UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2019

OR

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

Commission File Number 0-12305

REPRO MED SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

NEW YORK	**13-3044880**
(State or Other Jurisdiction of Incorporation or Organization)	(IRS Employer Identification No.)
24 CARPENTER ROAD, CHESTER, NY	**10918**
(Address of principal executive offices)	(Zip Code)

(845)-469-2042
Registrant's Telephone Number, Including Area Code

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

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

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

COMMON STOCK, $.01 PAR VALUE
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	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 Act). Yes ☐ No ☒

Based on the closing sales price of June 28, 2019, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was $54,741,695.

The number of issued and outstanding shares of the registrant's common stock, $0.01 par value was 39,686,746 at March 4, 2020, which excludes 2,737,231 shares of Treasury Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2020 Annual Meeting of Shareholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2019.

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PART I

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

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "believe", "plan," "goal," "seek," "positions," "vision", "confident," "future," "will" and similar references to future periods. Examples of forward-looking statements include, among others, statements we make regarding our ability to achieve our goals set forth in our Strategic Plan, under "Our Mission in Item 1 of this Form 10-K and under "Overview" in Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 of this Form 10-K and to defend pending litigation claims. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, readers should not rely on any of these forward-looking statements.

Important factors that could cause our actual results and financial condition to differ materially from those indicated in the forward-looking statements include, among others, those discussed in this Annual Report on Form 10-K, and in particular, the risks discussed under the caption "Risk Factors" in Item 1A and those discussed in other documents we file with the Securities and Exchange Commission ("SEC").

Any forward-looking statement made by us in this Annual Report on Form 10-K is based only on information currently available to us and speaks only as of the date on which it is made. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

ITEM 1. BUSINESS

OUR BUSINESS

REPRO MED SYSTEMS, INC. d/b/a KORU Medical Systems ("KORU Medical," "KORU", the "Company" "our" or "we"), designs, manufactures and markets proprietary and innovative portable medical devices, primarily for the ambulatory infusion market in compliance with the United States Food and Drug Administration (the "FDA") quality and regulatory system and international standards for quality system management. Our development and marketing focus is primarily concentrated on our mechanical infusion products, the FREEDOM Infusion Systems (which we refer to as the "FREEDOM System" when used with one or more accessories), which include the FREEDOM60® Syringe Driver, the FreedomEdge® Syringe Driver, HIgH-Flo Subcutaneous Safety Needle Sets™ and Precision Flow Rate Tubing™. The Company incorporated in the State of New York in March 1980.

OUR MISSION

Our mission is to improve the quality of life of patients around the world by delivering innovative, effective, and easy-to-use drug delivery systems that can be used at home or alternate site settings.

OUR STRATEGY

In January 2019, the Board of Directors approved our strategic plan to become the preferred drug delivery partner for specific infusion therapies in select markets. We intend to accomplish this objective by building on the market leading position of our FREEDOM® 60 Syringe Infusion System that allows for the self-administration of subcutaneous immunoglobulin ("SCIg") to treat Primary Immunodeficiency Diseases (PIDD), Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), and other disease states.

We have identified and intend to capitalize on multiple industry growth drivers, including a growing demand for and accelerating development of SCIg, increasing awareness of PIDD and CIDP, and the ongoing shift from institutional care to home and alternate site settings. We plan to continue to support the product demand for the accelerating adoption of Hizentra®, Cuvitru®, Xembify® and other formulations of SCIg therapy, and participate in the migration of other therapeutics into the global home health marketplace.

Furthermore, we plan to leverage our specialty pharmacy customer base by introducing additional innovative products and services to our channel, with a focus on value based health care, which includes clinical and cost advantages and user friendly products with compliance/data focused characteristics. We are focused on identifying new entrants into the SCIg market and outside the immunoglobulin space, where we can supply our infusion system in their clinical trials and ultimately commercialization.

The financial goals for our strategic plan through 2022 are:

- $50 million net revenue run rate
- 70%+ gross margins, and
- 20%+ annual organic revenue growth

OUR PRODUCTS

FREEDOM SYSTEM

The FREEDOM System comprises the FREEDOM60 Syringe Driver (standard 60/50ml syringe compatible) and FreedomEdge Syringe Driver (standard 30ml and 20ml syringe compatible), HIgH-Flo Subcutaneous Safety Needle Sets and Precision Flow Rate Tubing. The systems are portable, easy to operate, maintenance free and do not require batteries or electricity. The FREEDOM System operates at a lower pressure than an electrical, volumetric pump and maintains a balance between what a patient's subcutaneous tissues are able to absorb and what the system delivers, or what we refer to as DynEq®.

The FDA issued a 510(k) clearance for the KORU "Integrated Catch-Up Freedom Syringe Driver Infusion System," which is our FREEDOM System, effective August 31, 2017, which includes the Precision Flow Tubing and our HIgH-Flo Subcutaneous Safety Needle Sets. The FREEDOM System is cleared by the FDA for a wide range of flow rates and certain medications for subcutaneous and intravenous indications, including specific clearance for leading immune globulins that include Hizentra® and Cuvitru® and a variety of antibiotics. The FDA clearance (No. K162613) includes a Caution Statement regarding FDA's approved proper use.

Ambulatory infusion systems are most prevalent in the home care and alternate site markets. The use of the FREEDOM System for treatment of PIDD through SCIg administration continues to increase and remains the market leading delivery system in the U.S. for these infusions. There is an expanded indication for Hizentra® for patients with CIDP which is an acquired immune-mediated inflammatory disorder of the peripheral nervous system. It is expected that new SCIg drugs may enter the market. We believe the FREEDOM System is an ideal system for SCIg administration because:

- the patient is able to self-administer in any location;
- the system has less adverse events;
- the pump is easily configured for this application;
- it is the best value infusion system available in a heavily cost constrained market; and
- it has demonstrated ultimate effectiveness and an impeccable safety profile.

HIgH-Flo Subcutaneous Safety Needle Sets are a critical element of the FREEDOM System, are available in 26- and 24-gauge sizes, and feature unique design elements specific to subcutaneous self-administration. One such feature includes a back-cut needle designed for more comfort and less tissue damage with flexible wings to minimize patient discomfort.

Precision Flow Rate Tubing is designed for repeatable flow rates, and will not allow any free-flow, bolus or overdose of medication. The tubing regulates the flow rate and infusion time for various applications when used with the FREEDOM System. Each tubing set provides a different level of flow restriction and consistently delivers medication with low residual volume to minimize drug waste.

SALES AND DISTRIBUTION

The FREEDOM System is sold through both direct sales and medical device distributors to specialty pharmacy customers and home infusion providers. Our products and those of our competitors are sold principally through a small number of distributors so our specialty pharmacy customers receive the benefit of inventory management and one-stop shopping. We sell most of our products through two distributors in the U.S. and two distributors outside the U.S. As of December 31, 2019, these four distributors comprised approximately 67% of our net revenues.

Specialty pharmacies and home infusion providers are our primary call point, although we provide education and training materials to clinicians, patients and patient advocates both in the field and online.

MANUFACTURING AND RAW MATERIALS

We perform product assembly, calibration, pre- and post-assembly quality control inspection and testing, and final packaging for all of our products at our Chester, NY facility.

Our ability to meet customer demand depends, in part, on our ability to obtain timely and adequate delivery of components for our products. All of the components that go into the manufacturing of our products and accessories are sourced from third-party suppliers, and some of these components are single source including subassemblies from Command Medical Products, Inc., molded plastic parts from a supplier in Taiwan and tubing from Natvar, a Tekni-Plex Co., Inc.

RESEARCH AND DEVELOPMENT

We recognize the importance of innovation to our long-term success and are committed to research and new product development activities. Our product development team along with outside engineering resources is engaged in continuously improving existing product performance and researching new product opportunities to increase our pipeline. We spent $0.7 million on research and development for the year ended December 31, 2019, and $0.2 million for the year ended December 31, 2018. We intend to make additional investments in research and development over the next twelve months.

REGULATORY

Our medical devices and technologies, as well as our business activities, are subject to a complex set of regulations and rigorous enforcement, including by the U.S. Department of Justice, Health and Human Services-Office of the Inspector General, and numerous other federal, state, and non-U.S. governmental authorities. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our products.

Both before and after a product is commercially released, we have ongoing responsibilities under the FDA and other applicable non-U.S. government agency regulations. For instance, all medical devices marketed in the U.S. must be manufactured in accordance with the FDA's quality system regulations. Accordingly, our facility and procedures and those of our suppliers are also subject to periodic inspections by the FDA to determine compliance with applicable laws and regulations.

The FDA has announced its intention to pursue comprehensive reforms to its current 510(k) clearance pathway, which is used for clearance of low- to moderate-risk devices that are substantially equivalent to a device already on the market, and to its post-market safety monitoring process. We cannot predict with any certainty how these reforms may impact our business. See ITEM 1A. RISK FACTORS.

We are required to comply with federal, state, and local environmental laws; however, there is no significant effect of compliance on capital expenditures, earnings, or competitive position. We do not use significant amounts of hazardous materials in the assembly of our products.

COMPETITION AND THE MARKET

Competition for the Freedom System includes electronic (volumetric) pumps, elastomeric ("infuser") pumps, and at least one other fully mechanical pump. Safety, ease of use, familiarity, cost effectiveness, accuracy, pressure, etc. are driving influencers of pump selection. Electronic pumps deliver drugs at a programmed flow rate. They are expensive and require electricity or batteries, extensive training and maintenance and must be programmed by a qualified pharmacist or clinician. Elastomeric pumps are one-time-use balloon type devices used for infusion of drugs in intravenous ("IV") and surgical wound site applications. Pharmacies are required to fill them with drugs and deliver them to the patient. They are easy to use from the patient point of view but can be more costly and time consuming to fill, are temperature sensitive and have larger residual volumes than other delivery systems. Other mechanical pumps can be less expensive but may have larger residual volumes and lower performance than ours.

EMPLOYEES

As of December 31, 2019, we had 71 full time employees and 0 part time employees.

PATENTS AND INTELLECTUAL PROPERTY

We filed and received U.S. and foreign protection for many of our products relating to infusion systems and related components. We had seven patents granted in the U.S. and seven patents granted outside the U.S. in 2019. As of December 31, 2019, we had eleven applications pending in the U.S. and 45 applications pending in foreign jurisdictions. Expiration dates for the entire patent portfolio range from 2022 to 2037. In some cases where it was no longer deemed economically beneficial, we have allowed certain patent and/or trademark protections to lapse. In addition, the patent application process for both the U.S. and foreign countries is highly uncertain and involves complex legal and factual issues that differ from country to country. Consequently, there can be no assurance that patent applications relating to products or technology will result in patents being granted or that, if issued, the patents will afford protection against competitors with similar technology. There can be no assurance that we will have the financial resources necessary to enforce any patent rights we may hold. See ITEM 3. LEGAL PROCEEDINGS for details regarding our patent litigation.

EXECUTIVE OFFICERS

The following table sets forth certain information with respect to our executive officers as of March 4, 2020:

Name	Age	Position / Held Since
Donald B. Pettigrew	52	President and Chief Executive Officer (since February 2019) President and Chief Commercial Officer (from September 2018-February 2019)
Karen Fisher	53	Chief Financial Officer and Treasurer (since 2015)
Manuel Marques	47	Chief Operating Officer (since December 2018)

Executive officers hold office at the discretion of the Board of Directors.

Mr. Pettigrew has more than 23 years of sales and business development experience in the medical device industry, including the home infusion space. Prior to joining KORU in 2018, Mr. Pettigrew held senior leadership positions at market leading medical firms such as Moog, Inc. as Group Director, Global Business Development and Group Director, Global Sales and Professional Services from 2011 through 2018, where he led commercialization and business development for the IV infusion and enteral feeding franchises in both the U.S. and international markets. Mr. Pettigrew also held management positions at Baxter (formerly Gambro) from 2008-2011, Boston Scientific from 1995-2008, and E&J Gallo from 1990-1995. Mr. Pettigrew earned his B.A. in Biology from the University of Colorado.

Ms. Fisher has more than 25 years of financial experience at a variety of industries. Prior to joining KORU in 2015, Ms. Fisher was Assistant Controller, Senior Manager for Armored Autogroup, Inc., a worldwide consumer products company from February 2012 to January 2015. Before joining Armored Autogroup, Inc., she spent seven years at Gilman Ciocia, Inc., where she served in a variety of financial roles, including Chief Accounting Officer and Treasurer, and, earlier, as Controller. Before Gilman Ciocia, Inc., she held multiple financial management roles at The New York Times Company and Thomson Financial. Ms. Fisher is a Certified Public Accountant and a graduate of Arizona State University with a B.S. in accounting.

Mr. Marques was appointed as Chief Operating Officer in December 2018. Mr. Marques served as our Vice President of Operations and Engineering since February 2016, and joined KORU as Director of Manufacturing and Manufacturing Engineering in July 2015. Prior to joining KORU, Mr. Marques Served as Lean Manufacturing Champion at Nobel Biocare Procera LLC, a manufacturer of dental implants and CAD/CAM-based individualized prosthetics, from February 2013 until joining KORU. Mr. Marques has over 23 years of experience within the dental, medical device, and automotive industries, and holds two U.S. patents for cardiovascular medical devices. Mr. Marques obtained a B.S. in Mechanical Engineering Technology and also an M.S. in Engineering Management from the New Jersey Institute of Technology.

ITEM 1A. RISK FACTORS

RISK FACTORS

An investment in our common stock involves significant risks. Before making an investment in our common stock, you should carefully consider all of the information contained in this Annual Report on Form 10-K and our other filings with the SEC including the material risks and uncertainties that we have identified below. The risks and uncertainties identified below are not the only risks and uncertainties we face. If any of the material risks or uncertainties that we face were to occur, the trading price of our common stock could decline and you could lose part or all of your investment. Please note that additional risks not currently known to us or that we currently deem immaterial also may adversely affect our business, operations, results of operations, financial condition and prospects.

Risks Related to Our Business

We may be unable to compete successfully in our highly competitive industry.

We are a global company that faces competition from a wide range of international and domestic companies, including those that deliver electronic volumetric pumps, elastomeric infuser pumps and other mechanical devices. These include large medical device companies with multiple product lines, some of which may have greater financial and marketing resources than we do. We also face competition from companies that are even more specialized than ours with respect to particular markets or product lines. Some of those companies have greater financial and sales and marketing resources than we do or offer products at a lower price point than ours. In addition, former employees may develop products that are competitive with ours or capitalize on customer relationships developed while employed with us, subject to their continuing obligations under confidentiality agreements and other restrictive covenants that may survive their employment. We face competition on the basis of product features, clinical or economic outcomes, product quality, availability, price, services, technological innovation and other factors. In addition, we face changing customer preferences and requirements, changes in the ways health care services are delivered, including the transition of high-acuity care to lower-acuity, and non-acute care settings. Competition may increase further as additional companies begin to enter our markets or modify their existing products to compete directly with ours. If we are forced to reduce our prices due to increased competition, our business could suffer.

The medical technology industry has also experienced a significant amount of consolidation, resulting in larger companies with greater access to markets. Health care systems, other health care companies and even retail pharmacies are also consolidating, resulting in greater purchasing power for these companies. As a result, competition among medical device suppliers to provide goods and services has increased. Group purchasing organizations and integrated health delivery networks have also served to concentrate purchasing decisions for some customers, which has led to downward pricing pressure for medical device suppliers. Further consolidation in the industry could intensify competition among medical device suppliers and exert additional pressure on the prices of our products.

Consolidation in the medical industry could have a negative impact with payor and provider relationships and distributor relationships, as we could lose market share as consolidation occurs.

Technological developments by others may disrupt our business and negatively impact our revenues.

The medical device industry is subject to rapid technological change and discovery and frequent product introductions. The development of new or improved products, processes or technologies by other companies that provide better features, pricing or clinical outcomes or economic value may render our products or proposed products obsolete or less competitive. If our competitors respond more quickly to new or emerging technologies and changes in customer requirements or we do not introduce new versions or upgrades to our product portfolio in response to those requirements, our products may not be marketable. If competitors develop more effective or affordable products, or achieve earlier patent protection or product commercialization for new products than we do, our operations will likely be adversely affected.

If we are unable to successfully introduce new products or fail to keep pace with advances in technology, our business, financial condition and results of operations could be adversely affected.

