense and other assets	(206,560)	(177,346)
Increase in accounts payable	421,479	137,521
Decrease in accrued payroll and related taxes	(310,355)	(213,700)
Increase/(Decrease) in accrued expense	490,053	(30,823)
Decrease in accrued tax liability	(16,608)	(60,825)
NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES	(502,014)	1,352,899
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for capital expenditures	(158,193)	(188,006)
Purchase of certificate of deposit	—	(1,500,000)
Payments for patents	(188,274)	(137,858)
Proceeds on disposal of fixed asset	217,821	6,000
Proceeds from certificates of deposit	1,517,927	92,266
NET CASH PROVIDED BY/(USED IN) INVESTING ACTIVITIES	1,389,281	(1,727,598)
CASH FLOWS FROM FINANCING ACTIVITIES		
Stock issuances	508,900	51,250
Payment for cancelled shares	(2,820)	(1,755)
Finance lease	(3,122)	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	502,958	49,495
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	1,390,225	(325,204)
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	3,738,803	3,974,536
CASH AND CASH EQUIVALENTS, END OF PERIOD	\$ 5,129,028	\$ 3,649,332
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 280	\$ —
Taxes	\$ 103,465	\$ 378,000
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Issuance of common stock as compensation	\$ 256,525	\$ 103,333

The accompanying notes are an integral part of these financial statements

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

NOTE 1 NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF OPERATIONS

REPRO MED SYSTEMS, INC. (the “Company”, “KORU Medical” 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 September 30, 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 September 30, 2019, and the results of operations and cash flow for the three and nine month periods ended September 30, 2019, and 2018.

The results of operations for the nine months ended September 30, 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 was recorded at cost plus accrued interest. The certificate of deposit earned interest at a rate of 1.73% and matured in May 2019, at which time the funds were moved into a money market account earning interest at 2.25%. Effective September 24, 2019, the money market account interest rate dropped to 1.85%.

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 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.

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 that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in this update are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

In 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 September 30, 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 zero and \$1,292 for the three months ended September 30, 2019 and 2018, respectively and zero and \$9,045 for the nine months ended September 30, 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, a former 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 Company exercised three additional renewal options commencing September 1, 2019 through February 28, 2021.

The lease payments were \$36,264 and \$33,126 for the three months ended September 30, 2019 and 2018, respectively, and \$106,700 and \$99,378 for the nine months ended September 30, 2019 and 2018, respectively. The Company also paid property taxes in the amount of \$13,749 and \$12,431 for the three months ended September 30, 2019 and 2018, respectively and \$39,165 and \$37,863 for the nine months ended September 30, 2019 and 2018, respectively.

NOTE 3 PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	<u>September 30, 2019</u>	<u>December 31, 2018</u>
Land	\$ —	\$ 54,030
Building	—	171,094
Furniture, office equipment, and leasehold improvements	1,120,416	1,058,507
Manufacturing equipment and tooling	1,309,172	1,279,865
	<u>2,429,588</u>	<u>2,563,496</u>
Less: accumulated depreciation	(1,792,660)	(1,704,715)
Property and equipment, net	<u>\$ 636,928</u>	<u>\$ 858,781</u>

On May 21, 2019, the Company sold the house it owned for \$0.2 million.

Depreciation expense was \$69,740 and \$68,991 for the three months ended September 30, 2019 and 2018, respectively, and \$218,328 and \$202,975 for the nine months ended September 30, 2019 and 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 business tort 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 June 16, 2015, the California court entered a preliminary injunction against KORU Medical making certain statements regarding what products were cleared by the FDA for use, or could be safely used, with KORU Medical’s Freedom60 pump, without voiding the product warranty. On September 11, 2015, we requested an ex parte reexamination of the ‘703 patent by the US Patent and Trademark Office (“USPTO”). The ex parte 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. On June 26, 2019, the Examiner responded to EMED’s appeal brief and maintained all of the final rejections. 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 marketing and sales of our 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 resulted in the transfer of the third case to SDNY (“SDNY ‘576 matter”) on May 30, 2018.

