

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 June 30, 2020

Or

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

For the transition period from _____ to _____.

Commission File Number: 0-12305

REPRO MED SYSTEMS, INC.

(Exact name of registrant as specified in its charter)

New York
(State or Other Jurisdiction of Incorporation or Organization)

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 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 August 5, 2020, 43,909,570 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

	June 30, 2020 (Unaudited)	December 31, 2019
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 38,129,349	\$ 5,870,929
Accounts receivable less allowance for doubtful accounts of \$32,645 at June 30, 2020 and December 31, 2019	2,965,902	3,234,521
Inventory	3,667,288	2,388,477
Prepaid expenses	543,482	387,396
TOTAL CURRENT ASSETS	45,306,021	11,881,323
Property and equipment, net	818,064	611,846
Patents, net of accumulated amortization of \$319,120 and \$288,967 at June 30, 2020 and December 31, 2019, respectively	926,504	807,135
Right of use assets, net	306,101	373,734
Deferred tax asset	334,011	188,241
Other assets	19,812	19,582
TOTAL ASSETS	\$ 47,710,513	\$ 13,881,861
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Line of credit payable	\$ 3,500,000	\$ —
Accounts payable	920,006	572,656
Accrued expenses	2,686,200	1,296,612
Accrued payroll and related taxes	523,537	190,265
Accrued tax liability	523,190	204,572
Finance lease liability - current	3,195	5,296
Operating lease liability - current	139,618	136,888
TOTAL CURRENT LIABILITIES	8,295,746	2,406,289
Finance lease liability, net of current portion	1,030	2,646
Operating lease liability, net of current portion	166,483	236,846
TOTAL LIABILITIES	8,463,259	2,645,781
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value; 75,000,000 shares authorized, 46,640,120 and 42,239,788 shares issued, 43,902,889 and 39,502,557 shares outstanding at June 30, 2020 and December 31, 2019, respectively	466,401	422,398
Additional paid-in capital	34,886,850	6,293,069
Retained earnings	4,238,207	4,864,817
	39,591,458	11,580,284
Less: Treasury stock, 2,737,231 shares at June 30, 2020 and December 31, 2019, respectively, at cost	(344,204)	(344,204)
TOTAL STOCKHOLDERS' EQUITY	39,247,254	11,236,080
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 47,710,513	\$ 13,881,861

The accompanying notes are an integral part of these financial statements

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
NET SALES	\$ 7,708,904	\$ 5,348,812	\$ 14,038,913	\$ 10,323,090
Cost of goods sold	2,799,024	1,873,148	5,340,823	3,799,472
Gross Profit	4,909,880	3,475,664	8,698,090	6,523,618
OPERATING EXPENSES				
Selling, general and administrative	3,201,831	2,050,435	5,964,811	4,535,303
Litigation	2,346,914	1,124,947	2,446,072	1,617,462
Research and development	298,196	178,235	554,221	280,194
Depreciation and amortization	94,940	86,169	182,164	169,820
Total Operating Expenses	5,941,881	3,439,786	9,147,268	6,602,779
Net Operating (Loss)/Profit	(1,032,001)	35,878	(449,178)	(79,161)
Non-Operating (Expense)/Income				
Loss on currency exchange	(2,594)	(1,235)	(13,091)	(10,925)
(Loss)/Gain on disposal of fixed asset, net	(5,522)	49,980	(5,522)	49,740
Interest, net and other income, net	(5,002)	18,243	14,028	35,723
TOTAL OTHER (EXPENSE)/INCOME	(13,118)	66,988	(4,585)	74,538
(LOSS)/INCOME BEFORE TAXES	(1,045,119)	102,866	(453,763)	(4,623)
Income Tax Expense	(30,919)	(24,683)	(172,847)	(2,584)
NET (LOSS)/INCOME	\$ (1,076,038)	\$ 78,183	\$ (626,610)	\$ (7,207)
NET (LOSS)/INCOME PER SHARE				
Basic	\$ (0.03)	\$ 0.00	\$ (0.02)	\$ 0.00
Diluted	\$ (0.03)	\$ 0.00	\$ (0.02)	\$ 0.00
WEIGHTED AVERAGE NUMBER OF COMMON SHARES OUTSTANDING				
Basic	40,361,924	38,353,000	40,018,559	38,279,718
Diluted	40,524,754	39,299,800	40,201,134	39,219,752

The accompanying notes are an integral part of these financial statements

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

	For the Six Months Ended	
	June 30,	
	<u>2020</u>	<u>2019</u>
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	\$ (626,610)	\$ (7,207)
Adjustments to reconcile net loss to net cash provided by/(used in) operating activities:		
Stock based compensation expense	784,821	529,538
Stock based litigation settlement expense	1,285,102	—
Depreciation and amortization	182,164	169,820
Deferred capital gain - building lease	—	(3,763)
Deferred taxes	(145,770)	66,494
Loss/(Gain) on disposal of fixed asset	5,522	(49,740)
Changes in operating assets and liabilities:		
Decrease/(Increase) in accounts receivable	268,619	(1,867,342)
Increase in inventory	(1,278,811)	(467,706)
(Increase)/Decrease in prepaid expense and other assets	(156,316)	44,874
Increase in accounts payable	347,350	76,882
Increase/(Decrease) in accrued payroll and related taxes	333,272	(249,730)
Increase in accrued expense	1,389,588	346,181
Increase/(Decrease) in accrued tax liability	318,618	(72,210)
NET CASH PROVIDED BY/(USED IN) OPERATING ACTIVITIES	<u>2,707,549</u>	<u>(1,483,909)</u>
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for capital expenditures	(363,750)	(67,079)
Payments for patents	(149,523)	(136,182)
Proceeds on disposal of fixed asset	—	217,821
Proceeds from certificate of deposit	—	1,517,927
NET CASH (USED IN)/PROVIDED BY INVESTING ACTIVITIES	<u>(513,273)</u>	<u>1,532,487</u>
CASH FLOWS FROM FINANCING ACTIVITIES		
Line of credit advance	3,500,000	—
Issuance of equity	26,567,861	24,700
Payment for cancelled shares	—	(2,820)
Finance lease	(3,717)	(2,069)
NET CASH PROVIDED BY FINANCING ACTIVITIES	<u>30,064,144</u>	<u>19,811</u>
NET INCREASE IN CASH AND CASH EQUIVALENTS	32,258,420	68,389
CASH AND CASH EQUIVALENTS, BEGINNING OF PERIOD	5,870,929	3,738,803
CASH AND CASH EQUIVALENTS, END OF PERIOD	<u>\$ 38,129,349</u>	<u>\$ 3,807,192</u>
Supplemental Information		
Cash paid during the periods for:		
Interest	\$ 13,554	\$ 233
Taxes	\$ —	\$ —
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Issuance of common stock as compensation	\$ 120,004	\$ 212,898

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 June 30, 2020, have been prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) 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 June 30, 2020, and the results of operations and cash flow for the three and six months periods ended June 30, 2020, and 2019.