We need to successfully introduce new products to achieve our strategic business objectives. A significant element of our strategy is to increase revenue growth by investing in innovation and new product development, which will require substantial resources. Our successful product development will depend on many factors, including our ability to attract strong talent to lead our research and development efforts, properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory concurrence on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economical and timely manner, obtain appropriate

intellectual property protection for our products, gain and maintain market acceptance of our products, and differentiate our products from those of our competitors. In addition, patents attained by others can preclude or delay our commercialization of a product. There can be no assurance that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory concurrence or gain market acceptance. If we cannot successfully introduce new products or adapt to changing technologies, our products may become obsolete and our revenue and profitability could suffer.

Proposed changes to the FDA 510(k) clearance pathway and post-market safety monitoring process could adversely affect our ability to offer our new and existing products.

The FDA has announced its intention to pursue comprehensive reforms to its current 510(k) clearance pathway, which is used for clearance of low- to moderate-risk devices that are substantially equivalent to a device already on the market, and to its post-market safety monitoring process. The proposals, among other things, could prevent the use of certain older predicate devices as support for 510(k) clearance, provide for a "de novo" classification process to permit an evaluation of novel devices without a predicate device, establish an alternative 510(k) pathway for "well-understood" devices relying on objective safety and performance criteria, and expand post-market safety surveillance measures. These reforms could delay or prevent us from obtaining or maintaining 510(k) clearances or other premarket authorizations for our existing or new devices. Compliance with the new rules could require us to undertake significant additional costs prior to and following commercialization of our products, which may reduce the profitability of those products.

We are subject to costly and complex laws and governmental regulations and any adverse regulatory action may materially adversely affect our financial condition and business operations.

Our medical devices and technologies, as well as our business activities, are subject to a complex set of regulations and rigorous enforcement, including by the U.S. Department of Justice, Health and Human Services-Office of the Inspector General, and numerous other federal, state, and non-U.S. governmental authorities. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing and distribution of our products. We cannot guarantee that we will be able to obtain or maintain 510(k) clearance or premarket approval for our new products or enhancements or modifications to existing products, and the failure to maintain approvals or clearances, or obtain approval or clearance could have a material adverse effect on our business, results of operations, financial condition and cash flows. Even if we are able to obtain approval or clearance, it may:

- take a significant amount of time
- require the expenditure of substantial resources
- involve stringent clinical and pre-clinical testing, as well as increased post-market surveillance
- involve modifications, repairs, or replacements of our products, and
- limit the proposed uses of our products.

Both before and after a product is commercially released, we have ongoing responsibilities under the FDA and other applicable non-U.S. government agency regulations. For instance, all medical devices marketed in the U.S. must be manufactured in accordance with the FDA's quality system regulations. Accordingly, our facility and procedures and those of our suppliers are also subject to periodic inspections by the FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on the FDA's Form 483, warning letters, or other forms of enforcement. Additionally, as a manufacturer of medical devices, we are subject to annual registration and listing requirements, and associated user fees. If the FDA were to conclude that we are not in compliance with any applicable laws or regulations, or that any of our medical products are ineffective or pose an unreasonable health risk, the FDA could deem our products adulterated or misbranded, and take enforcement action against us. Possible enforcement actions include, but are not limited to: banning such medical products; detaining or seizing all adulterated or misbranded medical products; ordering recall, repair, replacement, or refund of such products; refusing to grant pending pre-market approval or 510(k) clearance applications; and/or requiring us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. The FDA and other non-U.S. government agencies may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future pre-market clearances or approvals, and could result in a substantial modification to our business practices and operations.

In addition, the FDA has taken the position that device manufacturers are prohibited from promoting their products other than for the uses and indications set forth in the approved product labeling, and any failure to comply could subject us to significant civil or criminal exposure, administrative obligations and costs, and/or other potential penalties from, and/or agreements with, the federal government.

Regulations regarding the development, manufacture and sale of medical devices are evolving and subject to future change.We cannot predict what impact, if any, those changes might have on our business; however, failure to comply with applicable regulatory requirements could have a material adverse effect on our business, financial condition, and results of operations.

Governmental regulations outside the U.S. have, and may continue to, become increasingly stringent and common. In the European Union, for example, a new Medical Device Regulation was published in 2017 which, when it enters into full force in 2020, will include significant additional premarket and post-market requirements. Penalties for regulatory non-compliance could be severe, including fines and revocation or suspension of a company's EU business license, mandatory price reductions and criminal sanctions. Future foreign governmental laws and regulations may have a material adverse effect on us.

Health care policy changes and industry cost-containment measures could result in downward pricing pressure for our products and limit our sales.

Most of our customers, and those to whom our customers supply medical devices, rely on third-party payers, including government programs and private health insurance plans, to reimburse some or all of the cost of the medical devices we manufacture. The continuing efforts of governmental authorities, insurance companies and other payers of health care costs to contain or reduce these costs and, more generally, to reform the health care system, could limit the prices we are able to charge for our products or the amounts of reimbursement available for our products or the drugs that they administer, which would put pressure on us to reduce our prices for our products and/or limit our sales. The adoption of some or all of these proposals could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Our business depends on an adequate supply of drugs to be administered by our products.

Demand for our products depends on the availability of drugs to be administered by them. Currently, most of our products require immunoglobulin therapies that rely on blood plasma collection for drugs such as Hizentra® and Cuvitru®. Any disruption in the supply of these drugs for any reason, including contamination, could significantly adversely affect our business. The change of any drug indication by the FDA or comparable foreign governmental agencies could also result in decreased demand for our products. In addition, pharmaceutical companies and other competitors have or are developing alternative therapies for disease states that are deliverable without a medical device. If there is not an adequate supply of drugs requiring administration by medical devices such as those provided by us or alternative therapies are developed, our sales may suffer and/or our products may become obsolete.

Issues with product quality could have an adverse effect upon our business, subject us to regulatory actions, cause a loss of customer confidence in us or our products, among other negative consequences.

Quality management plays an essential role in determining and meeting customer requirements, preventing defects, improving our products and services and assuring the safety and efficacy of our products. Our future success depends on our ability to maintain and continuously improve our quality management program. While we have a quality system that covers the lifecycle of our products, quality and safety issues may occur with respect to any of our products. A quality or safety issue may result in adverse inspection reports, voluntary or official action indicated, warning letters, import bans, product recalls (either voluntary or required by the FDA or similar governmental authorities in other countries) or seizures, monetary sanctions, injunctions to halt manufacture and distribution of products, civil or criminal sanctions, costly litigation, refusal of a government to grant approvals and licenses, restrictions on operations or withdrawal of existing approvals and licenses. An inability to address a quality or safety issue in an effective and timely manner may also cause negative publicity, a loss of customer confidence in us or our current or future products, which may result in the loss of sales and difficulty in successfully launching new products.

Defects or quality issues associated with our products could adversely affect the results of our operations.

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. These events could lead to recalls or safety alerts relating to our products (either voluntary or as required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs and lost sales and customers, enforcement actions and/or investigations by state and federal governments or other enforcement bodies, as well as negative publicity and damage to our reputation that could reduce future demand for our products. Personal injuries relating to the use of our products can also result in significant product liability claims being brought against us. A product liability claim, regardless of its merit or outcome, could not only result in significant legal defense costs, but also have a material adverse effect on our business and reputation and ability to attract and retain customers for our products. In some circumstances, adverse events could also cause delays in regulatory approval of new products or the imposition of post-market approval requirements.

Interruption of our manufacturing operations could adversely affect our future revenues and operating income.

There is a strict regulatory regime governing our manufacturing operations, which includes product assembly, calibration, pre- and post-assembly quality control inspection and testing, and final packaging for all of our products at our Chester, NY facility. Variations in the manufacturing process may result in production failures which could lead to launch delays, product shortage, unanticipated costs, lost revenues and damage to our reputation. A failure to identify and address manufacturing problems prior to the release of products to our customers may also result in a quality or safety issue that could result in a recall or other inability to sell our products.

Our products are manufactured and stored at a single manufacturing facility in Chester, NY. Loss or damage to our manufacturing and storage site due to weather, vandalism, terrorism, a natural disaster, issues in our manufacturing process, equipment failure or other factors, could adversely affect our ability to manufacture sufficient quantities of products or otherwise deliver products to meet customer demand or contractual requirements which may result in a loss of revenue and other adverse business consequences, including damage to our relationship with customers. Because of the time required to approve and license a manufacturing facility, a third party manufacturer may not be available on a timely basis (if at all) to replace production capacity in the event we lose manufacturing capacity or products are otherwise unavailable due to natural disaster, regulatory action or otherwise.

We take precautions to safeguard our facility and storage site, including acquiring insurance, adopting health and safety protocols and utilizing off-site storage of computer data. Our insurance may not cover our losses in any particular case. In addition, regardless of the level of insurance coverage, damage to our facilities may harm our business, financial condition and operating results.

We may need to substantially change our manufacturing operations in order to expand.

We currently have six options to extend our current lease of our manufacturing facility, which is also our headquarters, through August 2022. Although we believe our current space is sufficient to significantly increase current production requirements, we are considering various alternatives to expand our manufacturing operations and carry out our business plan. There is no guaranty that any of these alternatives will be realized on favorable terms, or at all. If we do find an appropriate alternative, we may need to expend significant resources to ensure continued regulatory compliance. Changes to our corporate headquarters and/or manufacturing operations could cause us to incur significant expenses and could delay or reduce our ability to manufacture our products for some time. Our financial condition and results of operation could be materially adversely affected by any such change.

We are subject to lawsuits.

We are currently party to several lawsuits with a competitor. In the future we may be party to lawsuits, settlement discussions, mediations, arbitrations and other disputes, including patent and product liability claims, whether brought by companies, individuals or governmental authorities. These current and future matters may result in a loss of patent protection, reduced revenue, incurrence of significant liabilities and diversion of our management's time, attention and resources. Our insurance coverage may not provide adequate protection against actual losses. In addition, we are subject to the risk that one or more of our insurers may become insolvent and become unable to pay claims that may be made in the future. Even if we maintain adequate insurance, claims could have a material adverse effect on our financial condition, liquidity and results of operations and on our ability to obtain suitable, adequate or cost-effective insurance in the future. Litigation and other disputes, including any adverse outcomes, may have an adverse impact on our business, operations or financial condition. Even claims without merit could subject us to adverse publicity and require us to incur significant legal fees.

The outcome of pending EMED legal proceedings could have a material adverse impact on our financial condition.

We are involved in several lawsuits with our competitor, EMED Technologies Corporation ("EMED"), wherein EMED has alleged our needle sets infringe various patents controlled by EMED. Certain of these lawsuits also allege antitrust violations, unfair business practices and various other claims. Although we believe we will prevail on the merits, an adverse outcome in this matter could materially and adversely affect our business, financial condition, results of operations and cash flows. See "*LEGAL PROCEEDINGS*" for a further description of this litigation.

If we are unable to protect our patents or other proprietary rights, or if we infringe the patents or other proprietary rights of others, our competitiveness and business prospects may be materially damaged.

Patent and other proprietary rights are essential to our business. We own patents, trade secrets, trademarks and/or other intellectual property rights related to many of our products. Our success depends to a significant degree on our ability to obtain and enforce patents, both in the U.S. and in other countries. We can lose the protection afforded by these intellectual property assets through patent expirations, legal challenges or governmental action. Additionally, our intellectual property rights may be challenged or infringed

upon by third parties, particularly in countries where property rights are not highly developed or protected, or we may be unable to enter into license agreements with third-party owners of intellectual property on reasonable terms. Unauthorized use of our intellectual property rights or inability to preserve existing intellectual property rights could adversely impact our competitive position and results of operations.

The patent position of a medical device company is often uncertain and involves complex legal and factual questions. Significant litigation concerning patents and products is pervasive in our industry. Patent claims include challenges to the coverage and validity of our patents on products or processes as well as allegations that our products infringe patents held by competitors or other third parties. A loss in any of these types of cases could result in a loss of patent protection or the ability to market products, which could lead to a significant loss of sales, or otherwise materially affect future results of operations. We also rely on trademarks, trade secrets and know-how to develop, maintain and strengthen our competitive positions. Third parties may know, discover or independently develop equivalent proprietary information or techniques, or they may gain access to our trade secrets or disclose our trade secrets to the public.

Although our employees, consultants, parties to collaboration agreements and other business partners are generally subject to confidentiality or similar agreements to protect our confidential and proprietary information, these agreements may be breached, and we may not have adequate remedies in the event of a breach of confidence. To the extent that our employees, consultants, parties to collaboration agreements and other business partners use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Furthermore, our intellectual property, other proprietary technology and other sensitive company data is potentially vulnerable to loss, damage or misappropriation from system malfunction, computer viruses, unauthorized access to our data or misappropriation or misuse thereof by those with permitted access and other events. While we have invested to protect our intellectual property, confidential information and other data, and continue to work diligently in this area, there can be no assurance that our precautionary measures will prevent breakdowns, breaches, cyber incidents or other events. Such events could have a material adverse effect on our reputation, business, financial condition or results of operations.

Misappropriation or other loss of our intellectual property from any of the foregoing would have an adverse effect on our competitive position and may cause us to incur substantial litigation costs.

We need to attract and retain key employees to be competitive.

Our ability to compete effectively depends upon our ability to attract and retain executives and other key employees, including people in technical, marketing, sales, research and quality assurance and regulatory compliance positions. We depend on key management personnel and attracting and retaining other qualified personnel, and our business could be harmed if we lose key management personnel or cannot attract and retain other qualified personnel. We do not maintain any “key man” insurance policies on the lives of any of our employees.

In addition, if we expect to grow our operations, it will be necessary for us to attract and retain additional qualified personnel. In particular, we will need to find experienced key employees to lead our research and development and quality assurance and regulatory compliance functions. The failure to attract, integrate, motivate, and retain additional skilled and qualified personnel could have a material adverse effect on our business. We compete for such personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. Our ability to recruit such talent will depend on a number of factors, including compensation and benefits, work location and work environment. There can be no assurance that we will be successful in attracting or retaining such personnel and the failure to do so could have a material adverse effect on our business, financial condition and results of operations.

We sell a majority of our products through only a few distributors.

Most of our customers prefer to purchase our products through distributors, rather than directly from us, because of “one-stop shopping” convenience and their ability to ship directly to patients. We sell most of our products through a small number of distributors, two in and two outside the U.S. As of December 31, 2019, these four distributors comprised approximately 67% of our net revenues. Any decline in business with the distributors outside the U.S. could have an adverse impact on our business. If we were unable to sell through the distributors outside the U.S., we would have to find other distributors or broaden our customer base and expand direct relationships with customers. Other distributors may not be available or may not agree to arrangements that are commercially reasonable. In the U.S. we could transition to direct customer purchase; however, customers may not want to purchase directly from us and may decide to purchase competitors’ products through their distributors. Moreover, a transition from distributors to direct customer purchase would be time consuming and costly.

If we are unable to obtain sufficient components or raw materials on a timely basis or for a cost-effective price, or if we experience other supply difficulties, our business and results of operations may be adversely affected.

Our ability to meet customer demand depends, in part, on our ability to obtain timely and adequate delivery of raw materials and components for our products. All of the materials and components that go into the manufacturing of our products are sourced from third-party suppliers.

The price and supply of materials and components for our products may be impacted or disrupted for reasons beyond our control. While we work with suppliers to ensure continuity of supply, no assurance can be given that these efforts will be successful. Although we do carry strategic inventory and maintain insurance to help mitigate the potential risk related to any supply disruption, there can be no assurance that such measures will be sufficient or effective. The termination, reduction or interruption in supply of raw materials and components and an inability to quickly develop acceptable alternative sources for such supply, could adversely impact our ability to manufacture and sell certain of our products in a timely or cost-effective manner.

Some of the components for our products are provided by a single supplier, including our Taiwan-based supplier of molded plastic parts and our U.S.-based supplier of tubing. We also rely on a single supplier to provide subassemblies for our products. We do not have long-term agreements in place with these suppliers, although we are in the process of negotiating such agreements with certain of our suppliers. We are also in the process of seeking alternative sources of supply for our products. Due to regulatory requirements relating to the qualification of suppliers, however, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost.

Additionally, volatility in our cost of energy, raw materials, components, subassemblies, transportation/freight, and manufacturing and distribution could adversely affect our results of operations. Climate change (including laws or regulations passed in response to it) could increase our costs, in particular our costs of supply, energy and transportation/freight. Material or sustained increases in the price of oil could have an adverse impact on the cost of many of the plastic materials we use to make and package our products, as well as our transportation/freight costs. These outcomes may in turn result in customers transitioning to available competitive products, loss of market share, negative publicity, reputational damage, loss of customer confidence or other negative consequences (including a decline in stock price).