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. The fourth case also names Andrew Sealfon, then President and CEO of KORU Medical, individually as a defendant. 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 California Court set an initial schedule for a preliminary motion phase and on August 30, 2019 EMED filed a second amended complaint. On September 30, 2019, KORU Medical and Sealfon filed a motion to dismiss that complaint, and Sealfon filed a separate motion to dismiss the case as to him for lack of jurisdiction. Ultimately, we expect this case to be coordinated or 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 proceeded 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. In April 2019, EMED served its damages expert's report opining that EMED's past infringement damages amount to \$1.5 million, and in May KORU Medical served its damages expert's rebuttal report opining that EMED's expert miscalculated damages which if properly calculated would amount to less than \$100,000. The Texas Court had set a trial date of August 19, 2019, for the trial of the ED Texas '476 matter. On June 24, 2019, the Texas Court Magistrate Judge issued a Report and Recommendation decision finding no infringement, literally or under the doctrine of equivalents, by KORU Medical's accused products. EMED filed its objections on June 26, 2019. On June 28, 2019 the United States District Judge for the Eastern District of Texas issued a Final Judgment in favor of KORU Medical and adopted the decision of the Magistrate Judge that was issued on June 24, 2019, overruled EMED's objections, awarded court costs to KORU Medical, and dismissed the case. A final judgment has been entered. KORU Medical has submitted its Bill of Costs for approximately \$16,000 and moved to declare the case exceptional and for recovery of its attorney fees and expenses of approximately \$2.3 million in defense of EMED's assertion of the '476 Patent. EMED has objected to our Bill of Costs, opposed the motion for fees, and filed a notice of appeal of the non-infringement judgment to the Court of Appeals for the Federal Circuit. On September 16, 2019, EMED filed its opening appeal brief. KORU Medical plans to oppose EMED's appeal. The ED Texas court has stayed proceedings in the district court until the appeal process is completed. KORU Medical's fee motion remains pending lifting of the stay.

The SDNY '576 matter proceeded in the New York court through claim construction on the '576 Patent, whereupon KORU Medical sought permission from the New York court to file a motion for summary judgement, to which EMED objected. The New York court granted KORU Medical's request, and on July 10, 2019, KORU Medical filed its motion for summary judgement. EMED opposed that motion, and on August 30, 2019, the New York court granted summary judgement, and dismissed the lawsuit. A final judgement has been entered. KORU Medical has submitted a Bill of Costs for approximately \$1,500, to which EMED has objected, and has moved the New York court to declare the case exceptional and for recovery of its attorney fees and expenses of at least \$1.16 million. EMED has opposed that motion, which is now fully briefed and has been referred to a United States District Court Magistrate Judge to prepare a report and recommendation. EMED also has appealed the New York court's judgment of non-infringement to the Court of Appeals of the Federal Circuit, which matter is pending. EMED's opening appeal brief is currently due November 8, 2019.

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 KORU Medical 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 (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 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.

As of September 30, 2019, the Company had 3,897,000 time based stock options outstanding to certain executives, key employees and consultants under the Plan, of which 1,650,000 were issued during the nine months ended September 30, 2019. The Company also had 1,000,000 performance based options outstanding under the Plan as of September 30, 2019, to its President and Chief Executive Officer, of which all were issued during the nine months ending September 30, 2019.

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 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, 2019 and September 30, 2018 was \$1.33 and \$0.68, 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, 2019 and September 30, 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.

	September 30,	
	2019	2018
Dividend yield	0.00%	0.00%
Expected Volatility	56.1 – 60.7%	62.8 – 65.2%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10 Years	5 Years
Risk-free rate	1.60 – 2.72%	2.80 – 2.90%

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

	Nine months Ended September 30,			
	2019		2018	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	2,419,000	\$ 1.00	1,038,000	\$ 0.41
Granted	1,650,000	\$ 1.92	1,018,000	\$ 1.23
Exercised	160,000	\$ 0.37	125,000	\$ 0.41
Forfeited	12,000	\$ 0.87	12,000	\$ 0.87
Outstanding at September 30	3,897,000	\$ 1.41	1,919,000	\$ 0.85
Options exercisable at September 30	1,037,885	\$ 0.81	666,969	\$ 0.40
Weighted average fair value of options granted during the period	—	\$ 1.33	—	\$ 0.68
Stock-based compensation expense		\$ 473,139	—	\$ 51,592

Total stock-based compensation expense totaled \$473,139 and \$51,592 for the nine months ended September 30, 2019 and 2018, respectively. Cash received from option exercises for the nine months ended September 30, 2019 and 2018 was \$58,900 and \$51,250, respectively.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2019 and 2018, was \$1.33 and \$0.68, respectively. The total intrinsic value of options exercised during the nine months ended September 30, 2019 and 2018, was \$30,022 and \$30,664, respectively.

