**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, 2020**

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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 30, 2020, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was $211,688,692.

As of March 23, 2021, 44,475,559 shares of common stock, $0.01 par value per share, were outstanding, which excludes 3,420,502 shares of Treasury Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2021 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, 2020.

**REPRO MED SYSTEMS, INC.**
**FORM 10-K**
**FOR THE YEAR ENDED DECEMBER 31, 2020**
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## PART I

Throughout this report, the "Company," "KORU Medical," "KORU," "we," "us" or "our" refers to Repro Med Systems, Inc. d/b/a KORU Medical Systems.

### 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," "intend," "seek," "expect," "will," and similar references to future periods. Examples of forward-looking statements include, among others, statements we make under "Our Strategy" in Business under Item 1 of this Form 10-K and "Overview" in Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 of this Form 10-K. 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

KORU Medical 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. 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™.

### 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

We 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 and diagnosis 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 Cutacuig®, Cuvitru®, Hizentra®, Xembify® and other formulations of SCIg therapy.

Furthermore, we plan to expand the range of therapies delivered by our products through a combination of (1) introducing additional innovative products and (2) forging partnerships with biopharmaceutical developers for their use in human clinical trials that could lead to their use in commercial applications. These actions capitalize on the migration of many current therapeutics from in-patient use to the global home health marketplace and the emerging pipeline of new drugs targeting home delivery through the subcutaneous route. Our focus is on user-friendly, cost-effective, and flexible products specifically designed to meet the emphasis placed by payors and biopharmaceutical manufacturers on supporting the patient journey meeting the demands of value-based health care.

Our revenues derive from three business sources: (i) domestic core, (ii) international core, and (iii) novel therapies. Our core revenues include sales of our products for the delivery of SCIg to treat PIDD, CIDP, and other disease states that are not included in novel therapies. Novel therapies currently include revenues from the use of our FREEDOM Systems in clinical trials.

The FREEDOM System comprises the FREEDOM60 Syringe Driver (standard 60/50ml syringe compatible) and FreedomEdge Syringe Driver (standard 30/20ml 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 can absorb and what the system delivers, or what we refer to as DynEq®.

**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 can absorb and what the system delivers, or what we refer to as DynEq®.

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 Hizentra® and Cuvitru® and a variety of antibiotics.

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 effectiveness and safety from millions of patient infusions.

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 without allowing unrestricted flow. 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 remote 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, 2020, these four distributors comprised approximately 69% of our net revenues with one of our U.S. distributors contributing approximately 51%.

Specialty pharmacies, home infusion providers, and distributors are our primary call points, 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. In the fourth quarter of 2020, we entered into an agreement with Command Medical Products, Inc. ("Command"), to manufacture and supply the Company's subassemblies, needle sets and tubing products for supply continuity and cost savings.

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 sourced including 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 enhance our product portfolio. We spent $1.3 million and $0.7 million on research and development for the years ended December 31, 2020 and 2019, respectively. 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, principally by the FDA, 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.

The FDA regulates, among other things, the research, development, testing, manufacturing, approval, labeling, storage, recordkeeping, advertising, promotion and marketing, distribution, post approval monitoring and reporting and import and export of medical devices in the U.S. to assure the safety and effectiveness of medical products for their intended use. Thus, both before and after a product is commercially released, we have ongoing responsibilities under the FDA. For instance, all medical devices marketed in the U.S. must be manufactured in accordance with the FDA's quality system regulations ("QSRs"). 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 Federal Trade Commission also regulates the advertising of our products. Further, we are subject to laws directed at preventing fraud and abuse, which subject our sales and marketing, training and other practices to government scrutiny.

Our business is also affected by patient privacy laws and government payor cost containment initiatives, as well as environmental health and safety laws and regulations.

*U.S. Device Classification and Clearance*

Except where an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the U.S. will require either a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the Federal Food, Drug and Cosmetic Act ("FFDCA"), also known as a 510(k) clearance, or approval of a pre-market approval ("PMA") application. For example, the use of our FREEDOM System with therapies not covered by the existing FDA clearance will require additional 510(k) clearance or PMA approval.

Under the 510(k) process, applicants must demonstrate to the FDA that a device is as safe and effective as, or substantially equivalent to, a legally marketed device, known as the "predicate" device. Applicants must submit performance data to establish substantial equivalence. In some instances, data from human clinical trials must also be submitted in support of a 510(k), and these data must be collected in a manner that conforms to the applicable Investigational Device Exemption ("IDE") regulations. The FDA must issue a substantial equivalence determination before commercial distribution can occur. Changes to cleared devices that will not significantly affect the safety or effectiveness of the device can generally be made without additional 510(k) submissions. Changes that will significantly affect the safety or effectiveness of the device will require a new 510(k) prior to marketing of the modified device. Notably, the FDA has announced its intention to pursue comprehensive reforms to its current 510(k) clearance pathway 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."

Under the PMA application process, the applicant must demonstrate that the device is safe and effective for its intended use. This approval process applies to most Class III devices, and generally requires clinical data to support the safety and effectiveness of the device, obtained in conformance with IDE regulations. The FDA will approve a PMA application if it finds that there is a reasonable assurance that the device is safe and effective for its intended purpose, and that the proposed manufacturing is in compliance with the QSRs. For novel technologies, the FDA will seek input from an advisory panel of medical experts regarding the safety and effectiveness of, and their benefit-risk analysis for the device. The PMA process is generally more detailed, lengthier and more expensive than the 510(k) process, though both processes can be expensive and lengthy, and requires payment of significant user fees, unless an exemption is available.

We are also required to comply with the regulations of every other country where we commercialize products before we can launch or maintain new products on the market. Many countries that previously did not have medical device regulations, or had minimal regulations, are now introducing them.

International sales of medical devices manufactured in the U.S. that are not approved by the FDA for use in the U.S., or that are banned or deviate from lawful performance standards, are subject to FDA export requirements. Additionally, exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. due to differing regulatory requirements; however, other countries, such as China, for example, require approval in the country of origin first. Most countries outside of the U.S. require that product approvals be recertified on a regular basis, generally every five years. The recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and, where needed, conduct appropriate testing to document continued compliance. Where recertification applications are required, they must be approved in order to continue selling our products in those countries.

*Post-Approval Regulation*

Even after a device is cleared or approved by FDA for marketing, numerous regulatory requirements continue to apply. The FDA and other worldwide regulatory agencies and competent authorities actively monitor compliance to local laws and regulations through review and inspection of design and manufacturing practices, record-keeping, reporting of adverse events, labeling and promotional practices. The FDA can ban certain medical devices, detain or seize adulterated or misbranded medical devices, order repair, replacement or refund of these devices and require notification of health professionals and others with regard to medical devices that present unreasonable risks of substantial harm to the public health. The FDA may also enjoin and restrain a company for certain violations of the FFDCA and the Safe Medical Devices Act pertaining to medical devices or initiate action for criminal prosecution of such violations. In addition, FDA and other governmental agencies such as the Department of Justice can take action against a company that promotes "off-label" uses. Regulatory agencies and authorities in the countries where we do business can halt production in or distribution within their respective country or otherwise take action in accordance with local laws and regulations. Any adverse regulatory action, depending on its magnitude, may restrict a company from effectively marketing and selling its products, may limit a company's ability to obtain future premarket clearances or approvals, and could result in a substantial modification to a company's business practices and operations.

*Manufacturing Regulation*

We must also comply with FDA and foreign agency regulations governing medical device manufacturing practices. The FDA and foreign agencies require manufacturers to register their establishments, and they monitor compliance with device manufacturing requirements through inspections of manufacturing facilities. If an inspector observes conditions that might be violative, the manufacturer must correct those conditions or explain them satisfactorily, or face potential regulatory action that might include physical removal of the product from the marketplace. We are an FDA-registered medical device manufacturer, and must demonstrate that we comply with the FDA's QSR and Current Good Manufacturing Practices ("cGMPs").

In the European Union ("EU"), we are required to comply with the new Medical Device Regulation ("MDR" or "EU MDR") effective May 2021, which will supersede the current Medical Device Directives. Medical devices which have a valid CE certificate to the current Medical Device Directives (issued before May 2021) can continue to be sold until May 2024 or until the CE certificate expires, whichever comes first, providing there are no significant changes to the design or intended use. The MDR was published in May 2017 with a 3-year transition period. That transition period was extended to May 2021 due to the COVID-19 pandemic. The CE mark required to sell medical devices in the EU is affixed following conformity assessment and either approval from an appointed independent notified body or through self-certification by the manufacturer. The selected pathway to CE marking is based on product risk classification. CE marking indicates conformity to the applicable essential requirements of the relevant Medical Device Directives and in the future to the general safety and performance requirements for the new MDR. The MDR will change multiple

aspects of the existing regulatory framework for CE marking, such as increased clinical evidence requirements and other new requirements, including Unique Device Identification ("UDI") as well as many other post-market obligations. MDR also significantly modifies and increases the compliance requirements for the industry and will require significant investment in the near future to implement.

We believe that our products and procedures are in compliance with all applicable FDA and international regulations. There is no assurance, however, that other products we are developing or products that we may develop in the future will be cleared by the FDA and classified as Class II products, or that additional regulations restricting the sale of our present or proposed products will not be promulgated by the FDA or other foreign agencies. In addition, changes in FDA, or other federal or state health, environmental or safety regulations or their applications could adversely affect our business.

*Other Healthcare Laws*

We are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. These laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it to have committed a violation;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other federal third-party payors that are false or fraudulent. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;

- federal criminal laws that prohibit executing a scheme to defraud any federal healthcare benefit program or making false statements relating to healthcare matters;

- the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information;

- the federal Physician Payment Sunshine Act, which requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the Centers for Medicare & Medicaid Services ("CMS") information related to payments or other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain health care professionals beginning in 2022, and teaching hospitals and ownership and investment interests held by the physicians described above and their immediate family members, and payments or other "transfers of value" to such physician owners; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers; state laws that require pharmaceutical and device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws that require device manufacturers to track and report information related to payments and other "transfers of value" to physicians and other healthcare providers or pricing, marketing expenditures and information; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

Violations of any of the laws described above include civil and criminal penalties, damages, fines, the curtailment or restructuring of an entity's operations, the debarment, suspension or exclusion from federal and state healthcare programs and/or imprisonment.

*Coverage and Reimbursement*

Our profitability and operations are subject to changes in legislative, regulatory and reimbursement policies and decisions as well as changes in private payer reimbursement coverage and payment decisions and policies. Our products are purchased by specialty pharmacies and ambulatory service providers or hospitals that typically bill various third-party payors, 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 and products provided to their patients. The ability of our customers to obtain appropriate coverage and reimbursement 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. Third-party payors are increasingly reducing coverage and reimbursement for certain healthcare services and products and challenging prices charged for healthcare services and products.

*Environmental Health and Safety Laws*

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 fully mechanical pumps as well as other types of pumps. 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.

Competition for infusion devices for new drugs includes a variety of technologies and companies. No single technological approach—autoinjectors, electronic (volumetric pumps), mechanical pumps, needle-free injectors, on-body wearable pumps, pen injectors, and pre-filled syringes—will meet the needs of all or even a majority of drugs. For drugs requiring infusion volumes over 3 mL, the segment most similar to the SCIg drugs currently delivered by the FREEDOM System, the most relevant approaches include mechanical pumps, on-body wearable pumps, and simple electronic pumps. Very few of these systems have been commercialized. Obstacles to their successful commercialization include high costs per infusion, increased environmental impact, complexity for users, and complex mechanisms with multiple failure modes.

**HUMAN CAPITAL RESOURCES**

As of December 31, 2020, we had 101 full time employees and no part time employees. As of December 31, 2020, approximately 67% of the Company's workforce was female and approximately 45% of the Company's employees in managerial roles were female. Approximately 52% were minorities (non-White) in the Company workforce as of December 31, 2020. None of our employees are represented by a collective bargaining agreement.

To help drive consistent execution of our business strategy, including our customer focused philosophy, and support their development, we provide training opportunities to our employees that align with their responsibilities over their career with us. We maintain a dedicated Internet-based learning platform with a broad portfolio of written, audio-visual and interactive enterprise-wide and discipline-specific policy and training materials. This platform includes a library of self-directed courses and virtual, instructor-led programs for employees at all levels of our organization. Managers and supervisors are provided training to help their employees progress in their professional development.

We believe our employees are key to achieving our business objectives. We have COVID-19 prevention protocols in place to minimize the spread of COVID-19 in our workplace. These protocols, which remain in place, meet or exceed the Centers for Disease Control guidelines and where applicable, state mandates.

Our key human capital measures include employee safety, turnover, absenteeism and production. We frequently benchmark our compensation practices and benefits programs against those of comparable industries and in the geographic areas where our facilities are located. We believe that our compensation and employee benefits are competitive and allow us to attract and retain skilled and unskilled labor throughout our organization. Our notable health, welfare and retirement benefits include:

- Company subsidized health insurance
- 401(k) Plan with Company matching contributions
- Paid time off
- Life and disability insurance

We strive to maintain an inclusive environment free from discrimination of any kind, including sexual or other discriminatory harassment. Our employees have multiple avenues available through which inappropriate behavior can be reported, including a confidential hotline. All reports of inappropriate behavior are promptly investigated with appropriate action taken to stop such behavior.

**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 two patents granted in the U.S. and nine patents granted outside the U.S. in 2020. As of December 31, 2020, we had six applications pending in the U.S. and 24 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 "NOTE 9 — COMMITMENTS AND CONTINGENCIES" in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K for details regarding our patent litigation that was settled in 2020.

**EXECUTIVE OFFICERS**

The following table sets forth certain information with respect to our executive officers as of March 22, 2021:

| Name | Age | Position / Held Since |
|---|---|---|
| James M. Beck | 72 | Interim Chief Executive Officer and Director* (since January 2021) |
| Karen Fisher | 55 | Chief Financial Officer, Secretary and Treasurer (since 2015) |
| Manuel Marques | 48 | Chief Operating Officer (since December 2018) |

_____
* Mr. Beck has been a Director since 2018

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

Mr. Beck has more than 40 years of healthcare services and distribution general management experience. Mr. Beck most recently served as Executive Chairman of Medical Specialties Distributors ("MSD"), a leading service solution provider serving the home infusion, home medical equipment, and oncology markets, from 2016 to 2018 and a director from 2007 to 2018. He previously served as President and Chief Executive Officer of MSD from 2007 to 2016. Prior to joining MSD, Jim held various executive and management positions with leading healthcare companies such as American Hospital Supply/Baxter Healthcare, AMSCO International, Spectrum Healthcare, and SHPS Health Management Solutions. Mr. Beck is currently an independent director of Hilco Vision owned by Windjammer Capital.

Ms. Fisher has more than 26 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 24 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.

***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, principally by the FDA, 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 design, development, and manufacturing; testing, , labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, promotion, and distribution of our products; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

In the U.S., our device products are subject to clearance or approval by FDA under the FFDCA. Before we can market a new medical device, or a new use of, new claim for, or significant modification to, an existing product, we must first receive either 510(k) clearance or approval of a PMA application from the FDA, unless an exemption applies. Under the 510(k) process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent," as defined in the statute, to a legally marketed predicate device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. If the manufacturer is unable to demonstrate substantial equivalence to FDA's satisfaction, or if there is no available predicate device, then the manufacturer may be required to seek approval through the PMA application process, which is generally more costly and time consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use. Accordingly, a PMA application typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies.

We cannot guarantee that we will be able to obtain or maintain FDA 510(k) clearance or premarket approval for our new products or enhancements or modifications to existing products (including the use of our FREEDOM System with therapies not covered by the existing FDA clearance), 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 laws and regulations. The FDA and other worldwide regulatory agencies actively monitor compliance with local laws and regulations through review and inspection of design and manufacturing practices, recordkeeping, reporting of adverse events, labeling and promotional practices. The results of these inspections can include inspectional observations on the FDA's Form 483, warning letters, or other forms of enforcement. If the FDA, state or foreign regulatory authorities 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, they could deem our products adulterated or misbranded, and take enforcement action against us. FDA, state and foreign regulatory authorities have broad enforcement powers. Possible enforcement actions include, but are not limited to: temporarily or permanently suspending the sale and/or distribution of 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. In addition, the FDA prohibits device manufacturers from promoting their products for uses and indications other than those set forth in the approved product labeling, and failure to comply with this prohibition 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. 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.

Regulations regarding the development, manufacture and sale of medical devices are evolving and subject to future change, and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. 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. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances or approvals, seizures or recalls of products, physician advisories or other field actions, operating restrictions and/or criminal prosecution. We may also initiate field actions as a result of a failure to strictly comply with our internal quality policies. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products, physician advisories or other field actions, or the withdrawal of product approval by the FDA or by comparable agencies in foreign countries could have a material adverse effect on our business, financial condition or results of operations.

Governmental regulations outside the U.S. have also, and may continue to, become increasingly stringent and common. In the EU, for example, a new MDR was published in 2017 which, when it enters into full force in 2021, 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 device approval, ability to distribute products and criminal sanctions. Future foreign governmental laws and regulations may have a material adverse effect on us.

In addition, exported devices are subject to the regulatory requirements of each country to which the device is exported. Some countries do not have medical device regulations, but in most foreign countries, medical devices are regulated. Frequently, regulatory approval may first be obtained in a foreign country prior to application in the U.S. due to differing regulatory requirements; however, other countries, such as China for example, require approval in the country of origin or legal manufacturer first. Most countries outside of the U.S. require that product approvals be renewed or recertified on a regular basis, generally every four to five years. The renewal or recertification process requires that we evaluate any device changes and any new regulations or standards relevant to the device and conduct appropriate testing to document continued compliance. Where renewal or recertification applications are required, they may need to be renewed and/or approved in order to continue selling our products in those countries. There can be no assurance that we will receive the required approvals for new products or modifications to existing products on a timely basis or that any approval will not be subsequently withdrawn or conditioned upon extensive post market study requirements.

Our global regulatory environment is becoming increasingly stringent and unpredictable, which could increase the time, cost and complexity of obtaining regulatory approvals for our products, as well as the clinical and regulatory costs of supporting those approvals. Several countries that did not have regulatory requirements for medical devices have established such requirements in recent years and other countries have expanded on existing regulations. Certain regulators are exhibiting less flexibility and are requiring local preclinical and clinical data in addition to global data. While harmonization of global regulations has been pursued, requirements continue to differ significantly among countries. In the United Kingdom, for example, the Medicines and Healthcare products Regulatory Agency (MHRA) is responsible for regulating the UK medical device market. With recent changes in the United Kingdom's membership with the European Union, the MHRA has and will continue to impose new regulatory obligations becoming effective in 2021 through 2023, for medical device manufacturers. We expect this global regulatory environment will continue to evolve, which could impact our ability to obtain future approvals for our products or could increase the cost and time to obtain such approvals in the future.

***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.***

As discussed above, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our future products under development.

In fact, 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. In May 2019, the FDA solicited public feedback on its plans to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates, including whether the FDA should publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. The FDA sought input on whether it should consider certain actions, such as whether to sunset certain older devices that were

used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

In September 2019, the FDA finalized a guidance to describe an optional "safety and performance based" premarket review pathway for manufacturers of "certain, well-understood device types" to demonstrate substantial equivalence under the 510(k) clearance pathway, by demonstrating that such device meets objective safety and performance criteria established by the FDA, obviating the need for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to maintain a list of device types appropriate for the "safety and performance-based pathway" and develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance. It is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

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.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

***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. Due to the COVID-19 pandemic, thousands of blood drives have been canceled as community organizations and businesses restrict access to many locations and there are less volunteers resulting in shortages of blood plasma donations. 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. We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances or approvals, seizure of our products, or delay in clearance or approval of future products.

These adverse events could also lead to safety alerts relating to our products or recalls (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. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

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.***

The FDA and other U. S. and non-U.S. government agencies regulate 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 the manufacturing facility in Chester, NY. Products are also stored in storage facilities in the local NY area. Loss or damage to our manufacturing and storage sites 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 construct, approve and register a manufacturing facility, we have entered into a supplier agreement with Command, to assist with current production requirements and 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.***

As of December 31, 2020, we currently have two 6-month options to extend our current lease of our manufacturing facility, which is also our headquarters, through August 2022. Although we believe this facility is sufficient to meet our current, and foreseeable future 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 have been and 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 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.

***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 on whom we depend, and our financial results depend on their purchasing patterns.***

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 the U.S. and two outside the U.S. As of December 31, 2020, these four distributors comprised approximately 69% of our net revenues with one U.S. distributor contributing 51%. Purchasing patterns by these distributors cannot always be predicted and fluctuate from quarter to quarter and year to year based on, among other things, their expectations of customer demand. 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.

***We and our customers are subject to extensive regulation by governments around the world, and if these regulations are not complied with, existing and future operations may be curtailed, and we could be subject to liability.***

Our devices and our customers' drug-device combination products that utilize our products are subject to extensive regulation by governmental authorities in the United States, Europe and other countries, including the FDA. Not only do these regulations present challenges during the regulatory approval process, but after our devices or our customers' drug-device combination products that utilize our products are approved for new indications and placed in the market, numerous regulatory requirements will apply. These include, but are not limited to QSR, labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or "off label" uses, medical device reporting regulations and post-market surveillance regulations, and laws and regulations that govern the development, testing, manufacturing, advertising, marketing and distribution of medical devices, including our devices and our customers' drug-device combination products that utilize our products. The FDA has broad post-market and regulatory enforcement powers.

If our devices are commercialized as part of a drug-delivery combination product we, as the manufacturer of the device component of that combination product, we are subject to unannounced and preapproval inspections by the FDA of our manufacturing facility to determine our compliance with QSR and cGMP.

Failure to comply with applicable regulatory requirements can result in an enforcement action by the FDA or other regulatory authority, which may include any or all of the following sanctions: fines, injunctions, consent decrees and civil penalties, recall or seizure of our products or our customers' drug-device combination products, operating restrictions, partial suspensions or total shutdown of production, refusing our customers' requests for regulatory approvals of their drug-device combination products or new intended uses, as applicable, refusing our requests for regulatory approval of our devices, withdrawing our customers' or our regulatory approvals that may be granted and criminal prosecution.

***The therapeutic efficacy of certain of our customers' drug-device combination products that utilize our device is either unproven in humans or has only been proven in limited circumstances, and we may not be able to successfully develop and sell our products in combination with our customers' drug-device combination products.***

While some of our customers use our products with established, approved drugs, in certain instances, the benefits of those drugs as injectable therapies are either unproven or have only been proven in limited circumstances. Our ability to generate revenue from our products will depend heavily on the successful development, commercialization and sales of drugs included in our customers' drug-device combination products, which is subject to many potential risks. For example, data developed in clinical trials or following the commercialization of drugs included in our customers' drug-device combination products may show that such therapies do not prove to be effective treatments for the targets they are being designed to act against (or as effective as other treatments available). In clinical trials or following commercialization, it may be shown that those drugs interact with human biological systems in unforeseen, ineffective or harmful ways. If those drugs are associated with undesirable side effects or have characteristics that are unexpected, the pharmaceutical companies that make those drugs may need to abandon clinical development or discontinue commercial sales or limit clinical development or sales to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. As a result of these and other risks described herein that are inherent in the development and sale of therapeutic agents, pharmaceutical companies may never successfully develop or successfully commercialize their drugs, or the commercialization of their drugs may be abandoned or severely limited, which may limit our profitability with respect to customers with drug-device combination products including those drugs and our device, and we may not be successful in achieving commercial scale production and sales of our injectable drug delivery systems in combination with certain drugs.

***Certain of the injectable therapies being targeted for use with our products are not approved, but are in various phases of clinical development. These injectable therapies may be independently terminated by their makers prior to submission of a regulatory filing or even after regulatory approval, resulting in the cessation of any revenue associated with that contract or program.***

We work with pharmaceutical and biotechnology companies who are targeting the use of our products with a variety of injectable therapies. Certain of those injectable therapies are not FDA approved, and are in various phases of clinical development. The clinical development of these pipeline therapies can be terminated by their developers at any stage. Furthermore, these pharmaceutical companies could obtain regulatory approval for their injectable therapies, and decide for business reasons not to market and sell their drugs with a drug-device combination product that utilizes our device. Prior investments we have made in manufacturing capacity or research and development will then not result in the generation of revenue that would have previously been anticipated.