Our failure to comply with laws and regulations relating to reimbursement of health care products may subject us to penalties and adversely impact our reputation, business, results of operations, financial condition and cash flows.

Our devices are purchased principally by specialty pharmacies and ambulatory service providers or hospitals that typically bill various third-party payers, such as governmental programs (e.g., Medicare, Medicaid and comparable non-U.S. programs), private insurance plans and managed care plans, for the healthcare services provided to their patients. The ability of those customers to obtain appropriate reimbursement from third-party payers for our products and the drugs they administer is critical because it affects which products customers purchase and the prices they are willing to pay. As a result, our devices are subject to regulation regarding quality and cost by U.S. governmental agencies, including the Centers for Medicare & Medicaid Services ("CMS"), as well as comparable state and non-U.S. agencies responsible for reimbursement and regulation of health care goods and services, including laws and regulations related to kickbacks, false claims, self-referrals and health care fraud. Many states have similar laws that apply to reimbursement by state Medicaid and other funded programs, and in some cases to all payers. In certain circumstances, insurance companies can attempt to bring a private cause of action against a manufacturer for causing a false claim to be filed under the Federal Racketeer Influenced and Corrupt Organizations Act. In addition, as a manufacturer of FDA-approved devices reimbursable by federal healthcare programs, we are subject to the Physician Payments Sunshine Act, which requires us to annually report certain payments and other transfers of value we make to U.S.-licensed physicians or U.S. teaching hospitals. Any failure to comply with these laws and regulations could subject us or our officers and employees to criminal and civil financial penalties. Similar reporting requirements applicable to medical device manufacturers have also been implemented by some states. Failure to comply with these state requirements could result in civil monetary penalties being assessed against us.

We may need additional funding in the future, and if we are unable to raise capital when needed, we may be forced to delay, reduce or eliminate our product development, commercial efforts, or sales efforts.

Producing and marketing our developed products is costly. Although we believe we currently have adequate capital to fulfill our near-term funding needs, we may need to raise substantial additional capital in the future in order to execute our business plan and help us fund the development and commercialization of new products.

We may finance future cash needs through public or private equity offerings and may also use debt financings or strategic collaboration and licensing arrangements. We may seek to access the public or private equity markets whenever conditions are favorable, even if we do not have an immediate need for additional capital. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience additional dilution; any debt financing, if available, may involve restrictive covenants and could result in high interest expense. If we raise additional funds through collaboration and licensing arrangements, it may require us to relinquish certain enumerated rights to our product candidates, processes, technologies, or development projects, or to enter into licenses on terms that are not favorable to us. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available from the foregoing sources, we may consider additional strategic financing options, or we may be required to delay, reduce the scope of, or eliminate our research or development and/or some of our commercialization efforts.

We may experience difficulties resulting from our new management structure, executive team and members of the Board of Directors.

Since July 2018, the composition of our executive team and Board of Directors has changed substantially. In addition, we have implemented a new management structure throughout the organization and have recently filled a number of these positions while we are actively recruiting to fill others. Although we believe the persons who currently and will serve in these positions are and will be qualified to do so, they may take time to integrate into the organization and with each other, if at all. Many of these persons have or will have had little to no experience with our company prior to joining us, which may result in delays in our ability to implement our business plans. If we are unable to integrate, motivate and retain the services of our new executives and other managers and our directors, or if integration takes longer than we expect, it may have an adverse effect on our business and financial condition.

Changes in tax or labor laws or exposure to additional income tax liabilities could increase our costs and reduce our margins.

Changes to the tax and labor laws in the U.S. or other countries in which we operate could have an adverse effect on our operating results. In particular, the Tax Cuts and Jobs Act of 2017 ("Tax Reform"), including, among other things, certain changes in tax rates, deductibility of interest, deductibility of executive compensation expense, expensing of capital expenditures, the ability to use certain tax credits, taxation on earnings from international business operations, and the system of taxation (from worldwide to territorial) could adversely affect our financial condition and results of operations. In certain instances, Tax Reform could have a negative effect on our tax rate and the carrying value of deferred tax balances. Taxing authorities may audit us from time to time and disagree with certain positions we have taken in respect of our tax liabilities. We regularly assess the likely outcomes of these audits in order to determine the appropriateness of our tax provision. However, we may not accurately predict the outcome of these audits, and as a result the actual outcome of these audits may have an adverse impact on our financial results.

Our manufacturing operations depend on low-cost labor. Recent increases in U.S. minimum wage requirements, as well as those imposed by the state of New York, will increase our costs for employees to support those operations, reduce our margins and negatively impact our profit.

A downturn in global economic conditions could adversely affect our operations.

Deterioration in the global economic environment, particularly in countries with government-sponsored healthcare systems, may cause decreased demand for our products and increased competition, which could result in lower sales volume and downward pressure on the prices for our products, longer sales cycles, and slower adoption of new technologies. A weakening of economic conditions in the U.S. and/or abroad may also adversely affect our suppliers, which could result in interruptions in supply.

We are subject to foreign currency exchange risk.

A portion of our revenues is currently, and we expect in the future to be, derived from international operations. Our revenues from sales outside the U.S. may be adversely affected by fluctuations in foreign currency exchange rates. We cannot predict with any certainty changes in foreign currency exchange rates or our ability to mitigate these risks. We may experience additional volatility as a result of inflationary pressures and other macroeconomic factors. If we cannot adequately mitigate foreign currency exchange rates, our revenues and profit may suffer.

Our distribution network and other operations outside the U.S. subject us to certain risks.

Approximately 16% of our net sales in the year ended December 31, 2019 came from our operations outside the U.S., and we intend to continue to pursue growth opportunities in foreign markets. Our foreign operations subject us to certain risks, including, among others, the effects of fluctuations in foreign currency exchange, uncertainties with respect to local economic and political conditions, competition from local companies, trade protectionism and restrictions on the transfer of goods across borders, U.S. diplomatic and trade relations with the governments of the foreign countries in which we operate, foreign regulatory requirements or changes in such requirements, local product preferences and product requirements, longer payment terms for accounts receivable than we experience in the U.S., difficulty in establishing, staffing and managing foreign operations, changes to international trade agreements and treaties, changes in tax laws, weakening or loss of the protection of intellectual property rights in some countries, and import or export licensing requirements.

In addition, we are subject to the U.S. Foreign Corrupt Practices Act and similar anti-corruption laws outside the U.S. Actual or alleged violation of these laws by our employees, consultants, sales agents or distributors could subject us to investigations by the U.S. or foreign governments, significant criminal or civil sanctions and other liabilities, and damage our reputation.

Brexit may impact our business in the United Kingdom.

One of our two most significant international distributors is located in the United Kingdom ("UK"), and the other is in Finland, a member of the European Union ("EU"). The June 2016 referendum result in the UK to exit the EU (commonly known as "Brexit"), and the subsequent commencement of the official withdrawal process by the UK government in March 2017, has created uncertainties affecting business operations in the UK and the EU. Until the terms of the transition period following the UK's exit from the EU on January 31, 2020 are determined, it is difficult to predict its impact. It is possible that the withdrawal could, among other things, affect the legal and regulatory environments to which our business and the businesses of our distributors are subject, impact trade between the UK and the EU and other parties, and create economic and political uncertainty in the region.

We are dependent on information technology systems and subject to privacy and security laws, and our systems and infrastructure face certain risks, including from cyber security breaches and data leakage.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization. While we do not believe that we have experienced any such system failure, accident, or security breach to date, if such an event were to occur and cause interruptions in our systems, it could result in a material disruption of our operations. To the extent that any disruption or security breach results in a loss of or damage to our data or applications or other data or applications relating to our technology, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities, damage to our reputation, and the further development of our product candidates could be delayed. Additionally, such disruptions and security breaches, when there is a risk of patient harm, may require devices changes to fix vulnerabilities and strengthen cybersecurity. Such changes could, in some cases, require reporting to and approval by the FDA prior to implementation, which could cause a delay in the continued marketing of the underlying product that will result in a loss of revenues to us. Furthermore, failure to adhere to good cybersecurity practices with regards to medical devices could result in enforcement action by the FDA including warning letters or other forms of enforcement.

We cannot guarantee that any of our strategic acquisitions, investments or alliances will be successful.

We may seek to supplement our internal growth through strategic acquisitions, investments and alliances. Such transactions are inherently risky, and the integration of any newly-acquired business requires significant effort and management attention. The success of any acquisition, investment or alliance may be affected by a number of factors, including our ability to properly assess and value the potential business opportunity or to successfully integrate any business we may acquire into our existing business. There can be no assurance that any past or future transaction will be successful.

Our operating results and financial condition may fluctuate.

Our operating results and financial condition may fluctuate from quarter to quarter and year to year for a number of reasons. Events such as a delay in product development, increases in litigation expenses, changes to our expectations or strategy or even a relatively small revenue shortfall may cause financial results for a period to be below our expectations or projections. As a result, we believe that period-to-period comparisons of our results of operations should not be relied upon as an indication of future performance. Our operating results and financial condition are also subject to fluctuation from all of the risks described throughout this section. These fluctuations may adversely affect our results of operations and financial conditions and our stock price.

Future material impairments in the value of our long-lived assets could negatively affect our operating results.

We review our long-lived assets, including identifiable intangible assets and property, plant and equipment, for impairment. Long-lived assets are reviewed when there is an indication that impairment may have occurred. Changes in market conditions or other changes in the future outlook of value may lead to impairment charges in the future. In addition, we may from time to time sell assets that we determine are not critical to our strategy. Future events or decisions may lead to asset impairments and/or related charges. Certain non-cash impairments may result from a change in our strategic goals, business direction or other factors relating to the overall business environment. Material impairment charges could negatively affect our results of operations.

Actions of activist stockholders could have an adverse effect on our business.

From time to time, we may be subject to proposals by stockholders urging us to take certain corporate actions. If activist stockholder activities ensue, our business could be adversely affected because responding to proxy contests and reacting to other actions by activist stockholders can be costly and time-consuming, disrupt our operations and divert the attention of management and our employees. For example, we may be required to retain the services of various professionals to advise us on activist stockholder matters, including legal, financial and communications advisors, the costs of which may negatively impact our future financial results. In addition, perceived uncertainties as to our future direction, strategy or leadership created as a consequence of activist stockholder initiatives may result in the loss of potential business opportunities, harm our ability to attract new investors, customers, employees, and joint venture partners, and cause our stock price to experience periods of volatility or stagnation.

Natural disasters, war and other events could adversely affect our suppliers and customers.

Natural disasters (including pandemics), war, terrorism, labor disruptions and international conflicts, and actions taken by the U.S. and other governments or by our customers or suppliers in response to such events, could cause significant economic disruption and political and social instability in the U.S. and areas outside of the U.S. in which we operate. Certain of the subassemblies used in our products are manufactured in Nicaragua, where there is currently civil unrest whose outcome cannot be predicted. This and similar events could increase the costs for or cause interruptions in the supply of materials, result in decreased demand for our products or adversely affect our manufacturing and distribution capabilities.

Our insurance coverage may be inadequate to cover all the liabilities we may incur.

We face the risk of exposure to liability claims if any product that we develop causes injury. Although we carry insurance at levels customary for companies in our industry, such coverage may become unavailable or be inadequate to cover all liabilities we may incur. There can be no assurance that we will be able to continue to maintain such insurance, or obtain comparable insurance at a reasonable cost, if at all. If we are unable to obtain sufficient insurance coverage at an acceptable cost or otherwise, or if the amount of any claim against us exceeds the coverage under our policies, we may face significant expenses.

Risks Related to Ownership of Our Common Stock

There may be circumstances in which the interests of our significant stockholders could be in conflict with your interests as a stockholder.

Two stockholders, together with their respective affiliates, beneficially own approximately 31% and 18%, of our outstanding common stock, respectively. An affiliate of Horton Freedom, L.P. currently serves on our Board of Directors. Circumstances may arise in which these stockholders may have an interest in exerting influence to pursue or prevent acquisitions, divestitures or other transactions, including the issuance of additional shares or debt, that, in their judgment, could enhance their investment in us or another company in which they invest. Such transactions might adversely affect us or other holders of our common stock. Furthermore, our significant concentration of share ownership may adversely affect the trading price of our common stock because investors may perceive disadvantages in owning shares in companies with significant stockholders.

We do not currently intend to pay dividends on our common stock.

We have never paid dividends on our common stock, and we do not intend to pay any dividends to holders of our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future.

Future sales and issuances of shares of our common stock or rights to purchase our common stock, including pursuant to our stock option plan, could result in additional dilution of the percentage ownership of our stockholders.

We may need additional capital in the future to continue our planned operations. To the extent we raise additional capital by issuing equity and/or convertible securities, our stockholders may experience substantial dilution. We may sell our common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell our common stock, convertible securities or other equity securities, investors may be materially diluted. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

We provide and intend to continue to provide additional equity-based compensation to our employees, officers, directors, consultants and independent contractors through a stock option plan. Under our stock option plan, 6,000,000 shares of our common stock have been reserved for issuance to our employees, including officers, which number may be increased with the approval of our stockholders. If our Board elects to issue additional stock options under the plan, our stockholders may experience additional dilution, which could cause our stock price to decline. Because stock options granted under the plan will generally only be exercised when the exercise price for such option is below the then market value of the common stock, the exercise of such options or the issuance of shares will cause dilution to the book value per share of our common stock and to existing and new investors.

There has been volatility in the price of shares of our common stock.

Since our common stock was listed on the Nasdaq Capital Market on October 17, 2019, it has traded between $3.83 per share to $6.62 per share. Our stock price is subject to wide fluctuations in response to a variety of factors, including:

- quarterly variations in operating results;
- announcements related to our ongoing litigation;
- announcement of new products or customers by our competitors;
- changes in financial estimates by securities analysts;
- low trading volume on the Nasdaq Capital Market;
- general economic conditions; or
- other events or factors that are beyond our control.

In addition, the stock market has experienced significant price and volume fluctuations that have particularly affected the trading prices of equity securities of many biotechnology companies. These fluctuations have often been unrelated or disproportionate to the operating performance of these companies. Any negative change in the public's perception of the prospects of medical device companies could further depress our stock price regardless of our results. Sales of substantial amounts of our common stock, particularly by our two most significant stockholders, or the perception that such sales might occur, could adversely affect prevailing market prices of our common stock and our stock price may decline substantially in a short time and our stockholders could suffer losses or be unable to liquidate their holdings.

If we do not maintain compliance with its listing standards, NASDAQ may delist our Common Stock from trading on its exchange

The Nasdaq Capital Market on which our common stock trades has continued listing standards that we must maintain on an ongoing basis in order to continue the listing of our common stock. If we fail to meet these continued listing requirements, our common stock may be subject to delisting. If our common stock is delisted and we are not able to list our common stock on another national securities exchange, we expect our securities would be quoted on an over-the-counter market. If this were to occur, our stockholders could face significant material adverse consequences, including limited availability of market quotations for our common stock and reduced liquidity for the trading of our common stock. In addition, we could experience a decreased ability to issue additional securities and obtain additional financing in the future, if or when needed.

We may fail to meet our publicly announced Strategic Plan goals or other expectations about our business, which could cause our stock price to decline.

We have publicly announced certain financial goals through 2020 under our Strategic Plan. Correctly identifying key factors affecting business conditions and predicting future events is inherently an uncertain process and we may not be able to meet our goals. Our goals are based on certain assumptions such as those relating to anticipated sales volumes and prices and cost reductions. If we are not able to meet our goals, the market price of our common stock could decline significantly.

We are a smaller reporting company and non-accelerated filer, and we cannot be certain if the reduced disclosure requirements applicable to us will make our common stock less attractive to investors.

We are currently a "smaller reporting company" and a "non-accelerated filer", as those terms are defined in the Securities Act. Accordingly, we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not "smaller reporting companies" and "non-accelerated filers," including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the provisions of Section 404(b) of the Sarbanes-Oxley Act of 2002 requiring that independent registered public accounting firms provide an attestation report on the effectiveness of internal control over financial reporting. Decreased disclosures in our SEC filings due to our status as a "smaller reporting company" and "non-accelerated filer" may make it harder for investors to analyze our results of operations and financial prospects.

We cannot predict if investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

Our significant shareholders, officers and directors can sell their stock, which may have a negative effect on our stock price and ability to raise additional capital, and may make it difficult for investors to sell their stock at any price.