The following table presents information pertaining to options outstanding at September 30, 2019:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$ 0.38 – 3.15	3,897,000	7 years	\$ 1.41	1,037,885	\$ 0.81

As of September 30, 2019, there was \$2,802,411 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 42 months. The total fair value of shares vested as of September 30, 2019 and 2018, was \$506,729 and \$139,569, respectively.

Performance Based Stock Options

The per share weighted average fair value of stock options granted during the nine months ended September 30, 2019 and 2018 was \$1.16 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 nine months ended September 30, 2019 and September 30, 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.

	September 30,	
	2019	2018
Dividend yield	0.00%	—
Expected Volatility	58.9%	—
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,			
	2019		2018	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	—	\$ —	—	\$ —
Granted	1,000,000	\$ 1.70	—	\$ —
Exercised	—	\$ —	—	\$ —
Forfeited	—	\$ —	—	\$ —
Outstanding at September 30	1,000,000	\$ 1.70	—	\$ —
Options exercisable at September 30	—	\$ —	—	\$ —
Weighted average fair value of options granted during the period	—	\$ 1.16	—	\$ —
Stock-based compensation expense	—	\$ 167,636	—	\$ —

Total performance stock-based compensation expense totaled \$167,636 and zero for the nine months ended September 30, 2019 and 2018, respectively.

The weighted-average grant-date fair value of options granted during the nine months ended September 30, 2019 and September 30, 2018, was \$1.16 and zero, respectively.

The following table presents information pertaining to performance based options outstanding at September 30, 2019:

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	10 years	\$ 1.70	—	\$ —

As of September 30, 2019, there was \$994,925 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, 2019 and 2018 was zero for both periods.

NOTE 6 DEBT OBLIGATIONS

On February 8, 2018, the Company issued a Promissory 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. 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 September 30, 2019, the Company had 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:

	<u>Three Months Ended</u> <u>September 30, 2019</u>	<u>Nine Months Ended</u> <u>September 30, 2019</u>
Operating lease cost	\$ 37,922	\$ 111,672
Finance lease cost:		
Amortization of right-of-use assets	\$ 1,061	\$ 3,182
Interest on lease liabilities	47	178
Total finance lease cost	<u>\$ 1,108</u>	<u>\$ 3,360</u>

Supplemental cash flow information related to leases was as follows:

	<u>Three Months Ended</u> <u>September 30, 2019</u>	<u>Nine Months Ended</u> <u>September 30, 2019</u>
Cash paid for amounts included in the measurement of lease liabilities:		
Finance cash flows from finance leases	\$ 1,053	\$ 3,122
Finance lease cost:		
Amortization of right-of-use assets	\$ 1,061	\$ 3,182
Interest on lease liabilities	47	178
Total finance lease cost	<u>\$ 1,108</u>	<u>\$ 3,360</u>

Supplemental balance sheet information related to leases was as follows:

	Nine Months Ended September 30, 2019
Operating Leases	
Operating lease right-of-use assets	\$ 406,954
Operating lease current liabilities	135,275
Operating lease long term liabilities	271,679
Total operating lease liabilities	<u>\$ 406,954</u>

Finance Leases	
Property and equipment, at cost	\$ 6,363
Accumulated depreciation	3,182
Property and equipment, net	<u>\$ 3,181</u>
Finance lease current liabilities	3,242
Finance lease long term liabilities	—
Total finance lease liabilities	<u>\$ 3,242</u>

	Nine Months Ended September 30, 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,	Operating Leases	Finance Leases
2019	\$ 37,922	\$ 1,100
2020	151,685	2,206
2021	149,476	—
2022	97,256	—
Total lease payments	436,339	3,306
Less imputed interest	(29,385)	(64)
Total	<u>\$ 406,954</u>	<u>\$ 3,242</u>

NOTE 8 SUBSEQUENT EVENTS

On September 30, 2019, R. John Fletcher was appointed Chairman of the Board. Mr. Fletcher succeeds Daniel S. Goldberger who resigned as Executive Chairman of the Company in connection with his appointment as Chief Executive Officer of a bioelectronic medical device company. Mr. Goldberger remains with KORU Medical as a non-executive member of the Board of Directors. In Mr. Fletcher's role as Chairman, he will receive 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.