***Our commercial success depends upon the attainment of significant market acceptance of drug product candidates to be included in our customers' drug-device combination products that utilize our device, if approved, among physicians, patients, healthcare payers or the medical community.***

Even if pharmaceutical companies obtain regulatory approval for their drug product candidates to be included in our customers' drug-device combination products that utilize our device, their product candidates may not gain sufficient levels of market acceptance among physicians, healthcare payers, patients or the medical community to make them commercially feasible. Market acceptance of our customers' product candidates, if they receive approval, depends on a number of factors, including the:

- efficacy and safety of the product candidates;
- clinical indications for which the product candidates are approved;
- acceptance by physicians, patients and the medical community of the product candidates as a safe and effective treatment;
- potential and perceived advantages of the product candidates over alternative treatments;
- safety of the product candidates seen in a broader patient group;
- prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- timing of market introduction of the product candidates as well as competitive products;
- cost of treatment in relation to alternative treatments;
- availability of coverage and adequate reimbursement and pricing by third party payers and government authorities;
- relative convenience and ease of administration; and
- effectiveness of the pharmaceutical companies' sales and marketing efforts.

If pharmaceutical companies' candidates are approved but fail to achieve market acceptance among physicians, patients or healthcare payers, we may not be able to generate anticipated revenue. This may limit our ability to generate anticipated revenue from our prior investments. Moreover, even if we achieve commercial scale production and sales of our injectable drug delivery systems in combination with certain injectable therapies, the makers of such therapies may face indirect competition from companies who develop and market other brand name, biosimilar or generic injectable therapies as well as alternative treatments and delivery methods that compete with our customers' drug-device combination products that utilize our products, which may have a material adverse effect on our results of operations, our financial condition and/or cash flows.

***Most brand name injectable therapies will face future competition from generic or biosimilar therapies, which could significantly reduce their commercial viability.***

Brand name injectable therapies will usually become exposed to competition from generic or biosimilar rivals at some time after their regulatory approval and commercial launch. The average selling price and market share of brand name injectable therapies can be significantly diminished following the introduction of generic or biosimilar competition. These factors may result in our customers using our products with their brand name injectable therapies seeking to withdraw such injectable therapy from the market, or change market tactics in a way that makes the use of our products cost prohibitive. This may result in the termination of supply contracts and the significant loss of revenue.

***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 needle set subassemblies for our products. We do not have long-term agreements in place with all of these suppliers, although we entered into a long-term agreement with our needle set subassembly supplier in 2020. Due to regulatory requirements relating to the qualification of suppliers, we may not be able to establish additional or replacement sources on a timely basis or without excessive cost.

Additionally, the sourcing of our needle sets and tubing products with Command are manufactured in Nicaragua. There could be a delay in providing the products timely due to their climate and international boundaries.

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 and natural gas 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.

These laws and regulations, among other things, constrain our business, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers of our products. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, healthcare providers and entities may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly to respond to. If our operations are found to be in violation of any of the healthcare laws or regulations described above or any other healthcare regulations that apply to us, we may be subject to penalties, including administrative, civil and criminal penalties, damages, fines, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm, disgorgement and the curtailment or restructuring of our operations. 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.

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

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

***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 additional capital in the future in order to execute our business plan and help us fund the development and commercialization of new products. We raised approximately $26.6 million from the equity offering in 2020.

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 evolving management structure and executive team.***

We have made a number of changes to our management structure throughout the organization since July 2018 and have filled a number of these positions while we are actively recruiting to fill others. In January 2021, we appointed an interim CEO to serve during the search process for a CEO. 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, 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. 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. 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.

Prior to the U.S. presidential election, President Biden proposed an increase in the U.S. corporate income tax rate from 21% to 28%, the creation of a 10% penalty on certain imports and a 15% minimum tax on worldwide book income.

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 14% of our net sales in the year ended December 31, 2020 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.

***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. On January 31, 2020, the UK withdrew from the EU. Under the withdrawal agreement agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020 (the "Transition Period") during which EU rules continued to apply. During the Transition Period, negotiations between the UK and the EU continued in relation to the future customs and trading relationship between the UK and the EU following the expiration of the Transition Period. Due to the current COVID-19 global pandemic, negotiations between the UK and the EU scheduled have either been postponed or occurred in a reduced forum via video conference. However, on December 24, 2020, the negotiators from the EU and UK reached an agreement on a new partnership. This agreement sets out the rules that apply between the EU and the UK as of January 1, 2021. 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 or triggering event 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. Most of 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 27% and 14%, 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, directors and consultants. 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. We may issue equity-based compensation outside of our stock option plan as inducement for new employees. If our Board elects to issue additional stock options or other equity-based compensation, our stockholders may experience additional dilution, which could cause our stock price to decline. Because stock options granted under our stock option 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 $3.78 per share to $12.42 per share. Our stock price is subject to wide fluctuations in response to a variety of factors, including:

- quarterly variations in operating results;
- announcement of new products or customers by our competitors;
- changes in financial estimates by securities analysts;
- trading volume on the Nasdaq Capital Market;
- announcements related to litigation;
- 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 the listing standards of the Nasdaq Capital Market, 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 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.***

12% and 7% 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 38% of our outstanding common stock as of December 31, 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. There can be no assurance that we will continue to meet all of these requirements, or any other requirement in the future. If we fail to meet the requirements, including maintaining minimum price, levels of stockholders' equity or market values of our common stock, 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 four of the six additional renewal options for September 1, 2019 through August 31, 2021. In January 2021, the Company exercised the remaining two renewal options, extending the lease through August 31, 2022.

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 a new location.

**ITEM 3. LEGAL PROCEEDINGS**

For information regarding legal proceedings, refer to "NOTE 9 — COMMITMENTS AND CONTINGENCIES" in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K.

**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**

**Market Information**

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.

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, and 2,000,000 are designated preferred stock. As of December 31, 2020, 43,259,617 shares of our common stock were issued and outstanding and there were approximately 585 stockholders of record. There were no shares of preferred stock issued and outstanding.

**Sales of Unregistered Securities**

Effective January 1, 2021, each non-employee director of the Company (other than the Chairman of the Board) and Board advisor are eligible to receive of $75,000 annually, to be paid quarterly $12,500 in cash and $6,250 in common stock. The Chairman of the Board is eligible to receive $100,000 annually, to be paid quarterly $12,500 in cash and $12,500 in common stock.

Prior to January 1, 2021, each non-employee director of the Company was eligible to receive $50,000 annually (effective January 1, 2019), plus $10,000 for chairing a Board committee (effective February 20, 2019), all to be paid quarterly half in cash and half in common stock. The Chairman of the Board was eligible to receive an additional $50,000 annually (effective October 1, 2019), all to be paid in common stock. All payments were and are pro-rated for partial service. The Company issued an aggregate 32,181 shares of common stock to its non-employee directors during the year ended December 31, 2020, respectively.

On January 7, 2020, Manuel Marques, the Company's Chief Operating Officer, exercised options held by him for an aggregate 175,000 shares of common stock for an aggregate exercise price of $85,500. Also, on December 15, 2020, Mr. Marques exercised options held by him for an aggregate 137,500 shares of common stock through the delivery of previously owned shares having an aggregate fair market value of $149,000.

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

On May 20, 2020, the Company entered into a Settlement Agreement with EMED Technologies Corporation ("EMED") to settle all claims in connection with all pending litigation matters between them. Pursuant to the Settlement Agreement, the Company issued to EMED (i) 95,238 restricted stock units, which vested on May 21, 2020 and 95,238 restricted stock units, which vested on January 1, 2021, and (ii) an option to purchase up to 400,000 shares of the Company's common stock at an exercise price of $11.21 per share prior to February 1, 2021, which was not exercised.

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.

**Issuer Purchases of Equity Securities**

On November 16, 2020, the Company announced that its Board of Directors had authorized a stock repurchase program under which the Company may purchase up to $10.0 million of its outstanding common stock through December 31, 2021. As of December 31, 2020, the Company had purchased 683,271 shares since inception of this plan.

The following table sets forth information regarding our repurchases of securities for each calendar month in the three months ended December 31, 2020:

| Period | Total Number of Shares Purchased | Average Price Paid per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs | Maximum Number (or Approximate Dollar Value) of Shares that May Yet Be Purchased Under the Plans or Programs |
|---|---|---|---|---|
| October 1 to 31, 2020 | — | $ 0.00 | — | $ — |
| November 1 to 30, 2020 | 189,050 | 4.56 | 189,050 | 9,135,964 |
| December 1 to 31, 2020 | 494,221 | 5.32 | 494,221 | $ 6,500,642 |
| Total | 683,271 | $ 5.11 | 683,271 | |

**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**

The Company designs, manufactures and markets proprietary portable and innovative medical devices primarily for the ambulatory infusion market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international standards for quality system management.

The Company had several significant accomplishments in 2020 including (i) record net sales; (ii) entering into an agreement with Command Medical Products, Inc. ("Command") to manufacture and supply the Company's subassemblies, needle sets and tubing products for supply continuity and cost savings; (iii) a non-cash no fault litigation settlement, which eliminates the associated distraction and litigation expenses related to that litigation going forward and (iv) the completion of a capital raise of net $26.6 million.

The Company remains committed to growth over the long-term, as we make short-term investments to execute on our strategic initiatives. In February 2019, the Company's Board of Directors approved a strategic plan through 2022, including certain financial goals. While those financial goals have not changed, given the results of the past year, the likely timing of attaining those goals has been pushed out. The Board plans to revisit the strategic plan with the Company's new Chief Executive Officer, to align the plan with her growth strategies and will update shareholders accordingly. Any strategic plan and related financial goals should not be relied upon as a predictor of future results. The Company's primary areas of focus for 2021 are expected to include (i) continued focus on improving the customer experience; (ii) continued research and development efforts to introduce compelling products into the markets we serve; (iii) expansion of sales into other drug therapies, both existing and new and expanded presence in international markets; (iv) the implementation of secondary sourcing of our needle and tubing sets to Command and (v) completion of our search for a new manufacturing facility and corporate headquarters.

KORU Medical continues to monitor its operations and government recommendations and has made modifications to its normal operations because of the COVID-19 pandemic, including requiring most of its non-production related team members to work remotely or on a staggered work shift. The Company has continued to maintain a manufacturing operational capacity at its manufacturing facility located in Chester, New York, and has instituted heightened cleaning and sanitization standards and several health and safety protocols and procedures to safeguard its team members who do continue to report in person. Until the duration of the pandemic is known, we cannot predict the effects the pandemic may have on our business, in particular with respect to demand for our products, our strategy, and our prospects, the effects on our customers, or the impact on our financial results. For example, our future net sales growth may continue to be impacted due to fewer new prescriptions for individuals with Primary Immune Deficiency Disease ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP") as a result of patients not seeking care during the pandemic.

Our revenues derive from three business sources: (i) domestic core, (ii) international core, and (iii) novel therapies. Our core revenues include sales of our products for the delivery of SCIg to treat PIDD, CIDP, and other disease states that are not included in novel therapies. Novel therapies currently include revenues from clinical trials.

Total net sales increased $1.0 million or 4.4% for the year ended December 31, 2020 as compared to the prior year period. The increase was due principally to an increase in domestic core product sales volume, as well as higher domestic novel therapies of $0.8 million. We believe the increase in domestic core product sales volume reflects growth in diagnosis of PIDD and CIDP (pre any COVID-19 impact to patient starts). Offsetting the favorable impact on net sales from the domestic core product sales volume increases in 2020 were higher allowances, which include (i) rebates resulting from the net impact of pricing increases at our largest distributor in the second half of 2019, and (ii) pricing decreases and growth rebates to secure our contractual position with several large customers in 2020. Further increasing allowances were payment discounts and distribution fees at our largest distributor under new contract terms entered into in the fourth quarter of 2019.

Our inventory position grew from $2.4 million at December 31, 2019 to $6.8 million at December 31, 2020 mostly to ensure timely order fulfillment as we transition manufacturing of our needle sets and tubing products for supply continuity to Command. As transition is completed, this inventory is expected to convert to a source of cash in the future.

**RESULTS OF OPERATIONS**

**Year Ended December 31, 2020 compared to Year Ended December 31, 2019**

***Net Sales***

The following table summarizes our net sales for the years ended December 31, 2020 and 2019:

| | Years Ended December 31, | | Change from Prior Year | | % of Net Sales | |
|---|---|---|---|---|---|---|
| | 2020 | 2019 | $ | % | 2020 | 2019 |
| **Net Sales** | | | | | | |
| Domestic Core | $ 18,895,923 | $ 18,458,183 | $ 437,740 | 2.4% | 78.2% | 79.7% |
| Novel Therapies | 1,782,530 | 1,009,605 | 772,925 | 76.6% | 7.3% | 4.3% |
| Total Domestic | 20,678,453 | 19,467,788 | 1,210,665 | 6.2% | 85.5% | 84.0% |
| | | | | | | |
| International Core | 3,368,519 | 3,685,910 | (317,391) | (8.6%) | 13.9% | 16.0% |
| Novel Therapies | 129,476 | 8,923 | 120,553 | 1,351.0% | 0.6% | 0.0% |
| Total International | 3,497,995 | 3,694,833 | (196,838) | (5.3%) | 14.5% | 16.0% |
| **Total** | $ 24,176,448 | $ 23,162,621 | $ 1,013,827 | 4.4% | | |

Total net sales increased $1.0 million or 4.4% for the year ended December 31, 2020 as compared to the prior year period. The increase was due principally to an increase in domestic core product sales volume, as well as higher domestic novel therapies of $0.8 million. We believe the increase in domestic core product sales volume reflects growth in diagnosis of PIDD and CIDP (pre any COVID-19 impact to patient starts). Offsetting the favorable impact on net sales from the domestic core product sales volume increases in 2020 were higher allowances, which include (i) rebates resulting from the net impact of pricing increases at our largest distributor in the second half of 2019, and (ii) pricing decreases and growth rebates to secure our contractual position with several large customers in 2020. Further increasing allowances were payment discounts and distribution fees at our largest distributor under new contract terms entered into in the fourth quarter of 2019.

***Gross Profit***

Our gross profit for the years ended December 31, 2020 and 2019 is as follows:

| | Years Ended December 31, | | Change from Prior Year | |
|---|---|---|---|---|
| | 2020 | 2019 | $ | % |
| Gross Profit | $ 14,936,086 | $ 14,853,810 | $ 82,276 | 0.6% |
| Stated as a Percentage of Net Sales | 61.8% | 64.1% | | |

Gross profit increased $0.1 million or 0.6% for the year ended December 31, 2020, compared to the same period last year reflecting net sales growth described above as well as favorable production variances. Gross profit percentage of 61.8% for the year ended December 31, 2020 was negatively impacted by higher allowances as described above, overtime costs related to COVID-19 absenteeism and an obsolescence reserve resulting from a discontinued product line, compared to the year ended December 31, 2019 of 64.1%.

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

Our selling, general and administrative, litigation and research and development costs for the years ended December 31, 2020 and 2019 are as follows:

| | Years Ended December 31, | | Change from Prior Year | |
|---|---|---|---|---|
| | 2020 | 2019 | $ | % |
| Selling, general and administrative | $ 12,028,309 | $ 9,771,744 | $ 2,256,565 | 23.1% |
| Litigation | 2,447,213 | 3,415,683 | (968,470) | (28.4%) |
| Research and development | 1,296,754 | 740,475 | 556,279 | 75.1% |
| | $ 15,772,276 | $ 13,927,902 | $ 1,844,374 | 13.2% |
| Stated as a Percentage of Net Sales | 65.2% | 60.1% | | |

Selling, general and administrative expenses increased $2.3 million, or 23.1%, for the year ended December 31, 2020 compared to the same period last year, due to an increase of $1.2 million of higher salary and related benefits, and recruiting fees. Also contributing to the increase were consulting fees of $0.8 million related to marketing, regulatory and strategic initiatives, as well as increased director fees and higher insurance premiums related to our directors' and officers' insurance policy of $0.5 million and other miscellaneous expenses of $0.3 million. Offsetting the increase were lower trade show and travel expenses of $0.5 million as a result of COVID-19 related travel restrictions.

Litigation fees decreased approximately $1.0 million compared to the same period last year due primarily to the negotiation of and entry into a litigation settlement agreement reached with EMED Technologies Corporation ("EMED") in May 2020 resulting in a non-cash expense of $2.2 million.

Research and development expenses increased $0.6 million for the year ended December 31, 2020 compared with the same period last year mostly due to increased salary and related benefits due to higher headcount and additional testing as we continue our development initiatives.

***Depreciation and amortization***

For the year ended December 31, 2020, depreciation and amortization expense increased approximately $0.1 million, or 23.0%, to $0.4 million compared with the same period last year. We continued to invest in capital assets, mostly related to manufacturing and computer equipment.

***Net (Loss)/Income***

| | Years Ended December 31, | | Change from Prior Year | |
|---|---|---|---|---|
| | 2020 | 2019 | $ | % |
| Net (Loss)/Income | $ (1,212,063) | $ 564,349 | $ (1,776,412) | (314.8%) |
| Stated as a Percentage of Net Sales | (5.0%) | 2.4% | | |

Our net loss for the year ended December 31, 2020 was $1.2 million, as compared to net income of $0.6 million for the year ended December 31, 2019, driven by the EMED settlement charge of $2.2 million and higher selling, general and administrative expenses of $2.3 million.

**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 (loss)/ income) before interest, income tax expense, depreciation and amortization, discontinued product expense, reorganization charges, litigation expenses including stock-based settlement expense, manufacturing initiative and stock-based compensation expenses. Prior to January 1, 2020, discontinued product expense and manufacturing initiative expenses were not included in our definition of Adjusted EBITDA. We believe that Adjusted EBITDA is used by investors and other users of our financial statements as a supplemental financial measure that, when viewed with our GAAP results and the accompanying reconciliation, we believe 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:** | **Years Ended December 31,** | |
|---|---|---|
| | **2020** | **2019** |
| GAAP Net (Loss)/Income | $ (1,212,063) | $ 564,349 |
| Income Tax Expense | 17,800 | 132,069 |
| Depreciation and Amortization | 418,595 | 340,229 |
| Interest Income, Net | (42,395) | (80,663) |
| Reorganization Charges | 95,700 | 354,926 |
| Discontinued Product Expense | 70,859 | — |
| Litigation | 2,447,213 | 3,415,683 |
| Manufacturing Initiative Expenses | 246,527 | 230,668 |
| Stock-based Compensation Expense | 1,618,732 | 1,204,844 |
| Non-GAAP Adjusted EBITDA | $ 3,660,968 | $ 6,162,105 |

*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, senior management and changes to the Board of Directors 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.

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

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

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

*Stock-based Compensation Expense.* We have excluded the effect of stock-based compensation expense in calculating our non-GAAP Adjusted EBITDA measure. We record non-cash compensation expense related to grants of options for executives, employees and consultants, and grants of restricted shares to our board. 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.

**LIQUIDITY AND CAPITAL RESOURCES**

Our principal source of liquidity is our cash of $27.3 million as of December 31, 2020, which includes the net proceeds from the 2020 capital raise totaling $26.6 million. In response to concerns about the potential impact of COVID-19, the Company elected to draw $3.5 million during the three months ended June 30, 2020, the full amount available on its line of credit, and paid it back during the three months ended September 30, 2020. Our principal source of operating cash inflows is from sales of our products to customers. Our principal cash outflows relate to the purchase and production of inventory, related costs, selling, general and administrative expenses. In 2020, the Company also purchased 683,271 shares of its common stock outstanding for $3.5 million under its stock repurchase program, pursuant to which the Company may purchase up to $10.0 million of its outstanding common stock through December 31, 2021.

Our inventory position grew from $2.4 million at December 31, 2019 to $6.8 million at December 31, 2020 mostly to ensure timely order fulfillment as we transition manufacturing of our needle sets and tubing products for supply continuity to Command. As transition is completed, this inventory is expected to convert to a source of cash in the future.

***Cash Flows***

The following table summarizes our cash flows:

| | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|
| Net cash (used in)/provided by operating activities | $ (743,323) | $ 320,620 |
| Net cash (used in)/provided by investing activities | $ (1,036,152) | $ 1,310,209 |
| Net cash provided by financing activities | $ 23,223,832 | $ 501,297 |

***Operating Activities***

Net cash used in operating activities of $0.7 million for the year ended December 31, 2020 was mostly attributable to non-cash charges for stock-based compensation and litigation settlement expense of $2.9 million, and an increase in accrued expenses and accrued payroll of $1.4 million, driven by the litigation settlement with EMED and customer rebates. Further adding to the increase was an increase in depreciation and amortization of $0.4 million and a decrease in accounts receivable of $0.7 million due to timing of collections. Offsetting these were primarily working capital changes which include an increase in inventory of $4.4 million as we built inventory to keep pace with sales growth and to ensure timely order fulfillment as we transition manufacturing to Command, an increase in prepaid expenses and other assets of $0.4 million relating to increased insurance premiums, and a decrease in accrued tax liability of $0.2 million resulting from book to tax differences related to stock option expense.

Net cash provided by operating activities of $0.3 million for the year ended December 31, 2019 resulted from non-cash charges for stock-based compensation of $1.2 million, depreciation and amortization of long-lived tangible and intangible assets 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.

***Investing Activities***

Our net cash used in investing activities of $1.0 million for the year ended December 31, 2020, was primarily for capital expenditures for research and development and strategic initiatives. 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.

***Financing Activities***

The $23.2 million provided by financing activities for the year ended December 31, 2020 is from the $26.6 million capital raise, net of expenses, and $0.1 million from options exercised, offset against the repurchase of the Company's common stock outstanding of $3.5 million. 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.

See "NOTE 11 — DEBT OBLIGATIONS" for further detail regarding the promissory note and loan agreement, and "NOTE 12 — EQUITY" regarding the equity offering in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K. Also, see "NOTE 5 — STOCK-BASED COMPENSATION" for further detail regarding the EMED settlement.

We believe that as of December 31, 2020, cash on hand and cash expected to be generated from future operating activities will be sufficient to fund our operations, including further research and development and capital expenditures, for the next 12 months.

***Debt and Borrowing Capacity***

Refer to "NOTE 11 — DEBT OBLIGATIONS" in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K for further details regarding debt.

**COMMITMENTS AND CONTRACTUAL OBLIGATIONS**

***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 has exercised four of the six additional renewal options through August 31, 2021. In January 2021, the Company exercised the remaining two renewal options, extending the lease through August 31, 2022.

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.

Refer to "NOTE 6 – LEASES" in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K for further details regarding our operating and finance leases.

**SIGNIFICANT ACCOUNTING POLICIES AND CRITICAL ACCOUNTING ESTIMATES**

The preparation of financial statements in conformity with generally accepted accounting principles of the United States ("GAAP") requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures of contingent liabilities in the financial statements and accompanying notes. The SEC has defined a company's critical accounting policies as the ones that are most important to the portrayal of the company's financial condition and results of operations, and which require the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified some of our more critical accounting estimates below. We also have other key accounting policies, which involve the use of estimates, judgments, and assumptions that are significant to understanding our results. For additional information, see "NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES" in the accompanying "Notes to Financial Statements" appearing in this

Annual Report on Form 10-K. Although we believe that our estimates, assumptions, and judgments are reasonable, they are based upon information presently available. Actual results may differ significantly from these estimates under different assumptions, judgments, or conditions.

***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 growth rebates are variable consideration and are recorded as a reduction of revenue in the same period the related sales are recorded or when it is probable the annual growth target will be achieved. Rebates are provided to distributors for the difference in selling price to distributor and pricing specified to select customers.

The Company established an allowance for charging off uncollectible trade accounts receivable that have both of the following characteristics: (a) They have a contractual maturity of one year or less, (b) They arose from the sale of goods or services.

***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.

We maintain reserves for excess and obsolete inventory resulting from the potential inability to sell certain products at prices in excess of current carrying costs. We make estimates regarding the future recoverability of the costs of these products and record provisions based on historical experience, expiration of sterilization dates and expected future trends. If actual product life cycles, product demand or acceptance of new product introductions are less favorable than projected by management, additional inventory write downs may be required, which could unfavorably affect future operating results.

**ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED**

Refer to "NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES" in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K.

**ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED**

Refer to "NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES" in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K.

**ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Not applicable.

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

**REPRO MED SYSTEMS, INC.**
**INDEX TO FINANCIAL STATEMENTS**

**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, 2020 and 2019, the related statements of operations, stockholders' equity, and cash flows for years then ended, and the related notes (collectively, 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, 2020, and 2019, and the results of its operations and its cash flows for the years then ended, 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 23, 2021

**REPRO MED SYSTEMS, INC.**
**BALANCE SHEETS**

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| CURRENT ASSETS | | |
| Cash and cash equivalents | $ 27,315,286 | $ 5,870,929 |
| Accounts receivable less allowance for doubtful accounts of $24,469 and $32,645 for December 31, 2020, and December 31, 2019, respectively | 2,572,954 | 3,234,521 |
| Inventory | 6,829,772 | 2,388,477 |
| Prepaid expenses | 807,780 | 387,396 |
| TOTAL CURRENT ASSETS | 37,525,792 | 11,881,323 |
| Property and equipment, net | 1,167,623 | 611,846 |
| Intangible assets, net of accumulated amortization of $199,899 and $288,967 at December 31, 2020 and December 31, 2019, respectively | 843,587 | 807,135 |
| Operating lease right-of-use assets | 236,846 | 373,734 |
| Deferred income tax assets, net | 125,274 | 188,241 |
| Other assets | 19,812 | 19,582 |
| TOTAL ASSETS | $ 39,918,934 | $ 13,881,861 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| CURRENT LIABILITIES | | |
| Accounts payable | $ 624,920 | $ 572,656 |
| Accrued expenses | 2,610,413 | 1,296,612 |
| Accrued payroll and related taxes | 287,130 | 190,265 |
| Accrued tax liability | — | 204,572 |
| Finance lease liability – current | 2,646 | 5,296 |
| Operating lease liability – current | 141,293 | 136,888 |
| TOTAL CURRENT LIABILITIES | 3,666,402 | 2,406,289 |
| Finance lease liability, net of current portion | — | 2,646 |
| Operating lease liability, net of current portion | 95,553 | 236,846 |
| TOTAL LIABILITIES | 3,761,955 | 2,645,781 |
| Commitments and contingencies (Refer to Note 9) | | |
| STOCKHOLDERS' EQUITY | | |
| Common stock, $0.01 par value, 75,000,000 shares authorized, 46,680,119 and 42,239,788 shares issued; 43,259,617 and 39,502,557 shares outstanding at December 31, 2020, and December 31, 2019, respectively | 466,801 | 422,398 |
| Additional paid-in capital | 35,880,986 | 6,293,069 |
| Treasury stock, 3,420,502 shares and 2,737,231 shares at December 31, 2020 and December 31, 2019, respectively, at cost | (3,843,562) | (344,204) |
| Retained earnings | 3,652,754 | 4,864,817 |
| TOTAL STOCKHOLDERS' EQUITY | 36,156,979 | 11,236,080 |
| TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY | $ 39,918,934 | $ 13,881,861 |

See accompanying Notes to Financial Statements.

**REPRO MED SYSTEMS, INC.**
**STATEMENTS OF OPERATIONS**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| NET SALES | $ 24,176,448 | $ 23,162,621 |
| Cost of goods sold | 9,240,362 | 8,308,811 |
| Gross Profit | 14,936,086 | 14,853,810 |
| | | |
| OPERATING EXPENSES | | |
| Selling, general and administrative | 12,028,309 | 9,771,744 |
| Litigation | 2,447,213 | 3,415,683 |
| Research and development | 1,296,754 | 740,475 |
| Depreciation and amortization | 418,595 | 340,229 |
| Total Operating Expenses | 16,190,871 | 14,268,131 |
| | | |
| Net Operating (Loss)/Profit | (1,254,785) | 585,679 |
| | | |
| Non-Operating Income | | |
| Gain/(Loss) on foreign currency exchange | 1,536 | (17,754) |
| Gain on disposal of fixed assets | 16,591 | 47,830 |
| Interest income, net | 42,395 | 80,663 |
| TOTAL OTHER INCOME | 60,522 | 110,739 |
| | | |
| (LOSS)/INCOME BEFORE TAXES | (1,194,263) | 696,418 |
| | | |
| Income tax expense | (17,800) | (132,069) |
| | | |
| NET (LOSS)/INCOME | $ (1,212,063) | $ 564,349 |
| | | |
| NET (LOSS)/INCOME PER SHARE | | |
| Basic | $ (0.03) | $ 0.01 |
| Diluted | $ (0.03) | $ 0.01 |
| | | |
| WEIGHTED AVERAGE COMMON SHARES OUTSTANDING | | |
| Basic | 41,929,736 | 38,778,074 |
| Diluted | 41,929,736 | 39,061,310 |

See accompanying Notes to Financial Statements.

**REPRO MED SYSTEMS, INC.**
**STATEMENTS OF STOCKHOLDERS' EQUITY**

| | Common Stock | | Additional Paid-in | Retained | Treasury | Total Stockholders' |
|---|---|---|---|---|---|---|
| | Shares | Amount | Capital | Earnings | Stock | Equity |
| 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 |
| Cancellations of common stock | (2,000) | (20) | (2,800) | — | — | (2,820) |
| Issuance upon options exercised | 160,000 | 1,600 | 57,300 | — | — | 58,900 |
| Issuance upon warrants exercised | 1,000,000 | 10,000 | 440,000 | — | — | 450,000 |
| Net income | — | — | — | 564,349 | — | 564,349 |
| BALANCE, DECEMBER 31, 2019 | 42,239,788 | $ 422,398 | $ 6,293,069 | $ 4,864,817 | $ (344,204) | $ 11,236,080 |
| Issuance of stock-based compensation | 32,181 | 322 | 240,638 | — | — | 240,960 |
| Compensation expense related to stock options | — | — | 1,377,772 | — | — | 1,377,772 |
| Litigation settlement options | — | — | 347,008 | — | — | 347,008 |
| Litigation settlement share issuance | 95,238 | 952 | 937,142 | — | — | 938,094 |
| Repurchases of shares | — | — | — | — | (3,499,358) | (3,499,358) |
| Issuance upon options exercised | 719,162 | 7,191 | 88,689 | — | — | 95,880 |
| Capital raise | 3,593,750 | 35,938 | 26,596,668 | — | — | 26,632,606 |
| Net loss | — | — | — | (1,212,063) | — | (1,212,063) |
| BALANCE, DECEMBER 31, 2020 | 46,680,119 | $ 466,801 | $ 35,880,986 | $ 3,652,754 | $ (3,843,562) | $ 36,156,979 |

See accompanying Notes to Financial Statements.

**REPRO MED SYSTEMS, INC.**
**STATEMENTS OF CASH FLOWS**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| CASH FLOWS FROM OPERATING ACTIVITIES | | |
| Net (Loss)/Income | $ (1,212,063) | $ 564,349 |
| Adjustments to reconcile net (loss)/income to net cash (used in)/provided by operating activities: | | |
| Stock-based compensation expense | 1,618,732 | 1,204,844 |
| Stock-based litigation settlement expense | 1,285,102 | — |
| Depreciation and amortization | 418,595 | 340,229 |
| Gain on disposal of fixed assets | (16,591) | (47,830) |
| Deferred capital gain – building lease | — | (3,763) |
| Deferred income taxes | 62,967 | (186,775) |
| Provision for doubtful accounts | (8,176) | (4,855) |
| Abandonment of intangible assets | 41,919 | — |
| Changes in operating assets and liabilities: | | |
| Decrease/(Increase) in accounts receivable | 669,743 | (1,803,812) |
| Increase in inventory | (4,441,295) | (284,598) |
| Increase in prepaid expenses and other assets | (420,614) | (140,805) |
| Increase in accounts payable | 52,264 | 119,158 |
| Increase/(Decrease) in accrued payroll and related taxes | 96,865 | (231,449) |
| Increase in accrued expenses | 1,313,801 | 607,963 |
| (Decrease)/Increase in accrued tax liability | (204,572) | 187,964 |
| NET CASH (USED IN)/PROVIDED BY OPERATING ACTIVITIES | (743,323) | 320,620 |
| | | |
| CASH FLOWS FROM INVESTING ACTIVITIES | | |
| Purchases of property and equipment | (920,604) | (201,174) |
| Purchases of intangible assets | (140,548) | (224,365) |
| Proceeds from certificates of deposit | — | 1,517,927 |
| Proceeds from disposal of property and equipment | 25,000 | 217,821 |
| NET CASH (USED IN)/PROVIDED BY INVESTING ACTIVITIES | (1,036,152) | 1,310,209 |
| | | |
| CASH FLOWS FROM FINANCING ACTIVITIES | | |
| Proceeds from issuance of equity | 26,728,486 | 508,900 |
| Purchase of treasury stock | (3,499,358) | — |
| Borrowings from indebtedness | 4,976,508 | — |
| Payments on indebtedness | (4,976,508) | — |
| Payments on finance lease liability | (5,296) | (4,783) |
| Payment for cancelled shares | — | (2,820) |
| NET CASH PROVIDED BY FINANCING ACTIVITIES | 23,223,832 | 501,297 |
| | | |
| NET INCREASE IN CASH AND CASH EQUIVALENTS | 21,444,357 | 2,132,126 |
| CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR | 5,870,929 | 3,738,803 |
| CASH AND CASH EQUIVALENTS, END OF YEAR | $ 27,315,286 | $ 5,870,929 |
| | | |
| Supplemental Information | | |
| Cash paid during the years for: | | |
| Interest | $ 27,736 | $ 342 |
| Income taxes | $ 321,983 | $ 130,879 |
| | | |
| Schedule of Non-Cash Investing and Financing Activities: | | |
| Non-cash equity issuance for the EMED Settlement | $ 938,094 | $ — |

See accompanying Notes to Financial Statements.

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

### NATURE OF OPERATIONS

REPRO MED SYSTEMS, INC. (the "Company," "KORU Medical," "KORU," "we," "us" or "our") designs, manufactures and markets proprietary portable and innovative medical devices primarily for the ambulatory infusion market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international standards for quality system management. The Company operates as one segment.

### BASIS OF PRESENTATION

We prepare our financial statements and accompanying notes in accordance with accounting principles generally accepted in the United States of America ("GAAP"). Certain prior year amounts have been reclassified to conform to the current year presentation in our Financial Statements.

### 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.

### 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.

We maintain reserves for excess and obsolete inventory resulting from the potential inability to sell certain products at prices in excess of current carrying costs. We make estimates regarding the future recoverability of the costs of these products and record provisions based on historical experience, expiration of sterilization dates and expected future trends. If actual product life cycles, product demand or acceptance of new product introductions are less favorable than projected by management, additional inventory write downs may be required, which could unfavorably affect future operating results.

### INTANGIBLE ASSETS

Certain of our identifiable intangible assets, including patents and trademarks, are amortized using the straight-line method over their estimated useful lives which range from 6 to 20 years. All of our intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Our management is responsible for determining if impairment exists and considers various factors when making these determinations. Amortization expense related to intangible assets for the years ended December 31, 2020 and 2019 was $62,177 and $49,388, respectively.

The estimated amortization expense for the succeeding years for the intangible assets is approximately:

| Year Ending December 31, | |
|---|---|
| 2021 | $ 59,724 |
| 2022 | 59,679 |
| 2023 | 58,886 |
| 2024 | 58,722 |
| 2025 | 58,138 |
| Thereafter | 548,438 |
| Total amortization expense | $ 843,587 |

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.

PROPERTY AND EQUIPMENT

Property and equipment are stated at original acquisition cost less accumulated depreciation. Additions and improvements are capitalized which increase the value or extend the life of an asset, while maintenance and repair costs are expensed as incurred. When assets are retired or otherwise disposed, the cost and related accumulated depreciation or amortization is removed from the respective accounts and any resulting gain or loss is included in income. Depreciation and amortization are calculated on the straight-line basis over the estimated useful lives of the assets which generally range from 3-10 years for furniture and office equipment, 3-12 years for manufacturing equipment and tooling and shorter of the lease term or their estimated useful lives for leasehold improvements. Depreciation and amortization expense related to property and equipment for the years ended December 31, 2020 and 2019 was $356,418 and $290,841, respectively.

STOCK-BASED COMPENSATION

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

NET INCOME PER COMMON SHARE

Basic earnings per share are computed on the weighted average of common shares outstanding during each year. Diluted earnings per share includes only an increase in the weighted average shares by the common shares issuable upon exercise of stock options. See "NOTE 5 — STOCK-BASED COMPENSATION" for further detail.

| | Years Ended | |
|---|---|---|
| | December 31, 2020 | December 31, 2019 |
| Net (loss)/income | $ (1,212,063) | $ 564,349 |
| Weighted Average Outstanding Shares: | | |
| Outstanding shares | 41,929,736 | 38,778,074 |
| Option shares includable | —(a) | 283,236 |
| | 41,929,736 | 39,061,310 |
| Net (loss)/income per share | | |
| Basic | $ (0.03) | $ 0.01 |
| Diluted | $ (0.03) | $ 0.01 |

(a) Option shares of 239,935 were not included as the impact is anti-dilutive.

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates. Important estimates include but are not limited to asset lives, valuation allowances, inventory valuation, and accruals.

REVENUE RECOGNITION

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

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

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

Provisions for distributor pricing and annual customer growth rebates are variable consideration and are recorded as a reduction of revenue in the same period the related sales are recorded or when it is probable the annual growth target will be achieved. Rebates are provided to distributors for the difference in selling price to distributor and pricing specified to select customers.

The Company established an allowance for charging off uncollectible trade accounts receivable that have both of the following characteristics: (a) They have a contractual maturity of one year or less, (b) They arose from the sale of goods or services.

The following table summarizes net sales by geography for the years ended December 31, 2020 and 2019:

| | Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Sales** | | |
| Domestic | $ 20,678,453 | $ 19,467,788 |
| International | 3,497,995 | 3,694,833 |
| **Total** | $ 24,176,448 | $ 23,162,621 |

LEASES

In February 2016, the FASB issued a standard related to leases to increase transparency and comparability among organizations by requiring the recognition of right-of-use ("ROU") assets and lease liabilities on the balance sheet. Most prominent among the changes in the standard is the recognition of ROU assets and lease liabilities by the Company for those leases classified as operating leases under current GAAP, while our accounting for capital leases remains substantially unchanged. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard became effective for us on January 1, 2019. The standard had a material impact on our balance sheets but did not have a material impact on our statements of operations. See "NOTE 6 — LEASES" for further detail.

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

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

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

ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

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

In December 2019, the FASB issued ASU No. 2019-12,*Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes* The amendments in this ASU simplify the accounting for income taxes by removing several exceptions including the exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments also improve consistent application of and simplify GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The implementation of this standard is not expected to have a material impact on the Company's operating results, cash flows, financial condition or related disclosures.

In March 2020, the FASB issued ASU No. 2020-04,*Reference Rate Reform*, which provided elective amendments for entities that have contracts, hedging relationships and other transactions that reference LIBOR or another reference rate expected to be discontinued because of reference rate reform. The amendments may be applied to impacted contracts and hedges prospectively through December 31, 2022. The Company is currently evaluating the impact this guidance will have on its financial statements.

The Company considers the applicability and impact of all recently issued accounting pronouncements. Recent accounting pronouncements not specifically identified in our disclosures are either not applicable to the Company or are not expected to have a material effect on our financial condition or results of operations.

FAIR VALUE MEASUREMENTS

Fair value is the exit price that would be received to sell an asset or paid to transfer a liability. Fair value is a market-based measurement that should be determined using assumptions that market participants would use in pricing an asset or liability. Valuation techniques used to measure fair value should maximize the use of observable inputs and minimize the use of unobservable inputs. To measure fair value, the Company uses the following fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable:

- Level 1 – Quoted prices in active markets for identical assets or liabilities.
- Level 2 – Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data by correlation or other means.
- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Value is determined using pricing models, discounted cash flow methodologies, or similar techniques and includes instruments for which the determination of fair value requires significant judgment or estimation.

The carrying amounts of cash and cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued expenses are considered to be representative of their fair values because of the short-term nature of those instruments. There were no transfers between levels in the fair value hierarchy during the year ended December 31, 2020.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. No impairment losses have been recorded through December 31, 2020.

**NOTE 2 — INVENTORY**

Inventory consists of:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Raw materials and work-in-process | $ 2,279,054 | $ 1,863,978 |
| Finished goods | 4,562,315 | 552,989 |
| Total | 6,841,369 | 2,416,967 |
| Less: reserve for obsolete inventory | (11,597) | (28,490) |
| Inventory, net | $ 6,829,772 | $ 2,388,477 |

**NOTE 3 — PROPERTY AND EQUIPMENT**

Property and equipment consists of the following at:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Furniture and office equipment | $ 753,536 | $ 679,032 |
| Leasehold improvements | 542,796 | 456,075 |
| Manufacturing equipment and tooling | 1,856,909 | 1,295,978 |
| Total property and equipment | 3,153,241 | 2,431,085 |
| Less: accumulated depreciation and amortization | (1,985,618) | (1,819,239) |
| Property and equipment, net | $ 1,167,623 | $ 611,846 |

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

**NOTE 4 — RELATED PARTY TRANSACTIONS**

BUILDING LEASE

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

The lease payments were $145,056 and $142,964 for the years ended December 31, 2020 and 2019, respectively. The Company also paid property taxes in the amount of $52,092 and $52,195 for years ended December 31, 2020 and 2019, respectively.

**NOTE 5 — STOCK-BASED COMPENSATION**

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

On May 20, 2020, the Company entered into a Settlement Agreement with EMED Technologies Corporation ("EMED") to settle all claims in connection with all pending litigation matters between them (the "Claims") as described in "NOTE 9 — COMMITMENTS AND CONTINGENCIES." Pursuant to the Settlement Agreement, the Company issued to EMED (i) 95,238 restricted stock units, which vested on May 21, 2020 and 95,238 restricted stock units vesting on January 1, 2021, and (ii) an option to purchase up to 400,000 shares of the Company's common stock at an exercise price of $11.21 per share prior to February 1, 2021, which can be settled in cash in lieu of common stock at the Company's sole discretion, provided that the number of shares of common stock and/or amount of cash paid by the Company upon exercise will be capped at a value of $16.21 per share. The option was recorded at $347,008, the estimated fair value of the option using the Black-Scholes option pricing model with a volatility rate of 52.68% and a risk-free rate of 0.17%. The Settlement Agreement includes mutual releases and covenants not to sue for any claim arising before May 20, 2020 and the Company covenants not to challenge any EMED patents that were the subject of the Claims unless EMED asserts them in the future against Company products. This was a non-cash settlement from which we recognized expense in the amount of $2.2 million in the second quarter of 2020.

Effective January 1, 2021, each non-employee director of the Company (other than the Chairman of the Board) and Board advisor are eligible to receive of $75,000 annually, to be paid quarterly $12,500 in cash and $6,250 in common stock. In addition, for chairing the Audit Committee, Compensation Committee and the Nominating and Corporate Governance Committee, each non-employee director is eligible to receive annually $15,000, $11,500 and $7,500 respectively, to be paid quarterly in cash and subject to proration for partial quarter service. The Chairman of the Board is eligible to receive $100,000 annually, to be paid quarterly $12,500 in cash and $12,500 in common stock.

Prior to January 1, 2021, each non-employee director of the Company was eligible to receive $50,000 annually (effective January 1, 2019), plus $10,000 for chairing a Board committee (effective February 20, 2019), all to be paid quarterly half in cash and half in common stock. The Chairman of the Board was eligible to receive an additional $50,000 annually (effective October 1, 2019), all to be paid in common stock. All payments were pro-rated for partial service. The Company issued an aggregate 32,181 shares of common stock to its non-employee directors during the year ended December 31, 2020, respectively.

Pursuant to Daniel S. Goldberger's employment agreement dated October 12, 2018, on February 1, 2019, when Donald B. Pettigrew was appointed to President and Chief Executive Officer, Mr. Goldberger was awarded a performance bonus in the amount of $270,000 to be paid half in cash and half in stock. 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 years ended December 31, 2020 and December 31, 2019 was $6.53 and $1.33, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the years ended December 31, 2020 and December 31, 2019. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued. These assumptions are subjective and generally require significant analysis and judgment to develop. We have recognized tax benefits associated with stock-based compensation of $62,393 and $61,333 for the years ended December 31, 2020 and 2019, respectively.

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Dividend yield | 0.00% | 0.00% |
| Expected volatility | 62.11 - 62.18% | 56.10 - 60.30% |
| Weighted-average volatility | — | — |
| Expected dividends | — | — |
| Expected term (in years) | 10 Years | 10 Years |
| Risk-free rate | 0.63 - 0.64% | 1.60 - 2.72% |

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

| | December 31, 2020 | | December 31, 2019 | |
|---|---|---|---|---|
| | Shares | Weighted Average Exercise Price | Shares | Weighted Average Exercise Price |
| Outstanding at January 1 | 3,647,000 | $ 1.32 | 2,419,000 | $ 1.00 |
| Granted | 360,000 | $ 9.54 | 1,650,000 | $ 1.92 |
| Exercised | 884,506 | $ 0.71 | 160,000 | $ 0.37 |
| Forfeited | 200,000 | $ 2.09 | 262,000 | $ 2.74 |
| Outstanding at year end | 2,922,494 | $ 2.46 | 3,647,000 | $ 1.32 |
| Options exercisable | 906,244 | $ 1.40 | 1,078,510 | $ 0.82 |
| Weighted average fair value of options granted during the period | — | $ 6.53 | — | $ 1.33 |
| Stock-based compensation expense | — | $ 874,869 | — | $ 594,956 |

Total stock-based compensation expense, net of forfeitures, for stock option awards totaled $874,869 and $594,956 for the years ended December 31, 2020 and 2019, respectively. Cash received from option exercises for the years ended December 31, 2020 and 2019 was $95,880 and $58,900, respectively.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2020, and 2019, was $2,350,264 and $2,202,678, respectively. The total intrinsic value of options exercised during the years ended December 31, 2020 and 2019, was $397,962 and $58,900, respectively.

The following table presents information pertaining to options outstanding as of December 31, 2020:

| Range of Exercise Price | Number Outstanding | Weighted Average Remaining Contractual Life | Weighted Average Exercise Price | Number Exercisable | Weighted Average Exercise Price |
|---|---|---|---|---|---|
| $0.50 - 9.76 | 2,922,494 | 7.3 years | $ 2.46 | 906,244 | $ 1.40 |

As of December 31, 2020, there was $3,376,990 of total unrecognized compensation cost related to non-vested share-based compensation arrangements granted under the Plan. That cost is expected to be recognized over a weighted-average period of 48 months. The total fair value of shares vested was $803,171 and $539,553 at December 31, 2020, and December 31, 2019, respectively.

**Performance-Based Stock Options**

The per share weighted average fair value of stock options granted during the years ended December 31, 2020, and 2019, was zero and $1.16, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the years ended December 31, 2020 and December 31, 2019. Historical information was the primary basis for the selection of the expected volatility, expected dividend yield and the expected lives of the options. The risk-free interest rate was selected based upon yields of the U.S. Treasury issues with a term equal to the expected life of the option being valued.

| | December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Dividend yield | — | 0.00% |
| Expected Volatility | — | 58.9% |
| Weighted-average volatility | — | — |
| Expected dividends | — | — |
| Expected term (in years) | — | 10 Years |
| Risk-free rate | — | 2.07% |

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

| | December 31, | | | |
|---|---|---|---|---|
| | **2020** | | **2019** | |
| | **Shares** | **Weighted Average Exercise Price** | **Shares** | **Weighted Average Exercise Price** |
| Outstanding at January 1 | 1,000,000 | $ 1.70 | — | $ — |
| Granted | — | $ — | 1,000,000 | $ 1.70 |
| Exercised | — | $ — | — | $ — |
| Forfeited | — | $ — | — | $ — |
| Outstanding at year end | 1,000,000 | $ 1.70 | 1,000,000 | $ 1.70 |
| Options exercisable | 333,333 | $ 1.70 | — | $ — |
| Weighted average fair value of options granted during the period | — | $ — | — | $ 1.16 |
| Stock-based compensation expense | — | $ 502,904 | — | $ 293,363 |

Total performance stock-based compensation expense totaled $502,904 and $293,363 for the years ended December 2020 and 2019, respectively.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2020 and 2019 was zero and $1,162,561, respectively.

The following table presents information pertaining to performance-based options outstanding as of December 31, 2020:

| **Range of Exercise Price** | **Number Outstanding** | **Weighted Average Remaining Contractual Life** | **Weighted Average Exercise Price** | **Number Exercisable** | **Weighted Average Exercise Price** |
|---|---|---|---|---|---|
| $1.70 | 1,000,000 | 8.4 years | $ 1.70 | 333,333 | $ 1.70 |

As of December 31, 2020, there was $366,294 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 25 months. The total fair value of shares vested as of December 31, 2020 and 2019 was $387,520 and zero, respectively.