A resale registration statement covering 17% and 8% of our outstanding common stock held by two stockholders, respectively, are freely tradeable in the market pursuant to a resale registration statement. These stockholders purchased those shares at prices significantly lower than the price at which our common stock is currently trading. In the event either of these significant stockholders choose to sell a substantial portion of their holdings, the price of our common stock may decline suddenly and sharply. This may make it difficult or impossible for other investors to sell their stock at any price.

Our officers and directors beneficially own approximately 39% of our outstanding common stock as of February 27, 2020. Each individual officer and director may be able to sell up to 1% of our outstanding common stock every ninety (90) days in the open market pursuant to Rule 144, which may have a negative effect on our stock price. In addition, if our officers and directors are selling their stock into the open market, it may make it difficult or impossible for investors to sell their stock at any price.

The price of our common stock may be adversely affected by the future issuance and sale of shares of our common stock or other equity securities.

We cannot predict the size of future issuances or sales of our common stock or other equity securities future acquisitions or capital raising activities, or the effect, if any, that such issuances or sales may have on the market price of our common stock. The issuance and sale of substantial amounts of common stock or other equity securities or announcement that such issuances and sales may occur, could adversely affect the market price of our common stock. Any decline in the price of our common stock may encourage short sales, which could place further downward pressure on the price of our common stock and may impair our ability to raise additional capital through the sale of equity securities.

You may find it difficult to sell our common stock.

Only recently has there been any active trading market in our common stock. We cannot assure you that such an active trading market for our common stock will be sustained. Regardless of whether an active and liquid public market exists, negative fluctuations in our actual or anticipated operating results will likely cause the market price of our common stock to fall, making it more difficult for you to sell our common stock at a favorable price, or at all.

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

We currently rent a masonry and steel frame building erected on 3.27 acres of land located at 24 Carpenter Road, Chester, New York 10918. This facility is used as our headquarters and for our general operations.

On February 28, 2019, we completed year twenty of a twenty year lease. 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. The Company exercised three additional renewal options for September 1, 2019 through February 28, 2021.

We believe our current facilities are suitable and adequate for our current business operations. We continue to seek another location with more square footage to provide us room for growth. In addition to the increased costs of occupying a larger space, we expect to incur additional costs in connection with construction and FDA compliance with respect to the new location.

ITEM 3. LEGAL PROCEEDINGS

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

The initial case involving EMED was filed by us in the United States District Court for the Eastern District of California on September 20, 2013 (the "California case"), in response to a letter from EMED claiming patent infringement by us, and seeking a declaratory judgment establishing the invalidity of the patent referenced in the letter – EMED's US patent 8,500,703 – "'703." EMED answered the complaint and asserted patent infringement of the '703 patent and several counterclaims relating generally to claims of unfair business practices against us. We responded by adding several claims against EMED, generally relating to claims of unfair business practices on EMED's part. Both parties have requested injunctive relief and monetary damages in unspecified amounts. On June 16, 2015, the California court entered a preliminary injunction against KORU Medical 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 US Patent and Trademark Office ("USPTO"). The ex parte reexamination resulted in a Final Office Action, dated July 19, 2017, rejecting all of EMED's claims in the issued patent. On January 25, 2018, EMED filed an Appeal Brief with a Petition for Revival, which was accepted. On April 9, 2018, the USPTO denied EMED's request for reconsideration of the order rejecting all claims in the '703 patent. On June 26, 2019, the Examiner responded to EMED's appeal brief and maintained all of the final rejections. On December 31, 2019, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued its decision sustaining the invalidity of claims 1-10 of the '703 patent, but reversing the Examiner's rejection of claim 11, 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. Both the California case and EMED's appeal of the USPTO rejections are pending. EMED's deadline to take action in response to the PTAB decision has not yet expired.

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 now rejected EMED '703 patent.

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

Following the PTAB's Final Written Decision in the IPR regarding the '476 patent, EMED filed a new patent application claiming priority back to the application that issued as '703, which is the patent at issue in the California case. Submitted for accelerated examination, this new application issued as US 9,808,576 – "'576" on November 7, 2017. On this same date, EMED filed a new case (the "third case") in the Texas Court claiming patent infringement of '576, also directed to our needle sets, and seeking unspecified

damages and a preliminary injunction against marketing and sales of our needle sets. We filed a Motion to Dismiss or Transfer Venue to the United States District Court for the Southern District of New York ("SDNY"), which resulted in the transfer of the third case to SDNY ("SDNY '576 matter") on May 30, 2018.

On April 23, 2018, EMED filed a new civil case (the "fourth case") against us in the 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 names Andrew Sealfon, then President and CEO of KORU Medical, individually as a defendant. As the result of a hearing on November 14, 2018, on December 7, 2018, the Court entered an order transferring the fourth case to the United States District Court for the Eastern District of California (the "California Court"). The California Court set an initial schedule for a preliminary motion phase and on August 30, 2019, EMED filed a second amended complaint. On September 30, 2019, KORU Medical and Sealfon filed a motion to dismiss that complaint, and Sealfon filed a separate motion to dismiss the case as to him for lack of jurisdiction. Ultimately, we expect this case to be coordinated or consolidated with the California case, or dismissed, as the California Court sees fit.

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

The ED Texas '476 matter proceeded under EMED's amended infringement contention to incorporate the surviving dependent Claim 9, which incorporates Claims 1 and 8 of the '476 patent, meaning that, to prove infringement on our part, EMED must prove more elements of infringement than it originally charged against us. In April 2019, EMED served its damages expert's report opining that EMED's past infringement damages amount to $1.5 million, and in May KORU Medical served its damages expert's rebuttal report opining that EMED's expert miscalculated damages which if properly calculated would amount to less than $100,000. The Texas Court had set a trial date of August 19, 2019, for the trial of the ED Texas '476 matter. On June 24, 2019, the Texas Court Magistrate Judge issued a Report and Recommendation decision finding no infringement, literally or under the doctrine of equivalents, by KORU Medical's accused products. EMED filed its objections on June 26, 2019. On June 28, 2019, the Texas Court issued a Final Judgment in favor of KORU Medical and adopted the decision of the Magistrate Judge that was issued on June 24, 2019, overruled EMED's objections, awarded court costs to KORU Medical, and dismissed the case. A final judgment has been entered. KORU Medical has submitted its Bill of Costs for approximately $16,000 and moved to declare the case exceptional and for recovery of its attorney fees and expenses of approximately $2.3 million in defense of EMED's assertion of the '476 Patent. EMED has objected to our Bill of Costs, opposed the motion for fees, and filed a notice of appeal of the non-infringement judgment to the Court of Appeals for the Federal Circuit. On September 16, 2019, EMED filed its opening appeal brief. On October 28, 2019, KORU Medical filed its responsive brief, and on November 7, 2019 EMED filed its reply brief. On November 20, 2019, KORU Medical filed a motion for leave to file a sur-reply brief to respond to a new argument raised by EMED in its reply brief, which EMED opposed, and which the Court has referred to the judicial panel that will hear the appeal for consideration. The appeal remains pending, with oral argument scheduled for April 8, 2020. The Texas Court has stayed proceedings in the district court until the appeal process is completed. KORU Medical's fee motion remains pending lifting of the stay.

The SDNY '576 matter proceeded in the New York court through claim construction on the '576 Patent, whereupon KORU Medical sought permission from the New York court to file a motion for summary judgement, to which EMED objected. The New York court granted KORU Medical's request, and on July 10, 2019, KORU Medical filed its motion for summary judgement. EMED opposed that motion, and on August 30, 2019, the New York court granted summary judgement, and dismissed the lawsuit. A final judgement has been entered. KORU Medical has submitted a Bill of Costs for approximately $1,500, to which EMED has objected, and has moved the New York court to declare the case exceptional and for recovery of its attorney fees and expenses of at least $1.16 million. EMED has opposed that motion, which was referred to a United States District Court Magistrate Judge to prepare a report and recommendation. 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 has filed objections to the Report and Recommendation, to which KORU Medical has responded, and which objections are now pending before the District Court Judge for resolution. EMED has also appealed the New York court's judgment of non-infringement to the Court of Appeals of the Federal Circuit, which matter also is pending. EMED's opening appeal brief was due November 8, 2019, but EMED filed its brief on November 12, 2019. EMED filed a motion to extend the time to file its opening brief, which KORU Medical opposed, but the motion was granted. KORU Medical filed its responsive brief on December 23, 2019, on January 9, 2020 EMED filed the joint appendix in support of the parties' briefing, and on January 13, 2020, EMED filed its reply brief. The appeal remains pending, waiting for the Court to schedule oral argument.

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

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

We are authorized to issue 77,000,000 shares of capital stock, of which 75,000,000 are designated common stock, $0.01 par value per share ("Common Stock"), and 2,000,000 are designated preferred stock. As of December 31, 2019, 39,502,557 shares of Common Stock were issued and outstanding and there were approximately 734 stockholders of record. There were no shares of preferred stock issued and outstanding.

Our Common Stock is traded on the Nasdaq Capital Market under the symbol, "KRMD". We have not paid any cash dividends on our Common Stock and do not plan to pay any such dividends in the foreseeable future. We currently intend to use all available funds for our business operations.

On February 20, 2019, the Board of Directors of the Company approved non-employee director compensation of $50,000 annually effective January 1, 2019, and an additional $10,000 annually for the chair of each Board committee effective February 20, 2019, in each case to be paid quarterly half in cash and half in common stock at the end of each fiscal quarter. In Mr. Fletcher's role as Chairman, he will receive an additional $50,000 in annual compensation, to be paid quarterly in shares of KORU common stock based on the closing price of the stock on the last day of each quarter. The Company issued an aggregate of 58,273 shares of common stock to its non-employee directors during the year ended December 31, 2019 that were not previously reported in a quarterly report on Form 10-Q filed by the Company.

During the year ended December 31, 2019, excluding those previously reported in a quarterly report on Form 10-Q filed by the Company, there were options exercised for an aggregate 160,000 shares of common stock.

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

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our consolidated financial statements and related notes included under ITEM 8 of this Annual Report on Form 10-K. This discussion contains forward-looking statements about our business and operations. Our actual results may differ materially from those we currently anticipate as a result of many factors, including those described under Part I – FORWARD LOOKING STATEMENTS and elsewhere in this Annual Report.

OVERVIEW

We manufacture and sell mechanical infusion pumps, and single-use flow rate tubing and needle sets that allow patients to self-administer subcutaneous and intravenous infusion therapy. During 2019 we continued to expand our market presence by executing on the objectives included in our Strategic Plan which was approved by our Board of Directors in January 2019.

We ended 2019 with record net sales of $23.2 million, an increase of 33.5% compared with the same period last year, driven primarily by higher sales volume in needle sets, tubing and pump sales, and to a lesser extent, price increases. The volume increase was driven by what we believe was a result of growth in diagnosis of primary immunodeficiency diseases ("PIDD") and expansion into the neurology market with expanded Hizentra® indication for chronic inflammatory demyelinating polyneuropathy ("CIDP").

Our gross margin percentage, which is gross profit stated as a percentage of net sales, improved to 64%, up from 62% in the prior year mostly due to higher volume and to a lesser extent price increases.

Net income was $0.6 million for the year, compared with $0.9 million for the previous year, driven by higher net sales, offset by increased legal fees for litigation activity and higher salary and related expenses resulting from the executive management changes and new hires.

Our cash balance at December 31, 2019, was $5.9 million up from $5.3 million last year.

We appointed R. John Fletcher as Chairman of the Board in September 2019 and shareholders elected Kathy S. Frommer as a new, independent member of our board in April 2019. We received FDA 510(k) clearance from the U.S. Food and Drug Administration for our High-Flo Super26 ™ Subcutaneous Needle Sets, filled key management roles throughout the organization, uplisted to the NASDAQ Capital Market, and rebranded our Company to KORU Medical Systems.

RESULTS OF OPERATIONS

Year Ended December 31, 2019 compared to Year Ended December 31, 2018

Net Sales

The following table summarizes our net sales for the years ended December 31, 2019, and 2018.

	Years Ended December 31,		Change from Prior Year		% of Net Sales	
	2019	2018	$	%	2019	2018
Net Sales						
Domestic	$ 19,467,788	$ 14,235,689	$ 5,232,099	36.8%	84.0%	82.0%
International	3,694,833	3,118,048	576,785	18.5%	16.0%	18.0%
Total	$ 23,162,621	$ 17,353,737	$ 5,808,884	33.5%		

Net sales increased $5.8 million or 33.5% compared with the prior year, driven by growth in all product categories (needles, tubing, and pumps) in the Freedom System. The growth includes clinical trials at several customers as well as price increases. We believe the volume growth continues to be driven the growth in the diagnosis of PIDD and expansion into the neurology market with expanded Hizentra® indications for CIDP.

Gross Profit

Our gross profit for the years ended December 31, 2019, and 2018 is as follows:

	Years Ended December 31,		Change from Prior Year	
	2019	2018	$	%
Gross Profit	$ 14,853,810	$ 10,810,488	$ 4,043,322	37.4%
Stated as a Percentage of Net Sales	64.1%	62.3%		

Gross profit for the year ended December 31, 2019 increased $4.0 million or 37.4% compared to the same period last year. Gross margin improved 1.8 percentage points for the year, driven mostly by volume and price increases.

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

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

	Years Ended December 31,		Change from Prior Year	
	2019	2018	$	%
Selling, general and administrative	$ 9,771,744	$ 8,196,562	$ 1,575,182	19.2%
Litigation	3,415,683	899,003	2,516,680	279.9%
Research and development	740,475	241,124	499,351	207.1%
	$ 13,927,902	$ 9,336,689	$ 4,591,213	49.2%
Stated as a Percentage of Net Sales	60.1%	53.8%		

Selling, general and administrative expenses increased $1.6 million, or 19.2%, for the year ended December 31, 2019, compared with the same period last year. The increase was mostly driven by higher salary and related benefits totaling $1.3 million, mostly due to the executive and senior management changes and headcount additions during the year, including a performance bonus payment to our former interim Chief Executive Officer in the amount of $0.3 million, as well as stock option expense totaling $0.9 million. Higher consulting fees of $0.3 million related to strategic initiatives, and higher investor relation expenses and director fees also contributed $0.4 million to the increase. Partially offsetting these expenses were lower general corporate counsel fees and recruiting fees of $0.4 million.

Litigation fees continued to increase, up $2.5 million compared to the same period last year, due to the continued defense and increased activity against our competitor. We have had several favorable rulings in the New York and Texas courts dismissing those cases and have filed motions for court costs and attorney fees of which one fee motion has been recommended to be granted by the Magistrate Judge in New York, and the fee motion in Texas is stayed pending appeal of the case. Refer to Note 9 Legal Proceedings in the Notes to the Financial Statements.

Research and development costs increased $0.5 million, or 207.1%, due to an increase in headcount and expanded product development initiatives compared with last year.

Depreciation and amortization

For the year ended December 31, 2019, depreciation and amortization expense increased $30,966, or 10.0%, compared with the same period last year. We continued to invest in capital assets, mostly related to production equipment, computer equipment and leasehold improvements, and in patent applications and their maintenance.

Net Income

	Years Ended December 31,		Change from Prior Year	
	2019	2018	$	%
Net Income	$ 564,349	$ 910,570	$ (346,221)	(38.0%)
Stated as a Percentage of Net Sales	2.4%	5.2%		

Our net income for the year ended December 31, 2019 was $0.6 million, as compared to net income of $0.9 million for the year ended December 31, 2018. This decrease was driven by increased selling, general and administrative expenses and litigation fees, as described above.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash of $5.9 million as of December 31, 2019. Additionally, we have a $1.5 million line of credit with no outstanding amounts against it. Our principal source of operating cash inflows is from sales of our products to customers. Our principal cash outflows relate to the purchase and production of inventory and related costs, selling, general and administrative expenses, and litigation fees.

We believe that as of December 31, 2019, cash on hand and cash expected to be generated from future operating activities will be sufficient to fund our operations, including further research and development, and capital expenditures, for the next 12 months. We believe KORU Medical's home infusion products continue to find a solid following in the subcutaneous immunoglobulin market and into new markets like neurology where Hizentra® received an expanded indication for CIDP.

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

Cash Flows

The following table summarizes our cash flows:

	Year Ended December 31, 2019	Year Ended December 31, 2018
Net cash provided by operating activities	$ 320,620	$ 1,479,662
Net cash provided by/(used in) investing activities	$ 1,310,209	$ (1,729,824)
Net cash provided by financing activities	$ 501,297	$ 14,429

Operating Activities

Net cash provided by operating activities of $0.3 million for the year ended December 31, 2019 resulted from the non-cash charges for stock based compensation of $1.2 million, depreciation and amortization of long lived tangible and intangible asset of $0.3 million, as well as increases in accrued expenses of $0.6 million primarily due to bonus, rebate and legal accruals and an increase in accrued taxes of $0.2 million. Partially offsetting these were higher accounts receivable of $1.8 million, increased inventory of $0.3 million as we build stock to keep pace with sales growth, as well as severance payments paid this year against last year's accrual and increases in prepaids of $0.1 million related to directors and officers insurance.