The results of operations for the six months ended June 30, 2020 and 2019 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, 2019, 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.

CERTIFICATE OF DEPOSIT

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

INVENTORY

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

PATENTS

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

INCOME TAXES

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

The Company believes that it has no uncertain tax positions requiring disclosure or adjustment. Generally, tax years starting with 2017 are subject to examination by income tax authorities.

PROPERTY, EQUIPMENT, AND DEPRECIATION

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

STOCK-BASED COMPENSATION

The Company maintains a stock option plan under which it grants stock options to certain executives, key employees and consultants. The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. All options are charged against income at their fair value. The entire compensation expense of the award is recognized over the vesting period. Shares of stock granted for director fees are recorded at the fair value of the shares at the grant date.

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

The preparation of financial statements in conformity with 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 sheet, but did not have a material impact on our income statements. See NOTE 6 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 December 2019, the FASB issued ASU No. 2019-12 Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The amendments in this ASU simplify the accounting for income taxes by removing several exceptions including the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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 June 30, 2020, 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 PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
Furniture, office equipment, and leasehold improvements	1,213,254	1,135,107
Manufacturing equipment and tooling	1,481,100	1,295,978
	2,694,354	2,431,085
Less: accumulated depreciation	(1,876,290)	(1,819,239)
Property and equipment, net	<u>\$ 818,064</u>	<u>\$ 611,846</u>

Depreciation expense was \$79,245 and \$75,073 for the three months ended June 30, 2020 and 2019, respectively, and \$152,013 and \$148,588 for the six months ended June 30, 2020 and 2019, respectively.

NOTE 3 LEGAL PROCEEDINGS

From 2013 until May 2020, we were involved in several lawsuits with our principal competitor, EMED Technologies Corporation (“EMED”). EMED alleged that our needle sets infringed various patents controlled by EMED. Certain of these lawsuits also alleged antitrust violations, unfair business practices, and various other business tort claims. On May 26, 2020, the parties announced the settlement of all of the litigation between KORU Medical and EMED. The settlement agreement provides KORU Medical with freedom to operate under EMED’s existing patent portfolio, dismissal of all litigation with prejudice (including the claims against Andrew Sealfon, our former President and Chief Executive Officer), and an equity payment by KORU Medical to EMED. The settled litigation is described below.

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 sought 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. On June 16, 2015, the California court entered a preliminary injunction against KORU Medical for making certain statements regarding products cleared for use by the FDA, or that 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 U.S. Patent and Trademark Office (“USPTO”). The ex parte reexamination resulted in the Patent Trial and Appeal Board (“PTAB”) of the USPTO determining that claims 1-10 of the ’703 patent are invalid, leaving claim 11 as the only surviving claim of the ’703 patent.

Claim 11 of the ’703 patent, however, was not asserted in the California case. EMED informed KORU Medical it will neither appeal the PTAB’s decision nor pursue a claim based on infringement of claim 11 of the ’703 patent in the California case.

The second court case was filed by EMED in the United States District Court for the Eastern District of Texas (the “Texas Court”) 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 invalid claims of the EMED ’703 patent.

On September 17, 2015, we requested an inter partes review (“IPR”) of the ’476 patent, and subsequently after a trial the PTAB issued a Final Written Decision in our favor, invalidating all claims but one (“dependent Claim 9”) of the ’476 patent. EMED appealed the PTAB’s ruling to the United States Court of Appeals for the Federal Circuit (the “CAFC”), which affirmed the PTAB’s Final Written Decision in our favor on April 3, 2018.

During the IPR proceedings regarding the ’476 patent, EMED filed a new patent application that subsequently 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 Texas Court claiming patent infringement of the ’576 patent by our needle sets, and seeking unspecified damages and a preliminary injunction against marketing and sales of our needle sets. We moved 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 Texas Court 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 named Andrew Sealfon, then President and Chief Executive Officer of KORU Medical, individually as a defendant. Following a hearing held on November 14, 2018 to address a motion we had filed to transfer venue, on December 7, 2018, the Texas Court transferred the fourth case to the United States District Court for the Eastern District of California (the “California Court”). We then moved to dismiss that complaint, and Andrew Sealfon filed a separate motion to dismiss the case as to him for lack of jurisdiction.

At the same hearing on November 14, 2018, the Texas Court granted EMED leave to amend its infringement contentions to assert infringement of that sole remaining claim 9 of the '476 patent. 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. We moved to dismiss the case for lack of infringement. On June 24, 2019, the Texas Court Magistrate Judge issued a Report and Recommendation decision granting summary judgment in our favor, finding no infringement, literally or under the doctrine of equivalents, by KORU Medical's accused products. EMED's objections were overruled and on June 28, 2019, the Texas Court issued a Final Judgment in favor of KORU Medical, awarded court costs to KORU Medical, and dismissed the case. A final judgment was entered and KORU Medical submitted its Bill of Costs for approximately \$16,000, which was ordered granted by the Texas Court. KORU Medical also moved to declare the case exceptional and for recovery of its attorney fees and expenses of approximately \$2.5 million in defense of EMED's assertion of the '476 Patent. EMED appealed the non-infringement judgment to the CAFC. On April 9, 2020, the CAFC issued a unanimous decision affirming the Texas Court's judgment of non-infringement. The Texas Court had stayed proceedings in the district court until the appeal process was completed.