**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.

At contract inception, we evaluate whether an arrangement is or contains a lease for which we are the lessee (that is, arrangements which provide us with the right to control a physical asset for a period of time). Operating leases are accounted for on the balance sheets with ROU assets being recognized in "Operating lease right-of-use assets" and lease liabilities recognized in "Operating lease liability – current" and "Operating lease liability, net of current portion." Finance leases are accounted for on the balance sheets recognized in "Property and equipment, net" and lease liabilities recognized in "Finance lease liability – current" and "Finance lease liability, net of current portion."

Operating lease expenses are recognized on a straight-line basis over the lease term. With respect to finance leases, amortization of the ROU asset is presented separately from interest expense related to the finance lease liability.

We have elected to combine lease and non-lease components for all lease contracts where we are the lessee. Additionally, for arrangements with lease terms of 12 months or less, we do not recognize ROU assets and lease liabilities and lease payments are recognized on a straight-line basis over the lease term with variable lease payments recognized in the period in which the obligation is incurred. ROU assets are measured for impairment when a triggering event occurs.

The components of lease expense were as follows:

| | Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Operating lease cost | $ 151,686 | $ 149,594 |
| Short-term lease cost | 65,227 | 21,362 |
| Total lease cost | $ 216,913 | $ 170,956 |
| | | |
| Finance lease cost: | | |
| Amortization of right-of-use assets | $ 5,302 | $ 4,837 |
| Interest on lease liabilities | 237 | 239 |
| Total finance lease cost | $ 5,539 | $ 5,076 |

Supplemental cash flow information related to leases was as follows:

| | Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| Cash paid for amounts included in the measurement of lease liabilities: | | |
| Operating cash flows from operating leases | $ 136,888 | $ 110,120 |
| Financing cash flows from finance leases | $ 5,296 | $ 4,783 |

Supplemental balance sheet information related to leases was as follows:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **Operating Leases** | | |
| Operating lease right-of-use assets | $ 236,846 | $ 373,734 |
| | | |
| Operating lease liability - current | 141,293 | 136,888 |
| Operating lease liability, net of current portion | 95,553 | 236,846 |
| Total operating lease liabilities | $ 236,846 | $ 373,734 |
| | | |
| **Finance Leases** | | |
| Property and equipment, at cost | $ 12,725 | $ 12,725 |
| Accumulated depreciation | (10,139) | (4,837) |
| Property and equipment, net | $ 2,586 | $ 7,888 |
| | | |
| Finance lease liability – current | 2,646 | 5,296 |
| Finance lease liability, net of current portion | — | 2,646 |
| Total finance lease liabilities | $ 2,646 | $ 7,942 |

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **Weighted Average Remaining Lease Term** | | |
| Operating leases | 1.4 Years | 2.4 Years |
| Finance leases | 0.7 Years | 1.3 Years |
| | | |
| **Weighted Average Discount Rate** | | |
| Operating leases | 4.75% | 4.75% |
| Finance leases | 4.75% | 4.75% |

Maturities of lease liabilities are as follows:

| Year Ending December 31, | Operating Leases | Finance Leases |
|---|---|---|
| 2021 | $ 149,476 | $ 2,705 |
| 2022 | 97,256 | — |
| 2023 | — | — |
| 2024 | — | — |
| 2025 | — | — |
| Thereafter | — | — |
| Total undiscounted lease payments | 246,732 | 2,705 |
| Less: imputed interest | (9,886) | (59) |
| Total lease liabilities | $ 236,846 | $ 2,646 |

**NOTE 7 — FEDERAL AND STATE INCOME TAXES**

Income tax expense consisted of the following:

| | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|
| State income tax: | | |
| Current, net of refund | $ 17,800 | $ 22,514 |
| Federal income tax: | | |
| Deferred | 62,967 | (186,775) |
| Current | (62,967) | 296,330 |
| Income tax expense | $ 17,800 | $ 132,069 |

The reconciliation of income taxes shown in the financial statements and amounts computed by applying the Federal expected tax rate of 21% for year 2020 and 2019 is as follows:

| | Year Ended December 31, 2020 | Year Ended December 31, 2019 |
|---|---|---|
| (Loss)/income before taxes | $ (1,194,263) | $ 696,418 |
| Income taxes computed at the federal statutory rate | $ (250,795) | $ 146,248 |
| State income and franchise tax | 17,800 | 22,514 |
| Permanent differences and other | 250,795 | (36,693) |
| Income tax expense | $ 17,800 | $ 132,069 |

The significant components of deferred income tax assets, net are as follows:

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| Deferred compensation cost | $ 239,036 | $ 259,068 |
| Depreciation and amortization | (135,092) | (71,331) |
| Allowance for bad debts and other | 21,330 | 504 |
| Deferred income tax assets, net | $ 125,274 | $ 188,241 |

Our U.S. federal and state income tax returns remain open to examination for the tax years 2017 through 2020.

**NOTE 8 — MAJOR CUSTOMERS**

For the years ended December 31, 2020 and December 31, 2019, approximately 51% and 53%, respectively, of the Company's net product revenues were derived from one major customer. As of December 31, 2020 and December 31, 2019, accounts receivable due from this customer was $1.4 million and $1.9 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 — COMMITMENTS AND CONTINGENCIES**

**LEGAL PROCEEDINGS**

The Company has been and may again become involved in legal proceedings, claims and litigation arising in the ordinary course of business. Except as described below, KORU Medical is not presently a party to any litigation or other legal proceeding that is believed to be material to its financial condition.

***Litigation***

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

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

**OTHER**

On November 11, 2020, the Company entered into a Manufacturing and Supply Agreement with Command Medical Products, Inc. ("Command"), pursuant to which Command has agreed to manufacture and supply the Company's subassemblies, needle sets and tubing products pursuant to the Company's specifications and purchase orders. The first binding purchase order pursuant to the Manufacturing and Supply Agreement was made on November 17, 2020 (the "Effective Date").

The Manufacturing and Supply Agreement provides for a term of five years from the Effective Date. Either party may terminate the Manufacturing and Supply Agreement upon a material breach by the other Party that has not been cured within 90 days, upon the bankruptcy or insolvency of the other Party or as expressly set forth elsewhere in the Agreement. If the Company terminates the Manufacturing and Supply Agreement other than for those reasons within the first three years from the Effective Date, the Company is obligated to pay an early termination fee to Command.

The Manufacturing and Supply Agreement also includes customary provisions relating to, among other things, delivery, inspection procedures, warranties, quality management, business continuity plans, handling and transport, intellectual property, confidentiality and indemnification.

**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 years ended December 31, 2020 and December 31, 2019 was $156,789 and $118,632, 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 (the "Original Note") to KeyBank National Association ("KeyBank") in the amount of $1.5 million as a variable rate revolving line of credit loan due on demand with an interest rate of LIBOR plus 2.25%, collateralized with a certificate of deposit in the amount of $1.5 million. On September 25, 2018, KeyBank released the certificate of deposit as collateral for the loan and the Company executed a Commercial Security Agreement as collateral for the loan.

On April 14, 2020, the Company issued a promissory note to KeyBank in the aggregate principal amount of $3.5 million (the "Note") as an extension of its line of credit, replacing its current line of credit agreement and Original Note. In response to concerns about the potential impact of COVID-19, the Company elected to draw the additional $2.0 million on April 23, 2020 available under the line, drawing the full amount available of $3.5 million on its line of credit. The Original Note was in the form of a variable rate revolving line of credit with an interest rate of LIBOR plus 2.25%. The $3.5 million Note is in the form of a variable rate non-disclosable revolving line of credit with an interest rate of Prime Rate announced by the Bank minus 0.75%. Interest is due monthly, and all principal and unpaid interest is due on June 1, 2021. The $3.5 million Note may be prepaid at any time prior to maturity with no prepayment penalties. The $3.5 million Note contains events of default and other provisions customary for a loan of this type. On July 29, 2020, the Company paid the balance of $3.5 million in full.

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

The Company had no amount outstanding against the line of credit as of December 31, 2020.

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

On April 27, 2020, the Company entered into a Progress Payment Loan and Security Agreement ("PPLSA") and a Master Security Agreement (the "MSA"), each dated as of April 20, 2020, with Key Equipment Finance, a division of the Bank ("KEF"), to provide up to $2.5 million in financing for equipment purchases from third party vendors. The PPLSA allows the Company to make draws with KEF to make certain payments to the equipment suppliers prior to the commencement of periodic payments under a term loan. Each draw under the PPLSA will bear interest at a variable rate equal to the then-current Prime Rate and will be secured by the financed equipment under the MSA. At the end of each calendar quarter or year, the advances made under the PPLSA will be converted to term loans, subject to KEF's approval of the equipment and certain other closing conditions being met. Once the draws under the PPLSA are converted into a term loan, each promissory note will bear interest at a fixed rate of 4.07% per annum, subject to adjustment based on KEF's cost of funds, with principal and interest payable in 84 equal consecutive monthly installments. Each fixed rate installment promissory note may be prepaid, subject to a penalty if prepaid before the fifth anniversary of its issuance. As of December 31, 2020, the Company had no amount outstanding against the PPLSA.

**NOTE 12 — EQUITY**

On June 18, 2020, the Company entered into a Purchase Agreement with Piper Sandler & Co. and Canaccord Genuity LLC, as representatives of the several underwriters named therein (the "Underwriters"), pursuant to which the Company agreed to issue and sell 3,125,000 shares of its common stock. Under the terms of the Purchase Agreement, the Company granted to the Underwriters an option, exercisable for a period of 30 days, to purchase up to an additional 468,750 shares of the Company's common stock, which the Underwriters exercised in full on June 19, 2020. The Underwriters purchased the shares pursuant to the Purchase Agreement, including the shares subject to the option, at a price of $7.52 per share. Proceeds to the Company, net of discounts, commissions, fees and expenses, were $26.6 million.

On November 16, 2020, the Company announced that its Board of Directors had authorized a stock repurchase program under which the Company may purchase up to $10.0 million of its outstanding common stock through December 31, 2021. As of December 31, 2020, the Company had purchased 683,271shares since inception of this plan.

**NOTE 13 — SUBSEQUENT EVENT**

On January 22, 2021, Donald B. Pettigrew, President and Chief Executive Officer, resigned his employment effective immediately. Also, on January 22, 2021, James M. Beck, currently serving as a director, was appointed as Chief Executive Officer on an interim basis. Mr. Beck has remained a director, and Robert Allen, also currently a director, replaced Mr. Beck as Chairman of the Compensation Committee.

In connection with Mr. Pettigrew's resignation, he entered into a Separation and General Release Agreement with the Company wherein the parties agreed that the Company will continue to pay Mr. Pettigrew his base salary and healthcare benefits for twelve months, and Mr. Pettigrew has forfeited all right to exercise his vested performance-based stock options. Mr. Pettigrew will have the right to exercise 1,000,000 of his non-qualified stock options for a period of 90 days. On February 16, 2021, Mr. Pettigrew exercised 1,000,000 shares of vested options at a strike price of $1.23 totaling $1,230,000 pursuant to his option agreements dated September 4, 2018 and January 22, 2021.

On February 5, 2021, the Company entered into an employment agreement dated as of January 22, 2021 with Mr. Beck, the Company's interim Chief Executive Officer. The following is a summary of Mr. Beck's employment agreement.

- Mr. Beck's monthly base compensation will be $40,000, pro-rated for any partial month and with a minimum guaranteed two months.

- Mr. Beck will receive a bonus based upon amounts payable to the person who first succeeds Mr. Beck as chief executive officer of the Company, which bonus will equal the initial annual base salary payable to such successor, prorated for Mr. Beck's term of employment and with a minimum guaranteed two months (the "Bonus"). The Bonus will be paid in cash sixty (60) days following Mr. Beck's termination of employment under the employment agreement. Notwithstanding the above, no Bonus will be paid to Mr. Beck in the event he becomes the chief executive officer of the Company following his tenure under the Employment Agreement, he resigns his employment prior to the appointment of his successor to the position of chief executive officer of the Company, he is terminated by the Company for "Cause" (as defined in the Employment Agreement), or he fails to use his best efforts in assisting in the orderly transition of his successor to the position of chief executive officer of the Company (as determined by the Board).

- Mr. Beck's employment with the Company is "at-will" at the discretion of the Board, subject to a 30-day notice of termination (except where termination is by the Company for Cause).

- Pursuant to the Company's 2015 Stock Option Plan, as amended, on February 15, 2021, Mr. Beck received a 10-year nonqualified option to purchase up to 150,000 shares of the Company's common stock at a per share exercise price equal to the fair market value of the common stock on the date of grant. Of these options, 100,000 were fully vested on the date of grant, and 50,000 will vest on March 22, 2021. The aforementioned options may be exercised for cash or by "cashless" or "net" exercise.

On March 15, 2021, Linda Tharby entered into an employment agreement with the Company providing for her appointment as President and Chief Executive Officer of KORU Medical Systems, effective April 12, 2021. Mr. Beck will resign from that position upon the appointment of Ms. Tharby, and will continue as a member of the Board of Directors.

Pursuant to this agreement, Ms. Tharby will receive an annual base salary of $550,000 and be eligible to earn an annual bonus, paid 70% in cash and 30% in shares of the Company's common stock, with a target of 80% of her base salary, based on achievement of objectives set in accordance with the Company's management incentive compensation plan for executives, payable by March 15 of the following year.

Under the agreement, Ms. Tharby received non-qualified stock options pursuant to the Company's 2015 Stock Option Plan, as amended, to purchase up to 1,000,000 shares of the Company's common stock at an exercise price of $3.875 per share, subject to vesting as follows, provided she is then employed by the Company: 25% on March 15, 2021 and 25% each twelve months thereafter.

In addition, Ms. Tharby will receive three restricted stock awards on April 12, 2021 as follows, each vesting subject to employment on the respective vesting date:

(1) 600,000 shares of common stock to vest vesting as follows: if the Company's Net Sales Growth (defined below) for any of the fiscal years ended December 31, 2022, 2023, 2024 or 2025 (each, a "Target Year") is at least the applicable Net Sales Target set forth on the schedule to the restricted stock award agreement, then, on the applicable Vesting Date, a corresponding portion of the restricted stock award will vest as set forth on such schedule. Additionally, if Net Sales Growth is less than any of the Net Sales Targets set forth in such schedule in any Target Year (a "Miss Year"), vesting of the restricted stock award in the following Target Years (each such subsequent Target Year, a "Catch-up Year") shall be further subject to the following catch-up vesting provisions: if the Net Sales Growth in the Miss Year(s) when averaged with the Net Sales in each Catch-up Year(s) equals or exceeds a Net Sales Target in any single Miss Year that has not previously been obtained, then on the applicable Vesting Date, an additional portion of the Award shall vest as if the applicable Net Sales Target had been met in the Miss Year(s). Notwithstanding the foregoing, the restricted stock award shall automatically vest in full upon the Company maintaining, for a period of at least two consecutive fiscal quarters after January 1, 2022, at least a specified run rate over the previous four fiscal quarters, as reported in the Company's filings pursuant to the Securities Exchange Act of 1934, as amended.

(2) 200,000 shares of common stock vesting 25% on April 12, 2022 and 25% on each twelve months thereafter.

(3) 200,000 shares of common stock, vesting as follows: (i) 50,000 shares on the first date on which the Company's Market Capitalization for a period of 90 consecutive days has been, or there has been a Change of Control (as defined in the employment agreement) of the Company with an enterprise value of, at least $500,000,000 but less than $600,000,000; (ii) 50,000 shares on the first date on which the Company's Market Capitalization for a period of 90 consecutive days has been, or there has been a Change of Control of the Company with an enterprise value of, at least $600,000,000 but less than $750,000,000; and (iii) 100,000 shares on the date on which the Company's Market Capitalization for a period of 90 consecutive days has been, or there has been a Change of Control of the Company with an enterprise value of, at least $750,000,000. "Market Capitalization" shall be determined by (A) multiplying the number of shares reported as outstanding on the cover of the Company's most recent Form 10-K or 10-Q, as applicable, as filed with the Securities and Exchange Commission, by (B) the Fair Market Value of the Common Stock (as defined in the Company's 2015 Stock Option Plan, as amended) on each day. Notwithstanding the foregoing, no portion of the restricted stock award shall vest on or following the fifth anniversary of the award date.

Upon termination of Ms. Tharby's employment by the Company without "cause" or by Ms. Tharby for "good reason" (as defined in the employment agreement) within 3 months prior to or 12 months following a "change of control" (as defined in the employment agreement) of the Company, all equity awards pursuant to the employment agreement will become fully vested.

Should the Company terminate Ms. Tharby's employment without "cause" or should she leave the Company for "good reason," she will be eligible for a severance package comprised of (i) base salary for 12 months, calculated at the rate of her then base salary, to be paid in accordance with the Company's normal payroll practices; (ii) her Annual Bonus as if earned for the year of termination; and (iii) if termination occurs on or after January 1, 2022, acceleration of her stock options and restricted stock award set forth under (2) above for the year of termination (i.e., 25% of total award), if not then vested. For the same period, the Company will also cover the cost of health insurance, which is continued by Ms. Tharby through COBRA election.

The employment agreement contains customary confidentiality and assignment of invention provisions and mutual non-disparagement covenant, as well as one-year non-competition and non-solicitation covenants. The Company has agreed to reimburse Ms. Tharby up to $12,500 in legal fees associated with the employment agreement.

**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 principal executive officer or CEO, and principal 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, 2020. Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2020, 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 principal executive officer and principal 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, 2020. 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, 2020, 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 year ended December 31, 2020 that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 October 10, 2017 between Repro Med Systems, Inc. and Manuel Marques (incorporated by reference to the Company's Form 10-K filed with the SEC on March 4, 2020).* |
| 10.3 | Employment Agreement effective as of January 22, 2021 between Repro Med Systems, Inc. and James M. Beck (incorporated by reference to the Company's Form 8-K filed with the SEC on February 11, 2021).* |
| 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 | Form of Non-Qualified Stock Option (filed herewith). |
| 10.6 | Form of Incentive Stock Option (filed herewith). |
| 10.7 | Management Incentive Compensation Plan (incorporated by reference to the Company's Form 8-K filed with the SEC on April 14, 2020). |
| 10.8 | Manufacturing and Supply Agreement dated as of November 11, 2020 between Repro Med Systems, Inc. and Command Medical Products (incorporated by reference to the Company's Form 10-Q filed with the SEC on November 12, 2020). Certain information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed. |
| 10.9 | Separation Agreement and General Release dated January 24, 2021 between the Company and Donald B. Pettigrew (filed herewith).+ |
| 10.10 | Promissory Note in the aggregate principal amount of $3.5 million dated April 14, 2020 issued by the Company to KeyBank National Association (incorporated by reference to the Company's Form 8-K filed with the SEC on April 30, 2020). |
| 10.11 | Commercial Security Agreement dated April 14, 2020 between the Company and KeyBank National Association (incorporated by reference to the Company's Form 8-K filed with the SEC on April 30, 2020). |
| 10.12 | Loan Agreement dated April 20, 2020 between the Company and KeyBank National Association(incorporated by reference to the Company's Form 8-K filed with the SEC on April 30, 2020). |

*continued*

| Exhibit No. | Description |
|---|---|
| 10.13 | Progress Payment Loan and Security Agreement dated as of April 20, 2020 between the Company and Key Equipment Finance, a Division of KeyBank National Association (incorporated by reference to the Company's Form 8-K filed with the SEC on April 30, 2020). |
| 10.14 | Master Security Agreement dated as of April 20, 2020 between the Company and Key Equipment Finance, a Division of KeyBank National Association (incorporated by reference to the Company's Form 8-K filed with the SEC on April 30, 2020). |
| 10.15 | Employment Agreement effective as of March 15, 2021 between Repro Med Systems, Inc. and Linda Tharby(filed herewith).* ^ |
| 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). |

_____

\+ Certain schedules, appendices and/or exhibits to this agreement have been omitted in accordance with Item 601 of Regulation S-K. A copy of any omitted schedule and/or exhibit will be furnished supplementally to the Securities and Exchange Commission staff upon request.

* Denotes management compensatory agreement or arrangement.

^ Certain information has been omitted from this exhibit because it is not material and would be competitively harmful if publicly disclosed.

**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 23, 2021.

REPRO MED SYSTEMS, INC.

/s/ James M. Beck
James M. Beck, Interim 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 23, 2021.

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

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

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

/s/ David Anderson
David Anderson, 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 the Registrant's Securities**
**Registered Pursuant to Section 12 of the**
**Securities Exchange Act of 1934**

The following discussion summarizes the terms and provisions of the capital stock of Repro Med Systems, Inc. (the "Company" or "we" or "our"). This description is summarized from, and qualified in its entirety by reference to, our restated certificate of incorporation and amended and restated bylaws, copies of which are filed as exhibits to the Form 10-K of which this Exhibit 4.1 is a part.

We have 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, $0.01 par value per share. As of March 23, 2021, we had 44,405,165 shares of common stock and no shares of preferred stock issued and outstanding. The common stock is the only class of the Company's securities registered under Section 12 of the Securities Act of 1933, as amended.

**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 (the "Board") 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.

Our common stock is listed on the Nasdaq Capital Market under the symbol "KRMD". The stock transfer agent for our securities is Continental Stock Transfer and Trust Company of New York, New York.

**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. Our Board 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. Since no shares of preferred stock are currently outstanding, there are currently no redemption or sinking fund provisions applicable to our 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 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, 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.

**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, without shareholder approval, to issue our preferred stock, the terms of which, including voting power, are set by our Board;

- preclude cumulative voting in elections of directors;

- permit our Board 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 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 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.

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.

EXHIBIT 10.5

REPRO MED SYSTEMS, INC.

2015 STOCK OPTION PLAN

NONQUALIFIED STOCK OPTION AWARD

This NONQUALIFIED STOCK OPTION AWARD (this "***Agreement***"), dated as of _____, _____ (the "***Date of Grant***"), is delivered by Repro Med Systems, Inc., a New York corporation (the "***Company***"), to _____ (the "***Grantee***").

The Company's 2015 Stock Option Plan (the "***Plan***") provides for the grant of nonqualified stock options to purchase shares of common stock, par value $0.01 per share, of the Company ("***Company Stock***"). The Compensation Committee of the Board of Directors of the Company (the "***Committee***") has decided to make a nonqualified stock option grant to encourage the Grantee to contribute materially to the growth of the Company, thereby benefiting the Company's stockholders, and aligning the economic interests of the Grantee with those of the stockholders. A copy of the Plan is attached to this Agreement. All capitalized terms not otherwise defined in this Agreement shall have the meaning ascribed to such terms in the Plan.

NOW, THEREFORE, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1. Grant of Option. Subject to the terms and conditions set forth in this Agreement and in the Plan, the Company hereby grants to the Grantee a nonqualified stock option (the "***Option***") to purchase _____ shares of Company Stock ("***Shares***") at an exercise price of $____ per Share (the "***Strike Price***").

2. Exercisability of Option. The Option shall become exercisable on the following dates (each, a "***Vesting Date***"):_____, provided the Grantee is still employed by the Company on the respective Vesting Date.

3. Option Term.

(a) The Option shall have a term of ten (10) years from the Date of Grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan.

(b) If the Grantee's employment with or service as a director of the Company (collectively, "***Service***") terminates without cause (as determined by the Committee in its sole discretion) and for any reason other than death or disability, the then vested portion of the Option shall continue to be exercisable until the earlier of the 90th day after the date of the Grantee's termination or the date the Option expires by its terms. The portion of the Option not vested as of the date of such termination of Service shall expire as of such date and shall not be exercisable.

(c) If the Grantee's Service to the Company is terminated by the Company for cause (as determined by the Committee in its sole discretion), the Option shall expire on the date of such termination, and no portion shall be exercisable after the date of such termination.

(d) In the event of the Grantee's termination of Service due to death or disability during Service to the Company, the vested portion of the Option shall continue to be exercisable until the earlier of (i) the date the Option expires by its terms and (ii) 12 months after the date of such termination.

(e) In the event of the Grantee's death occurs after Service termination but during the 90 day period following such termination , the vested portion of the Option shall continue to be exercisable until the earlier of (i) the date the Option expires by its terms and (ii) the first anniversary of the Grantee's death.