On October 14, 2019, KORU Medical announced that its common stock was approved for listing on The Nasdaq Capital Market and began trading on October 17, 2019 under its then current symbol "REPR".

On October 23, 2019, the Company announced it will operate under a new dba name, KORU Medical Systems, in place of RMS Medical Products. Reflecting this change, the Company's common stock commenced trading under the new ticker symbol "KRMD" effective October 24, 2019.

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, the impact of recent accounting pronouncements 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, “KORU Medical,” the “Company,” “we,” “us” and “our” refer to Repro Med Systems, Inc.

OVERVIEW

The third quarter of 2019 ended with record net sales results of \$6.6 million, an increase of 45.5% compared with the same period last year. The increase was driven by organic growth mostly from increased volume and to a lesser extent from price increases, two unusually large orders from a domestic distributor and a new customer in Europe, as well as clinical trials. The large domestic distributor orders followed the acquisition of Medical Specialties Distributors, LLC by McKesson Medical-Surgical, Inc. as they move forward with their integration. We cannot predict whether such large distributor orders or volume generally will continue in the future.

We ended the third quarter with \$0.8 million in open orders. Excluding the two large orders, clinical trials and adjusting for the open orders for the quarter, net sales grew in excess of 25% year over year. We believe the organic volume growth continues to be the result of growth in diagnosis of primary immunodeficiency diseases (“PID”) and expansion into the neurology market with expanded Hizentra[®] indication for chronic inflammatory demyelinating polyneuropathy (“CIDP”). Our gross margin percentage improved nearly 2.6 percentage points versus the same period last year mostly due to price increases. Net income was \$0.7 million for period ended September 30, 2019, compared with \$0.4 million for the previous year, driven by the increase in net sales, partially offset by increased legal fees for litigation activity and higher salary and related expenses resulting from the executive management changes and recently announced new hires. Our cash balance at September 30, 2019, was \$5.1 million, which included \$0.5 million for the exercise of outstanding warrants.

RESULTS OF OPERATIONS

Three months ended September 30, 2019 compared to September 30, 2018

Net Sales

The following table summarizes our net sales for the three months ended September 30, 2019 and 2018:

	<u>Three Months Ended September 30,</u>		<u>Change from Prior Year</u>		<u>% of Sales</u>	
	<u>2019</u>	<u>2018</u>	<u>\$</u>	<u>%</u>	<u>2019</u>	<u>2018</u>
Sales						
Domestic	\$ 5,856,203	\$ 3,699,410	\$ 2,156,793	58.3%	88.5%	81.4%
International	761,194	847,777	(86,583)	(10.2%)	11.5%	18.6%
Total	<u>\$ 6,617,397</u>	<u>\$ 4,547,187</u>	<u>\$ 2,070,210</u>	<u>45.5%</u>		

Total net sales increased \$2.1 million or 45.5% for the three months ended September 30, 2019, compared with the same period last year. This growth was driven by organic growth mostly from increased volume and to a lesser extent from price increases, two unusually large orders, one from a domestic distributor and one from a new customer in Europe, as well as clinical trials. We cannot predict whether such large orders will continue in the future. We ended the quarter with open orders totaling \$0.8 million.

Excluding the two large orders, clinical trials in both periods, and adjusting for the open orders, net sales increased in excess of 25% year over year. We believe organic volume growth continues to be due to growth in the diagnosis of PIDD and expansion into the neurology market with the expanded Hizentra® indication for CIDP. Internationally, net sales were down mostly due to open orders totaling \$0.1 million at the end of the period.