The SDNY '576 matter proceeded in the New York court through claim construction on the '576 Patent, whereupon KORU Medical filed a motion for summary judgement of non-infringement. That motion was granted on August 30, 2019, and the New York court dismissed the lawsuit and entered a final judgement. KORU Medical submitted a Bill of Costs for approximately \$1,500, to which EMED objected, and 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. On November 12, 2019, the Magistrate Judge issued a Report and Recommendation that KORU Medical's fee motion be granted, and KORU Medical be awarded approximately \$1.1 million in fees and expenses. EMED filed objections to that Report and Recommendation. EMED also appealed the New York court's judgment of non-infringement to the CAFC, which the parties had fully briefed, and were awaiting a decision from the CAFC Court.

The aforementioned district court litigation has now been finally dismissed with prejudice, and all associated appeals dismissed.

NOTE 4 STOCK-BASED COMPENSATION

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

As of June 30, 2020, the Company had options to purchase 3,785,000 shares of Common Stock outstanding to certain executives, key employees and consultants under the Plan, of which 60,000 were issued during the six months ended June 30, 2020.

On May 20, 2020, the Company entered into a Settlement Agreement with EMED as described above in NOTE 3 LEGAL PROCEEDINGS. Pursuant to the Settlement Agreement, the Company issued to EMED (i) 95,238 restricted stock units, which vested on May 21, 2020 and 95,238 restricted stock units vesting on January 1, 2021, and (ii) an option to purchase up to 400,000 shares of the Company's common stock at an exercise price of \$11.21 per share prior to February 1, 2021, which can be settled in cash in lieu of common stock at the Company's sole discretion, provided that the number of shares of common stock and/or amount of cash paid by the Company upon exercise will be capped at a value of \$16.21 per share. The option was recorded at \$347,008, the estimated fair value of the option using the Black-Scholes option pricing model with a volatility rate of 52.68% and a risk-free rate of 0.17%.

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

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

2015 STOCK OPTION PLAN, as amended

Time Based Stock Options

The per share weighted average fair value of stock options granted during the six months ended June 30, 2020 and June 30, 2019 was \$6.68 and \$1.16, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the six months ended June 30, 2020 and June 30, 2019. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued.

	June 30,	
	2020	2019
Dividend yield	0.00%	0.00%
Expected Volatility	62.1%	58.9-60.3%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10 Years	10 Years
Risk-free rate	0.63%	2.12-2.72%

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

	Six Months Ended June 30,			
	2020		2019	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	3,647,000	\$ 1.32	2,419,000	\$ 1.00
Granted	60,000	\$ 9.76	1,300,000	\$ 1.66
Exercised	722,000	\$ 0.58	65,000	\$ 0.38
Forfeited	200,000	\$ 2.09	—	\$ —
Outstanding at June 30	2,785,000	\$ 1.64	3,654,000	\$ 1.24
Options exercisable at June 30	812,760	\$ 1.37	804,260	\$ 0.63
Weighted average fair value of options granted during the period		\$ 6.68	—	\$ 1.16
Stock-based compensation expense	—	\$ 290,991	—	\$ 274,731

Total stock-based compensation expense totaled \$290,991 and \$274,731 for the six months ended June 30, 2020 and 2019, respectively. Cash received from option exercises for the six months ended June 30, 2020 and 2019 was \$95,880 and \$24,700, respectively.

The weighted-average grant-date fair value of options granted during the six months ended June 30, 2020 and 2019 was \$0.4 million and \$1.5 million, respectively. The total intrinsic value of options exercised during the six months ended June 30, 2020 and 2019 was \$253,386 and \$12,796, respectively.

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

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.50 – 9.76	2,785,000	7.6 years	\$ 1.64	812,760	\$ 1.37

As of June 30, 2020, there was \$2,011,224 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 48 months. The total fair value of shares vested as of June 30, 2020 and 2019, was \$1,110,068 and \$313,714, respectively.

Performance Based Stock Options

The per share weighted average fair value of stock options granted during the six months ended June 30, 2020 and 2019 was zero and \$1.16, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the six months ended June 30, 2020 and June 30, 2019. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued.

	June 30,	
	2020	2019
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:

	Six Months Ended June 30,			
	2020		2019	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	1,000,000	\$ 1.70	—	\$ —
Granted	—	\$ —	1,000,000	\$ 1.70
Exercised	—	\$ —	—	\$ —
Forfeited	—	\$ —	—	\$ —
Outstanding at June 30	1,000,000	\$ 1.70	1,000,000	\$ 1.70
Options exercisable at June 30	—	\$ —	—	\$ —
Weighted average fair value of options granted during the period	—	\$ —	—	\$ 1.16
Stock-based compensation expense	—	\$ 373,826	—	\$ 41,909

Total performance stock-based compensation expense totaled \$373,826 and \$41,909 for the six months ended June 30, 2020 and 2019, respectively.

The weighted-average grant-date fair value of options granted during the six months ended June 30, 2020 and June 30, 2019, was zero and \$1,162,561, respectively.

The following table presents information pertaining to performance based options outstanding at June 30, 2020:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$1.70	1,000,000	8.9 years	\$ 1.70	—	\$ 1.70

As of June 30, 2020, there was \$495,372 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 June 30, 2020 and 2019 was zero for both periods.

NOTE 5 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. On September 25, 2018, KeyBank released the certificate of deposit as collateral for the loan and the Company executed a Commercial Security Agreement as collateral for the loan.

On April 14, 2020, the Company issued a promissory note to the KeyBank National Association (the “Bank”) in the aggregate principal amount of \$3.5 million (the “Note”) as an extension of its line of credit, replacing its current line of credit agreement and promissory note with the Bank dated February 8, 2018 (the “Original Note”). The Company drew on the additional \$2.0 million on April 23, 2020. The Original Note was in the form of a variable rate revolving line of credit with an interest rate of LIBOR plus 2.25%. The \$3.5 million Note is in the form of a variable rate non-disclosable revolving line of credit with an interest rate of Prime Rate announced by the Bank minus 0.75%. Interest is due monthly, and all principal and unpaid interest is due on June 1, 2021. The \$3.5 million Note may be prepaid at any time prior to maturity with no prepayment penalties. The \$3.5 million Note contains events of default and other provisions customary for a loan of this type.

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

The Company had \$3.5 million and zero outstanding against the line of credit as of June 30, 2020 and 2019, respectively.