Net cash provided by operating activities of $1.5 million for the year ended December 31, 2018, was primarily attributable to net income of $0.9 million, non-cash charges of $0.3 million for depreciation and amortization of long lived tangible and intangible assets, stock based compensation of $0.4 million, and a decrease in accounts receivable of $0.5 million. Partially offsetting these was an increase in inventory of $0.4 million, as we build to increase our reserve of inventory.

Investing Activities

Our net cash provided by investing activities of $1.3 million for the year ended December 31, 2019, was mostly the result of the maturation of a certificate of deposit for $1.5 million and the sale of the house the Company owned for $0.2 million, offset by capital expenditures of $0.2 million and patent applications and maintenance of existing applications of $0.2 million. Our net cash used for investing activities of $1.7 million for the year ended December 31, 2018, was mostly the result of the purchase of a certificate of deposit.

Financing Activities

The $0.5 million provided by financing activities for the year ended December 31, 2019 was a result of warrants and options exercised during the period. Net cash provided by financing activities was $14,429 for the year ended December 31, 2018, resulting mostly from the exercise of options less payment for cancelled shares.

Lease Commitments

We currently rent a masonry and steel frame building erected on 3.27 acres of land located at 24 Carpenter Road, Chester, New York 10918. This facility is used as our headquarters and for our general operations.

On February 28, 2019, we completed year twenty of a twenty year lease. 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. The Company exercised three additional renewal options for September 1, 2019, through February 28, 2021.

We believe our current facilities are suitable and adequate for our current business operations. As we execute on our strategic plan, we continue to seek another location with more square footage to provide us room for growth. In addition to the increased costs of occupying a larger space, we expect to incur additional costs in connection with construction and FDA compliance with respect to the new location.

ACCOUNTING POLICIES

Preparation in conformity with accounting principles generally accepted in the United States ("GAAP") requires us to make estimates and assumptions that affect the amounts reported in our financial statements and accompanying notes. These estimates are based on our best knowledge of current events and actions we may undertake in the future. Estimates used in accounting are, among other items, allowance for excess and obsolete inventory, useful lives for depreciation and amortization of long lived assets, contingencies and allowances for doubtful accounts. Actual results may ultimately differ from our estimates, although we do not generally believe such differences would materially affect the financial statements in any individual year.

NON-GAAP FINANCIAL MEASURES

Management of the Company believes that investors' understanding of the Company's performance is enhanced by disclosing non-GAAP financial measures as a reasonable basis for comparison of the Company's ongoing results of operations. These non-GAAP measures should not be considered a substitute for GAAP-basis measures and results. Our non-GAAP measures may not be comparable to non-GAAP measures of other companies. The table below provides a disclosure of these non-GAAP financial measures to the most closely analogous measure determined in accordance with GAAP.

Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. They are limited in value because they exclude charges that have a material effect on our reported results and, therefore, should not be relied upon as the sole financial measures to evaluate our financial results. The non-GAAP financial measures are meant to supplement, and to be viewed in conjunction with, GAAP financial results.

We disclose and discuss Adjusted EBITDA as a non-GAAP financial measure in our public releases, including quarterly earnings releases, and other filings with the Securities and Exchange Commission. We define Adjusted EBITDA as earnings (net income) before interest, income taxes, depreciation and amortization, reorganization charges, litigation and stock option expenses. We believe that Adjusted EBITDA is used by investors and other users of our financial statements as a supplemental financial measure that, when viewed with our GAAP results and the accompanying reconciliation, we believe provides additional information that is useful to gain an understanding of the factors and trends affecting our business. We also believe the disclosure of Adjusted EBITDA helps investors meaningfully evaluate and compare our cash flow generating capacity from quarter to quarter and year to year. Adjusted EBITDA is used by management as a supplemental internal measure for planning and forecasting overall expectations and for evaluating actual results against such expectations. Because management uses Adjusted EBITDA for such purposes, the Company uses Adjusted EBITDA as a significant criterion for determining the amount of annual cash incentive compensation paid to our executive officers and employees. We have historically found that Adjusted EBITDA is superior to other metrics for our company-wide cash incentive program, as it is more easily explained and understood by our typical employee.

A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net Income to Non-GAAP Adjusted EBITDA:	**Year Ended December 31,**	
	2019	**2018**
GAAP Net Income	$ 564,349	$ 910,570
Tax Expense	132,069	266,380
Depreciation/Amortization	340,229	309,263
Interest Income, Net	(80,663)	(28,104)
Reorganization Charges	354,926	996,447
Litigation	3,415,683	899,003
Stock Option Expense	888,319	248,040
Non-GAAP Adjusted EBITDA	$ 5,614,912	$ 3,601,599

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

Litigation. We have excluded litigation expenses in calculating our non-GAAP Adjusted EBITDA measure. We continue to evaluate our business performance excluding litigation fees, which we expect will continue in future periods.

Stock Option Expense. We have excluded the effect of stock option expenses in calculating our non-GAAP Adjusted EBITDA measure. Although stock option compensation is a key incentive offered to our employees, we continue to evaluate our business performance excluding stock option compensation expenses. We record non-cash compensation expense related to grants of options and depending upon the size, timing and the terms of the grants, the non-cash compensation expense may vary significantly but will recur in future periods.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

In August 2018, the FASB issued ASU No. 2018-13 Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure for Fair Value Measurement. The amendments in this ASU modify the disclosure requirements on fair value measurements in Topic 820 based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of this ASU. An entity is permitted to early adopt any removed or modified disclosures upon issuance of this ASU and delay adoption of the additional disclosures until their effective date. The adoption of this ASU, effective January 1, 2020, is not expected to have a material effect on our financial statement disclosures.

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

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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Repro Med Systems, Inc.
Chester, New York

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Repro Med Systems, Inc. (the "Company") as of December 31, 2019 and 2018, the related statements of operations, changes in equity, and cash flows for years then ended December 31, 2019, and 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019, and 2018, and the results of its operations and its cash flows for the years then ended December 31, 2019, and 2018, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ McGrail Merkel Quinn & Associates, P.C.

We have served as the Company's auditor since 2014.

Scranton, Pennsylvania
March 4, 2020

REPRO MED SYSTEMS, INC.
BALANCE SHEETS

	December 31, 2019	December 31, 2018
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 5,870,929	$ 3,738,803
Certificates of deposit	—	1,517,927
Accounts receivable less allowance for doubtful accounts of $32,645 and $37,500 for December 31, 2019, and December 31, 2018, respectively	3,234,521	1,425,854
Inventory	2,388,477	2,103,879
Prepaid expenses	387,396	246,591
TOTAL CURRENT ASSETS	11,881,323	9,033,054
Property and equipment, net	611,846	858,781
Patents, net of accumulated amortization of $288,967 and $239,581 at December 31, 2019 and December 31, 2018, respectively	807,135	632,156
Right of use assets, net	373,734	—
Deferred tax asset	188,241	1,466
Other assets	19,582	19,582
TOTAL ASSETS	$ 13,881,861	$ 10,545,039
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Deferred capital gain - current	$ —	$ 3,763
Accounts payable	572,656	453,498
Accrued expenses	1,296,612	688,649
Accrued payroll and related taxes	190,265	421,714
Accrued tax liability	204,572	16,608
Finance lease liability - current	5,296	—
Operating lease liability - current	136,888	—
TOTAL CURRENT LIABILITIES	2,406,289	1,584,232
Finance lease liability, net of current portion	2,646	—
Operating lease liability, net of current portion	236,846	—
TOTAL LIABILITIES	2,645,781	1,584,232
STOCKHOLDERS' EQUITY		
Common stock, $0.01 par value, 75,000,000 shares authorized, 42,239,788 and 40,932,911 shares issued; 39,502,557 and 38,195,680 shares outstanding at December 31, 2019, and December 31, 2018, respectively	422,398	409,329
Additional paid-in capital	6,293,069	4,595,214
Retained earnings	4,864,817	4,300,468
	11,580,284	9,305,011
Less: Treasury stock, 2,737,231 shares at December 31, 2019 and December 31, 2018, respectively, at cost	(344,204)	(344,204)
TOTAL STOCKHOLDERS' EQUITY	11,236,080	8,960,807
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 13,881,861	$ 10,545,039

The accompanying notes are an integral part of these Financial Statements.

REPRO MED SYSTEMS, INC.
STATEMENTS OF OPERATIONS

	For the Years Ended	
	December 31, 2019	**December 31 2018**
NET SALES	$ 23,162,621	$ 17,353,737
Cost of goods sold	8,308,811	6,543,249
Gross Profit	14,853,810	10,810,488
OPERATING EXPENSES		
Selling, general and administrative	9,771,744	8,196,562
Litigation	3,415,683	899,003
Research and development	740,475	241,124
Depreciation and amortization	340,229	309,263
Total Operating Expenses	14,268,131	9,645,952
Net Operating Profit	585,679	1,164,536
Non-Operating Income/(Expense)		
Gain on sale of fixed asset	47,830	4,930
Loss on foreign currency exchange	(17,754)	(20,620)
Interest income, net	80,663	28,104
INCOME BEFORE TAXES	696,418	1,176,950
Income tax expense	132,069	266,380
NET INCOME	$ 564,349	$ 910,570
NET INCOME PER SHARE		
Basic	$ 0.01	$ 0.02
Diluted	$ 0.01	$ 0.02
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic	38,778,074	38,128,260
Diluted	39,061,310	38,921,622

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

REPRO MED SYSTEMS, INC.
STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE FISCAL YEARS ENDED DECEMBER 31, 2019 AND DECEMBER 31, 2018

	Common Stock		Additional Paid-in	Retained	Treasury	Total Stockholders'
	Shares	Amount	Capital	Earnings	Stock	Equity
BALANCE, DECEMBER 31, 2017	40,731,529	$ 407,315	$ 4,216,718	$ 3,389,898	$ (344,204)	$ 7,669,727
Issuance of stock based compensation	99,134	991	117,050	—	—	118,041
Compensation expense related to stock options	—	—	248,040	—	—	248,040
Cancellation of common stock	(22,752)	(227)	(36,594)	—	—	(36,821)
Issuance of options exercised	125,000	1,250	50,000	—	—	51,250
Net income for the year ended December 31, 2018	—	—	—	910,570	—	910,570
BALANCE, DECEMBER 31, 2018	40,932,911	$ 409,329	$ 4,595,214	$ 4,300,468	$ (344,204)	$ 8,960,807
Issuance of stock based compensation	148,877	1,489	315,036	—	—	316,525
Compensation expense related to stock options	—	—	888,319	—	—	888,319
Cancellation of common stock	(2,000)	(20)	(2,800)	—	—	(2,820)
Issuance of options exercised	160,000	1,600	57,300	—	—	58,900
Issuance of warrants exercised	1,000,000	10,000	440,000	—	—	450,000
Net income for the year ended December 31, 2019	—	—	—	564,349	—	564,349
BALANCE, DECEMBER 31, 2019	42,239,788	$ 422,398	$ 6,293,069	$ 4,864,817	$ (344,204)	$ 11,236,080

The accompanying notes are an integral part of these Financial Statements.

REPRO MED SYSTEMS, INC.
STATEMENTS OF CASH FLOWS

	For the Years Ended	
	December 31, 2019	**December 31, 2018**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income	$ 564,349	$ 910,570
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock based compensation expense	1,204,844	366,081
Depreciation and amortization	340,229	309,263
Gain on sale of fixed asset	(47,830)	(4,930)
Deferred capital gain	(3,763)	(22,480)
Deferred taxes	(186,775)	(23,141)
Provision for returns and doubtful accounts	(4,855)	(39,567)
Changes in operating assets and liabilities:		
(Increase)/ Decrease in accounts receivable	(1,803,812)	475,662
Increase in inventory	(284,598)	(445,198)
Increase in prepaid expense	(140,805)	(75,852)
Decrease in other assets	—	12,000
Increase/(Decrease) in accounts payable	119,158	(900)
(Decrease)/Increase in accrued payroll and related taxes	(231,449)	86,811
Increase in accrued expense	607,963	30,589
Increase/(Decrease) in accrued tax liability	187,964	(99,246)
NET CASH PROVIDED BY OPERATING ACTIVITIES	320,620	1,479,662
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for capital expenditures	(201,174)	(297,018)
Payments for patents	(224,365)	(184,148)
Purchase of certificate of deposit	—	(1,500,000)
Proceeds from certificates of deposit	1,517,927	245,342
Proceeds on sale of fixed assets	217,821	6,000
NET CASH PROVIDED BY/(USED IN) INVESTING ACTIVITIES	1,310,209	(1,729,824)
CASH FLOWS FROM FINANCING ACTIVITIES		
Stock issuances	508,900	51,250
Finance lease	(4,783)	—
Payment for cancelled shares	(2,820)	(36,821)
NET CASH PROVIDED BY FINANCING ACTIVITIES	501,297	14,429
Net Increase (Decrease) in CASH AND CASH EQUIVALENTS	2,132,126	(235,733)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	3,738,803	3,974,536
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 5,870,929	$ 3,738,803
Supplemental Information		
Cash paid during the years for:		
Interest	$ 342	$ —
Taxes	$ 130,879	$ 378,000
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Issuance of common stock as compensation	$ 316,525	$ 118,041

The accompanying notes are an integral part of these Financial Statements.

NOTE 1 NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF OPERATIONS

REPRO MED SYSTEMS, INC. (the "Company", "KORU") 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.

CASH AND CASH EQUIVALENTS

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

CERTIFICATES OF DEPOSIT

The certificate of deposit was recorded at cost plus accrued interest. The certificate of deposit earned interest at a rate of 1.73% and matured in May 2019, at which time the funds were moved into a money market account earning interest at 2.25%. As of December 31, 2019, the money market account interest rate was 1.71%.

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

NET INCOME PER COMMON SHARE

Basic earnings per share are computed on the weighted average of common shares outstanding during each year. Diluted earnings per share include only an increase in the weighted average shares by the common shares issuable upon exercise of employee, director and consultant stock options (See Note 5).

	For the Years Ended	
	December 31, 2019	**December 31, 2018**
Net income	$ 564,349	$ 910,570
Weighted Average Outstanding Shares:		
Outstanding shares	38,778,074	38,128,260
Option shares includable	283,236	793,362
	39,061,310	38,921,622
Net income per share		
Basic	$ 0.01	$ 0.02
Diluted	$ 0.01	$ 0.02

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

The preparation of financial statements in conformity with U.S. generally accepted accounting principles 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.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

In August 2018, the FASB issued ASU No. 2018-13 Fair Value Measurement (Topic 820): Disclosure Framework – Changes to the Disclosure for Fair Value Measurement. The amendments in this ASU modify the disclosure requirements on fair value measurements in Topic 820 based on the concepts in the Concepts Statement, including the consideration of costs and benefits. The amendments in this ASU are effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes in unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted upon issuance of this ASU. An entity is permitted to early adopt any removed or modified disclosures upon issuance of this ASU and delay adoption of the additional disclosures until their effective date. The adoption of this ASU, effective January 1, 2020, is not expected to have a material effect on our financial statement disclosures.

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

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 December 31, 2019, the Company does not believe that any of its assets are impaired.

NOTE 2 INVENTORY

Inventory consists of:

	December 31, 2019	December 31, 2018
Raw materials and Work-in-process	$ 1,863,978	$ 1,155,632
Finished goods	552,989	1,020,930
Total	2,416,967	2,176,562
Less: reserve for obsolete inventory	28,490	72,683
Inventory, net	$ 2,388,477	$ 2,103,879

NOTE 3 PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	December 31, 2019	December 31, 2018	Estimated Useful Lives
Land	$ —	$ 54,030	
Building	—	171,094	20 years
Furniture, office equipment, and leasehold improvements	1,135,107	1,058,507	3-10 years
Manufacturing equipment and tooling	1,295,978	1,279,865	3-12 years
Total	2,431,085	2,563,496	
Less: accumulated depreciation	1,819,239	1,704,715	
Property and equipment, net	$ 611,846	$ 858,781	

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

Depreciation expense was $286,004 and $273,450 for the years ended December 31, 2019, and ended December 31, 2018, respectively.