Gross Profit

Our gross profit for the three months ended September 30, 2019 and 2018 is as follows:

	<u>Three Months Ended September 30,</u>		<u>Change from Prior Year</u>	
	<u>2019</u>	<u>2018</u>	<u>\$</u>	<u>%</u>
Gross Profit	\$ 4,382,908	\$ 2,891,568	\$ 1,491,340	51.6%
Stated as a Percentage of Net Sales	66.2%	63.6%		

Gross profit increased \$1.5 million or 51.6% in the three months ended September 30, 2019, compared to the same period in 2018. This increase in the quarter was mostly driven by the increase in net sales. Gross profit improved 2.6 percentage points compared with the same period last year, mostly due to price increases.

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, 2019 and 2018 are as follows:

	<u>Three Months Ended September 30,</u>		<u>Change from Prior Year</u>	
	<u>2019</u>	<u>2018</u>	<u>\$</u>	<u>%</u>
Selling, general and administrative	\$ 2,441,381	1,917,127	\$ 524,254	27.3%
Litigation	864,009	286,487	577,522	201.6%
Research and development	170,260	126,923	43,337	34.1%
	<u>\$ 3,475,650</u>	<u>2,330,537</u>	<u>\$ 1,145,113</u>	<u>49.1%</u>
Stated as a Percentage of Net Sales	52.5%	51.3%		

Selling, general and administrative expenses during the three months ended September 30, 2019 increased \$0.5 million, or 27.4%, over the same period last year. Driving the increase was higher salary and related benefits including \$0.3 million of stock option expense, due to the addition of the Executive Chairman of the Board, our new President and Chief Executive Officer and other executive changes, including the additions of Vice Presidents of Medical Affairs, Growth and Innovation, and Sales and Marketing, adding \$0.6 million year over year. Partially offsetting these increases was attrition in regulatory totaling \$0.1 million.

Litigation fees continue to be higher than the previous year period, up \$0.6 million as we continue to defend ourselves against our competitor through several motions and court proceedings, as well as in the patent office. We have had some favorable rulings in the courts and have filed motions for court costs and attorney fees. Refer to Note 4 Legal Proceedings in the Notes to the Financial Statements.

Research and development expenses increased \$43,337, or 34.1%, over last year due to increased headcount and expanded product development initiatives compared to last year.

Depreciation and amortization

Depreciation and amortization expense increased by 5.7% to \$82,774 in the three months ended September 30, 2019 compared with \$78,345 in the three months ended September 30, 2018. We continued to invest in capital assets, mostly related to production equipment, computer equipment and leasehold improvements, and in patent applications and their maintenance.

Net Income

	<u>Three Months Ended September 30,</u>		<u>Change from Prior Year</u>	
	<u>2019</u>	<u>2018</u>	<u>\$</u>	<u>%</u>
Net Income	\$ 651,813	\$ 386,553	\$ 265,260	68.6%
Stated as a Percentage of Net Sales	9.9%	8.5%		

Our net income for the three months ended September 30, 2019 was \$0.7 million compared to \$0.4 million for the same period last year. The increase is mostly driven by the increase in net sales, partially offset by selling general and administrative fees, as well as litigation fees as described above.

Nine months ended September 30, 2019 compared to September 30, 2018

Net Sales

The following table summarizes our net sales for the nine months ended September 30, 2019 and 2018:

	Nine months Ended September 30,		Change from Prior Year		% of Sales	
	2019	2018	\$	%	2019	2018
Sales						
Domestic	\$ 14,308,994	\$ 10,657,010	\$ 3,651,984	34.3%	84.5%	81.5%
International	2,631,493	2,425,727	205,766	8.5%	15.5%	18.5%
Total	\$ 16,940,487	\$ 13,082,737	\$ 3,857,750	29.5%		

Total net sales increased \$3.9 million or 29.5% for the nine months ended September 30, 2019 driven by growth in all product categories (pumps, needles, and tubing) in the Freedom Infusion System. The nine month period includes clinical trials at several customers, and two unusually large orders from a domestic distributor and a new customer in Europe. We ended the third quarter with \$0.8 million in open orders. Excluding both large orders, clinical trials and adding in the open orders, the net sales increase would have been 24%, demonstrating strength in continued organic growth driven by increased volume and to a lesser extent price increases. We believe the organic volume growth continues to be driven by growth in the diagnosis of PIDD and expansion into the neurology market with expanded Hizentra® indication for CIDP.