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

On April 27, 2020, the Company entered into a Progress Payment Loan and Security Agreement (“PPLSA”) and a Master Security Agreement (the “MSA”), each dated as of April 20, 2020, with Key Equipment Finance, a division of the Bank (“KEF”), to provide up to \$2.5 million in financing for equipment purchases from third party vendors. The PPLSA allows the Company to make draws with KEF to make certain payments to the equipment suppliers prior to the commencement of periodic payments under a term loan. Each draw under the PPLSA will bear interest at a variable rate equal to the then-current Prime Rate and will be secured by the financed equipment under the MSA. At the end of each calendar quarter or year, the advances made under the PPLSA will be converted to term loans, subject to KEF’s approval of the equipment and certain other closing conditions being met. Once the draws under the PPLSA are converted into a term loan, each promissory note will bear interest at a fixed rate of 4.07% per annum, subject to adjustment based on KEF’s cost of funds, with principal and interest payable in 84 equal consecutive monthly installments. Each fixed rate installment promissory note may be prepaid, subject to a penalty if prepaid before the fifth anniversary of its issuance. As of June 30, 2020, the Company had zero outstanding against the PPLSA.

NOTE 6 LEASES

We have finance and operating leases for our corporate office and certain office and computer equipment. Our leases have remaining lease terms of 1 to 3 years, some of which include options to extend the leases annually and some with options to terminate the leases within 1 year.

The components of lease expense were as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Operating lease cost	\$ 37,921	\$ 37,921	\$ 75,843	\$ 73,750
Finance lease cost:				
Amortization of right-of-use assets	\$ 1,855	\$ 1,061	\$ 3,711	\$ 2,121
Interest on lease liabilities	65	59	152	131
Total finance lease cost	\$ 1,920	\$ 1,120	\$ 3,863	\$ 2,252

Supplemental cash flow information related to leases was as follows:

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2020	2019	2020	2019
Cash paid for amounts included in the measurement of lease liabilities:				
Finance cash flows from finance leases	\$ 1,869	\$ 1,041	\$ 3,717	\$ 2,069
Finance lease cost:				
Amortization of right-of-use assets	\$ 1,855	\$ 1,061	\$ 3,711	\$ 2,121
Interest on lease liabilities	65	59	152	131
Total finance lease cost	\$ 1,920	\$ 1,120	\$ 3,863	\$ 2,252

Supplemental balance sheet information related to leases was as follows:

	For the Six Months Ended June 30,	
	2020	2019
Operating Leases		
Operating lease right-of-use assets	\$ 306,101	\$ 439,782
Operating lease current liabilities	139,618	133,417
Operating lease long term liabilities	166,483	306,365
Total operating lease liabilities	\$ 306,101	\$ 439,782
Finance Leases		
Property and equipment, at cost	\$ 12,725	\$ 6,363
Accumulated depreciation	(8,549)	(2,121)
Property and equipment, net	\$ 4,176	\$ 4,242
Finance lease current liabilities	3,195	4,295
Finance lease long term liabilities	1,030	—
Total finance lease liabilities	\$ 4,225	\$ 4,295

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Weighted Average Remaining Lease Term		
Operating leases	2 Years	3 Years
Finance leases	1 Year	1 Year
Weighted Average Discount Rate		
Operating leases	4.75%	4.75%
Finance leases	4.75%	4.75%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
2020	75,843	1,664
2021	149,476	2,705
2022	97,256	—
Total lease payments	322,575	4,369
Less imputed interest	(16,474)	(144)
Total	\$ 306,101	\$ 4,225

NOTE 7 RELATED PARTY TRANSACTIONS

BUILDING LEASE

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

The lease payments were \$36,264 for both three months ended June 30, 2020, and 2019 and \$72,528 and \$70,436 for the six months ended June 30, 2020 and 2019, respectively. The Company also paid property taxes in the amount of \$13,238 and \$12,989 for three months ended June 30, 2020 and 2019, respectively and \$26,659 and \$25,416 for the six months ended June 30, 2020 and 2019, respectively.

PART I – ITEM 2. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

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

Our actual results may vary materially from the forward-looking statements made in this report due to important factors such as uncertainties associated with COVID-19, future operating results, Food and Drug Administration regulations, introduction of competitive products, acceptance of and demand for new and existing products, ability to penetrate new markets, success in enforcing and obtaining patents, reimbursement related risks, government regulation of the home health care industry, success of the research and development effort, expanding the market of FREEDOM60[®] demand in the SCIG market, availability of sufficient capital if or when needed, dependence on key personnel, and the impact of recent accounting pronouncements. When used in this report, the words “estimate,” “project,” “believe,” “may,” “will,” “anticipate,” “intend,” “expect” and similar expressions are intended to identify forward-looking statements. Such statements reflect current views with respect to future events based on currently available information and are subject to risks and uncertainties that could cause actual results to differ materially from those contemplated in such forward-looking statements. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. The Company does not undertake any obligation to release publicly any revision to these forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events.

Throughout this report, “KORU Medical,” the “Company,” “we,” “us” and “our” refer to Repro Med Systems, Inc.

OVERVIEW

The Company continues to monitor its operations and government recommendations and has made modifications to its normal operations because of the COVID-19 outbreak, including requiring most of its non-production related team members to work remotely or on a staggered work shift. The Company has continued to maintain a manufacturing operational capacity at its manufacturing facility located in Chester, New York, and has instituted heightened cleaning and sanitization standards and several health and safety protocols and procedures to safeguard its team members who do continue to report in person.

On April 14, 2020, the Company issued a promissory note to the KeyBank National Association (the "Bank") in the aggregate principal amount of \$3.5 million as an extension of its line of credit, replacing its current line of credit agreement and promissory note with the Bank dated February 8, 2018 (the "Original Note"). In response to concerns about the potential impact of COVID-19, the Company elected to draw the additional \$2.0 million available under the line of credit, drawing the full amount available of \$3.5 million on its line of credit.

On April 20, 2020, the Company entered into a Loan Agreement with the Bank (the "PPP Loan Agreement") pursuant to the Paycheck Protection Program under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"), providing for a loan in the principal amount of \$1.5 million (the "PPP Loan"). The PPP Loan was funded on April 27, 2020. On May 13, 2020, the Company returned the funds it received.