4. Exercise Procedures.

(a) Subject to the provisions of Paragraphs 2 and 3 above, the Grantee may exercise part or all of the exercisable Option by giving the Company written notice to exercise in the manner provided in this Agreement, specifying the number of Shares as to which the Option is to be exercised and tendering payment for such Shares. The Grantee shall pay an amount equal to the Strike Price multiplied by the number of Shares as to which the Option is to be exercised (the "***Exercise Price***") (i) by certified or official bank check (or the equivalent thereof acceptable to the Company); or (ii) by delivery of shares of Common Stock acquired at least six months prior to the option exercise date and having a fair market value (as defined in the Plan and determined as of the exercise date) equal to all or part of the Exercise Price and a certified or official bank check (or the equivalent thereof acceptable to the Company) for any remaining portion of the Exercise Price; or (iii) by "net exercise", as a result of which the Grantee will receive (X) the number of Shares as to which the Option is to be exercised less (Y) such number of shares of Common Stock as is equal to (I) the aggregate Exercise Price for the portion of the Option being exercised divided by (II) the fair market value (as defined in the Plan) on the date of exercise.

(b) The Company's obligation to deliver Shares upon exercise of the Option shall be subject to all applicable laws, rules and regulations and also to such approvals by governmental agencies as may be deemed appropriate by the Committee, including such actions as Company counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Grantee (or other person having the right to exercise the Option) represent that the Grantee (or such other person) is purchasing Shares for his/her own account and not with a view to or for sale in connection with any distribution of the Shares, or such other representation as the Committee deems appropriate.

(c) All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. Subject to Committee approval, the Grantee may elect to satisfy any tax withholding obligation of the Company with respect to the Option by having Shares withheld from delivery having a value equal to the amount of the tax withheld. The election must be in a form and manner prescribed by the Committee and shall be subject to the prior approval of the Committee.

5 . Restrictions on Exercise. Except as the Committee may otherwise permit pursuant to the Plan, only the Grantee may exercise the Option during the Grantee's lifetime and, after the Grantee's death, the Option shall be exercisable (subject to the limitations

specified in the Plan) solely by the legal representatives of the Grantee, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, to the extent that the Option is exercisable pursuant to this Agreement.

6 . Grant Subject to Plan Provisions. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and exercise of the Option are subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (a) rights and obligations with respect to withholding taxes, (b) the registration, qualification or listing of the Shares, (c) changes in capitalization of the Company and (d) other requirements of applicable law. The Committee shall have the discretionary authority to interpret and construe the Option pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

**7.** Restrictions on Sale or Transfer of Shares.

(a) The Grantee agrees that he or she shall not sell, transfer, pledge, donate, assign, mortgage, hypothecate or otherwise encumber the Shares underlying the Option unless the Shares are registered under the Securities Act of 1933, as amended (the "***Securities Act***"), or the Company is given an opinion of counsel reasonably acceptable to the Company that such registration is not required under the Securities Act.

(b) As a condition to receive any Shares upon the exercise of the Option, the Grantee agrees to be bound by the Company's policies regarding the limitations on the transfer of such Shares, and understands that the Grantee will be prohibited from selling, transferring, pledging, donating, assigning, mortgaging, hypothecating or otherwise encumbering the Shares.

8 . No Employment or Other Rights. The grant of the Option shall not confer upon the Grantee any right to be retained by or in the service of the Company and shall not interfere in any way with the right of the Company to terminate the Grantee's service at any time. The right of the Company to terminate at will the Grantee's service at any time for any reason is specifically reserved.

9 . No Stockholder Rights. Neither the Grantee, nor any person entitled to exercise the Option, shall have any of the rights and privileges of a stockholder with respect to the Shares subject to the Option, until certificates for Shares have been issued upon the exercise of the Option.

1 0 . Assignment and Transfers. Except as the Committee may otherwise permit pursuant to the Plan, the rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Grantee, and the Option and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's

parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

11. Applicable Law. The validity, construction, interpretation and effect of this instrument shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to the conflicts of laws provisions thereof.

12. Notice. Any notice to the Company provided for in this instrument shall be addressed to the Company in care of the Chief Financial Officer at the headquarters of the Company, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of the Company, or to such other address as the Grantee may designate to the Company in writing. Any notice shall be delivered by hand, or enclosed in a properly sealed envelope addressed as stated above, registered and deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service.

*[SIGNATURE PAGE FOLLOWS]*

IN WITNESS WHEREOF, the Company has caused its duly authorized officer to execute this Agreement, and the Grantee has executed this Agreement, effective as of the Date of Grant.

Repro Med Systems, Inc.

By:_____
Name:
Title:

I hereby accept the Option described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby further agree that all of the decisions and determinations of the Committee shall be final and binding.

Grantee:_____
Name:

EXHIBIT 10.6

**INCENTIVE STOCK OPTION AGREEMENT**

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

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

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

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

1. (a) The Company hereby grants to the Employee, as a matter of incentive and to encourage stock ownership in the Company, and not in lieu of, or to provide an increase in, any salary or other compensation for their services, the right and option to purchase, on the terms and conditions hereinafter set forth, up to _____ Shares of Common Stock, at the purchase price of $____ per Share.

(b) The Option shall vest and become exercisable as follows: _____ (each, a "***Vesting Date***"), provided the Employee is employed by the Company on the respective Vesting Date. [Notwithstanding the foregoing, upon occurrence of a Triggering Event within six (6) months following a Change of Control, the Option shall vest and become exercisable in full with respect to all remaining Shares not then vested or previously forfeited or cancelled. As used in this Section 1(b):

"***Change of Control***" shall be deemed to have occurred upon the happening of any of the following events: (a) any "person," including a "group," as such terms are defined in Sections 13(d) and 14(d) of the Securities Exchange Act of 1934, as amended, and the rules promulgated thereunder, becomes the beneficial owner, directly or indirectly, whether by purchase or acquisition or agreement to act in concert or otherwise, of more than 50% of the outstanding shares of Common Stock of the Company; (b) a cash tender or exchange offer for at least 50% of the outstanding shares of Common Stock of the Company is commenced; (c) the shareholders of the Company approve an agreement to merge, consolidate, liquidate, or sell all or substantially all of the assets of the Company; or (d) the individuals who, as of the Date of Grant, are members of the Board cease for any reason to constitute at least fifty percent (50%) of the Board.

"***Triggering Event***" means termination of Employee's employment by the Company without Cause or by Employee for Good Reason.

"***Cause***" shall have the meaning ascribed to such term in any employment agreement that is in effect at the time of a Triggering Event or, if there is no such agreement or such term is not

defined therein, shall mean the Company's good faith determination of: (A) Employee's engagement in dishonesty or illegal conduct; (B) Employee's embezzlement, misappropriation or fraud; (C) Employee's conviction of or plea of guilty or no contest to a felony; (D) Employee's conduct in furtherance of a hostile work environment or engaged in discrimination in violation of any state or federal anti-harassment or discrimination statute; (E) Employee's breach of any obligation under this Agreement or any other written agreement between Employee and the Company; or (F) Employee's knowing and intentional violation of the Company Code of Conduct.

"***Good Reason***" shall have the meaning ascribed to such term in any employment agreement that is in effect at the time of a Triggering Event or, if there is no such agreement or such term is not defined therein, shall mean, without Employee's consent, (i) a material reduction by the Company of Employee's base salary; (ii) a material breach by the Company of an employment agreement between Employee and the Company; (iii) a material adverse change by the Company in Employee's material authorities or material responsibilities which causes Employee's position with the Company to become substantially of less authority or responsibility than Employee's position immediately prior to such change; or (iv) a change of more than seventy-five (75) miles in the principal location at which Employee provides services to the Company; provided that Good Reason shall not be deemed to have occurred unless: (A) Employee provides the Company with written notice that Employee intends to terminate their employment hereunder for one of the grounds set forth above within fifteen (15) days of such reason(s) occurring; (B) if such ground is capable of being cured, the Company has failed to cure such ground within a period of thirty (30) days from the date of such written notice; and (C) Employee terminates their employment within sixty (60) days from the date that Good Reason first occurs.]

(c) No fewer than 100 Shares may be purchased at any one time unless the number purchased is the total number at the time purchasable under the Option, and provided further that this Option may not be exercised in whole or in any part while there is "outstanding" any other "qualified stock option" or "restricted stock option" (as those terms are defined in the Internal Revenue Code) which was granted, before the date of this Agreement, to the Employee to purchase stock in the Company at a price (determined as of the Date of Grant of this Option) higher than the option price of this Option. This Option shall terminate on the tenth anniversary of the Date of Grant or on such earlier date as may be provided herein or fixed pursuant hereto, and shall not be exercisable thereafter either by the Employee or their legal representatives.

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

(b) With the consent of the Committee, as an alternative to cash, payment upon exercise may be made by delivery of Shares of Common Stock of the Company acquired prior to the Option exercise date, and/or surrender of the right to receive Shares of Common Stock that are being offered for purchase under the Option (as contemplated by section 1.422-5 (b) of the treasury regulations), and in each case such Shares having a Fair Market Value (as defined in the Plan and determined as of the exercise date) equal to all or part of the Option exercise price and a certified or official bank check (or the equivalent thereof acceptable to the Company) for any remaining portion of the full Option exercise price.

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

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

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

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

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

governmental regulatory body that the Committee shall, in its sole discretion, determine to be necessary or advisable. The Company shall make reasonable efforts to take all such steps as may be required by law and applicable regulations, including rules and regulations of the Securities and Exchange Commission, and any stock exchange on which the Shares may then be listed, in connection with the issuance or sale of any Shares purchased upon the exercise of such Option or the listing of such Shares on said exchange.

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

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

10. Noting herein contained shall confer on the Employee any right to continue in the employ of the Company or any of its subsidiaries or shall interfere in any way with the right of the Company and/or its subsidiaries to terminate the Employee's employment or change their responsibilities, duties, or compensation at any time.

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

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

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

**REPRO MED SYSTEMS, INC.**

By: _____
Name:
Title:

**ACCEPTED BY:**

_____
**Name:**

EXHIBIT 10.9

**SEPARATION AND GENERAL RELEASE AGREEMENT**

This SEPARATION AND GENERAL RELEASE AGREEMENT (this "***Agreement***") is made and entered into by and between Donald B. Pettigrew ("***Executive***") and Repro Med Systems, Inc., a New York corporation (the "***Company***"). Executive and the Company are referred to herein, collectively, as the "***Parties***," and each, a "***Party***."

WHEREAS, Executive was employed by the Company pursuant to that certain Employment Agreement dated as of September 4, 2018 (the "***Employment Agreement***") and is party to those certain Nonqualified Stock Option Award dated September 4, 2018 (the "***Nonqualified Option Agreement***") and Incentive Stock Option Agreement dated June 3, 2019 (the "***Incentive Option Agreement***"), each by and between Executive and the Company, copies of which Employment Agreement, Nonqualified Option Agreement and Incentive Option Agreement are attached hereto as Exhibit A and are expressly incorporated herein;

WHEREAS, Executive's employment by the Company was terminated effective as of January 22, 2021 (the "***Termination Date***"); and

WHEREAS, subject to the terms and conditions hereof (and in accordance with the Employment Agreement), Executive and the Company seek to amicably conclude the employment relationship, reinforce certain continuing obligations of Executive after the Termination Date, and provide for certain severance payments and benefits for Executive, which payments and benefits are conditioned upon Executive's execution and non-revocation of this Agreement and his full compliance with all of his continuing obligations.

NOW, THEREFORE, in consideration of the mutual promises, agreements and representations contained herein, with the foregoing background incorporated by reference, and intending to be legally bound hereby, the Parties agree as follows:

1. **Definitions**. Any capitalized term used herein and not otherwise defined herein shall have the meaning provided therefor in the Employment Agreement. As used in this Agreement:

(a) "***Executive***" means Executive and his heirs, administrators, personal representatives, executors, successors and assigns;

(b) "***Company Group***" means: the Company and each of its affiliates, predecessors, successors, transferees, assignees, employee benefit programs (and the trustees, administrators, and fiduciaries of such programs), shareholders, and all officers, directors, employees, agents, and representatives of the Company.

(c) "***Severance Period***" means the twelve (12) month period commencing as of the Termination Date.

2. **Severance Payments and Other Benefits**.

(a) Severance Payments. The Company shall pay Executive all accrued but unpaid compensation he has earned through the Termination Date, in accordance with the Company's normal payroll schedule, policies and practices and subject to regular W-2 withholdings and other deductions. Additionally, in consideration for signing this Agreement and Executive's continued compliance with the release and waiver provisions set forth herein and the other covenants and obligations of Executive made in this

Agreement (including as incorporated by reference in Section 5(a) hereof), in accordance with Section 5 of the Employment Agreement, the Company shall pay to Executive by direct deposit, in each case, in accordance with the Company's normal payroll schedule, policies and practices, and subject to regular W-2 withholdings and other deductions, an amount equal to twelve (12) months of his current Base Salary as of the Termination Date (i.e., $360,000), to be paid over the Severance Period (collectively, the "***Severance Payments***"). Provided that Executive complies with the terms and conditions of this Agreement, the Severance Payments shall begin on the next regular payroll date following the later of the Effective Date (as defined herein) and Executive's full compliance with Section 5(b) below, which compliance will be determined in Company's sole discretion.

(b) Health Insurance. For the Severance Period, the Company will pay premiums for Executive's health insurance as enrolled on the Termination Date ("***Health Coverage***").

(c) Options. Employee shall be entitled to exercise options to purchase 1,000,000 shares of common stock pursuant and in accordance with the Nonqualified Option Agreement. Employee shall forfeit all right to exercise any other options under the Nonqualified Option Agreement and under the Incentive Option Agreement.

(d) Unemployment Forbearance. As further consideration for this Agreement, to the extent Executive is eligible to apply for unemployment compensation, the Company agrees not to contest any application by Executive for unemployment compensation in connection with his former employment by the Company.

(e) Benefits. The Severance Payments, Health Coverage, and other benefits provided in Sections 2(a) through 2(d) above shall be referred to herein, collectively, as the "***Benefits***."

(f) Non-Disparagement. Provided Executive has not breached this Agreement, the Company agrees not to make, publish or communicate to any person any comments or statements (whether written or oral) that denigrate or disparage the reputation or stature of the Executive.

(g) Public Announcement. Executive shall have the right to review any public announcement (e.g. press release) regarding his separation from the Company prior to its release. The press release will state that Executive voluntarily resigned his employment. The Company will consider in good faith any comments thereto provided by Executive.

(h) No Other Compensation or Benefits. Unless otherwise stated in this Agreement, Executive acknowledges that all other compensation and/or benefits provided by any member of the Company Group to Executive terminated as of the Termination Date. Executive acknowledges that Executive has received from the Company, subject to regular W-2 withholdings and other deductions, all wages and compensation earned as of the Termination Date (except such wages and compensation to be paid pursuant to Section 2(a) above), including, but not limited to, reimbursement of expenses. All Company Group-sponsored benefits programs and/or insurance in which Executive is enrolled will cease as of the Termination Date, except as provided for in section 2(b) herein. As applicable, the Company Group's relevant service providers will provide Executive with all necessary notices regarding continuation of benefits after the Termination Date, if available.

3. **General Release of Claims**. In consideration for the mutual promises and undertakings contained herein, and for other good and valuable consideration:

(a) Executive, on behalf of himself and each of his, heirs, affiliates, agents,

executors, representatives, successors and assigns hereby freely, knowingly and irrevocably releases and discharges each member of the Company Group from any and all rights, actions, causes of action, suits, debts, contracts, controversies, agreements, promises, damages, judgments, claims, demands, losses, liabilities or obligations whatsoever, of whatever kind, based on whatever legal theory, including, but not limited to, obligations in law or equity, which exist or may exist, whether vested or otherwise, whether known or unknown, that Executive or any of his affiliates, agents or other representatives ever had, now has or may have through the Effective Date (collectively, the "***Executive Claims***"), including, but not limited to: any alleged violation of Title VII of the Civil Rights Act of 1964, Sections 1981 through 1988 of Title 42 of the United States Code, the Americans with Disabilities Act, the Age Discrimination in Employment Act, the Older Workers Benefit Protection Act, the Fair Labor Standards Act, the Occupational Safety and Health Act, the Family and Medical Leave Act, the Executive Retirement Income Security Act, the National Labor Relations Act, the Immigration Reform Control Act, the Consolidated Omnibus Budget Reconciliation Act, any applicable state, city or local civil rights laws and any applicable state, city or local wage and hour laws, each of those laws as they may have been amended, any other federal, state, city or local civil law, regulation, ordinance or public policy relating to claims of compensation or benefits owed or prohibiting employment discrimination, breach of contract or wrongful discharge and any associated claims for costs, attorney's fees or other expenses which Executive ever had or now has through the Effective Date. Executive further agrees to waive any claim for damages occurring at any time after the Effective Date because of alleged continuing effects of any alleged discriminatory or other wrongful acts or omissions involving any member of the Company Group or related to Executive's employment, including arising under the Employment Agreement or related to the termination of his employment, that occurred prior to the Effective Date. It is expressly agreed and understood that this is a GENERAL RELEASE as to any and all Executive Claims against any member of the Company Group; *provided*, *however*, nothing in this Agreement shall preclude Executive from preserving (collectively, the "***Executive Preserved Claims***") (a) his rights to workers' compensation or unemployment compensation (if applicable) or (b) his rights under this Agreement arising after the Effective Date. Executive represents, warrants, acknowledges and agrees that, as of the Effective Date, he is not aware of any facts or circumstances that could reasonably be expected to give rise to any claim, demand, suit or other proceeding or action against any Company Group member in respect of any Executive Preserved Claim.

(b) The Company Group hereby freely, knowingly and irrevocably releases and discharges Executive from any and all rights, actions, causes of action, suits, debts, contracts, controversies, agreements, promises, damages, judgments, claims, demands, losses, liabilities or obligations whatsoever, of whatever kind, based on whatever legal theory, including, but not limited to, obligations in law or equity, which exist or may exist, whether vested or otherwise, whether known or unknown, that the Company Group ever had, now has or may have through the Effective Date (collectively, the "***Company Claims***"), and any associated claims for costs, attorney's fees or other expenses, which the Company Group ever had or now has through the Effective Date, except for any Company Claims against the Company Group arising from or relating to Executive's acts or omissions that constitute fraud. It is expressly agreed and understood that this is a GENERAL RELEASE as to any and all Company Claims against the Executive; provided, however, nothing in this Agreement shall preclude the Company Group from preserving (collectively, the "***Company Group Preserved Claims***") its rights under this Agreement arising after the Effective Date. The Company represents, warrants, acknowledges and agrees that, as of the Effective Date, it is not aware of any facts or circumstances that could reasonably be expected to give rise to any claim, demand, suit or other proceeding or action against any the Executive in respect of any Company Group Preserved Claim.

4 . **Older Workers' Benefit Protection Act** . Executive and Company intend for this Agreement to comply with Section 201 of the Older Workers Benefit Protection Act of 1990. Accordingly, to extent Executive is over forty (40) years of age at the time he receives this Agreement,

Executive acknowledges and represents as follows: (a) Executive has read and understands this Agreement and all of its terms, conditions, requirements and obligations; (b) by executing this Agreement, Executive does not waive rights or claims that may arise after the date this Agreement is executed; (c) Executive knowingly and voluntarily waives such claims as Executive may have under the Age Discrimination in Employment Act in exchange for consideration of value to which Executive is not otherwise entitled; (d) Executive has been advised in writing by Company to consult with an attorney before signing this Agreement, has had the opportunity to consult with an attorney before signing this Agreement, and is fully satisfied that Executive understands it completely; (e) Executive has had a period of twenty-one (21) days commencing on the date Executive received this Agreement in which to consider this Agreement before signing it, and Executive was permitted to use as much or as little of that period as Executive wished prior to signing; however, Executive acknowledges that no proposal or actual change that Executive makes with respect to this Agreement will restart this twenty-one (21) day period; and (f) for a period of seven (7) days following the execution of this Agreement, Executive may revoke this Agreement, and this Agreement shall not become effective or enforceable until this seven (7) day revocation period has expired (the "***Effective Date***"); (g) should Executive wish to revoke this Agreement, Executive must deliver written notice of Executive's revocation to Company no later than 5:00 p.m. Eastern Standard Time on the seventh (7th) day after Executive has signed this Agreement; and (h) if Executive revokes this Agreement, it shall not be effective or enforceable, and Executive will not receive the Benefits referenced in Section 2, above. To the extent Executive is not over forty (40) years of age at the time he receives this Agreement, the "***Effective Date***" is the date on which Executive signs this Agreement, and Executive shall have no right to revoke this Agreement after Executive signs this Agreement.

5. **Obligations of Executive**. In consideration of this Agreement, and in addition to the general release of claims set forth above and Executive's other covenants and obligations in this Agreement, Executive shall perform the following obligations in exchange for the Severance Payments and other Benefits described above:

(a) Certain Continuing Obligations and Restrictive Covenants. Executive expressly acknowledges and agrees that he remains bound by the terms of the Sections 7 (Confidentiality), 8 (Non-Competition; Non-Solicitation; Non-Disparagement), and 9 (Assignment of Developments) of his Employment Agreement.

(b) Return of Property. To the extent he has not already done so, Executive shall immediately return to the Company Group all Company Group property or Confidential Information (as that term is defined in the Employment Agreement) in his possession or control in whatever tangible or intangible form, including any materials or information (e.g., keys, passwords or access credentials) necessary to access such property or Confidential Information.

(c) Cooperation. Executive agrees to cooperate with the Company Group regarding prior or pending business matters with which Executive is or was involved. Such cooperation includes, but is not limited to, making available to the Company Group such correspondence, documents and records that have applicability to the past, present and future business operations of the Company Group and making full and adequate disclosure to the Company Group of all matters involving the Company Group of which Executive has knowledge. In addition, Executive shall cooperate with and make himself available to the Company Group in connection with any investigation, litigation, arbitration or other proceeding brought by or against any member of the Company Group, whether or not Executive is a party in such matter, or in connection with any threatened or potential investigation, litigation, arbitration or other proceeding by or against any member of the Company Group, including making himself available to answer questions by any member of the Company Group and giving testimony and depositions. Additionally, Executive will cooperate in executing documents required to effectuate the purpose and

intent of this Section 5(c). Upon the request of any Company Group member or Executive in the event any regular and substantial services are required from Executive, the Parties agree to negotiate in good faith and enter into a consulting agreement with Executive with respect to such services.

(d) Covenant Not to Sue. Executive covenants and represents that he has not filed or caused to be filed any lawsuit, complaint, charge, action or other proceeding against any Company Group member with respect to any Claim he is releasing in this Agreement, and Executive further covenants and agrees not to sue any Company Group member with respect to any matter arising on or before the Effective Date that Executive has released pursuant to this Agreement. Executive's covenants include, but are not limited to, proceedings to negate, modify or reform this Agreement; *provided*, *however*, that nothing in this Agreement is intended to, nor shall it, release or interfere with Executive's protected right to file a charge with, or to participate in an investigation or proceeding pursuant to, the statutes administered by the Equal Employment Opportunity Commission or equivalent state agency, including a charge contesting the validity of this Agreement under the Age Discrimination in Employment Act, or the right of any governmental agency to pursue any such claim regarding Executive. In any event, Executive understands that, by signing this Agreement, he waives any right he may have to recover money or other relief in any lawsuit or proceeding that he brings or which is brought on his behalf by any agency or third party against any Company Group member based on events arising through the Effective Date. Except where otherwise permitted under this Section 5(d), Executive agrees that such action shall be dismissed with prejudice upon the presentation of this Agreement to the court and Executive agrees that he will not accept relief or recovery from such action. If Executive institutes such action notwithstanding this Section 5(d), Executive agrees that he will be responsible for the reasonable attorney's fees and costs incurred by any member of the Company Group in defending such action if in fact the court dismisses such action on the basis of this Agreement. Notwithstanding anything herein to the contrary, the limitations on monetary recovery shall not apply to the extent of any monetary award provided to Executive by the U.S. Securities and Exchange Commission ("***SEC***") in connection with any proceedings brought before or on behalf of the SEC with respect to the Company.

(e) Confidentiality. Executive specifically represents and agrees that, except as provided in this Section 5(e), he will not disclose to any person or entity the terms of this Agreement or the fact of or nature of Benefits provided under this Agreement. Executive acknowledges that the Company may publicly disclose the terms of this Agreement and the fact of or nature of Benefits provided under this Agreement as required by law, including securities laws. Executive may communicate to future employers the restrictions on his disclosure of Confidential Information (as defined above). The confidentiality obligations of this Agreement shall further not apply to: (A) disclosures Executive is required to make by applicable laws, regulations, or orders of courts of competent jurisdiction; (B) disclosures to third parties who have a legitimate need to know the amount or terms of this Agreement (such as attorneys, accountants, lenders, financial or tax advisors, acting in their capacities as such); or (C) any action brought to enforce the terms of this Agreement, but only to the extent necessary to prosecute that action. Should Executive or his agents (including attorneys) disclose the terms of this Agreement, the fact of payment by Company, or the amount of payment by Company, the person or entity to whom the information is disclosed shall be advised that the information is confidential and must be so kept. Any breach of confidentiality by a person or entity to whom Executive or his agents (including attorneys) discloses confidential information is chargeable to Executive. Executive understands and agrees that the confidentiality provisions of this Agreement are material terms of the Agreement.