Gross Profit

Our gross profit for the nine months ended September 30, 2019 and 2018 is as follows:

	Nine months Ended September 30,		Change from Prior Year	
	2019	2018	\$	%
Gross Profit	\$ 10,906,526	\$ 8,096,976	\$ 2,809,550	34.7%
Stated as a Percentage of Net Sales	64.4%	61.9%		

Gross profit increased \$2.8 million or 34.7% in the nine months ended September 30, 2019, compared to the same period last year. Gross margin improved 2.5 percentage points during the period and was driven mostly by price increases and to a lesser extent some production efficiencies.

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, 2019 and 2018 are as follows:

	Nine months Ended September 30,		Change from Prior Year	
	2019	2018	\$	%
Selling, general and administrative	\$ 6,976,684	\$ 5,513,727	\$ 1,462,957	26.5%
Litigation	2,481,471	592,787	1,888,684	318.6%
Research and development	450,454	160,735	289,719	180.3%
	\$ 9,908,609	\$ 6,267,249	\$ 3,641,360	58.1%
Stated as a Percentage of Net Sales	58.5%	47.9%		

Selling, general and administrative expenses increased \$1.5 million, or 26.5%, during the nine months ended September 30, 2019 compared to the same period last year. The increase is mostly driven by higher salary and related benefits totaling \$1.3 million, due to the addition of the Executive Chairman of the Board, our new President and Chief Executive Officer, including a performance bonus payment to our former interim Chief Executive Officer in the amount of \$0.3 million, as well as the addition of Vice Presidents for

Medical Affairs, Growth and Innovation and Sales and Marketing and other executed changes. Included in the \$1.3 million of salary and related benefits is \$0.5 million in stock option expense. Higher consulting fees of \$0.2 million related to strategic initiatives, and higher investor relation expenses and director fees also contributed \$0.2 million to the increase. Partially offsetting these increases was lower recruiting fees of \$0.2 million.

Litigation expenses continued to increase, up \$1.9 million compared to the same period last year as we continue to defend ourselves against our competitor through several motions and court proceedings, as well as in the patent office. We have had several favorable rulings in the courts and have filed motions for court costs and attorney fees. Refer to Note 4 Legal Proceedings in the Notes to the Financial Statements.

Research and development expense increased by \$0.3 million, or 180.3%, primarily due to increased headcount and expanded product development initiatives compared to last year.

Depreciation and amortization

Depreciation and amortization expense increased by 10.4% to \$252,594 in the nine months ended September 30, 2019 compared with \$228,900 in the nine months ended September 30, 2018. We continued to invest in capital assets, mostly related to production equipment, computer equipment and leasehold improvements, and in patent applications and their maintenance.

Net Income

	<u>Nine months Ended September 30,</u>		<u>Change from Prior Year</u>	
	<u>2019</u>	<u>2018</u>	<u>\$</u>	<u>%</u>
Net Income	\$ 644,606	\$ 1,265,703	\$ (621,097)	(49.1%)
Stated as a Percentage of Net Sales	3.8%	9.7%		

Our net income for the nine months ended September 30, 2019 was \$0.6 million compared to a net income of \$1.3 million for the nine months ended September 30, 2018. This decrease was driven by increased selling, general and administrative expenses and litigation fees, as described above.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash of \$5.1 million as of September 30, 2019. Additionally, we have 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.

We believe that as of September 30, 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 KORU Medical's home infusion products continue to find a solid following in the subcutaneous immunoglobulin ("SCIg") market and 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:

	<u>Nine months Ended</u> <u>September 30, 2019</u>	<u>Nine months Ended</u> <u>September 30, 2018</u>
Net cash (used in)/provided by operating activities	\$ (502,014)	\$ 1,352,899
Net cash provided by/(used in) investing activities	\$ 1,389,281	\$ (1,727,598)
Net cash provided by financing activities	\$ 502,958	\$ 49,495

Operating Activities

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.

Net cash provided by operating activities of \$1.4 million for the nine months ended September 30, 2018 was primarily the result of net income of \$1.3 million, non-cash charges of \$0.2 million for depreciation and amortization of long lived tangible and intangible assets and stock based compensation of \$0.2 million, a decrease in accounts receivable of \$0.4 million and an increase in accounts payable of \$0.1 million. Partially offsetting these were increases in inventory and payments for insurance renewals and severance, bonus and commission payments accrued for at December 31, 2017.