On May 20, 2020, the Company entered into a Settlement Agreement with EMED Technologies Corporation ("EMED") to settle all claims in connection with all pending litigation matters between them (the "Claims"). Pursuant to the Settlement Agreement, the Company issued to EMED (i) 95,238 restricted stock units, which vested on May 21, 2020 and 95,238 restricted stock units vesting on January 1, 2021, and (ii) an option to purchase up to 400,000 shares of the Company's common stock at an exercise price of \$11.21 per share prior to February 1, 2021, which can be settled in cash in lieu of common stock at the Company's sole discretion, provided that the number of shares of common stock and/or amount of cash paid by the Company upon exercise will be capped at a value of \$16.21 per share. The Settlement Agreement includes mutual releases and covenants not to sue for any claim arising before May 20, 2020 and the Company covenants not to challenge any EMED patents that were the subject of the Claims unless EMED asserts them in the future against Company products. The aggregate non-cash litigation settlement expense recognized during the period ended June 30, 2020 was \$2.2 million.

On June 18, 2020, the Company entered into a Purchase Agreement with Piper Sandler & Co. and Canaccord Genuity LLC, as representatives of the several underwriters named therein (the "Underwriters"), pursuant to which the Company agreed to issue and sell 3,125,000 shares of its common stock. Under the terms of the Purchase Agreement, the Company granted to the Underwriters an option, exercisable for a period of 30 days, to purchase up to an additional 468,750 shares of the Company's common stock, which the Underwriters exercised in full on June 19, 2020. The Underwriters purchased the shares pursuant to the Purchase Agreement, including the shares subject to the option, at a price of \$7.52 per share with proceeds to the Company net of discounts, commissions, fees and expenses of \$26.5 million.

We ended the second quarter of 2020 with net sales of \$7.7 million, an increase of 44% compared with the same period last year, driven primarily by higher sales volume in needle sets, tubing and pump sales, due to what we believe was continued demand increases which included clinical trials, as well as increased purchasing to support the trends towards at-home infusion therapy and in response to the uncertainties created by COVID-19.

Our gross margin percentage, which is gross profit stated as a percentage of net sales, was 63.7% down from 65.0% in the prior year mostly due to overtime costs related to COVID-19 absenteeism. Gross margin was 65.4% when adjusted for overtime.

Net loss was \$1.1 million for the quarter, compared with net income of \$0.1 million for the previous year, driven by the \$2.2 million stock based litigation settlement expense, partially offset by higher net sales compared with last year.

As of June 30, 2020, the Company had \$38.1 million cash on hand, including \$26.5 million resulting from the capital raise during the quarter described above, and a draw of \$3.5 million on the line of credit.

RESULTS OF OPERATIONS

Three months ended June 30, 2020 compared to June 30, 2019

Net Sales

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

	Three Months Ended June 30,		Change from Prior Year		% of Sales	
	2020	2019	\$	%	2020	2019
Sales						
Domestic	\$ 6,745,810	\$ 4,569,226	\$ 2,176,584	47.6%	87.5%	85.4%
International	963,094	779,586	183,508	23.5%	12.5%	14.6%
Total	\$ 7,708,904	\$ 5,348,812	\$ 2,360,092	44.1%		

Total net sales increased \$2.4 million or 44.1% for the three months ended June 30, 2020 compared with the same period last year, driven primarily by higher sales volume in needle sets, tubing and pump sales, mostly due to what we believe was continued demand increases which included clinical trials, as well as increased purchasing to support the trends towards at-home infusion therapy and in response to the uncertainties created by COVID-19.

Gross Profit

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

	Three Months Ended June 30,		Change from Prior Year	
	2020	2019	\$	%
Gross Profit	\$ 4,909,880	\$ 3,475,664	\$ 1,434,216	41.3%
Stated as a Percentage of Net Sales	63.7%	65.0%		

Gross profit increased \$1.4 million or 41.3% in the three months ended June 30, 2020, compared to the same period in 2019. This increase in the quarter was mostly driven by the increase in net sales of \$2.4 million. Gross margin declined compared with last year mostly due to overtime costs related to COVID-19 absenteeism. Gross margin was 65.4% when adjusted for overtime.

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 June 30, 2020 and 2019 are as follows:

	Three Months Ended June 30,		Change from Prior Year	
	2020	2019	\$	%
Selling, general and administrative	\$ 3,201,831	\$ 2,050,435	\$ 1,151,396	56.2%
Litigation	2,346,914	1,124,947	1,221,967	108.6%
Research and development	298,196	178,235	119,961	67.3%
	\$ 5,846,941	\$ 3,353,617	\$ 2,493,324	74.3%
Stated as a Percentage of Net Sales	75.9%	62.7%		

Selling, general and administrative expenses increased \$1.2 million, or 56.2%, during the three months ended June 30, 2020 compared to the same period last year, mostly due to higher salary and related benefits of \$0.9 million due to new hires in second half of last year, severance and a bonus for employee service during the COVID-19 pandemic. Adding to the increase were consulting and recruiting fees of \$0.2 million related to marketing, regulatory and strategic initiatives and several new hires in regulatory and sales. Also contributing to the increase were higher distribution related fees incurred with our largest distributor, higher director fees and insurance premiums related to our directors and officers insurance policy, in aggregate totaling \$0.2 million. Offsetting these increases were lower trade show and travel expenses of \$0.1 million due to COVID-19 related travel restrictions.

Litigation fees increased \$1.2 million compared to the same period last year primarily due to the negotiation of and entry into a litigation settlement agreement with EMED in May 2020 resulting in a non-cash expense of \$2.2 million.

Research and development expenses increased \$0.1 million during the three months ended June 30, 2020 compared with the same period last year mostly due to increased salary and related benefits due to higher headcount as we continue to increase our development initiatives.

Depreciation and amortization

Depreciation and amortization expense increased by 10.2% to \$94,940 in the three months ended June 30, 2020 compared with \$86,169 in the three months ended June 30, 2019. We continue to invest in capital assets, mostly related to manufacturing and computer equipment, and in patent applications and their maintenance.

Net (Loss)/Income

	<u>Three Months Ended June 30,</u>		<u>Change from</u>
	<u>2020</u>	<u>2019</u>	<u>Prior Year</u>
			<u>\$</u>
Net (Loss)/Income	\$ (1,076,038)	\$ 78,183	\$ (1,154,221)
Stated as a Percentage of Net Sales	(14.0%)	1.5%	

Our net loss for the three months ended June 30, 2020 was \$1.1 million, compared to net income of \$0.1 million for the three months ended June 30, 2019, driven by the litigation settlement expense and higher selling, general and administrative expenses, partially offset by higher sales, as described above.