NOTE 4 RELATED PARTY TRANSACTIONS

BUILDING LEASE

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

The lease payments were $142,964 and $132,504 for the years ended December 31, 2019, and 2018, respectively. The Company also paid property taxes in the amount of $52,195 and $50,072 for the years ended December 31, 2019, and 2018, respectively.

NOTE 5 STOCK-BASED COMPENSATION

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

As of December 31, 2019, the Company had 3,647,000 time-based stock options outstanding to certain executives, key employees and consultants under the Plan, of which 1,400,000, net of forfeitures, were issued during the twelve months ended December 31, 2019. The Company also had 1,000,000 performance-based options outstanding under the Plan as of December 31, 2019, to its President and Chief Executive Officer, of which all were issued during the twelve months ended December 31, 2019.

On February 20, 2019, the Board of Directors of the Company approved an increase in compensation for each non-employee director from $25,000 to $50,000 annually effective January 1, 2019, and an additional $10,000 annually for the chair of each Board committee effective February 20, 2019, in each case to be paid quarterly half in cash and half in common stock at the end of each fiscal quarter. On September 30, 2019, the Board of Directors of the Company named R. John Fletcher, a current KORU director, as Chairman, replacing Executive Chairman, Daniel S. Goldberger, who will remain as a non-executive member of KORU's Board of Directors. In Mr. Fletcher's role as Chairman, he will receive an additional $50,000 in annual compensation, to be paid quarterly in shares of KORU 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 on April 1, 2019. The number of shares that were issued totaled 90,604 and was based upon the closing price of the Common Stock of the Company on February 1, 2019, as reported by the OTCQX. These shares were issued on April 3, 2019.

2015 STOCK OPTION PLAN, as amended

Time-Based Stock Options

The per share weighted average fair value of stock options granted during the year ended December 31, 2019, and December 31, 2018 was $1.33 and $0.83, 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 year ended December 31, 2019, and December 31, 2018. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued.

	December 31, 2019	December 31, 2018
Dividend yield	0.00%	0.00%
Expected Volatility	56.1-60.3%	61.1%-65.2%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10 Years	5-10 Years
Risk-free rate	1.60-2.72%	2.8%-3.15%

The following table summarizes the status of the Company's stock option plan:

	December 31, 2019		December 31, 2018	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	2,419,000	$ 1.00	1,038,000	$ 0.41
Granted	1,650,000	$ 1.92	1,518,000	$ 1.34
Exercised	160,000	$ 0.37	125,000	$ 0.41
Forfeited	262,000	$ 2.74	12,000	$ 0.87
Outstanding at year end	3,647,000	$ 1.32	2,419,000	$ 1.00
Options exercisable	1,078,510	$ 0.82	785,094	$ 0.55
Weighted average fair value of options granted during the period		$ 1.33		$ 0.83
Stock-based compensation expense		$ 594,956		$ 248,040

Total stock-based compensation expense, net of forfeitures, for stock option awards totaled $594,956 and $248,040 for the year ended December 31, 2019, and 2018, respectively. Cash received from option exercises for the years ended December 31, 2019 and 2018 was $58,900 and $51,250, respectively.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2019, and 2018, was $2,202,678 and $1,255,234 respectively. The total intrinsic value of options exercised during the years ended December 31, 2019, and 2018, was $58,900 and $51,250, respectively.

The following table presents information pertaining to options outstanding as of December 31, 2019:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.38-3.15	3,647,000	6.0 years	$ 1.32	1,078,510	$ 0.82

As of December 31, 2019, there was $2,188,008 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 44 months. The total fair value of vested options was $539,553 and $258,666 at December 31, 2019, and December 31, 2018, respectively.

Performance-Based Stock Options

The per share weighted average fair value of stock options granted during the year ended December 31, 2019, and 2018, was $1.16 and zero, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the year ended December 31, 2019, and December 31, 2018. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued.

	December 31,	
	2019	2018
Dividend yield	0.00%	—
Expected Volatility	58.9%	—
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10 Years	—
Risk-free rate	2.07%	—

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

	December 31,			
	2019		2018	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	—	$ —	—	$ —
Granted	1,000,000	$ 1.70	—	$ —
Exercised	—	$ —	—	$ —
Forfeited	—	$ —	—	$ —
Outstanding at year end	1,000,000	$ 1.70	—	$ —
Options exercisable	—	$ —	—	$ —
Weighted average fair value of options granted during the period	—	$ 1.16	—	$ —
Stock-based compensation expense	—	$ 293,363	—	$ —

Total performance stock-based compensation expense totaled $293,363 and zero for the years ended December 2019 and 2018, respectively.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2019 and 2018, was $1,162,561 and zero, respectively.

The following table presents information pertaining to performance-based options outstanding as of December 31, 2019:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$1.70	1,000,000	10 years	$ 1.70	—	$ —

As of December 31, 2019, there was $869,198 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 December 31, 2019, and 2018 was zero for both periods.

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:

	Year Ended December 31, 2019
Operating lease cost	$ 149,594
Finance lease cost:	
Amortization of right-of-use assets	$ 4,837
Interest on lease liabilities	239
Total finance lease cost	$ 5,076

Supplemental cash flow information related to leases was as follows:

	Year Ended December 31, 2019
Cash paid for amounts included in the measurement of lease liabilities:	
Finance cash flows from finance leases	$ 4,783
Finance lease cost:	
Amortization of right-of-use assets	$ 4,837
Interest on lease liabilities	239
Total finance lease cost	$ 5,076

Supplemental balance sheet information related to leases was as follows:

	Year Ended December 31, 2019
Operating Leases	
Operating lease right-of-use assets	$ 373,734
Operating lease current liabilities	136,888
Operating lease long term liabilities	236,846
Total operating lease liabilities	$ 373,734
Finance Leases	
Property and equipment, at cost	$ 12,725
Accumulated depreciation	4,837
Property and equipment, net	$ 7,888
Finance lease current liabilities	5,296
Finance lease long term liabilities	2,646
Total finance lease liabilities	$ 7,942

	Year Ended December 31, 2019
Weighted Average Remaining Lease Term	
Operating leases	2.4 Years
Finance leases	1.3 Years
Weighted Average Discount Rate	
Operating leases	4.75%
Finance leases	4.75%

Maturities of lease liabilities are as follows:

Year Ended December 31,	Operating Leases	Finance Leases
2020	$ 151,686	$ 5,533
2021	149,476	2,705
2022	97,256	—
Total lease payments	398,418	8,238
Less imputed interest	(24,684)	(296)
Total	$ 373,734	$ 7,942

NOTE 7 FEDERAL AND STATE INCOME TAXES

The provision for income taxes as of December 31, 2019, and 2018 consisted of:

	December 31, 2019	December 31, 2018
State income tax:		
Current, net of refund	$ 22,514	$ 12,391
Federal income tax:		
Deferred	(186,775)	23,141
Current	296,330	230,848
Total	$ 132,069	$ 266,380

The reconciliation of income taxes shown in the financial statements and amounts computed by applying the Federal expected tax rate of 21% for year 2019 and 2018 is as follows:

	December 31, 2019	December 31, 2018
Income before tax	$ 696,418	$ 1,176,950
Computed expected tax	$ 146,248	$ 247,160
State income and franchise tax	22,514	12,391
Other	(36,693)	6,829
Provision for taxes	$ 132,069	$ 266,380

The components of deferred tax assets at December 31, 2019, and 2018, respectively, are as follows:

	December 31, 2019	December 31, 2018
Deferred compensation cost	$ 259,068	$ 79,632
Depreciation and amortization	(71,331)	(79,640)
Allowance for bad debts and other	504	1,474
Deferred tax asset	$ 188,241	$ 1,466

NOTE 8 MAJOR CUSTOMERS

For the years ended December 31, 2019, and December 31, 2018, approximately 53% and 52%, respectively, of the Company's net product revenues were derived from one major customer. As of December 31, 2019, and December 31, 2018, accounts receivable due from this customer were $1.9 million and $0.8 million, respectively.

The largest customer in both years is a domestic medical products and supplies distributor. Although a number of larger infusion customers have elected to consolidate their purchases through one or more distributors in recent years, we continue to maintain strong direct relationships with them. We do not believe that their continued purchase of FREEDOM System products and related supplies is contingent upon the distributor.

NOTE 9 LEGAL PROCEEDINGS

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

The initial case involving EMED was filed by us in the United States District Court for the Eastern District of California on September 20, 2013 (the "California case"), in response to a letter from EMED claiming patent infringement by us, and seeking a declaratory judgment establishing the invalidity of the patent referenced in the letter – EMED's US patent 8,500,703 – "'703." EMED answered the complaint and asserted patent infringement of the '703 patent and several counterclaims relating generally to claims of unfair business practices against us. We responded by adding several claims against EMED, generally relating to claims of unfair business practices on EMED's part. Both parties have requested injunctive relief and monetary damages in unspecified amounts. On June 16, 2015, the California court entered a preliminary injunction against KORU Medical 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 US Patent and Trademark Office ("USPTO"). The ex parte reexamination resulted in a Final Office Action, dated July 19, 2017, rejecting all of EMED's claims in the issued patent. On January 25, 2018, EMED filed an Appeal Brief with a Petition for Revival, which was accepted. On April 9, 2018, the USPTO denied EMED's request for reconsideration of the order rejecting all claims in the '703 patent. On June 26, 2019, the Examiner responded to EMED's appeal brief and maintained all of the final rejections. On December 31, 2019, the Patent Trial and Appeal Board ("PTAB") of the USPTO issued its decision sustaining the invalidity of claims 1-10 of the '703 patent, but reversing the Examiner's rejection of claim 11, 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. Both the California case and EMED's appeal of the USPTO rejections are pending. EMED's deadline to take action in response to the PTAB decision has not yet expired.

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 now rejected EMED '703 patent.

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

Following the PTAB's Final Written Decision in the IPR regarding the '476 patent, EMED filed a new patent application claiming priority back to the application that issued as '703, which is the patent at issue in the California case. Submitted for accelerated examination, this new application issued as US 9,808,576 – "'576" on November 7, 2017. On this same date, EMED filed a new case (the "third case") in the Texas Court claiming patent infringement of '576, also directed to our needle sets, and seeking unspecified damages and a preliminary injunction against marketing and sales of our needle sets. We filed a Motion to Dismiss or Transfer Venue to the United States District Court for the Southern District of New York ("SDNY"), which resulted in the transfer of the third case to SDNY ("SDNY '576 matter") on May 30, 2018.

On April 23, 2018, EMED filed a new civil case (the "fourth case") against us in the 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 names Andrew Sealfon, then President and CEO of KORU Medical, individually as a defendant. As the result of a hearing on November 14, 2018, on December 7, 2018, the Court entered an order transferring the fourth case to the United States District Court for the Eastern District of California (the "California Court"). The California Court set an initial schedule for a preliminary motion phase and on August 30, 2019, EMED filed a second amended complaint. On September 30, 2019, KORU Medical and Sealfon filed a motion to dismiss that complaint, and Sealfon filed a separate motion to dismiss the case as to him for lack of jurisdiction. Ultimately, we expect this case to be coordinated or consolidated with the California case, or dismissed, as the California Court sees fit.

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

The ED Texas '476 matter proceeded under EMED's amended infringement contention to incorporate the surviving dependent Claim 9, which incorporates Claims 1 and 8 of the '476 patent, meaning that, to prove infringement on our part, EMED must prove more elements of infringement than it originally charged against us. In April 2019, EMED served its damages expert's report opining that EMED's past infringement damages amount to $1.5 million, and in May KORU Medical served its damages expert's rebuttal report opining that EMED's expert miscalculated damages which if properly calculated would amount to less than $100,000. The Texas Court had set a trial date of August 19, 2019, for the trial of the ED Texas '476 matter. On June 24, 2019, the Texas Court Magistrate Judge issued a Report and Recommendation decision finding no infringement, literally or under the doctrine of equivalents, by KORU Medical's accused products. EMED filed its objections on June 26, 2019. On June 28, 2019, the Texas Court issued a Final Judgment in favor of KORU Medical and adopted the decision of the Magistrate Judge that was issued on June 24, 2019, overruled EMED's objections, awarded court costs to KORU Medical, and dismissed the case. A final judgment has been entered. KORU Medical has submitted its Bill of Costs for approximately $16,000 and moved to declare the case exceptional and for recovery of its attorney fees and expenses of approximately $2.3 million in defense of EMED's assertion of the '476 Patent. EMED has objected to our Bill of Costs, opposed the motion for fees, and filed a notice of appeal of the non-infringement judgment to the Court of Appeals for the Federal Circuit. On September 16, 2019, EMED filed its opening appeal brief. On October 28, 2019, KORU Medical filed its responsive brief, and on November 7, 2019 EMED filed its reply brief. On November 20, 2019, KORU Medical filed a motion for leave to file a sur-reply brief to respond to a new argument raised by EMED in its reply brief, which EMED opposed, and which the Court has referred to the judicial panel that will hear the appeal for consideration. The appeal remains pending, with oral argument scheduled for April 8, 2020. The Texas Court has stayed proceedings in the district court until the appeal process is completed. KORU Medical's fee motion remains pending lifting of the stay.

The SDNY '576 matter proceeded in the New York court through claim construction on the '576 Patent, whereupon KORU Medical sought permission from the New York court to file a motion for summary judgement, to which EMED objected. The New York court granted KORU Medical's request, and on July 10, 2019, KORU Medical filed its motion for summary judgement. EMED opposed that motion, and on August 30, 2019, the New York court granted summary judgement, and dismissed the lawsuit. A final judgement has been entered. KORU Medical has submitted a Bill of Costs for approximately $1,500, to which EMED has objected, and has moved the New York court to declare the case exceptional and for recovery of its attorney fees and expenses of at least $1.16 million. EMED has opposed that motion, which was referred to a United States District Court Magistrate Judge to prepare a report and recommendation. 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 has filed objections to the Report and Recommendation, to which KORU Medical has responded, and which objections are now pending before the District Court Judge for resolution. EMED has also appealed the New York court's judgment of non-infringement to the Court of Appeals of the Federal Circuit, which matter also is pending. EMED's opening appeal brief was due November 8, 2019, but EMED filed its brief on November 12, 2019. EMED filed a motion to extend the time to file its opening brief, which KORU Medical opposed, but the motion was granted. KORU Medical filed its responsive brief on December 23, 2019, on January 9, 2020 EMED filed the joint appendix in support of the parties' briefing, and on January 13, 2020, EMED filed its reply brief. The appeal remains pending, waiting for the Court to schedule oral argument.

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

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

NOTE 10 EMPLOYEE BENEFITS

We provide a safe harbor 401(k) plan for our employees that allows for employee elective contributions, Company matching contributions and discretionary profit-sharing contributions. Employee elective contributions are funded through voluntary payroll deductions. The Company makes safe harbor matching contributions in an amount equal to 100% of the employee's contribution, not to exceed 3% of employee's compensation plus 50% of employee's pay contributed between 3% and 5% of employee's compensation. Company matching expense for the period ended December 31, 2019, and December 31, 2018, was $118,632 and $121,834, respectively. The Company has not provided for a discretionary profit-sharing contribution.

NOTE 11 DEBT OBLIGATIONS

On February 8, 2018, the Company issued a Promissory Note to KeyBank National Association ("KeyBank") in the amount of $1.5 million as a variable rate revolving line of credit loan due on demand with an interest rate of LIBOR plus 2.25%, collateralized with a certificate of deposit in the amount of $1.5 million. The Company entered into this arrangement to establish a credit lending history and, in the event needed, to have additional cash on hand for future expansion. On September 25, 2018, KeyBank released the certificate of deposit as collateral for the loan and the Company executed a Commercial Security Agreement as collateral for the loan. As of December 31, 2019, and 2018, the Company had no outstanding amounts against the line of credit.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

An evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer or CEO, and Chief Financial Officer or CFO, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2019. Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2019, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our CEO and CFO, to allow timely decisions regarding required disclosure.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed under the supervision of the Company's Chief Executive Officer and Chief Financial Officer, and implemented in conjunction with management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external purposes in accordance with generally accepted accounting principles.