(f) Breach. Executive acknowledges and agrees that if he breaches any provision of this Agreement, it shall constitute a material breach of this Agreement and Executive shall be liable to Company for any harm caused to it thereby. Executive also agrees to pay reasonable attorney's fees that Company incurs as a result of Executive's breach of the Agreement.

6 . **Tax Consequences**. Neither the Company nor any other member of the Company Group makes or has made any representation regarding any tax consequences associated with the terms of this Agreement. Executive understands and agrees that neither the Company nor any other member of the Company Group has any responsibility for any tax liability Executive may incur as a consequence of this Agreement or any payment hereunder.

7 . **Applicable Law; Severability.** This Agreement shall be governed by and construed under the laws of the State of New York, exclusive of applicable principles of conflict of laws. 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 with applicable law, and with all other terms; and the remaining provisions of this Agreement shall remain valid and fully enforceable.

8. **Governing Law, Interpretation and Venue; Waiver of Jury Trial .** This Agreement shall be governed by, and construed in accordance with, the laws of the State of New York, without regard to its conflict of laws provisions. If a dispute arises between the Parties concerning the subject matter of this Agreement, or the Employment Agreement, the Nonqualified Option Agreement or Incentive Option Agreement as incorporated herein, the Parties consent to the sole and exclusive jurisdiction of the state courts situated in Orange County, New York and the federal United States District Court for the Southern District of New York. THE PARTIES HEREBY IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT THEY MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY RELATING TO THIS AGREEMENT, WHETHER BASED ON CONTRACT, TORT OR ANY OTHER THEORY.

9. **Severability**. If any provision of this Agreement is held by a court of competent jurisdiction to be invalid or to conflict with applicable federal, state or local law, the Agreement shall be reformed to remove that invalid provision and/or amended in writing to render that invalid provision enforceable. However, all remaining provisions of the Agreement shall remain in full force and effect; *provided* that, if the provisions in Section 2(a) through 2(e) hereof related to the Severance Payments and/or other Benefits are considered invalid or unenforceable, other than as a result of any act or omission of Executive, the Parties agree to enter into a new agreement, substantially similar to this Agreement except to the extent of any invalid or unenforceable provision, with severance provisions that provide substantially similar payments and benefits.

10. **No Admission of Wrongdoing**. Executive and Company acknowledge and agree that neither this Agreement, nor the furnishing of the consideration for this Agreement, shall be deemed or construed at any time for any purpose as an admission by the Company or Executive of any liability or unlawful conduct of any kind.

11. **Entire Agreement; Amendment** . This Agreement, together with the surviving provisions of the Employment Agreement, set forth the entire agreement between Executive and the Company with respect to the subject matter hereof and thereof and supersede any other prior agreements or understandings between the Parties to the extent of such subject matter. Executive acknowledges that he has not relied on any representations, promises or agreements of any kind made to him in connection with his decision to sign this Agreement, except for those set forth in or otherwise referenced in this Agreement. This Agreement may not be modified, altered or changed except upon express written consent of the Parties wherein specific reference is made to this Agreement.

12. **Authority to Execute**. The persons signing this Agreement hereby represent and warrant that they have the full power, authority and legal right and capacity to execute, deliver and perform all transactions contemplated in this Agreement, and that they have obtained the appropriate consent to bind their respective Parties to the terms of this Agreement.

13. **Attorney Consultation**. The Company hereby advises Executive to consult with an attorney prior to executing this Agreement, and Executive acknowledges that he has been so advised. Executive acknowledges that it has been his decision alone whether or not to consult with an attorney regarding this Agreement.

*[Signature page follows]*

IN WITNESS WHEREOF, Executive and the Company now voluntarily and knowingly execute this Agreement effective as of the Effective Date.

**EXECUTIVE**:

/s/ Donald B. Pettigrew
DONALD B. PETTIGREW

Date: 1/24/21

**COMPANY:**

REPRO MED SYSTEMS, INC.

By: R. John Fletcher

Name: R. John Fletcher
Title: Chairman of the Board

Date: January 24, 2021

**EXHIBIT A**

**Employment Agreement, Nonqualified Option Agreement and Incentive Option Agreement**

(see attached)

EXHIBIT 10.15

*CERTAIN INFORMATION, IDENTIFIED BY [***], HAS BEEN OMITTED BECAUSE IT IS NOT MATERIAL AND WOULD CAUSE COMPETITIVE HARM IF DISCLOSED.*

# EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "***Agreement***"), dated as of March 15, 2021 (the "***Effective Date***"), is made by and between Repro Med Systems, Inc. d/b/a KORU Medical Systems, a New York corporation, having its principal place of business at 24 Carpenter Road, Chester, NY 10918 (the "***Company***"), and Linda Tharby, an individual residing at [personal information redacted] ("***Executive***").

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

WHEREAS, the relationship between the Company and Executive is one in which the Company reposes special trust and confidence in the Executive.

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, and intending to be legally bound hereby, the parties hereto agree as follows:

## 1. Employment and Duties.

( a ) Position. The Company hereby employs Executive as an employee and, effective as of the Start Date (defined below), as President and Chief Executive Officer of Company. In that capacity, Executive shall report directly to the Board of Directors of the Company (the "***Board***"), shall have the duties, authority and responsibilities customarily held by a person holding the positions of President and Chief Executive Officer in companies engaged in business similar to Company's business and of similar size to Company, and shall render such other services as may reasonably be assigned to her from time to time by the Board.

( b ) Duties. Executive agrees that she shall: (i) faithfully and to the best of her ability perform all of the duties that may be required of her pursuant to the terms of this Agreement; (ii) devote substantially all of her business time and attention to the performance of Executive's duties hereunder; and (iii) not engage in any other business, profession or occupation for compensation or otherwise without the prior written consent of the Chairman of the Board; provided, that nothing herein shall preclude Executive from (i) beginning on the second anniversary of Effective Date and with the prior written consent of the Board, serving on the board of directors of other for-profit companies that do not compete with the Company, (ii) serving on civic or charitable boards or committees, and (iii) managing personal investments, so long as all such activities described in (i) through (iii) herein do not interfere with the performance of Executive's duties and responsibilities under this Agreement.

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

(d) Term. Subject to Sections 2, 4 and 5 of this Agreement, the term of Executive's employment pursuant to this Agreement shall commence on the Effective Date and continue until the fifth ($5^{th}$) anniversary of the Effective Date (the "***Initial Term***"); provided, however, that the term of Executive's employment pursuant to this Agreement shall be automatically extended for successive one-year periods thereafter (each, a "***Renewal Term***" and together with the Initial Term, the "***Term***"), in each case unless either party hereto provides the other party hereto with written notice that such period shall not be so extended at least sixty (60) days in advance of the expiration of the Initial Term or the then-current Renewal Term, as applicable (a "***Non-Renewal***").

**2. At-Will Employment.** The Company and the Executive agree that the Executive's employment with the Company is "at-will," meaning that Executive may terminate her employment at any time for any reason or no reason, and that Company may terminate Executive's employment at any time for any reason or no reason, subject to the terms, conditions, and obligations set forth in Section 4 and Section 5 of this Agreement.

**3. Compensation and Related Matters.**

(a) Base Salary. Commencing April 12, 2021 (the "***Start Date***"), the Company shall pay Executive a salary at the annual rate of $550,000 (the "***Base Salary***"), less such deductions as are required by law or that Executive may elect in accordance with Company policy and procedure, payable in equal periodic installments in accordance with Company's customary payroll practices. The Base Salary shall be prorated for any partial year of employment on the basis of a 365-day year commencing on the Start Date and each anniversary thereof. The Board shall review the Base Salary annually based on performance and market conditions, and may increase (but not decrease) the Base Salary in its discretion.

(b) Annual Bonus. For each completed Company fiscal year during the Term (each, a "***Bonus Year***"), Executive shall be eligible to receive an annual bonus (the "***Annual Bonus***"), payable seventy percent (70%) in cash and thirty percent (30%) in shares of the Company's common stock, which is equivalent to not less than eighty percent (80%) of the then-current Base Salary (the "***Annual Bonus Target***"), based on achievement as determined in the sole discretion of the Board of objectives which will be set by Executive and the Board as part of the annual budget process in accordance with the Company's management incentive compensation plan for executives. The Annual Bonus, if any, shall be paid by March 15 in the year following the applicable Bonus Year (the "***Bonus Payment Date***"). For the year ended December 31, 2021, Executive shall be entitled to receive an Annual Bonus equal to eighty percent (80%) of Base Salary pro-rated for time of service from the Start Date. Notwithstanding anything to the contrary herein, the Annual Bonus shall not be paid if Executive resigns without "Good Reason" (as defined below) or is terminated at any time for "Cause" (as defined below) prior to the Bonus Payment Date. Shares paid as part of the Annual Bonus will be net-settled for tax withholding to the extent permitted by law. The Board shall review the Annual Bonus Target annually based on performance and market conditions, and may increase (but not decrease) the Annual Bonus Target in its discretion.

(c) Equity Awards.

(i) Stock Option Grant. Executive shall be provided a one-time grant on the Effective Date of one million (1,000,000) non-qualified stock options to purchase shares of the Company's common stock, par value $0.01 per share (the "***Common Stock***"), pursuant and subject to the Company's 2015 Stock Option Plan, as amended (the "***Stock Option Plan***"), pursuant to an award agreement in substantially the form set forth as Exhibit A hereto, with an exercise price equal to the Fair Market Value (as defined in the Stock Option Plan) of the Common Stock on the Effective Date (the "***Option***").

(ii) Time-Vested Restricted Stock. On the Start Date, the Company shall issue to Executive two hundred thousand (200,000) restricted shares of Common Stock subject to Executive's execution and delivery of a Restricted Stock Agreement in substantially the form attached as Exhibit B hereto (the "***Time-Vested Restricted Stock***").

(iii) Net Sales Growth Restricted Stock. On the Start Date, the Company shall issue to Executive six hundred thousand (600,000) restricted shares of Common Stock subject to Executive's execution and delivery of a Restricted Stock Agreement in substantially the form attached as Exhibit C hereto (the "***Net Sales Growth Restricted Stock***").

(iv) Market Cap Restricted Stock. On the Start Date, the Company shall issue to Executive two hundred thousand (200,000) restricted shares of Common Stock subject to Executive's execution and delivery of a Restricted Stock Agreement in substantially the form attached as Exhibit D hereto (the "***Market Cap Restricted Stock***" and, together with the Time-Vested Restricted Stock and the Net Sales Growth Restricted Stock, the "***Restricted Stock***").

(v) Registration. To the extent permitted by law, the Company shall include the shares of Common Stock underlying the Annual Bonus, Option and Restricted Stock on the first Form S-8 that the Company files during the Term. Without limiting the foregoing, the Company shall register all such shares of Common Stock no later than the first anniversary of the Start Date. Executive agrees that, during the Term, she will not sell any shares of Common Stock underlying the Annual Bonus for a period of at least six (6) months following the payment of such shares.

(vi) Change of Control Termination. Upon a Change of Control Termination, the shares of Common Stock underlying the Option and Restricted Stock shall automatically vest in full. "***Change of Control Termination***" as used herein means Executive's employment being terminated by the Company (or its successor) without Cause or by the Executive for Good Reason within three (3) months before or twelve (12) months after any of the following occur: (A) the acquisition by any person or group, other than the Company, of 50% or more of the voting stock of the Company; (B) within any two year period the individuals who constituted the Board at the beginning of the period shall cease for any reason to constitute a majority of the Board, provided that the election of each subsequent member who was approved in advance by two-thirds of the members of the Board in office at the beginning of such two year period or whose election or nomination for election was previously so approved, shall be considered as though such individual was a member of the Board at the beginning of the period;

(C) the consummation of a merger, consolidation or reorganization, the result of which is that the shareholders of the Company immediately prior to the merger, consolidation or reorganization do not own and control immediately after the merger, consolidation or reorganization at least 50% of the value of the outstanding equity and combined voting power of the then outstanding voting securities of the Company entitled to vote generally in the election of directors of the Board; or (D) a sale, exclusive license or other disposition (in one transaction or a series of related transactions) of all or substantially all of the Company's assets (each of A through D, a "***Change of Control***").

(d) Expenses. Executive shall receive reimbursement from the Company for all reasonable and documented out-of-pocket expenses incurred by Executive in performing services hereunder. All expenses must be accounted for and paid in accordance with the standard policies and procedures established by the Company for reimbursement of expenses. The Company shall reimburse Executive for reasonable and documented legal fees associated with negotiating this Agreement, up to a maximum of $12,500. For the avoidance of doubt, to the extent that any reimbursements (including any taxable benefits reimbursements) are subject to the provisions of Section 409A of the Code: (a) to be eligible to obtain reimbursement for such expenses Executive must submit expense reports within 30 days after the expense is incurred, (b) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (c) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (d) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

(e) Vacation; Paid Time Off . Executive shall be entitled to five (5) weeks of paid vacation per calendar year (pro-rated according to the Company's standard policies and procedures related to accrual of vacation and/or paid time off), to be taken at such times and for such periods as shall not interfere with the duties required to be rendered by Executive hereunder. Executive shall not be paid for accrued but unused vacation or paid time off upon termination of Executive's employment for any reason, unless otherwise required by law. Prior to the Start Date, Executive shall be on unpaid leave from employment.

( f ) Other Benefits. Executive shall be eligible to participate in such insurance, medical, dental, disability, and retirement plans and other programs as may be approved from time to time by the Company for the benefit of its executives (the "***Benefit Plans***"), in accordance with their terms, except any such Benefit Plans with respect to which Executive voluntarily executes a legally effective waiver. Nothing herein shall affect the Company's right to amend, modify, or terminate any Benefit Plans at any time for any reason.

( g ) Indemnification and Directors and Officers Liability Insurance. In addition to any indemnification provided under the Company's by-laws, a directors' and officers' liability insurance policy (or policies) shall be kept in place, during Executive's employment and thereafter for the duration of any period in which a civil, equitable, criminal or administrative proceeding may be brought against the Executive, providing coverage to the Executive that is no less favorable to the Executive in any respect (including with respect to scope, exclusions, amounts, and deductibles) than the coverage then being provided with respect to periods after the Effective Date to any other senior executive or director of the Company.

**4. Termination of Employment.**

( a ) Termination by Company. The Company may terminate Executive's employment with the Company at any time (i) without Cause (as defined below); or (ii) with Cause (as defined below). For purposes of this Agreement, **"*Cause*"** shall mean Executive's: (A) gross negligence or willful misconduct with respect to the Company, including, without limitation engagement in dishonesty with respect to the Company's business or illegal conduct that is injurious to the Company, its business or its reputation; (B) embezzlement, theft or fraud; (C) conviction of or plea of guilty or no contest to a felony; (D) personal conduct in furtherance of a hostile work environment or personal engagement in discrimination in violation of any state or federal anti-harassment or discrimination statute; (E) breach of any material obligation under this Agreement or any other written agreement between Executive and the Company; or (F) knowing and intentional violation of the Company Code of Ethics.

For purposes of this provision, no act or failure to act on the part of Executive shall be considered "willful" or "intentional" unless it is done, or omitted to be done, by Executive in bad faith or without reasonable belief that Executive's action or omission was in the best interests of the Company. Any act, or failure to act, based on authority given pursuant to a resolution duly adopted by the Board or on the advice of counsel for the Company shall be conclusively presumed to be done, or omitted to be done, by Executive in good faith and in the best interests of the Company.

Except for a failure, breach, conduct or refusal which, by its nature, cannot reasonably be expected to be cured, Executive shall have ten (10) days from the delivery of written notice by the Company within which to cure any acts constituting Cause; provided however, that, if the Company reasonably expects irreparable injury from a delay of ten (10) days, the Company may give Executive notice of such shorter period within which to cure as is reasonable under the circumstances.

( b ) Without Good Reason by Executive. Executive may terminate her employment with the Company without "Good Reason" (as defined below) by giving Company not less than sixty (60) days' prior written notice.

( c ) For Good Reason By Executive. Executive may terminate her employment under this Agreement for Good Reason. "Good Reason" shall mean, in each case to the extent not consented by Executive: (i) a breach by the Company of any material provision of this Agreement or any other written agreement between Executive and the Company; (ii) material a reduction of the Executive's authority, duties, responsibilities, or requiring Executive to report to any individual or governing body other than the Company's Board; (iii) a reduction of the Executive's then-current Base Salary or Annual Bonus Target; (iv) an involuntary relocation of Executive's principal place of employment by more than 100 miles or two (2) hours one-way driving time, provided that the Executive is required to report to such place in person; (v) the Company's failure to obtain an agreement from any successor to the Company to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no succession had taken place, except where such assumption occurs by operation of law; (vi) the Company's Common Stock no longer being publicly traded;

or (vii) the Company's failure to renew this Agreement at the end of the Initial Term or the then-current Renewal Term.

Notwithstanding the foregoing, no action by the Company shall constitute Good Reason unless and until (A) the Company shall have received, within thirty (30) days of Executive's discovery of the existence of the condition constituting Good Reason, written notice from the Executive alleging that such Good Reason exists and setting forth the basis therefore in reasonable detail (the "***Good Reason Notice***"); and (B) within thirty (30) days after the receipt of said notice by the Company, the Company shall have failed to cure or correct the circumstances giving rise to such Good Reason.

( d ) Death. Executive's employment hereunder shall terminate upon her death.

( e ) Disability. The Company may terminate Executive's employment hereunder if: (i) as a result of Executive's incapacity due to physical or mental illness, Executive shall have been absent from her duties hereunder for a period of 120 consecutive days or a total of 180 days during any 365-day period and is unable during such absence to perform the essential duties of her job with or without a reasonable accommodation; and (ii) if within ten (10) days after written notice of termination is given by the Company to Executive (which may occur at or after the end of such period), Executive shall not have returned (without further absence due to the same disability) to the performance of her duties hereunder on a full-time basis ("***Disability***"). Any question as to the existence of Executive's Disability as to which Executive and the Company cannot agree shall be determined in writing by a qualified independent physician mutually acceptable to Executive and the Company. If Executive and the Company cannot agree as to a qualified independent physician, each shall appoint such a physician and those two physicians shall select a third who shall make such determination in writing. The determination of Disability made in writing to the Company and Executive shall be final and conclusive for all purposes of this Agreement. During any period that Executive fails to perform her duties hereunder as a result of incapacity due to such physical or mental illness (the "***Disability Period***"), Executive shall continue to receive her Base Salary as set forth in Section 3(a) of this Agreement until her employment is terminated pursuant to this Section 4(e), provided that payments so made to Executive during the Disability Period shall be reduced by the sum of the amounts, if any, payable to Executive under Social Security and/or a disability benefit plans of the Company.

**5. Compensation Upon Termination of Employment.**

( a ) Earned and Unpaid Base Salary. If Executive's employment terminates for any reason, the Company shall pay the Executive her full Base Salary earned through the effective date of termination of Executive's employment (the "***Termination Date***") and reimburse Executive for all expenses incurred in accordance with this Agreement (the "***Accrued Amounts***"), and the Company shall have no further obligations whatsoever to Executive under this Agreement except as may be provided in Section 5(b) or Section 5(c). The Accrued Amounts shall be paid to Executive in accordance with applicable laws, not to exceed thirty (30) days after the Termination Date.

( b ) Severance. If Executive's employment is terminated by the Company pursuant to Section 4(a)(i) above or by Executive pursuant to Section 4(c) above, then the Company shall pay Executive the Accrued Amounts pursuant to Section 5(a) and, subject to her execution of a general release of claims in favor of the Company and its affiliates substantially in the form attached as Exhibit E, the Company shall pay Executive (subject to adjustment pursuant to Section 18 hereof, as applicable):

(i) an amount equal to twelve (12) months of her Base Salary as in effect as of the Termination Date. Such amount shall be paid in accordance with the normal payroll cycle over the twelve (12) month period following the Termination Date, in accordance with the Company's customary payroll practices;

(ii) an Annual Bonus for the year of termination at 100% of the Annual Bonus Target, payable in in cash. Such amount shall be paid in accordance with the normal payroll cycle over the twelve (12) month period following the Termination Date, in accordance with the Company's customary payroll practices;

(iii) reimbursement from the Company for any COBRA premiums paid by Executive for the continuation of Executive's health insurance as currently enrolled on the Termination Date, for the same twelve (12) month period after the Termination Date; and

(iv) if termination occurs after January 1, 2022, acceleration of vesting of the Option and Time-Vested Restricted Stock Award as follows: (A) if the Option is not then fully vested, 250,000 shares of the Option shall automatically vest on the Termination Date; and (B) if the Time-Vested Restricted Stock is not then fully vested, 50,000 of such Time-Vested Restricted Stock shall automatically vest on the Termination Date (the foregoing (i)-(iv), collectively, "***Severance***").

Other than as set forth in this Section 5(b), the Company shall have no further obligations to Executive under this Agreement following termination of Executive's employment pursuant to Sections 4(a)(i) or 4(c) above.

( c ) Death and Disability. If Executive's employment is terminated by her death or Disability following the end of a completed fiscal year but prior to the Annual Bonus Payment Date, in addition to the Accrued Amounts paid under Section 5(a), the Company shall pay Executive the earned Annual Bonus, if any, in connection with the completed fiscal year prior to the Termination Date that would have been earned and payable to Executive under Section 3(b) had Executive remained an employee of the Company through the Annual Bonus Payment Date for that fiscal year. The earned Annual Bonus shall be paid in accordance with Section 3(b).

( d ) Breach of Severance Obligations. A material breach of the Company's obligations to pay Executive the Severance (other than as a result of the Company's good faith dispute as to the existence of "Good Reason" or "Cause" or activities referenced in Section 5(e) below) that remains uncured for a period of thirty (30) days after written notice thereof shall relieve Executive of her post-employment non-competition and non-solicitation restrictions owed to the Company hereunder or in any other agreement with the Company.

( e ) Clawback. Notwithstanding anything to the contrary contained in this Agreement: (i) if the Company's financial results for any time period, and the Company's financial statements covering all or part of such period, are subsequently restated and such restatement shows Clawback Compensation was incorrectly paid or vested, the Executive shall be required to forfeit the Clawback Compensation that was incorrectly paid or vested as a result of such previously reported incorrect financial results, as applicable, in such period; (ii) to the extent Executive's fraud or other Misconduct resulted in the receipt or vesting of Clawback Compensation, the Executive shall forfeit such improperly paid or vested Clawback Compensation; or (iii) if Executive, without the consent of the Company, while employed by the Company or after termination of such employment, breaches any of Section 8 of this Agreement and fails to cure (if curable) such breach after written notice thereof and a reasonable opportunity to cure, then Executive shall forfeit the Clawback Compensation. Further, if Executive otherwise has engaged in or engages in any activity referred to in the preceding clauses (i) – (iii), she shall forfeit any compensation, gain or other value realized on the vesting or exercise of the Clawback Compensation required to be returned to the Company, or the sale of shares of Common Stock acquired in respect thereof, and must promptly repay such amounts to the Company. "***Clawback Compensation***" means the Annual Bonus, Option, Restricted Stock and any shares of Common Stock issued thereunder. "***Misconduct***" means willful misconduct, or an act or omission done, or omitted to be done, by Executive negligently or in bad faith or without reasonable belief that Executive's action or omission was in the best interests of the Company but shall exclude any act or omission done, or omitted to be done, at the direction of the Board or on the advice of counsel for the Company. For the avoidance of doubt, approval by the Board of a public filing shall not constitute approval of an act or omission unless the Board has been informed of such act or omission. This clawback provision shall terminate upon a Change in Control. In addition, and without limiting the foregoing, any incentive-based or other compensation paid to Executive under this Agreement or any other agreement or arrangement with the Company which is subject to recovery under any law, government regulation, or stock exchange listing requirement will be subject to such deductions and clawback as may be required to be made pursuant to such law, government regulation, or stock exchange listing requirement (or any policy adopted by the Company pursuant to any such law, government regulation or stock exchange listing requirement).

**6 . Representations and Warranties of Executive**. Executive represents and warrants to the Company that (i) she is free to accept employment hereunder and that she has no prior or other obligations or commitments of any kind that would in any way hinder or interfere with her acceptance of, or the full performance of, such employment, and (ii) the representations and warranties set forth on Schedule I hereto are true and correct as of the Effective Date.