Six months ended June 30, 2020 compared to June 30, 2019

Net Sales

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

	<u>Six Months Ended June 30,</u>		<u>Change from Prior Year</u>		<u>% of Sales</u>	
	<u>2020</u>	<u>2019</u>	<u>\$</u>	<u>%</u>	<u>2020</u>	<u>2019</u>
Sales						
Domestic	\$ 12,086,676	\$ 8,452,791	\$ 3,633,885	43.0%	86.1%	81.9%
International	1,952,237	1,870,299	81,938	4.4%	13.9%	18.1%
Total	<u>\$ 14,038,913</u>	<u>\$ 10,323,090</u>	<u>\$ 3,715,823</u>	<u>36.0%</u>		

Total net sales increased \$3.7 million or 36.0% for the six months ended June 30, 2020. The volume increase was driven by what we believe was continued growth in diagnosis of primary immunodeficiency diseases (“PIDD”) and expansion into the neurology market with expanded Hizentra® indication for chronic inflammatory demyelinating polyneuropathy (“CIDP”) and clinical trials, as well as increased purchasing to support the trend towards at-home infusion therapy and in response to the uncertainties created by COVID-19.

Gross Profit

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

	<u>Six Months Ended June 30,</u>		<u>Change from Prior Year</u>	
	<u>2020</u>	<u>2019</u>	<u>\$</u>	<u>%</u>
Gross Profit	\$ 8,698,090	\$ 6,523,618	\$ 2,174,472	33.3%
Stated as a Percentage of Net Sales	62.0%	63.2%		

Gross profit increased \$2.2 million or 33.3% in the six months ended June 30, 2020, compared to the same period last year. Gross margin declined compared with last year mostly due to overtime costs related to COVID-19 absenteeism in the second quarter, as well as the expense for an obsolescence reserve resulting from a discontinued product line. Excluding these items gross margin would have been 63.4%.

Selling, general and administrative, Litigation and Research and development

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

	<u>Six Months Ended June 30,</u>		<u>Change from Prior Year</u>	
	<u>2020</u>	<u>2019</u>	<u>\$</u>	<u>%</u>
Selling, general and administrative	\$ 5,964,811	\$ 4,535,303	\$ 1,429,508	31.5%
Litigation	2,446,072	1,617,462	828,610	51.2%
Research and development	554,221	280,194	274,027	97.8%
	<u>\$ 8,965,104</u>	<u>\$ 6,432,959</u>	<u>\$ 2,532,145</u>	39.4%
Stated as a Percentage of Net Sales	63.9%	62.3%		

Selling, general and administrative expenses increased \$1.4 million, or 31.5%, during the six months ended June 30, 2020 compared to the same period last year, mostly due to higher salary and related benefits and recruiting fees in aggregate \$1.0 million, resulting from new hires after June 30, 2019. Also contributing to the increase were consulting fees of \$0.3 million related to marketing, regulatory and strategic initiatives, as well as higher distribution related fees incurred with our largest distributor, director fees and insurance premiums related to our directors and officers insurance policy in aggregate totaling \$0.3 million. Offsetting the increases were lower trade show and travel expenses of \$0.2 million due to the impact of COVID-19 related travel restrictions.

Litigation fees increased \$0.8 million compared to the same period last year due primarily to the negotiation of and entry into a litigation settlement agreement reached with EMED in May 2020 resulting in a non-cash expense of \$2.2 million.

Research and development expenses increased \$0.3 million during the six months ended June 30, 2020 compared with the same period last year mostly due to increased salary and related benefits due to higher headcount as we continue to increase our development initiatives.

Depreciation and amortization

Depreciation and amortization expense increased by 7.3% to \$182,164 in the six months ended June 30, 2020 compared with \$169,820 in the six months ended June 30, 2019. We continued to invest in capital assets, mostly related to manufacturing and computer equipment, and in patent applications and their maintenance.

Net (Loss)/Income

	<u>Six Months Ended June 30,</u>		<u>Change from</u>
	<u>2020</u>	<u>2019</u>	<u>Prior Year</u>
			<u>\$</u>
Net Loss	\$ (626,610)	\$ (7,207)	\$ (619,403)
Stated as a Percentage of Net Sales	(4.5%)	(0.1%)	

Our net loss for the six months ended June 30, 2020 was \$0.6 million compared to a net loss of \$7,207 for the six months ended June 30, 2019, driven by the EMED settlement charge, higher selling, general and administrative expenses, partially offset by higher sales all as described above.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of \$38.1 million as of June 30, 2020, which includes the net proceeds from the recent capital raise described below totaling \$26.5 million and a \$3.5 million draw against our line of credit. In response to concerns about the potential impact of COVID-19, the Company elected to draw \$3.5 million, the full amount available on its line of credit. 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.

On June 18, 2020, the Company entered into a Purchase Agreement with Piper Sandler & Co. and Canaccord Genuity LLC, as representatives of the several underwriters named therein (the "Underwriters"), pursuant to which the Company agreed to issue and sell 3,125,000 shares of its common stock. Under the terms of the Purchase Agreement, the Company granted to the Underwriters an option, exercisable for a period of 30 days, to purchase up to an additional 468,750 shares of the Company's common stock, which the Underwriters exercised in full on June 19, 2020. The Underwriters purchased the shares pursuant to the Purchase Agreement, including the shares subject to the option, at a price of \$7.52 per share with proceeds to the Company net of discounts, commissions, fees and expenses of \$26.5 million.

On May 20, 2020, the Company entered into a Settlement Agreement with EMED Technologies Corporation (“EMED”) to settle all claims in connection with all pending litigation matters between them (the “Claims”). Pursuant to the Settlement Agreement, the Company issued to EMED (i) 95,238 restricted stock units, which vested on May 21, 2020 and 95,238 restricted stock units vesting on January 1, 2021, and (ii) an option to purchase up to 400,000 shares of the Company’s common stock at an exercise price of \$11.21 per share prior to February 1, 2021, which can be settled in cash in lieu of common stock at the Company’s sole discretion, provided that the number of shares of common stock and/or amount of cash paid by the Company upon exercise will be capped at a value of \$16.21 per share. The Settlement Agreement includes mutual releases and covenants not to sue for any claim arising before May 20, 2020 and the Company covenants not to challenge any EMED patents that were the subject of the Claims unless EMED asserts them in the future against Company products. This was a non-cash settlement from which we recognized expense in the amount of \$2.2 million in the second quarter of 2020.