There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal control can provide only reasonable assurance with respect to financial statement preparation. Further, because of changes in conditions, the effectiveness of internal control may vary over time.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2019. This assessment was based on criteria for effective internal control over financial reporting described in "Internal Control - Integrated Framework," issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management determined that, as of December 31, 2019, the Company maintained effective internal control over financial reporting.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the fiscal quarter ended December 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 2, 2020, upon recommendation of the Compensation Committee of the Board of Directors, the Board of Directors approved annual performance bonuses pursuant to their employment contracts and objectives set by the Company to the following persons in the following amounts: Donald Pettigrew, President and Chief Executive Officer - $262,440; Karen Fisher, Chief Financial Officer - $94,725; and Manuel Marques, Chief Operating Agreement - $83,525.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Information regarding our executive officers required by Item 10 of Part III is set forth in Item 1 of Part I "Business — Executive Officers." Information required by Item 10 of Part III regarding our directors and any material changes to the process by which security holders may recommend nominees to the Board of Directors is included in our Proxy Statement relating to our 2020 Annual Meeting of Shareholders, and is incorporated herein by reference. Information relating to our Code of Ethics and to compliance with Section 16(a) of the 1934 Act is set forth in our Proxy Statement relating to our 2020 Annual Meeting of Shareholders and is incorporated herein by reference. We intend to disclose amendments to our Code of Ethics, as well as waivers of the provisions thereof, on our website under the heading "Investors - Governance" at www.korumedical.com.

ITEM 11. EXECUTIVE COMPENSATION

Information required by Item 11 of Part III is included in our Proxy Statement relating to our 2020 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Information required by Item 12 of Part III is included in our Proxy Statement relating to our 2020 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information required by Item 13 of Part III is included in our Proxy Statement relating to our 2020 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by Item 14 of Part III is included in our Proxy Statement relating to our 2020 Annual Meeting of Shareholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

All financial statement schedules have been omitted because they are not required, not applicable, not present in amounts sufficient to require submission of the schedule, or the required information is otherwise included.

The following exhibits are filed herewith or incorporated by reference as part of this Annual Report.

Exhibit No.	Description
3.1(i)	Restated Certificate of Incorporation effective March 1, 2019 (incorporated by reference to our Form 10-K filed with the SEC on March 5, 2019).
3.1(ii)	Amended and Restated By-Laws dated December 5, 2018 (incorporated by reference to our Form 8-K filed with the SEC on December 7, 2018).
4.1	Description of Securities, filed herewith.
10.1	Amended and Restated Employment Agreement made as of January 1, 2020 between Repro Med Systems, Inc. and Karen Fisher (incorporated by reference to the Company's Form 8-K filed with the SEC on January 24, 2020).*
10.2	Employment Agreement made as of September 4, 2018 between Repro Med Systems, Inc. and Donald B. Pettigrew (incorporated by reference to the Company's Form 8-K filed with the SEC on September 4, 2018).*
10.3	Employment Agreement made as of October 10, 2017 between Repro Med Systems, Inc. and Manuel Marques, filed herewith.*
10.4	2015 Stock Option Plan, as amended (incorporated by reference to the Company's Proxy Statement on Schedule 14A filed with the SEC on July 28, 2016).
10.5	Common Stock Purchase Agreement dated as of December 17, 2018 by and among Repro Med Systems, Inc., the Sellers named therein and the Purchasers named therein (incorporated by reference to the Company's Form 8-K filed with the SEC on December 17, 2018).
23.1	Consent of Independent Auditors, filed herewith.
31.1	Certification of the Principal Executive Officer of registrant required under Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
31.2	Certification of the Principal Financial Officer of registrant required under Section 302 of the Sarbanes-Oxley Act of 2002, filed herewith.
32.1	Certification of the Principal Executive Officer of registrant required under Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.
32.2	Certification of the Principal Financial Officer of registrant required under Section 906 of the Sarbanes-Oxley Act of 2002, filed herewith.
101	Interactive Data File (Annual Report on Form 10-K, for the year ended December 31, 2019), furnished in XBRL (eXtensible Business Reporting Language).

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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 on March 4, 2020.

REPRO MED SYSTEMS, INC.

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

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

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on March 4, 2020.

/s/ R. John Fletcher
R. John Fletcher, Chairman of the Board

/s/ Robert T. Allen
Robert T. Allen, Director

/s/ David Anderson
David Anderson, Director

/s/ James M. Beck
James M. Beck, Director

/s/ Kathy S. Frommer
Kathy S. Frommer, Director

/s/ Daniel S. Goldberger
Daniel S. Goldberger, Director

/s/ Joseph M. Manko, Jr.
Joseph M. Manko, Jr., Director

EXHIBIT 4.1

DESCRIPTION OF CAPITAL STOCK

Repro Med Systems, Inc. ("we" or "our") has authorized capital stock consisting of 77,000,000 shares, of which 75,000,000 are designated common stock, $0.01 par value per share, and 2,000,000 are designated preferred stock. As of March 3, 2020, we had 39,502,557 shares of common stock and no shares of preferred stock issued and outstanding. Unless stated otherwise, the following discussion summarizes the terms and provisions of our restated certificate of incorporation and our amended and restated bylaws. This description is summarized from, and qualified in its entirety by reference to, our restated certificate of incorporation and amended and restated bylaws, which are filed as Exhibits to our Form 10-K for the fiscal year ended December 31, 2019.

Common Stock

The holders of shares of our common stock are entitled to one vote per share on all matters to be voted upon by our stockholders and there are no cumulative rights. The holders of shares of our common stock are entitled to receive ratably any dividends that may be declared from time to time by our board of directors out of funds legally available for that purpose. In the event of our liquidation, dissolution or winding up, the holders of shares of our common stock are entitled to share ratably in all assets remaining after payment of liabilities. Our common stock has no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. The outstanding shares of our common stock are fully paid and non-assessable.

Preferred Stock

We are authorized to issue "blank check" preferred stock, which may be issued in one or more series upon authorization of our board of directors. Our board of directors is authorized to fix the designation of the series, the number of authorized shares of the series, dividend rights and terms, conversion rights, voting rights, redemption rights and terms, liquidation preferences and any other rights, powers, preferences and limitations applicable to each series of preferred stock. The authorized shares of our preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. If the approval of our stockholders is not required for the issuance of shares of our preferred stock, our board may determine not to seek stockholder approval.

A series of our preferred stock could, depending on the terms of such series, impede the completion of a merger, tender offer or other takeover attempt. Our board of directors will make any determination to issue preferred shares based upon its judgment as to the best interests of our stockholders. Our directors, in so acting, could issue preferred stock having terms that could discourage an acquisition attempt through which an acquirer may be able to change the composition of our board of directors, including a tender offer or other transaction that some, or a majority, of our stockholders might believe to be in their best interests or in which stockholders might receive a premium for their stock over the then-current market price of the stock.

Registration Rights

On December 17, 2018, RMS and certain of its existing stockholder and other parties named therein entered into a Common Stock Purchase Agreement providing for the sale in a private placement transaction of certain shares of our common stock from the existing stockholders to the selling stockholders. The initial closing of the private placement occurred on December 18, 2018 and the final closing occurred on December 20, 2018. We did not issue any securities and did not receive any proceeds from sale of these shares. Pursuant to the purchase agreement, we filed a resale registration statement under the Securities Act covering these shares.

Anti-Takeover Effects of Provisions of Our Charter Documents

Provisions in our restated certificate of incorporation and amended and restated bylaws contain certain provisions that could make it more difficult for a third party to acquire control of the Company or otherwise take shareholder action. These provisions, for example:

- empower our board of directors, without shareholder approval, to issue our preferred stock, the terms of which, including voting power, are set by our board of directors;
- preclude cumulative voting in elections of directors;
- permit our board of directors to alter, amend or repeal our amended and restated bylaws or to adopt new bylaws;
- prescribe the procedure that a shareholder must follow to nominate directors or bring business before shareholders' meetings; and
- require the request of holders of at least 10% of the outstanding shares of our common stock entitled to vote at a meeting to call a special shareholders' meeting.

Limitations of Liability and Indemnification of Directors and Officers

Our restated certificate of incorporation includes a provision that eliminates the personal liability of directors for monetary damages for any breach of fiduciary duty as a director, except where such liability is imposed under the New York Business Corporation Law (the "NYBCL"). The NYBCL provides that a corporation may indemnify an individual made a party to a proceeding because he is or was a director against liability incurred in the proceeding unless (i) the act or omission was material to the matter giving rise to the proceeding and was committed in bad faith or was the result of active and deliberate dishonesty; (ii) the director actually received an improper personal benefit; or (iii) in the case of any criminal proceeding, the director had reasonable cause to believe the act or omission was unlawful, provided however, that if the proceeding was by or in the right of the corporation, no indemnification may be made if the director is adjudged liable to the corporation. The Board of Directors of the Company (the "Board") may also indemnify an employee or agent of the corporation who was or is a party to any proceeding by reason of the fact that he is or was an employee or agent of the corporation.

Our restated certificate of incorporation and amended and restated by-laws provide that, to the maximum extent permitted by the New York law and the federal securities laws, we must indemnify and, upon request advance, expenses to a director or officer made, or threatened to be made, a party to any action or proceeding (other than a shareholder derivative action) by reason of such person being a director or officer, if such director or officer acted in good faith for a purpose which he or she reasonably believed to be in, or not opposed to, the best interests of the corporation and, in criminal actions or proceedings, in addition, had no reasonable cause to believe that his or her conduct was unlawful. Indemnification would cover reasonable expenses, including attorneys' fees, judgments, fines, amounts paid in settlement and reasonable expenses (including attorneys' fees).

The limitation of liability, indemnification and advancement provisions in our restated certificate of incorporation and amended and restated by-laws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duty. These provisions also may have the effect of reducing the likelihood of derivative litigation against directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act, may be permitted to directors, officers or persons controlling us pursuant to the foregoing provisions, we have been advised that in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

Transfer Agent

The stock transfer agent for our securities is Continental Stock Transfer and Trust Company of New York, New York. Their address is 1 State Street, 30th Floor, New York, NY 10004. Their phone number is (212) 509-4000.

EXHIBIT 10.3

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement"), made effective as of October 10, 2017 (the "Effective Date"), is made by and among Repro Med Systems, Inc., a New York corporation, having its principal place of business at 24 Carpenter Road, Chester, NY 10918 (the "Company"), and Manuel Marques, an individual having a domicile at [ADDRESS] ("Employee").

WHEREAS, the Company desires to employ Employee, and Employee desires to be employed by the Company, upon the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises set forth herein, and for other good and valuable consideration, the- receipt and sufficiency of which is hereby acknowledged, intending to be legally bound hereby, the parties hereto agree as follows:

1. Employment.

(a) Position. The Company hereby employs Employee as Vice President of Operations & Engineering of the Company. Employee shall report directly to the Chief Operating Officer of the Company (the "COO") and shall have the duties, authority and responsibilities customarily held by a person holding the position of Vice President of Operations & Engineering in companies engaged in business similar to the Company's business and shall render such other services as may be reasonably assigned to him from time to time by the COO.

(b) Duties. Employee hereby agrees to be employed as Vice President of Operations & Engineering. During the Term (as defined below), Employee agrees that he shall: (i) faithfully and to the best of his ability perform all of the duties that may be required of him pursuant to the terms of this Agreement; (ii) devote substantially all of his business time and attention to the performance of Employee's duties hereunder; and (iii) not engage in any other business, profession or occupation for compensation or otherwise which would conflict or interfere with the performance of such services either directly or indirectly without the prior written consent of the COO.

(c) Place of Performance. The principal place of Employee's employment shall be at the Company's office located in Chester, New York. In addition, Employee may be required to travel elsewhere on Company business during the Term.

2. Term. The initial term of this Agreement shall commence on the Effective Date and continue for a period of one (l) year (the "Initial Term"), unless and until terminated as otherwise provided in this Agreement. Upon expiration of the Initial Term, this Agreement shall automatically renew for additional successive one (1) year terms unless and until either party provides written notice of nonrenewal at least sixty (60) days prior to the end of the then current term (each, a "Renewal Term," and together with the Initial Term, the "Term"), or unless and until terminated as otherwise provided in this Agreement.

3. Compensation and Related Matters.

(a) Base Salary. During the Term, the Company shall pay to Employee (i) an annual base salary of $200,000, less such deductions as are required by law or that Employee may elect in accordance with Company policy and procedure, payable in equal periodic installments in accordance with the Company's customary payroll practice, but no less frequently than monthly. The agreement further called for the award of a stock option grant of 250,000 incentive stock options that vest quarterly (25% a year) over a four year term and in accordance with the company's current stock option plan. Vesting is automatically accelerated if Employee's employment is terminated by the company without cause (as defined in the employment agreement) after two years from this agreement.

(b) Bonuses. For each complete calendar year of the Term, Employee shall be eligible to earn an annual bonus of (the "Annual Bonus") 20% of base compensation in accordance with Company policy and procedure for granting of bonuses to management.

(c) Expenses. During the Term, Employee shall receive (i) reimbursement from the Company for all reasonable and documented out-of-pocket expenses incurred by Employee in performing services hereunder, in each case, that such expenses are accounted for in accordance with the standard policies and procedures established by the Company for reimbursement of expenses.

(d) Vacation Paid Time Off. During the Term, Employee shall be entitled to paid vacation and other paid time-off in accordance with Company's policies for management and Employees. Employee's original date of hire shall be used in determining amount of time off available.

(e) Other Benefits. During the Term, Employee shall be entitled to participate, in a manner at least as favorable as that provided to other similarly situated Employees of the Company, in such life insurance, medical, dental, disability, pension and retirement plans and other programs as may be approved from time to time by the Company for the benefit of its Employees, except any such plan or program with respect to which Employee voluntarily executes a legally effective waiver. Nothing herein shall affect the Company's right to amend, modify or terminate any retirement or other benefit plan at any time for any reason.

4. Termination of Employment.

(a) Termination by Employee. Employee may terminate his employment with the Company for any reason by giving the Company not less than sixty (60) days' prior written notice.

(b) Termination by Company. The Company may terminate Employee's employment with the Company (i) for any reason by giving Employee not less than sixty (60) days' prior written notice or (ii) immediately for Cause (as defined below). For purposes of this Agreement, "Cause" shall mean: (u) Employee's engagement in dishonesty or illegal conduct, which is, in each case, materially injurious to the Company; (v) Employee's embezzlement, misappropriation or fraud, whether or not related to the Employee's engagement by the Company; (w) Employee's conviction of or plea of guilty or nolo contendere to a crime that constitutes a felony (or state law equivalent); (x) Employee's conviction of or plea of guilty or nolo contendere to a crime that constitutes a misdemeanor involving moral turpitude which is, in each case, materially injurious to the Company; (y) Employee's material breach of any material obligation under this Agreement or any other written agreement between Employee and the Company, which breach is not cured (to the extent curable) within fifteen (15) days after written notice thereof from the Company to the Employee; or (z) any material and willful failure by Employee to comply with the Company's written policies or rules, as they may be in effect from time to time

(c) Death. Employee's employment hereunder shall terminate upon his death.

(d) Disability. The Company may terminate Employee's employment hereunder if (i) as a result of Employee's incapacity due to physical or mental illness, Employee shall have been absent from his duties hereunder,

with the approval of a physician selected or approved by the Company, for a period of 120 consecutive days or 180 days during any 365-day period, and (ii) within ten (10) days after written notice of termination is given by the Company to Employee (which may occur at or after the end of such period), Employee shall not have returned to the performance of his duties hereunder on a full-time basis. During any period that Employee fails to perform his duties hereunder as a result of incapacity due to physical or mental illness (a "Disability Period"), Employee shall continue to receive his compensation pursuant to this Agreement until his employment is terminated pursuant to this Section 4; provided that payments so made to Employee during the Disability Period shall be reduced by the sum of the amounts, if any, payable to Employee under disability benefit plans of the Company.

5. Compensation upon Termination of Employment.

(a) Accrued and Unpaid Compensation. If Employee's employment is terminated for any reason, the Company shall pay Employee his full Base Salary through the effective date of the termination of Employee's employment ("Termination Date"), plus all accrued and unpaid benefits (including all health and welfare benefits in which Employee was a participant in accordance with their terms), and the Company shall have no further obligations whatsoever to Employee under this Agreement except as expressly provided otherwise in this Agreement.

(b) Severance. If Employee's employment is terminated by the Company other than for Cause (as defined below) or pursuant to Sections 4(c) or 4(d) above, then, subject to his execution of a customary general release of claims in favor of the Company and its affiliates, Employee shall be entitled to receive an amount equal to (i) if the Termination Date is less than twelve (12) months after the Effective Date, the cash portion of his Base Salary as in effect as of the Termination Date, paid over time as if he were employed until the date that is six (6) months after the Effective Date; (ii) if the Termination Date is more than twelve (12) months after the Effective Date, twelve (12) months of the cash portion of his Base Salary in effect as of the Termination Date. Such amount shall be paid with the normal payroll cycle over the term, following the Termination Date, in accordance with the Company's customary payroll practices. (c) Change of Control (CIC). Upon qualified termination following a CIC, all outstanding, unvested previously granted options will be treated as having accelerated vesting and become fully vested upon triggering event. If terminated without Cause

within eighteen (18) months of CIC event, the cash portion of Base Salary shall be paid for the equivalent of (18) months of Base Salary.