Investing Activities

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. Our net cash used for investing activities of \$1.7 million for the nine months ended September 30, 2018 was mostly the result of the purchase of a certificate of deposit.

Financing Activities

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. Net cash provided by financing activities was \$49,495 for the nine months ended September 30, 2018 mostly resulted from the exercise of options.

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, 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 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.

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 option 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.

A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net Income to Non-GAAP Adjusted EBITDA:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
GAAP Net Income	\$ 651,813	\$ 386,553	\$ 644,606	\$ 1,265,703
Tax Expense	186,681	103,263	189,265	337,956
Depreciation/Amortization	82,774	78,345	252,594	228,900
Interest Income, Net	(23,368)	(6,972)	(59,091)	(13,088)
Reorganization Charges	—	232,471	354,926	383,668
Litigation	864,009	286,487	2,481,471	592,787
Stock Option Expense	324,135	24,922	640,775	51,592
Non-GAAP Adjusted EBITDA	<u>\$ 2,086,044</u>	<u>\$ 1,105,069</u>	<u>\$ 4,504,546</u>	<u>\$ 2,847,518</u>

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. We continue to evaluate our business performance excluding litigation fees, which we expect to continue in future periods.

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.

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.

There have been no changes in the Company’s internal control over financial reporting during the quarter ended September 30, 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 business tort 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 June 16, 2015, the California court entered a preliminary injunction against KORU Medical making certain statements regarding what products were cleared by the FDA for use, or could be safely used, with KORU Medical’s Freedom60 pump, without voiding the product warranty. On September 11, 2015, we requested an ex parte reexamination of the ‘703 patent by the US Patent and Trademark Office (“USPTO”). The ex parte 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. On June 26, 2019, the Examiner responded to EMED’s appeal brief and maintained all of the final rejections. 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 marketing and sales of our 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 resulted in the transfer of the third case to SDNY (“SDNY ‘576 matter”) on May 30, 2018.

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. The fourth case also names Andrew Sealton, then President and CEO of KORU Medical, individually as a defendant. 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 California Court set an initial schedule for a preliminary motion phase and on August 30, 2019 EMED filed a second amended complaint. On September 30, 2019, KORU Medical and Sealton filed a motion to dismiss that complaint, and Sealton filed a separate motion to dismiss the case as to him for lack of jurisdiction. Ultimately, we expect this case to be coordinated or 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 proceeded 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. In April 2019, EMED served its damages expert’s report opining that EMED’s past infringement damages amount to \$1.5 million, and in May KORU Medical served its damages expert’s rebuttal report opining that EMED’s expert miscalculated damages which if properly calculated would amount to less than \$100,000. The Texas Court had set a trial date of August 19, 2019, for the trial of the ED Texas ‘476 matter. On June 24, 2019, the Texas Court Magistrate Judge issued a Report and Recommendation decision finding no infringement, literally or under the doctrine of equivalents, by KORU Medical’s accused products. EMED filed its objections on June 26, 2019. On June 28, 2019 the United States District Judge for the Eastern District of Texas issued a Final Judgment in favor of KORU Medical and adopted the decision of the Magistrate Judge that was issued on June 24, 2019, overruled EMED’s objections, awarded court costs to KORU Medical, and dismissed the case. A final judgment has been entered. KORU Medical has submitted its Bill of Costs for approximately \$16,000 and moved to declare the case exceptional and for recovery of its attorney fees and expenses of approximately \$2.3 million in defense of EMED’s assertion of the ‘476 Patent. EMED has objected to our Bill of Costs, opposed the motion for fees, and filed a notice of appeal of the non-infringement judgment to the Court of Appeals for the Federal Circuit. On September 16, 2019, EMED filed its opening appeal brief. KORU Medical plans to oppose EMED’s appeal. The ED Texas court has stayed proceedings in the district court until the appeal process is completed. KORU Medical’s fee motion remains pending lifting of the stay.