The Company’s operations continue to remain active, as we currently qualify as an “essential business” under New York state government guidelines. With the COVID-19 outbreak, the need to ensure vulnerable patients have access to home-based treatments is more apparent than ever. Home infusion therapy keeps high-risk patients with immune diseases and other conditions out of institutional settings and allows them to receive treatment at home.

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

Cash Flows

The following table summarizes our cash flows:

	Six Months Ended June 30, 2020	Six Months Ended June 30, 2019
Net cash provided by/(used in) operating activities	\$ 2,707,549	\$ (1,483,909)
Net cash (used in)/provided by investing activities	\$ (513,273)	\$ 1,532,487
Net cash provided by financing activities	\$ 30,064,144	\$ 19,811

Operating Activities

Net cash provided by operating activities of \$2.7 million for the six months ended June 30, 2020 was mostly attributable to non-cash charges for stock-based compensation and litigation settlement expense of \$2.1 million, an increase in accounts payable, accrued expenses and accrued payroll of \$2.1 million, driven by the litigation settlement with EMED, the capital raise and customer rebates.

Further adding to the increase was an increase in tax liability of \$0.3 million, resulting from book tax differences related to option expense. Collection against accounts receivable also contributed \$0.3 million. Offsetting these were an increase in inventory of \$1.3 million as we built inventory to keep pace with sales growth and to insure timely order fulfillment.

Net cash used in operating activities of \$1.5 million for the six months ended June 30, 2019 was mostly attributable to increased accounts receivable of \$1.9 million as one of our major customer’s payment terms changed on January 1, 2019 from net 30 to net 60 days, and increased inventory of \$0.5 million as we look to build stock to keep pace with sales growth. Partially offsetting these were our non-cash charges for stock based compensation of \$0.5 million and depreciation and amortization of long lived tangible and intangible asset of \$0.2 million.

Investing Activities

Net cash used in investing activities of \$0.5 million for the six months ending June 30, 2020 was for capital expenditures for research and development and strategic initiatives as well as for patent and trademark applications. Net cash of \$1.5 million provided by investing activities for the six months ended June 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 and patent application and maintenance of \$0.2 million.

Financing Activities

The \$30.1 million provided by financing activities for the six months ended June 30, 2020 is from the \$26.5 million capital raise, net of expenses, a \$3.5 million draw on the line of credit and \$0.1 million from options exercised. The \$19,811 provided by financing activities for the six months ended June 30, 2019 is a result of options exercised less payments for cancelled shares and leased office equipment.

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 December 2019, the FASB issued ASU No. 2019-12 Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The amendments in this ASU simplify the accounting for income taxes by removing several exceptions including the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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, and litigation, manufacturing initiative and stock option expenses. Prior to January 1, 2020, discontinued product expense and manufacturing initiative expense was not included in our definition of Adjusted EBITDA. We believe that Adjusted EBITDA is used by investors and other users of our financial statements as a supplemental financial measure that, when viewed with our GAAP results and the accompanying reconciliation, we believe 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 (Loss)/Income to Non-GAAP Adjusted EBITDA:	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
GAAP Net (Loss)/Income	\$ (1,076,038)	\$ 78,183	\$ (626,610)	\$ (7,207)
Tax Expense	30,919	24,683	172,847	2,584
Depreciation/Amortization	94,940	86,169	182,164	169,820
Interest Expense/(Income), Net	5,002	(18,243)	(14,028)	(35,723)
Reorganization Charges	—	—	—	354,926
Discontinued Product Expenses	(31,581)	—	77,977	—
Litigation Expenses	2,346,914	1,124,947	2,446,072	1,617,462
Manufacturing Initiative Expenses	25,957	—	135,759	—
Stock Option Expense	363,851	194,765	664,817	316,640
Non-GAAP Adjusted EBITDA	<u>\$ 1,759,964</u>	<u>\$ 1,490,504</u>	<u>\$ 3,038,998</u>	<u>\$ 2,418,502</u>

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

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

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

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

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 June 30, 2020, that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

From 2013 until May 2020, we were involved in several lawsuits with our principal competitor, EMED Technologies Corporation ("EMED"). EMED alleged that our needle sets infringed various patents controlled by EMED. Certain of these lawsuits also alleged antitrust violations, unfair business practices, and various other business tort claims. On May 26, 2020, the parties announced the settlement of all of the litigation between KORU Medical and EMED. The settlement agreement provides KORU Medical with freedom to operate under EMED's existing patent portfolio, dismissal of all litigation with prejudice (including the claims against Andrew Sealton, our former President and Chief Executive Officer), and an equity payment by KORU Medical to EMED. The settled litigation is described below.

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 sought 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. On June 16, 2015, the California court entered a preliminary injunction against KORU Medical for making certain statements regarding products cleared for use by the FDA, or that 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 U.S. Patent and Trademark Office ("USPTO"). The ex parte reexamination resulted in the Patent Trial and Appeal Board ("PTAB") of the USPTO determining that claims 1-10 of the '703 patent are invalid, leaving claim 11 as the only surviving claim of the '703 patent. Claim 11 of the '703 patent, however, was not asserted in the California case. EMED informed KORU Medical it will neither appeal the PTAB's decision nor pursue a claim based on infringement of claim 11 of the '703 patent in the California case.

The second court case was filed by EMED in the United States District Court for the Eastern District of Texas (the "Texas Court") 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 invalid claims of the EMED '703 patent.

On September 17, 2015, we requested an inter partes review ("IPR") of the '476 patent, and subsequently after a trial the PTAB issued a Final Written Decision in our favor, invalidating all claims but one ("dependent Claim 9") of the '476 patent. EMED appealed the PTAB's ruling to the United States Court of Appeals for the Federal Circuit (the "CAFC"), which affirmed the PTAB's Final Written Decision in our favor on April 3, 2018.