6 . Representations and Warranties of Employee. Employee represents and warrants to the Company that he is free to accept employment hereunder and that he has no prior or other obligations or commitments of any kind that would in any way hinder or interfere with his acceptance of, or the full performance of, such employment.

7. Confidentiality.

(a) During the Term and at all times thereafter, Employee shall keep Confidential Information (as defined below) strictly confidential. Employee shall not at any time, directly or indirectly, disclose or divulge any Confidential Information, except (i) if required by law, regulation or legal or regulatory process, but only in accordance with Section 7(b) below, or (ii) to his affiliates and his and their respective directors, officers, employees, managing members, general partners, agents and consultants (including attorneys, financial advisors and accountants) ("Representatives"), as applicable, to the extent necessary to permit such Representatives to assist Employee in any Permitted Use (as defined below); provided that Employee shall require each such Representative to be bound by the terms of this Section 7 to the same extent as if they were parties hereto and Employee shall be responsible for any breach of this Section 7 by any of its Representatives.

(b) If Employee or any of his Representatives is required, in the written opinion of Employee's counsel, to disclose any Confidential Information, by law, regulation or legal or regulatory process, Employee shall (i) take all reasonable steps to preserve the privileged nature and confidentiality of the Confidential Information, including requesting that the Confidential Information not be disclosed to non-parties or the public, (ii) give the Company prompt prior written notice of such request or requirement so that the Company may seek, at its sole cost and expense, an appropriate protective order or other remedy, and (iii) cooperate with the Company, at the Company's sole cost and expense, to obtain such protective order. In the event that such protective order or other remedy is not obtained, Employee (or such other persons to whom such request is directed) will furnish only that portion of the Confidential Information which, on the advice of such person's counsel, is legally required to be disclosed and, upon the Company's request, use its reasonable best efforts to obtain assurances that confidential treatment will be accorded to such information.

(c) For the purposes hereof, "Confidential Information" shall mean all information, data, documents, agreements, files and other materials, whether disclosed orally or disclosed or stored in written, electronic or other form or media, which is obtained from or disclosed by the Company or its Representatives before or after the date hereof regarding the Company or its clients, including, without limitation, all analyses, compilations, reports, forecasts, studies, samples and other documents which contain or otherwise reflect or are generated from such information, data, documents, agreements, files or other materials. The term "Confidential Information" as used herein does not include information that at the time of disclosure or thereafter is generally available to and known by the public (other than as a result of its disclosure directly or indirectly by Employee or any of his Representatives in violation of this Agreement).

(d) Employee shall make no use whatsoever, directly or indirectly, of any Confidential Information, except for (i) the purposes of performing Employee's duties and obligations to the Company, (ii) evaluating Employee's ownership interest in the Company and (iii) use for the benefit of the Company as part of the solicitation of existing or prospective customers of the Company (the "Permitted Uses").

(e) Upon the termination of Employee's employment or upon the Company's request at any time and for any reason, Employee shall immediately deliver to the Company all materials (including all soft and hard copies) in Employee's possession which contain or relate to Confidential Information.

8. Assignment of Developments.

(a) All inventions, modifications, discoveries, designs, developments, improvements, processes, works of authorship, documentation, formulae, data, techniques, know-how, secrets or intellectual property rights or any interest therein made by Employee, either alone or in conjunction with others, at any place or at any time during the Term, whether or not reduced to writing or practice during such period, which result, in whole or in part, from (i) any services performed directly or indirectly for the Company by Employee or (ii) Employee's use of the Company's time, equipment, supplies, facilities or information (collectively, the "Company Developments") shall be and hereby is the exclusive property of the Company without any further compensation to Employee. In addition, without limiting the generality of the foregoing, all Company

Developments which are copyrightable work by Employee are intended to be "work made for hire" as defined in Section 81 of the Copyright Act of 1976, as amended, and shall be and hereby are the property of the Company.

(b) Employee shall promptly disclose any Company Developments to the Company. If any Company Development is not the property of the Company by operation of law, this Agreement or otherwise, Employee will, and hereby does, without further consideration, assign to the Company all right, title and interest in such Company Development and will reasonably assist the Company and its nominees in every way, at the Company's expense, to secure, maintain and defend the Company's rights in such Company Development. Employee shall sign all instruments necessary for the filing and prosecution of any applications for, or extension or renewals of, letters patent (or other intellectual property registrations or filings) of the United States or any foreign country which the Company desires to file. Employee hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Employee's agent and attorney-in-fact (which designation and appointment shall be deemed coupled with an interest and shall survive Employee's death or incapacity), to act for and in Employee's behalf to execute and file any such applications, extensions or renewals and to do all other lawfully permitted acts to further the prosecution and issuance of such letters patent or other intellectual property registrations or filings, or such other similar documents, with the same legal force and effect as if executed by Employee.

9. Non-Competition; Non-Solicitation•, Non-Disparagement.

(a) During the Term and for the Restricted Period (as defined below), Employee shall not engage in any Prohibited Activity anywhere in the world. For the purposes of this Agreement, (i) "Restricted Period" shall mean: (A) in the event of a termination of Employee's employment by the Company without Cause prior to the third anniversary of the Effective Date, a period of six (6) months after the Termination Date; (B) in the event of a termination of Employee's employment by the Company without Cause on or after the third anniversary of the Effective Date, a period of one (1) year after the Termination Date; and (C) in the event of any termination of Employee's employment for any reason other than a termination by the Company without Cause, a period of two (2) years after the Termination Date; and (ii) "Prohibited Activity" shall mean the design, development, marketing, sale, re-sale, manufacture or distribution of medical device products, or other similar activities, on Employee's behalf or on behalf of another (including as a shareholder, member, employee, employer, owner, operator, manager, advisor, consultant, agent, partner, joint venturer or investor of another person or entity). Prohibited Activity also includes activity that may require or inevitably require disclosure of trade secrets, proprietary information or other Confidential Information of the

Company except as otherwise permitted hereunder. Notwithstanding the foregoing, nothing herein shall prohibit Employee from purchasing or owning less than 5% of the publicly traded securities of any entity that develops software related to the wealth management industry, provided that such ownership represents a passive investment and that Employee is not a controlling person of, or a member of a group that controls, such entity.

(b) During the Restricted Period, Employee shall not, directly or indirectly, (i) solicit, hire, recruit, attempt to hire or recruit, or induce the termination of employment of any employee of the Company, (ii) solicit, contact (including but not limited to e-mail, regular mail, express mail, telephone, fax, and instant message), attempt to contact or meet with any (x) existing or prospective customer of the Company for purposes of offering or accepting goods or services similar to or competitive with those offered by the Company, or (y) competitor of the Company for any purpose related to the business or services of the competitor or the Company, or (iii) induce, influence or encourage any existing or prospective customer, supplier or other business partner of the Company for purposes of diverting their business or services from the Company.

(c) Employee shall not, during the Term or thereafter, make, publish or communicate to any person or in any public forum any comments or statements (whether written or oral) that denigrate or disparage the reputation or stature of the Company, its affiliates or any of their respective officers, directors, managers or employees (acting in their capacity as officers, directors, managers or employees of the Company or its affiliates).

(d) Employee acknowledges that the restrictions contained in this Section 9 are reasonable and necessary to protect the legitimate interests of the Company and constitute a material inducement to the Company to enter into this Agreement and Offer employment to Employee under this Agreement. In the event that any covenant contained in this Section 9 should ever be adjudicated to exceed the time, geographic, product or service, or other limitations permitted by applicable law in any jurisdiction, then any court is expressly empowered to reform such covenant, and such covenant shall be deemed reformed, in such jurisdiction to the maximum time, geographic, product or service, or other limitations permitted by applicable law. The covenants contained in this Section 9 and each provision hereof are severable and distinct covenants and provisions. The invalidity or unenforceability of any such covenant or provision as written shall not invalidate or render unenforceable the remaining covenants or provisions hereof, and any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such covenant or provision in any other jurisdiction.

1 0 . Amendment' Waiver. This Agreement may be amended, and the observance of any term of this Agreement may be waived (either generally or in a particular instance and either retroactively or prospectively), only by an instrument in writing signed by the parties hereto. Waiver of any term or condition of this Agreement will not be construed as a waiver of any

subsequent breach or waiver of the same term or condition, or a waiver of any other term or condition of this Agreement.

11. Applicable Law; Severability. This Agreement shall be governed by and construed under the laws of the State of New York, exclusive of the body of law known as conflicts of law. Should a court or other body of competent jurisdiction determine that any term or provision of this Agreement is excessive in scope or duration or is illegal, invalid or unenforceable, then the parties agree that such term or provision shall not be voided or made unenforceable, but rather shall be modified so as to be valid, legal and enforceable to the maximum extent possible, under the purposes stated in the preceding sentence and with applicable law, and all other terms and provisions of this Agreement shall remain valid and fully enforceable.

12. Submission to Jurisdiction; Waiver of Jury Trial.

(a) ANY LEGAL SUIT, ACTION OR PROCEEDING ARISING OUT OF OR BASED UPON THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY MAY BE INSTITUTED IN THE FEDERAL COURTS OF THE UNITED STATES OF AMERICA OR THE COURTS OF THE STATE OF NEW YORK IN EACH CASE LOCATED IN CHESTER, NEW YORK, AND EACH PARTY IRREVOCABLY SUBMITS TO THE EXCLUSIVE JURISDICTION OF SUCH COURTS IN ANY SUCH SUIT, ACTION OR PROCEEDING. SERVICE OF PROCESS, SUMMONS, NOTICE OR OTHER DOCUMENT BY MAIL TO SUCH PARTY'S ADDRESS SET FORTH HEREIN SHALL BE EFFECTIVE SERVICE OF PROCESS FOR ANY SUIT, ACTION OR OTHER PROCEEDING BROUGHT IN ANY SUCH COURT.

(b) EACH PARTY ACKNOWLEDGES AND AGREES THAT ANY CONTROVERSY WHICH MAY ARISE UNDER THIS AGREEMENT IS LIKELY TO INVOLVE COMPLICATED AND DIFFICULT ISSUES AND, THEREFORE, EACH SUCH PARTY IRREVOCABLY AND UNCONDITIONALLY WAIVES ANY RIGHT IT MAY HAVE TO A TRIAL BY JURY IN RESPECT OF ANY LEGAL ACTION ARISING OUT OF OR RELATING TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY OR THEREBY.

13. Equitable Relief. In the event of a breach or threatened breach by Employee of Sections 7 through 9, Employee hereby consents and agrees that the Company shall be entitled to seek, in addition to other available remedies, a temporary or permanent injunction or other equitable relief against such breach or threatened breach from any court of competent jurisdiction, without the necessity of showing any actual damages or that monetary damages would not afford an adequate remedy, and without the necessity of posting any bond or other

security. The aforementioned equitable relief shall be in addition to, not in lieu of, legal remedies, monetary damages or other available forms of relief.

14. Further Assurances. The Company and Employee shall each take all actions as may be reasonably necessary or appropriate in furtherance of their respective obligations and covenants set forth in this Agreement, including, without limitation, executing and delivering such additional agreements, certificates, instruments and other documents as may be deemed necessary or appropriate.

15. Assignability; Third-Party Beneficiary. This Agreement will be binding upon, enforceable by and inure solely to the benefit of, the parties and their respective permitted successors and assigns. Except as otherwise expressly provided in this Agreement, this Agreement shall not be assigned by any party hereto without the prior written consent of the nonassigning parties. Except as otherwise expressly provided in this Agreement, nothing in this Agreement is intended to or will confer upon any person, other than the parties to this Agreement and their respective heirs, successors and assigns, any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement. Notwithstanding anything to the contrary herein, nothing in this Agreement shall preclude the Company from consolidating or merging into or with, transferring all or substantially all of its equity or assets to, or otherwise assigning this Agreement by operation of law to another person or entity without the consent of Employee; provided that, in each case, such other person or entity shall assume this Agreement and all obligations of the Company hereunder. Upon such consolidation, merger, transfer of equity or assets, or assignment by operation of law, and such assumption, the term the "Company" as used herein, shall mean such other person or entity and this Agreement shall continue in full force and effect.

16. Notices. All notices and other communications under this Agreement must be in writing and will be deemed given if delivered personally, faxed, sent by internationally recognized overnight courier, mailed by registered or certified mail (return receipt requested), postage prepaid, or sent by electronic mail (without a failed transmission response) to the parties at the following addresses (or at such other address for a party as such party specifies by like notice) :

If to the Company:	If to Employee:
Repro Med Systems, Inc. 24 Carpenter Road Chester, NY 10918 Attention: Andrew Sealfon Telephone: 845-469-2042 Fax: 845-469-5518 Email: Asealfon@rmsmedpro.com	Manuel Marques [ADDRESS] Telephone: [_____] Email: [_____]

All such notices, consents, requests, demands, waivers and other communications so delivered, mailed or sent shall be deemed to have been received (i) if by personal delivery, on the day delivered, (ii) if by certified or registered mail, on the earlier of the date of receipt and the third business day after the mailing thereof, (iii) if by next-day or overnight mail or delivery service such as Federal Express or UPS, on the day delivered or (iv) if by fax or electronic mail, on the day on which such fax or electronic mail was sent, provided that a copy is also sent by certified or registered mail or by next-day or overnight mail or delivery service such as Federal Express or UPS.

17. Termination of Agreement; Survival. This Agreement shall terminate upon termination of Employee's employment as provided herein; provided, however, that the provisions of Sections 3, 5, 7, 8, 9, 12, 13 and 14 shall survive termination of this Agreement. All of such provisions, except those of Section 5, shall survive expiration of this Agreement.

18. Counterparts. This Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which when executed shall be deemed to be an original but all of which taken together shall constitute one and the same agreement.

19. Electronic Execution and Delivery. The parties may execute and deliver this Agreement by facsimile, electronic mail of a .PDF or other electronic means under which the signature of or on behalf of such party can be seen, and such execution and delivery will be considered valid, binding and effective for all purposes.

20. Entire Agreement; Termination of Prior Consulting Agreement. This Agreement, constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, among or between any of the parties with respect to the subject matter hereof and thereof, including without limitation any prior consulting agreement but excluding any separate confidentiality and/or assignment of inventions agreement Employee may have previously signed.

[signature page follows]

IN WITNESS WHEREOF, the authorized representatives of the parties have executed this Agreement as of the date first set forth above.

COMPANY:
REPRO MED SYSTEMS, INC.

By: /s/ Andrew I. Sealfon
Name: Andrew I. Sealfon
Title: CEO and President

EMPLOYEE:

/s/ Manuel Marques
Manuel Marques

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-3 (No. 333- 229498) and related Prospectus of Repro Med Systems, Inc. of our reports dated March 4, 2020, with respect to the financial statements of Repro Med Systems, Inc. appearing in this Annual Report on Form 10-K for the year ended December 31, 2019.

/s/ McGrail Merkel Quinn & Associates, P.C.

Scranton, Pennsylvania
March 4, 2020

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 Annual Report on Form 10-K of REPRO MED SYSTEMS, INC.;

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:

   (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 the 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.

/s/ Donald B. Pettigrew
Donald B. Pettigrew
President and Chief Executive Officer
Date: March 4, 2020

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 Annual Report on Form 10-K of REPRO MED SYSTEMS, INC.;

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:

   (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 the 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.

/s/ Karen Fisher
Karen Fisher
Chief Financial Officer and Treasurer
Date: March 4, 2020

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 Annual Report of REPRO MED SYSTEMS, INC. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Donald B. Pettigrew, Principal Executive Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(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 as of the dates and for the periods expressed in the Report.

/s/ Donald B. Pettigrew
Donald B. Pettigrew
President and Chief Executive Officer
Date: March 4, 2020

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 Annual Report of REPRO MED SYSTEMS, INC. (the "Company") on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission (the "Report"), I, Karen Fisher, Principal Financial Officer and Treasurer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(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 as of the dates and for the periods expressed in the Report.

/s/ Karen Fisher
Karen Fisher
Chief Financial Officer and Treasurer
Date: March 4, 2020