**7. Confidentiality.**

(a) During Executive's employment and at all times thereafter, Executive shall keep Confidential Information (as defined below) strictly confidential. Executive 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 her attorneys, financial advisors and accountants (**"*Representatives*"**), as applicable, to the extent necessary to permit such Representatives to assist Executive in any Permitted Use (as defined below); provided that Executive shall require each such Representative to be bound by obligations of confidentiality comparable to the terms of this Section 7 and Executive shall be responsible for any breach of this Section 7 by any of her Representatives.

(b) If Executive or any of her Representatives is required, in the written opinion of Executive's counsel provided to the Company prior to such disclosure, to disclose any Confidential Information, by law, regulation or legal or regulatory process, Executive shall: (i) if permitted by applicable law, 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 (ii) 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, Executive will (x) furnish only that portion of the Confidential Information which, in the opinion of Executive's counsel, is legally required to be disclosed and, (y) upon the Company's request, use its reasonable best efforts to obtain assurances that confidential treatment will be accorded to such information, and (z) take 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.

( c ) **"*Confidential Information*"** shall mean all trade secrets, 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: (i) information that at the time of disclosure is generally available to and known by the public (other than as a result of its disclosure directly or indirectly by Executive or any of her Representatives in violation of this Agreement); (ii) information that was previously known to Executive prior to the time it was obtained from or disclosed by the Company or its representatives to Executive, as documented by her business records; or (iii) information that is independently developed by Executive after the Term without use of or reliance on the Confidential Information, as documented by her business records.

(d) Executive shall make no use whatsoever, directly or indirectly, of any Confidential Information, except for the purposes of performing Executive's duties and obligations to the Company.

(e) Upon the termination of Executive's employment and upon the Company's request at any time and for any reason, Executive shall promptly deliver to the Company all materials (including all soft and hard copies) in Executive's possession or control which contain or relate to Confidential Information, as well as all information necessary to access such Confidential Information.

( f ) Permitted Communications. Nothing herein prohibits or restricts Executive (or Executive's attorney) from initiating communications directly with, responding to an inquiry from, or providing testimony before the Securities and Exchange Commission (SEC), the Financial Industry Regulatory Authority (FINRA), any other self-regulatory organization, or any other federal or state regulatory authority regarding a possible securities law violation.

**8. Non-Competition; Non-Solicitation; Non-Disparagement.**

(a) During Executive's employment and for the duration of the Restricted Period, Executive shall not engage in any Prohibited Activity anywhere in the world. For the purposes of this Agreement, (i) "***Restricted Period***" shall mean twelve (12) months following termination of Executive's employment under this Agreement; and (ii) "***Prohibited Activity***" shall mean the design, development, marketing, sale, re-sale, manufacture or distribution of home infusion products, or other similar activities, or the engagement in any other business in which the Company is actively engaged immediately prior to the commencement of the Restricted Period, in each case on Executive'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).

(b) During Executive's employment and for the duration the Restricted Period, Executive 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, or instant message), attempt to contact or meet with any existing customer of the Company, or a prospective customer of the Company that is being actively pursued by the Company and has invited further contact, as evidenced by written records of the Company, in each case for purposes of offering goods or services competitive with those offered by the Company; or (iii) induce, influence or encourage any existing customer, supplier or other business partner of the Company for purposes of diverting their business or services from the Company. General solicitations (e.g., newspaper and Internet postings) that are not specifically and intentionally directed to the Company's employees shall not be prohibited by Section 8(b)(i).

(c) Executive shall not, during her employment hereunder or thereafter, make, publish or communicate to any person 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. The Company, its affiliates and its directors and executive officers shall not, during Executive's employment hereunder or thereafter, make, publish or communicate to any person any comments or statements (whether written or oral) that denigrate or disparage the reputation or stature of Executive.

(d) Executive acknowledges that the restrictions contained in this Section 8 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 Executive under this Agreement. In the event that any covenant contained in this Section 8 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 hereby expressly

requested and empowered to reform such covenant, and such covenant, if not so reformed by such court, 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 8 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.

**9. 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 Executive, either alone or in conjunction with others, at any place or at any time during her employment, 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 Executive or (ii) Executive'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 Executive. In addition, without limiting the generality of the foregoing, all Company Developments which are copyrightable work by Executive 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) Executive 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, Executive 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. Executive 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. Executive hereby irrevocably designates and appoints the Company and its duly authorized officers and agents as Executive's agent and attorney-in-fact (which designation and appointment shall be deemed coupled with an interest and shall survive Executive's death or incapacity), to act for and on Executive'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 Executive.

**10. 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 applicable principles of conflict of laws. 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 THE SOUTHERN DISTRICT OF 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 Executive of Sections 7 through 9, or a breach by the Company of Section 8(c), each party hereby consents and agrees that the other party 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 the Executive 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 heirs, 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 non-assigning 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 to another person or entity without the consent of Executive; 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 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:

Repro Med Systems, Inc.
24 Carpenter Road
Chester, NY 10918
Attn: Chairman of the Board of Directors
Email: [personal information redacted]

If to the Executive:

Linda Tharby
[personal information redacted]
Email: [personal information redacted]

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(c)(v) (only to the extent any Annual Bonus has been paid or Options or Restricted Stock has vested prior to termination), 3(g), 5(b) through 5(e), and 7 through 23 shall survive termination of this Agreement.

**18. Section 409A**. It is intended by the parties that all provisions in this Agreement shall be interpreted in a manner consistent with Section 409A of the Internal Revenue Code of 1986, as amended, and regulations and guidance related thereto ("***Section 409A***"). Notwithstanding anything anywhere to the contrary, if Executive is a "specified employee" (within the meaning of Section 409A), any payments or arrangements due upon a termination of Executive's employment under any arrangement that constitutes a "deferral of compensation" (within the meaning of Section 409A), and which do not otherwise qualify under the exemptions under Section 409, shall be delayed and paid or provided on the earlier of (i) the date which is six months after Executive's "separation from service" (as such term is defined in Section 409A) for any reason other than death, and (ii) the date of Executive's Death. Each in a series of payments under this Agreement or otherwise shall be treated as separate payments for purposes of Section 409A. "Termination of employment," "resignation" or words of similar import, as used in this Agreement, shall mean with respect to any payments subject to Section 409A, Executive's "separation from service" as defined by Section 409A. If any payment subject to Section 409A is contingent on the delivery of a release by Executive and could occur in either of two calendar years, the payment will occur in the second calendar year. To the extent that reimbursements or other in-kind benefits under this Agreement constitute "nonqualified deferred compensation" subject to Section 409A, (x) all such expenses or other reimbursements hereunder shall be paid on or prior to the last day of the taxable year following the taxable year in which such expenses were incurred by Executive, (y) no such reimbursement, expenses eligible for reimbursement or in-kind benefits shall in any way affect the expenses eligible for reimbursement or in-kind benefits to be provided in any other taxable year, and (z) Executive's right to such reimbursement or in-kind benefits shall not be subject to liquidation or exchange for any other benefit. Nothing in this Agreement shall be construed as a guarantee of any particular tax treatment to Executive. Executive shall be solely responsible for the tax consequences with respect to all amounts and benefits provided under this Agreement, and in no event shall the Company, its affiliates, or their respective past, present or future employees, officers, directors, consultants, agents, counsel or any other person or entity have any responsibility or liability if this Agreement does not satisfy any applicable requirement(s) of such Section 409A.

**19. Section 280G.**

(a) If (i) the aggregate of all amounts and benefits due to Executive under this Agreement or under any Company plan, program, agreement or arrangement, would, if received by Executive in full and valued under Section 280G of the Code, constitute "parachute payments" as such term is defined in and under Section 280G of the Code (collectively, "***280G Benefits***"), and if (ii) such aggregate would, if reduced by all federal, state and local taxes applicable thereto, including the excise tax imposed pursuant to Section 4999 of the Code, be less than the amount

Executive would receive, after all taxes, if Executive received aggregate 280G Benefits equal (as valued under Section 280G of the Code) to only three times Executive's "base amount", as defined in and under Section 280G of the Code, less $1.00, then (iii) such cash 280G Benefits (in reverse order of maturity, to the extent that the reduction of such cash 280G Benefits can achieve the intended result) shall be reduced or eliminated to the extent necessary so that the 280G Benefits received by Executive will not constitute parachute payments. The determinations with respect to this Section 19(a) shall be made by an independent auditor (the "***Auditor***") paid by the Company. The Auditor shall be the Company's regular independent auditor unless Executive reasonably objects to the use of that firm, in which event the Auditor will be a nationally recognized firm chosen by the parties hereto.

(b) It is possible that, after the determinations and selections made pursuant to Section 19(a), Executive will receive 280G Benefits that are, in the aggregate, either more or less than the amount provided under Section 19(a) (hereafter referred to as an "***Excess Payment***" or "***Underpayment***", respectively). If it is established, pursuant to a final determination of a court or an Internal Revenue Service proceeding that has been finally and conclusively resolved, that an Excess Payment has been made, Executive shall promptly repay the Excess Payment to the Company, together with interest on the Excess Payment at the applicable federal rate (as defined in and under Section 1274(d) of the Code) from the date of Executive's receipt of such Excess Payment until the date of such repayment. In the event that it is determined (x) by a court or (y) by the Auditor upon request by any of the parties hereto, that an Underpayment has occurred, the Company shall promptly pay an amount equal to the Underpayment to Executive, together with interest on such amount at the applicable federal rate from the date such amount would have been paid to Executive had the provisions of Section 19(a) not been applied until the date of payment.

**20. Counterparts.** This Agreement may be executed in one or more counterparts, and by the 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.

**21. 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.

**22. Entire Agreement.** This Agreement constitutes the entire agreement and supersedes all prior agreements and understandings, both written and oral, among, by or between any of the parties with respect to the subject matter hereof and thereof, including without limitation any separate confidentiality agreement Executive may have previously signed.

**23. Priority.** In the event of a conflict between this Agreement and any of the agreements or documents memorializing the Option or the Restricted Stock, including an equity or incentive plan governing the terms of such grants of equity, this Agreement shall control.

[signature page follows]

IN WITNESS WHEREOF, the parties have executed this Employment Agreement as of the Effective Date.

EXECUTIVE:

/s/ Linda Tharby
Linda Tharby

COMPANY:

Repro Med Systems, Inc.

By: /s/ R. John Fletcher
R. John Fletcher
Chairman of the Board

**EXHIBIT A**

REPRO MED SYSTEMS, INC.

2015 STOCK OPTION PLAN

NONQUALIFIED STOCK OPTION AWARD

This NONQUALIFIED STOCK OPTION AWARD (this " ***Agreement***"), dated March 15, 2021 (the "***Date of Grant***"), is delivered by Repro Med Systems, Inc., a New York corporation (the "***Company***"), to Linda Tharby (the "***Grantee***").

The Company's 2015 Stock Option Plan (the " ***Plan***") provides for the grant of nonqualified stock options to purchase shares of common stock, par value $0.01 per share, of the Company ("***Company Stock***"). The Company and Grantee have entered into that certain Employment Agreement dated as of March 15, 2021 (the "***Employment Agreement***"), which sets forth the terms and conditions pursuant to which Grantee will provide services to the Company. The Compensation Committee of the Board of Directors of the Company (the "***Committee***") has decided to make a nonqualified stock option grant to encourage the Grantee to contribute materially to the growth of the Company, thereby benefiting the Company's stockholders, and aligning the economic interests of the Grantee with those of the stockholders. A copy of the Plan is attached to this Agreement. All capitalized terms not otherwise defined in this Agreement shall have the meaning ascribed to such terms in the Plan.

NOW, THEREFORE, the parties to this Agreement, intending to be legally bound hereby, agree as follows:

1 . Grant of Option. Subject to the terms and conditions set forth in this Agreement, the Employment Agreement and the Plan, the Company hereby grants to the Grantee a nonqualified stock option (the "***Option***") to purchase up to one million (1,000,000) shares of Company Stock (" ***Shares***") at an exercise price of $____ per Share (the "***Strike Price***").

2. Exercisability of Option.

(a) The Option shall become exercisable on the following dates (each, a " ***Vesting Date***"): 25% of the Shares shall vest on the one (1) year anniversary of the Date of Grant (the "***Vesting Commencement Date***"), and the remaining Shares shall vest as follows: 25% of the Shares at the end of each successive twelve (12) month period following the Vesting Commencement Date, provided the Grantee is still employed by the Company pursuant to the Employment Agreement on the respective Vesting Date.

(b) The exercisability of the Option is cumulative, but shall not exceed 100% of the Shares subject to the Option.

3. Option Term.

(a) The Option shall have a term of ten (10) years from the Date of Grant and shall terminate at the expiration of that period, unless it is terminated at an earlier date pursuant to the provisions of this Agreement or the Plan.

(b) If the Grantee's employment with the Company terminates without Cause (as defined in the Employment Agreement) and for any reason other than death or disability, the then vested portion of the Option shall continue to be exercisable until the earlier of the 90th day after the date of the Grantee's termination or the date the Option expires by its terms. The portion of the Option not vested as of the date of such termination of employment shall expire as of such date and shall not be exercisable.

(c) If the Grantee's employment with the Company is terminated by the Company for Cause (as defined in the Employment Agreement), the Option shall expire on the date of such termination, and no portion shall be exercisable after the date of such termination.

(d) In the event of the Grantee's termination of employment due to death or disability during employment with the Company, the vested portion of the Option shall continue to be exercisable until the earlier of (i) the date the Option expires by its terms and (ii) 12 months after the date of such termination.

(e) In the event of the Grantee's death occurs after employment termination but during the 90 day period following such termination , the vested portion of the Option shall continue to be exercisable until the earlier of (i) the date the Option expires by its terms and (ii) the first anniversary of the Grantee's death.

4. Exercise Procedures.

(a) Subject to the provisions of Paragraphs 2 and 3 above, the Grantee may exercise part or all of the exercisable Option by giving the Company written notice to exercise in the manner provided in this Agreement, specifying the number of Shares as to which the Option is to be exercised and tendering payment for such Shares. The Grantee shall pay an amount equal to the Strike Price multiplied by the number of Shares as to which the Option is to be exercised (the "***Exercise Price***") (i) by certified or official bank check (or the equivalent thereof acceptable to the Company); or (ii) with the consent of the Committee, by delivery of shares of Common Stock acquired at least six months prior to the option exercise date and having a Fair Market Value (as defined in the Plan and determined as of the exercise date) equal to all or part of the Exercise Price and a certified or official bank check (or the equivalent thereof acceptable to the Company) for any remaining portion of the Exercise Price; or (iii) with the consent of the Committee, by surrender of the right to receive Shares of Common Stock that are being offered for purchase under the Option (as contemplated by section 1.422-5(b) of the treasury regulations), having a Fair Market Value (as defined in the Plan) equal to all or part of the Exercise Price and a certified or official bank check (or the equivalent thereof acceptable to the Company) for any remaining portion of the Exercise Price.

(b) The Company's obligation to deliver Shares upon exercise of the Option shall be subject to all applicable laws, rules and regulations and also to such approvals by governmental agencies as may be deemed appropriate by the Committee, including such actions as Company counsel shall deem necessary or appropriate to comply with relevant securities laws and regulations. The Company may require that the Grantee (or other person having the right to exercise the Option) represent that the Grantee (or such other person) is purchasing Shares for his/her own account and not with a view to or for sale in connection with any distribution of the Shares, or such other representation as the Committee deems appropriate.

(c) All obligations of the Company under this Agreement shall be subject to the rights of the Company as set forth in the Plan to withhold amounts required to be withheld for any taxes, if applicable. Subject to Committee approval, the Grantee may elect to satisfy any tax withholding obligation of the Company with respect to the Option by having Shares withheld from delivery having a value equal to the amount of the tax withheld. The election must be in a form and manner prescribed by the Committee and shall be subject to the prior approval of the Committee.

5. Restrictions on Exercise. Except as the Committee may otherwise permit pursuant to the Plan, only the Grantee may exercise the Option during the Grantee's lifetime and, after the Grantee's death, the Option shall be exercisable (subject to the limitations specified in the Plan) solely by the legal representatives of the Grantee, or by the person who acquires the right to exercise the Option by will or by the laws of descent and distribution, to the extent that the Option is exercisable pursuant to this Agreement.

6. Grant Subject to Plan Provisions. This grant is made pursuant to the Plan, the terms of which are incorporated herein by reference, and in all respects shall be interpreted in accordance with the Plan. The grant and exercise of the Option are subject to interpretations, regulations and determinations concerning the Plan established from time to time by the Committee in accordance with the provisions of the Plan, including, but not limited to, provisions pertaining to (a) rights and obligations with respect to withholding taxes, (b) the registration, qualification or listing of the Shares, (c) changes in capitalization of the Company and (d) other requirements of applicable law. The Committee shall have the discretionary authority to interpret and construe the Option pursuant to the terms of the Plan, and its decisions shall be conclusive as to any questions arising hereunder.

**7.** Restrictions on Sale or Transfer of Shares.

(a) The Grantee agrees that he or she shall not sell, transfer, pledge, donate, assign, mortgage, hypothecate or otherwise encumber the Shares underlying the Option unless the Shares are registered under the Securities Act of 1933, as amended (the "***Securities Act***"), or the Company is given an opinion of counsel reasonably acceptable to the Company that such registration is not required under the Securities Act.

(b) As a condition to receive any Shares upon the exercise of the Option, the Grantee agrees to be bound by the Company's policies regarding the limitations on the transfer of such Shares, and understands that the Grantee will be prohibited from selling, transferring, pledging, donating, assigning, mortgaging, hypothecating or otherwise encumbering the Shares.

8. No Employment or Other Rights. The grant of the Option shall not confer upon the Grantee any right to be retained by or in the service of the Company and shall not interfere in any way with the right of the Company to terminate the Grantee's employment at any time. The right of the Company to terminate at will the Grantee's employment at any time for any reason is specifically reserved.

9. No Stockholder Rights. Neither the Grantee, nor any person entitled to exercise the Option, shall have any of the rights and privileges of a stockholder with respect to the Shares subject to the Option, until certificates for Shares have been issued upon the exercise of the Option.

10. Assignment and Transfers. Except as the Committee may otherwise permit pursuant to the Plan, the rights and interests of the Grantee under this Agreement may not be sold, assigned, encumbered or otherwise transferred except, in the event of the death of the Grantee, by will or by the laws of descent and distribution. In the event of any attempt by the Grantee to alienate, assign, pledge, hypothecate, or otherwise dispose of the Option or any right hereunder, except as provided for in this Agreement, or in the event of the levy or any attachment, execution or similar process upon the rights or interests hereby conferred, the Company may terminate the Option by notice to the Grantee, and the Option and all rights hereunder shall thereupon become null and void. The rights and protections of the Company hereunder shall extend to any successors or assigns of the Company and to the Company's parents, subsidiaries, and affiliates. This Agreement may be assigned by the Company without the Grantee's consent.

11. Applicable Law. The validity, construction, interpretation and effect of this instrument shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to the conflicts of laws provisions thereof.

12. Notice. Any notice to the Company provided for in this instrument shall be addressed to the Company in care of the Chief Financial Officer at the headquarters of the Company, and any notice to the Grantee shall be addressed to such Grantee at the current address shown on the payroll of the Company, or to such other address as the Grantee may designate to the Company in writing. Any notice shall be delivered by hand, or enclosed in a properly sealed envelope addressed as stated above, registered and deposited, postage prepaid, in a post office regularly maintained by the United States Postal Service.

13. Priority. In the event of a conflict between this Agreement and the Employment Agreement, including the provisions therein governing accelerated vesting upon a Change in Control (as defined in the Employment Agreement) or vesting upon termination, the Employment Agreement shall control.

*[SIGNATURE PAGE FOLLOWS]*

IN WITNESS WHEREOF, the Company has caused its duly authorized officer to execute this Agreement, and the Grantee has executed this Agreement, effective as of the Date of Grant.

Repro Med Systems, Inc.

By:_____
Name: R. John Fletcher
Title: Chairman of the Board

I hereby accept the Option described in this Agreement, and I agree to be bound by the terms of the Plan and this Agreement. I hereby further agree that all of the decisions and determinations of the Committee shall be final and binding.

Grantee:_____
Linda Tharby

**EXHIBIT B**

**RESTRICTED STOCK AGREEMENT**

THIS RESTRICTED STOCK AGREEMENT (this "***Agreement***"), dated as of April 12, 2021 (the "***Effective Date***"), is made by and between Repro Med Systems, Inc. d/b/a KORU Medical Systems, a New York corporation, having its principal place of business at 24 Carpenter Road, Chester, NY 10918 (the "***Company***"), and Linda Tharby, an individual residing at [personal information redacted] ("***Executive***").

WHEREAS, Company and Executive have entered into an Employment Agreement dated as of March 15, 2021 (the "***Employment Agreement***"), which provides for the award to Executive of certain shares of the Company's common stock, par value $0.01 per share ("***Common Stock***"), subject to certain restrictions as described in this Agreement.

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, and intending to be legally bound hereby, the parties hereto agree as follows:

1. Restricted Stock Award. As of the Effective Date, the Company hereby issues to Executive two hundred thousand (200,000) shares of Common Stock (the "***Restricted Stock***"), subject to the restrictions and other conditions of this Agreement and the Employment Agreement (the "***Award***").

2. Restrictions.

(a) Vesting. The Award shall vest on the following dates (each, a "***Vesting Date***"): 25% of the Award shall vest on the first anniversary of the Effective Date, and the remainder of the Award shall vest 25% at the end of each twelve (12) month period thereafter, provided the Executive is still employed by the Company on the respective Vesting Date.

(b) Forfeiture. In the event all or a portion of the Award has not vested at the time the employment of Executive with the Company terminates for any reason, the unvested portion of the Award shall thereupon be forfeited immediately and without further action by the Company.

(c) Legend. Until such time as the Award has vested, the Company may, at any time, place legends referencing the restrictions described in this Section 2 and any applicable federal and/or state securities laws restrictions on certificates representing shares of Restricted Stock issued pursuant to this Agreement. The legend may include the following:

> "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS SET FORTH IN THE AWARD AGREEMENT BETWEEN THE CORPORATION AND THE REGISTERED HOLDER, A COPY OF WHICH IS ON FILE AT THE PRINCIPAL OFFICE OF THE CORPORATION."

3. Taxes.

(a) Executive understands, acknowledges and agrees that the value of the Restricted Stock is subject to state and federal income taxes and certain rules which require the Company to withhold amounts necessary to pay these taxes. Executive hereby authorizes the Company to reduce the number of shares of Restricted Stock to which Executive is entitled on the Vesting Date by the number of shares of Restricted Stock required to satisfy the tax withholding requirements (based on the Fair Market Value of shares at such time). Such shares of Restricted Stock shall be returned to the Company. Executive's acknowledgement and acceptance of these tax withholding provisions are conditions precedent to the right of Executive to receive the Restricted Stock under the Employment Agreement and this Agreement.

(b) In lieu of the reduction of shares delivered described in paragraph (a) above, Executive may pay to the Company the amount of tax required to be withheld in cash, by check or in other form satisfactory to the Company. Such payment must be made by the date which is ten (10) days after the Vesting Date.

(c) The Restricted Stock will be released to Executive when vested and the applicable withholding obligations have been satisfied.

(d) Executive understands that Section 83(a) of the Code taxes as ordinary income the difference between the amount, if any, paid for the shares of Common Stock and the Fair Market Value of such shares at the time the Restrictions on such shares lapse. Executive understands that, notwithstanding the preceding sentence, Executive may elect to be taxed at the time of the Award Date, rather than at the time the Restrictions lapse, by filing an election under Section 83(b) of the Code (an "***83(b) Election***") with the Internal Revenue Service with a copy to the Company within 30 days of the Award Date. In the event Executive files an 83(b) Election, Executive will recognize ordinary income in an amount equal to the difference between the amount, if any, paid for the shares of Common Stock and the Fair Market Value of such shares as of the Award Date. Executive acknowledges that the foregoing is only a summary of the effect of United States federal income taxation with respect to the award of Restricted Stock hereunder, and does not purport to be complete. EXECUTIVE FURTHER ACKNOWLEDGES THAT THE COMPANY IS NOT RESPONSIBLE FOR FILING EXECUTIVE'S 83(b) ELECTION, AND THE COMPANY HAS DIRECTED EXECUTIVE TO SEEK INDEPENDENT ADVICE REGARDING THE APPLICABLE PROVISIONS OF THE CODE, THE INCOME TAX LAWS OF ANY MUNICIPALITY, STATE OR FEDERAL GOVERNMENT OR FOREIGN COUNTRY IN WHICH EXECUTIVE MAY RESIDE, AND THE TAX CONSEQUENCES OF EXECUTIVE'S DEATH.