During the IPR proceedings regarding the '476 patent, EMED filed a new patent application that subsequently 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 Texas Court claiming patent infringement of the '576 patent by our needle sets, and seeking unspecified damages and a preliminary injunction against marketing and sales of our needle sets. We moved 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 Texas Court 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 named Andrew Sealton, then President and Chief Executive Officer of KORU Medical, individually as a defendant. Following a hearing held on November 14, 2018 to address a motion we had filed to transfer venue, on December 7, 2018, the Texas Court transferred the fourth case to the United States District Court for the Eastern District of California (the “California Court”). We then moved to dismiss that complaint, and Andrew Sealton filed a separate motion to dismiss the case as to him for lack of jurisdiction.

At the same hearing on November 14, 2018, the Texas Court granted EMED leave to amend its infringement contentions to assert infringement of that sole remaining claim 9 of the '476 patent. 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. We moved to dismiss the case for lack of infringement. On June 24, 2019, the Texas Court Magistrate Judge issued a Report and Recommendation decision granting summary judgment in our favor, finding no infringement, literally or under the doctrine of equivalents, by KORU Medical's accused products. EMED's objections were overruled and on June 28, 2019, the Texas Court issued a Final Judgment in favor of KORU Medical, awarded court costs to KORU Medical, and dismissed the case. A final judgment was entered and KORU Medical submitted its Bill of Costs for approximately \$16,000, which was ordered granted by the Texas Court. KORU Medical also moved to declare the case exceptional and for recovery of its attorney fees and expenses of approximately \$2.5 million in defense of EMED's assertion of the '476 Patent. EMED appealed the non-infringement judgment to the CAFC. On April 9, 2020, the CAFC issued a unanimous decision affirming the Texas Court's judgment of non-infringement. The Texas Court had stayed proceedings in the district court until the appeal process was completed.

The SDNY '576 matter proceeded in the New York court through claim construction on the '576 Patent, whereupon KORU Medical filed a motion for summary judgement of non-infringement. That motion was granted on August 30, 2019, and the New York court dismissed the lawsuit and entered a final judgement. KORU Medical submitted a Bill of Costs for approximately \$1,500, to which EMED objected, and 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. On November 12, 2019, the Magistrate Judge issued a Report and Recommendation that KORU Medical's fee motion be granted, and KORU Medical be awarded approximately \$1.1 million in fees and expenses. EMED filed objections to that Report and Recommendation. EMED also appealed the New York court's judgment of non-infringement to the CAFC, which the parties had fully briefed, and were awaiting a decision from the CAFC Court.

The aforementioned district court litigation has now been finally dismissed with prejudice, and all associated appeals dismissed.

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

Our business could be adversely affected by the COVID-19 pandemic.

The COVID-19 pandemic has and will continue affecting economies and businesses around the world. We are closely monitoring the impact of COVID-19 on all aspects of our business, including how it may impact our employees and business operations. While we did not incur significant disruptions during the quarter ended June 30, 2020 from the COVID-19 pandemic, we may experience disruptions that could severely impact our results of operations and financial condition. We are unable to predict the impact that COVID-19 will have on our operating results and financial condition due to numerous uncertainties. These uncertainties include the geographic spread of the pandemic, the severity of the virus, the impact of the virus directly on our employees or those of our suppliers, the duration of the outbreak, governmental actions, travel restrictions and social distancing, business closures or business disruptions (including those impacting our supply chain), the effectiveness of actions taken in the United States and other countries to contain and treat the disease, the availability of plasma and drugs that are administered by our products, changes to our operations, or whether the United States and additional countries are required to move to complete lock-down status, among others. Our sales representatives are unable to hold in-person meetings with customers and health care providers to discuss our products, which may impact our sales. As local jurisdictions continue to put restrictions in place, our ability to continue to manufacture our products may also be limited. Such events may result in a period of business and manufacturing disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. The health of our workforce and our ability to meet staffing needs at our facility cannot be predicted and is vital to our operations. We will continue to monitor the COVID-19 situation closely and intend to follow health and safety guidelines as they evolve. Further, the spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of,

COVID-19 may be difficult to assess or predict, it has resulted in significant disruption of global financial markets, which could reduce our ability to access capital, negatively affecting our liquidity. In addition, the recession resulting from the spread of COVID-19 could materially affect our business and the value of our common stock. The ultimate long-term impact of COVID-19 is highly uncertain and cannot be predicted with confidence.

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

Each non-employee director of the Company is eligible to receive of \$50,000 annually (effective January 1, 2019) plus \$10,000 for chairing a Board committee (effective February 20, 2019), all to be paid quarterly half in cash and half in common stock and pro-rated for partial service. The Chairman of the Board is eligible to receive an additional \$50,000 annually (effective October 1, 2019), all to be paid in common stock. The Company issued an aggregate of 7,999 and 17,188 shares of common stock to its non-employee directors during the three-month and six-month period ended June 30, 2020, respectively.

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

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

On May 20, 2020, the Company entered into a Settlement Agreement with EMED Technologies Corporation (“EMED”) to settle all claims in connection with all pending litigation matters between them (the “Claims”). Pursuant to the Settlement Agreement, the Company issued to EMED (i) 95,238 restricted stock units, which vested on May 21, 2020 and 95,238 restricted stock units vesting on January 1, 2021, and (ii) an option to purchase up to 400,000 shares of the Company’s common stock at an exercise price of \$11.21 per share prior to February 1, 2021, which can be settled in cash in lieu of common stock at the Company’s sole discretion, provided that the number of shares of common stock and/or amount of cash paid by the Company upon exercise will be capped at a value of \$16.21 per share. The Settlement Agreement includes mutual releases and covenants not to sue for any claim arising before May 20, 2020 and the Company covenants not to challenge any EMED patents that were the subject of the Claims unless EMED asserts them in the future against Company products.

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

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.

August 5, 2020

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

August 5, 2020

/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 this equivalent function):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2020

/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 this equivalent function):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 5, 2020

/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 period ending June 30, 2020 as filed with the Securities and Exchange Commission, I, Donald B. Pettigrew, Principal Executive Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 5, 2020

/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 period ending June 30, 2020 as filed with the Securities and Exchange Commission, I, Karen Fisher, Principal Financial Officer, hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: August 5, 2020

/s/ Karen Fisher

Karen Fisher
Chief Financial Officer and Treasurer