The SDNY ‘576 matter proceeded in the New York court through claim construction on the ‘576 Patent, whereupon KORU Medical sought permission from the New York court to file a motion for summary judgement, to which EMED objected. The New York court granted KORU Medical’s request, and on July 10, 2019, KORU Medical filed its motion for summary judgement. EMED opposed that motion, and on August 30, 2019, the New York court granted summary judgement, and dismissed the lawsuit. A final judgement has been entered. KORU Medical has submitted a Bill of Costs for approximately \$1,500, to which EMED has objected, and has moved the New York court to declare the case exceptional and for recovery of its attorney fees and expenses of at least \$1.16 million. EMED has opposed that motion, which is now fully briefed and has been referred to a United States District Court Magistrate Judge to prepare a report and recommendation. EMED also has appealed the New York court’s judgment of non-infringement to the Court of Appeals of the Federal Circuit, which matter is pending. EMED’s opening appeal brief is currently due November 8, 2019.

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 KORU Medical 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 stock. The following are material changes to our risk factors since our Annual Report on Form 10-K for the year ended December 31, 2018:

Our common stock is now listed on the Nasdaq Stock Market LLC (Nasdaq Capital Market) and is no longer subject to penny stock regulations.

If we fail to continue to meet the listing standards of the Nasdaq Stock Market LLC (“Nasdaq”), our common stock may be delisted, which could have a material adverse effect on the liquidity of our common stock.

Our common stock is currently listed on the Nasdaq Capital Market. Nasdaq has requirements that a company must meet in order to remain listed on Nasdaq. In particular, Nasdaq rules require us to maintain a minimum bid price of \$1.00 per share of our common stock. If the closing bid price of our common stock were to fall below \$1.00 per share for 30 consecutive trading days or we do not meet other listing requirements, we would fail to be in compliance with Nasdaq listing standards. There can be no assurance that we will continue to meet the minimum bid price requirement, or any other requirement in the future. If we fail to meet the minimum bid price requirement, The Nasdaq Stock Market LLC may initiate the delisting process. In addition, we may be unable to meet other applicable Nasdaq listing requirements, including maintaining minimum levels of stockholders’ equity or market values of our common stock in which case, our common stock could be delisted. If our common stock were to be delisted, the liquidity of our common stock would be adversely affected and the market price of our common stock could decrease.

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

On February 20, 2019, the Board of Directors of the Company approved non-employee director compensation of \$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 an aggregate of 12,447 and 47,143 shares of common stock to its non-employee directors during the three and nine month period ended September 30, 2019, 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, half in cash and half in common stock, to be paid on April 1, 2019. The number of shares of common stock 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.

During the three months ended September 30, 2019, 350,000 options were issued to key employees under the Company’s 2015 Stock Option Plan, as amended (the “Plan”). There are 6,000,000 options authorized for issuance under the Plan. During the three months ended September 30, 2019, 95,000 options were exercised at an exercise price of \$0.36.

The following table describes the options issued to Company key employees for the three months ended September 30, 2019:

Date Issued	Options Awarded	Vesting Schedule	Exercise Price \$
7/1/2019	250,000	Vest 25% annually on anniversary date	2.83
8/19/2019	100,000	Vest 25% annually on anniversary date	3.15

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.

PART II – ITEM 6. EXHIBITS.

- 31.1 [Certification of Principal Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002](#)
- 31.2 [Certification of Principal Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act 2002](#)
- 32.1 [Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002](#)
- 32.2 [Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act 2002](#)
- 101* 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”.

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 6, 2019

/s/ Donald B. Pettigrew
Donald B. Pettigrew, President and Chief Executive Officer
(Principal Executive Officer)

November 6, 2019

/s/ Karen Fisher
Karen Fisher, Chief Financial Officer and Treasurer
(Principal Financial Officer)

EXHIBIT 31.1

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

I, 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");
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the 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 6, 2019

/s/ Donald B. Pettigrew
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");
- 2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
- 3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
- 5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the 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 6, 2019

/s/ Karen Fisher

Karen Fisher

Chief Financial Officer and Treasurer

EXHIBIT 32.1

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

In connection with the Quarterly Report of Repro Med Systems, Inc. (the "Company") on Form 10-Q (the "Report") for the quarterly period ending September 30, 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: November 6, 2019

/s/ Donald B. Pettigrew

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 quarterly period ending September 30, 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: November 6, 2019

/s/ Karen Fisher

Karen Fisher
Chief Financial Officer and Treasurer