4 . Certain Changes in Capitalization and Reorganization Events. If there is any change in the outstanding shares of Common Stock by reason of a stock dividend or distribution, stock split-up, recapitalization, combination or exchange of shares of Common Stock, or by reason of any merger, consolidation, spinoff or other corporate reorganization in which the Company is the surviving corporation, the number of shares of Restricted Stock subject to the Award shall be equitably adjusted by the Company's Board of Directors, whose determination shall be final, binding and conclusive.

5 . Stock Certificates. Stock certificates issued in respect of this Award shall be registered in the name of Executive and shall be deposited in escrow with the Secretary of the Company or other escrow agent appointed by the Company. The deposited certificates shall remain in escrow until the Award has vested in full. Executive shall, upon the execution of this Agreement, execute Joint Escrow Instructions in the form attached to this Agreement as Exhibit A. The Joint Escrow Instructions shall be delivered to the Secretary of the Company as escrow agent thereunder. Executive shall deliver to such escrow agent a stock assignment duly endorsed in blank, in the form attached to this Agreement as Exhibit B, and hereby instructs the Company to deliver to such escrow agent, on behalf of Executive, the certificate(s) evidencing the Award issued hereunder. Such materials shall be held by such escrow agent pursuant to the terms of such Joint Escrow Instructions.

6 . Restricted Stock Not Transferable. Prior to vesting, no Restricted Stock or any interest or right therein or part thereof shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect; provided, however, that this Section 6 shall not prevent transfers by will or by applicable laws of descent and distribution.

7 . Rights as Stockholder. Subject to the provisions of Sections 2(b), 2(c), and 6 in this Agreement, Executive shall exercise all rights and privileges of a shareholder of the Company with respect to the Restricted Stock deposited in escrow. Executive shall be deemed to be the holder for purposes of receiving any dividends that may be paid with respect to such shares of Restricted Stock and for the purpose of exercising any voting rights relating to such shares of Restricted Stock, even if some or all of such shares of Restricted Stock have not yet vested, provided that any dividends otherwise payable on the Restricted Stock shall be held in escrow from and after the dividend payment date until the Restricted Stock vests, at which time the amount of the dividend shall be paid to Executive.

8 . Conformity to Securities Laws. Executive acknowledges that this Agreement is intended to conform to the extent necessary with all provisions of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, including without limitation Rule 16b-3 under the Exchange Act. Notwithstanding anything herein to the contrary, the Award is granted only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.

9 . Not a Contract of Employment. Nothing in this Agreement shall confer upon Executive any right to continue in the employ of the Company or shall interfere with or restrict in any way the rights of the Company, which are hereby expressly reserved, to discharge Executive at any time for any reason whatsoever, with or without cause, except as may otherwise be provided by any written agreement entered into by and between the Company and Executive.

10. 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 THE SOUTHERN DISTRICT OF 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.

11. Notices. All notices and other communications under this Agreement must be in writing and will be deemed given if (i) delivered personally, (ii) sent by internationally recognized overnight courier, (iii) mailed by registered or certified mail (return receipt requested), postage prepaid, or (iv) sent by electronic mail (provided that a copy is also sent by certified or registered mail or by internationally recognized overnight courier) 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:
Repro Med Systems, Inc.
24 Carpenter Road
Chester, NY 10918
Attn: Chairman of the Board of Directors
Email: [personal information redacted]

If to the Executive:
Linda Tharby
[personal information redacted]

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 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.

12. Counterparts. This Agreement may be executed in one or more counterparts, and by the 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.

13. 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.

14. Entire 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.

15. Priority. In the event of a conflict between this Agreement and the Employment Agreement, including the provisions therein governing accelerated vesting upon a Change in Control (as defined in the Employment Agreement) or vesting upon termination, the Employment Agreement shall control.

[signature page follows]

IN WITNESS WHEREOF, the parties have executed this Restricted Stock Agreement as of the Effective Date.

EXECUTIVE:

_____
Linda Tharby

COMPANY:

Repro Med Systems, Inc.

By: _____
R. John Fletcher
Chairman of the Board

**EXHIBIT C**

**RESTRICTED STOCK AGREEMENT**

THIS RESTRICTED STOCK AGREEMENT (this "***Agreement***"), dated as of April 12, 2021 (the "***Effective Date***"), is made by and between Repro Med Systems, Inc. d/b/a KORU Medical Systems, a New York corporation, having its principal place of business at 24 Carpenter Road, Chester, NY 10918 (the "***Company***"), and Linda Tharby, an individual residing at [personal information redacted] ("***Executive***").

WHEREAS, Company and Executive have entered into an Employment Agreement dated as of March 15, 2021 (the "***Employment Agreement***"), which provides for the award to Executive of certain shares of the Company's common stock, par value $0.01 per share ("***Common Stock***"), subject to certain restrictions as described in this Agreement.

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, and intending to be legally bound hereby, the parties hereto agree as follows:

1. Restricted Stock Award. As of the Effective Date, the Company hereby issues to Executive six hundred thousand (600,000) shares of Common Stock (the "***Restricted Stock***"), subject to the restrictions and other conditions of this Agreement and the Employment Agreement (the "***Award***").

2. Restrictions.

(a) Vesting. If the Company's Net Sales Growth (defined below) for any of the fiscal years ended December 31, 2022, 2023, 2024 or 2025 (each, a "***Target Year***") is at least the applicable Net Sales Target set forth on Schedule I hereto, then, on the applicable Vesting Date, a corresponding portion of the Award shall vest as set forth on Schedule I hereto. Additionally, if Net Sales Growth is less than any of the Net Sales Targets set forth in Schedule 1 in any Target Year (a "***Miss Year***"), vesting of the Award in the following Target Years (each such subsequent Target Year, a "***Catch-up Year***") shall be further subject to the following catch-up vesting provisions: if the Net Sales Growth in the Miss Year(s) when averaged with the Net Sales in each Catch-up Year(s) equals or exceeds a Net Sales Target in any single Miss Year that has not previously been obtained, then on the applicable Vesting Date, an additional portion of the Award shall vest as if the applicable Net Sales Target had been met in the Miss Year(s). Notwithstanding the foregoing, the Award shall automatically vest in full upon the Company maintaining, for a period of at least two consecutive fiscal quarters after January 1, 2022, a run rate over the previous four fiscal quarters of at least $[***], as reported in the Company's filings pursuant to the Securities Exchange Act of 1934, as amended.

(b) Definitions. "***Net Sales Growth***" means the percentage growth of the Company's net sales as first reported in an earnings press release, Form 8-K or Form 10-K, as applicable, approved by the Board for a fiscal year as compared to the immediately preceding fiscal year, excluding net sales attributable to any acquisition, business combination, or other transaction with a third party (e.g., distribution rights), as compared to the immediately

preceding fiscal year occurring in that Target Year, and shall be FX Neutral. For Target Years following an acquisition, business combination or other transaction with a third party, net sales attributable to such transaction will be added to the base calculation of net sales and included in the calculation of Net Sales Growth. "***Vesting Date***" means the effective date of vesting of a portion of the Award, which date shall be no later than the date the Board approves the applicable earnings press release, Form 8-K or Form 10-K reporting such results and shall be prior to the date such results are publicly released. "***FX Neutral***" means the neutralization of the impact of foreign currency exchanges on the calculation of Net Sales Growth of the Company for each Target Year for which an Award is calculated.

(c) Forfeiture. In the event all or a portion of the Award has not vested at the time the employment of Executive with the Company terminates for any reason, the unvested portion of the Award shall thereupon be forfeited immediately and without further action by the Company.

(d) Legend. Until such time as the Award has vested, the Company may, at any time, place legends referencing the restrictions described in this Section 2 and any applicable federal and/or state securities laws restrictions on certificates representing shares of Restricted Stock issued pursuant to this Agreement. The legend may include the following:

> "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS SET FORTH IN THE AWARD AGREEMENT BETWEEN THE CORPORATION AND THE REGISTERED HOLDER, A COPY OF WHICH IS ON FILE AT THE PRINCIPAL OFFICE OF THE CORPORATION."

3. Taxes.

(a) Executive understands, acknowledges and agrees that the value of the Restricted Stock is subject to state and federal income taxes and certain rules which require the Company to withhold amounts necessary to pay these taxes. Executive hereby authorizes the Company to reduce the number of shares of Restricted Stock to which Executive is entitled on the Vesting Date by the number of shares of Restricted Stock required to satisfy the tax withholding requirements (based on the Fair Market Value of shares at such time). Such shares of Restricted Stock shall be returned to the Company. Executive's acknowledgement and acceptance of these tax withholding provisions are conditions precedent to the right of Executive to receive the Restricted Stock under the Employment Agreement and this Agreement.

(b) In lieu of the reduction of shares delivered described in paragraph (a) above, Executive may pay to the Company the amount of tax required to be withheld in cash, by check or in other form satisfactory to the Company. Such payment must be made by the date which is ten (10) days after the Vesting Date.

(c) The Restricted Stock will be released to Executive when vested and the applicable withholding obligations have been satisfied.

(d) Executive understands that Section 83(a) of the Code taxes as ordinary income the difference between the amount, if any, paid for the shares of Common Stock and the Fair Market Value of such shares at the time the Restrictions on such shares lapse. Executive understands that, notwithstanding the preceding sentence, Executive may elect to be taxed at the time of the Award Date, rather than at the time the Restrictions lapse, by filing an election under Section 83(b) of the Code (an "***83(b) Election***") with the Internal Revenue Service with a copy to the Company within 30 days of the Award Date. In the event Executive files an 83(b) Election, Executive will recognize ordinary income in an amount equal to the difference between the amount, if any, paid for the shares of Common Stock and the Fair Market Value of such shares as of the Award Date. Executive acknowledges that the foregoing is only a summary of the effect of United States federal income taxation with respect to the award of Restricted Stock hereunder, and does not purport to be complete. EXECUTIVE FURTHER ACKNOWLEDGES THAT THE COMPANY IS NOT RESPONSIBLE FOR FILING EXECUTIVE'S 83(b) ELECTION, AND THE COMPANY HAS DIRECTED EXECUTIVE TO SEEK INDEPENDENT ADVICE REGARDING THE APPLICABLE PROVISIONS OF THE CODE, THE INCOME TAX LAWS OF ANY MUNICIPALITY, STATE OR FEDERAL GOVERNMENT OR FOREIGN COUNTRY IN WHICH EXECUTIVE MAY RESIDE, AND THE TAX CONSEQUENCES OF EXECUTIVE'S DEATH.

4 . Certain Changes in Capitalization and Reorganization Events. If there is any change in the outstanding shares of Common Stock by reason of a stock dividend or distribution, stock split-up, recapitalization, combination or exchange of shares of Common Stock, or by reason of any merger, consolidation, spinoff or other corporate reorganization in which the Company is the surviving corporation, the number of shares of Restricted Stock subject to the Award shall be equitably adjusted by the Company's Board of Directors, whose determination shall be final, binding and conclusive.

5 . Stock Certificates. Stock certificates issued in respect of this Award shall be registered in the name of Executive and shall be deposited in escrow with the Secretary of the Company or other escrow agent appointed by the Company. The deposited certificates shall remain in escrow until the Award has vested in full. Executive shall, upon the execution of this Agreement, execute Joint Escrow Instructions in the form attached to this Agreement as Exhibit A. The Joint Escrow Instructions shall be delivered to the Secretary of the Company as escrow agent thereunder. Executive shall deliver to such escrow agent a stock assignment duly endorsed in blank, in the form attached to this Agreement as Exhibit B, and hereby instructs the Company to deliver to such escrow agent, on behalf of Executive, the certificate(s) evidencing the Award issued hereunder. Such materials shall be held by such escrow agent pursuant to the terms of such Joint Escrow Instructions.

6 . Restricted Stock Not Transferable. Prior to vesting, no Restricted Stock or any interest or right therein or part thereof shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect; provided, however, that this Section 6 shall not prevent transfers by will or by applicable laws of descent and distribution.

7 . Rights as Stockholder. Subject to the provisions of Sections 2(c), 2(d), and 6 in this Agreement, Executive shall exercise all rights and privileges of a shareholder of the Company with respect to the Restricted Stock deposited in escrow. Executive shall be deemed to be the holder for purposes of receiving any dividends that may be paid with respect to such shares of Restricted Stock and for the purpose of exercising any voting rights relating to such shares of Restricted Stock, even if some or all of such shares of Restricted Stock have not yet vested, provided that any dividends otherwise payable on the Restricted Stock shall be held in escrow from and after the dividend payment date until the Restricted Stock vests, at which time the amount of the dividend shall be paid to Executive.

8 . Conformity to Securities Laws. Executive acknowledges that this Agreement is intended to conform to the extent necessary with all provisions of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, including without limitation Rule 16b-3 under the Exchange Act. Notwithstanding anything herein to the contrary, the Award is granted only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.

9 . Not a Contract of Employment. Nothing in this Agreement shall confer upon Executive any right to continue in the employ of the Company or shall interfere with or restrict in any way the rights of the Company, which are hereby expressly reserved, to discharge Executive at any time for any reason whatsoever, with or without cause, except as may otherwise be provided by any written agreement entered into by and between the Company and Executive.

10. 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 THE SOUTHERN DISTRICT OF 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.

11. Notices. All notices and other communications under this Agreement must be in writing and will be deemed given if (i) delivered personally, (ii) sent by internationally recognized overnight courier, (iii) mailed by registered or certified mail (return receipt requested), postage prepaid, or (iv) sent by electronic mail (provided that a copy is also sent by certified or registered mail or by internationally recognized overnight courier) 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:
Repro Med Systems, Inc.
24 Carpenter Road
Chester, NY 10918
Attn: Chairman of the Board of Directors
Email: [personal information redacted]

If to the Executive:
Linda Tharby
[personal information redacted]

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 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.

12. Counterparts. This Agreement may be executed in one or more counterparts, and by the 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.

13. 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.

14. Entire 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.

15. Priority. In the event of a conflict between this Agreement and the Employment Agreement, including the provisions therein governing accelerated vesting upon a Change in Control (as defined in the Employment Agreement) or vesting upon termination, the Employment Agreement shall control.

[signature page follows]

IN WITNESS WHEREOF, the parties have executed this Restricted Stock Agreement as of the Effective Date.

EXECUTIVE:

_____
Linda Tharby

COMPANY:

Repro Med Systems, Inc.

By: _____
R. John Fletcher
Chairman of the Board

**Schedule I**

[***]

**EXHIBIT D**

**RESTRICTED STOCK AGREEMENT**

THIS RESTRICTED STOCK AGREEMENT (this "***Agreement***"), dated as of April 12, 2021 (the "***Effective Date***"), is made by and between Repro Med Systems, Inc. d/b/a KORU Medical Systems, a New York corporation, having its principal place of business at 24 Carpenter Road, Chester, NY 10918 (the "***Company***"), and Linda Tharby, an individual residing at [personal information redacted] ("***Executive***").

WHEREAS, Company and Executive have entered into an Employment Agreement dated as of the March 15, 2021 (the "***Employment Agreement***"), which provides for the award to Executive of certain shares of the Company's common stock, par value $0.01 per share ("***Common Stock***"), subject to certain restrictions as described in this Agreement.

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, and intending to be legally bound hereby, the parties hereto agree as follows:

1. Restricted Stock Award. As of the Effective Date, the Company hereby issues to Executive two hundred thousand (200,000) shares of Common Stock (the "***Restricted Stock***"), subject to the restrictions and other conditions of this Agreement and the Employment Agreement (the "***Award***").

2. Restrictions.

(a) Vesting. The Award shall vest on the following dates (each, a "***Vesting Date***"), provided Executive is employed by the Company on such date: (i) 50,000 shares of Restricted Stock shall vest on the first date on which the Company's Market Capitalization for a period of ninety (90) consecutive days has been, or there has been a Change of Control (as defined in the Employment Agreement) of the Company with an enterprise value of, at least $500,000,000 but less than $600,000,000; (ii) 50,000 shares of Restricted Stock shall vest on the first date on which the Company's Market Capitalization for a period of ninety (90) consecutive days has been, or there has been a Change of Control of the Company with an enterprise value of, at least $600,000,000 but less than $750,000,000; and (iii) 100,000 shares of Restricted Stock shall vest on the date on which the Company's Market Capitalization for a period of ninety (90) consecutive days has been, or there has been a Change of Control of the Company with an enterprise value of, at least $750,000,000. "***Market Capitalization***" shall be determined by (A) multiplying the number of shares reported as outstanding on the cover of the Company's most recent Form 10-K or 10-Q, as applicable, as filed with the Securities and Exchange Commission, by (B) the Fair Market Value of the Common Stock (as defined in the Company's 2015 Stock Option Plan, as amended) on each day. Notwithstanding the foregoing, no portion of the Award shall vest on or following the fifth ($5^{th}$) anniversary of the Effective Date.

(b) Forfeiture. In the event all or a portion of the Award has not vested at the time the employment of Executive with the Company terminates for any reason, the unvested portion of the Award shall thereupon be forfeited immediately and without further action by the Company.

(c) Transfer. Executive agrees that shares of Restricted Stock shall not be sold, transferred, pledged, hypothecated or assigned for a period of twelve (12) months following the applicable Vesting Date (the "***Restricted Transfer Period***").

(d) Legend. Until such time as the Restricted Transfer Period has expired, the Company may, at any time, place legends referencing the restrictions described in this Section 2 and any applicable federal and/or state securities laws restrictions on certificates representing shares of Restricted Stock issued pursuant to this Agreement. The legend may include the following:

> "THE SECURITIES REPRESENTED BY THIS CERTIFICATE ARE SUBJECT TO RESTRICTIONS SET FORTH IN THE AWARD AGREEMENT BETWEEN THE CORPORATION AND THE REGISTERED HOLDER, A COPY OF WHICH IS ON FILE AT THE PRINCIPAL OFFICE OF THE CORPORATION."

3. Taxes.

(a) Executive understands, acknowledges and agrees that the value of the Restricted Stock is subject to state and federal income taxes and certain rules which require the Company to withhold amounts necessary to pay these taxes. Executive hereby authorizes the Company to reduce the number of shares of Restricted Stock to which Executive is entitled on the Vesting Date by the number of shares of Restricted Stock required to satisfy the tax withholding requirements (based on the Fair Market Value of shares at such time). Such shares of Restricted Stock shall be returned to the Company. Executive's acknowledgement and acceptance of these tax withholding provisions are conditions precedent to the right of Executive to receive the Restricted Stock under the Employment Agreement and this Agreement.

(b) In lieu of the reduction of shares delivered described in paragraph (a) above, Executive may pay to the Company the amount of tax required to be withheld in cash, by check or in other form satisfactory to the Company. Such payment must be made by the date which is ten (10) days after the Vesting Date.

(c) The Restricted Stock will be released to Executive when vested and the applicable withholding obligations have been satisfied.

(d) Executive understands that Section 83(a) of the Code taxes as ordinary income the difference between the amount, if any, paid for the shares of Common Stock and the Fair Market Value of such shares at the time the Restrictions on such shares lapse. Executive understands that, notwithstanding the preceding sentence, Executive may elect to be taxed at the time of the Award Date, rather than at the time the Restrictions lapse, by filing an election under Section 83(b) of the Code (an "***83(b) Election***") with the Internal Revenue Service with a copy to the Company within 30 days of the Award Date. In the event Executive files an 83(b) Election, Executive will recognize ordinary income in an amount equal to the difference between the

amount, if any, paid for the shares of Common Stock and the Fair Market Value of such shares as of the Award Date. Executive acknowledges that the foregoing is only a summary of the effect of United States federal income taxation with respect to the award of Restricted Stock hereunder, and does not purport to be complete. EXECUTIVE FURTHER ACKNOWLEDGES THAT THE COMPANY IS NOT RESPONSIBLE FOR FILING EXECUTIVE'S 83(b) ELECTION, AND THE COMPANY HAS DIRECTED EXECUTIVE TO SEEK INDEPENDENT ADVICE REGARDING THE APPLICABLE PROVISIONS OF THE CODE, THE INCOME TAX LAWS OF ANY MUNICIPALITY, STATE OR FEDERAL GOVERNMENT OR FOREIGN COUNTRY IN WHICH EXECUTIVE MAY RESIDE, AND THE TAX CONSEQUENCES OF EXECUTIVE'S DEATH.

4 . Certain Changes in Capitalization and Reorganization Events. If there is any change in the outstanding shares of Common Stock by reason of a stock dividend or distribution, stock split-up, recapitalization, combination or exchange of shares of Common Stock, or by reason of any merger, consolidation, spinoff or other corporate reorganization in which the Company is the surviving corporation, the number of shares of Restricted Stock subject to the Award shall be equitably adjusted by the Company's Board of Directors, whose determination shall be final, binding and conclusive.

5 . Stock Certificates. Stock certificates issued in respect of this Award shall be registered in the name of Executive and shall be deposited in escrow with the Secretary of the Company or other escrow agent appointed by the Company. The deposited certificates shall remain in escrow until the Award has vested in full and the Restricted Transfer Period has expired. Executive shall, upon the execution of this Agreement, execute Joint Escrow Instructions in the form attached to this Agreement as Exhibit A. The Joint Escrow Instructions shall be delivered to the Secretary of the Company as escrow agent thereunder. Executive shall deliver to such escrow agent a stock assignment duly endorsed in blank, in the form attached to this Agreement as Exhibit B, and hereby instructs the Company to deliver to such escrow agent, on behalf of Executive, the certificate(s) evidencing the Award issued hereunder. Such materials shall be held by such escrow agent pursuant to the terms of such Joint Escrow Instructions.

6 . Restricted Stock Not Transferable. Prior to the expiration of the Restricted Transfer Period, no Restricted Stock or any interest or right therein or part thereof shall be subject to disposition by transfer, alienation, anticipation, pledge, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy), and any attempted disposition thereof shall be null and void and of no effect; provided, however, that this Section 6 shall not prevent transfers by will or by applicable laws of descent and distribution.

7 . Rights as Stockholder. Subject to the provisions of Sections 2(b), 2(c), and 6 in this Agreement, Executive shall exercise all rights and privileges of a shareholder of the Company with respect to the Restricted Stock deposited in escrow. Executive shall be deemed to be the holder for purposes of receiving any dividends that may be paid with respect to such shares of Restricted Stock and for the purpose of exercising any voting rights relating to such shares of Restricted Stock, even if some or all of such shares of Restricted Stock have not yet vested, provided that any dividends otherwise payable on the Restricted Stock shall be held in escrow from and after the dividend payment date until the Restricted Stock vests, at which time the amount of the dividend shall be paid to Executive.

8 . Conformity to Securities Laws. Executive acknowledges that this Agreement is intended to conform to the extent necessary with all provisions of the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and any and all regulations and rules promulgated thereunder by the Securities and Exchange Commission, including without limitation Rule 16b-3 under the Exchange Act. Notwithstanding anything herein to the contrary, the Award is granted only in such a manner as to conform to such laws, rules and regulations. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such laws, rules and regulations.

9 . Not a Contract of Employment. Nothing in this Agreement shall confer upon Executive any right to continue in the employ of the Company or shall interfere with or restrict in any way the rights of the Company, which are hereby expressly reserved, to discharge Executive at any time for any reason whatsoever, with or without cause, except as may otherwise be provided by any written agreement entered into by and between the Company and Executive.

10. 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 THE SOUTHERN DISTRICT OF 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.

11. Notices. All notices and other communications under this Agreement must be in writing and will be deemed given if (i) delivered personally, (ii) sent by internationally recognized overnight courier, (iii) mailed by registered or certified mail (return receipt requested), postage prepaid, or (iv) sent by electronic mail (provided that a copy is also sent by certified or registered mail or by internationally recognized overnight courier) 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:
Repro Med Systems, Inc.
24 Carpenter Road
Chester, NY 10918
Attn: Chairman of the Board of Directors
Email: [personal information redacted]

If to the Executive:
Linda Tharby
[personal information redacted]

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 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.

12. Counterparts. This Agreement may be executed in one or more counterparts, and by the 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.

13. 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.

14. Entire 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.

15. Priority. In the event of a conflict between this Agreement and the Employment Agreement, including the provisions therein governing accelerated vesting upon a Change in Control (as defined in the Employment Agreement) or vesting upon termination, the Employment Agreement shall control.

[signature page follows]

IN WITNESS WHEREOF, the parties have executed this Restricted Stock Agreement as of the Effective Date.

EXECUTIVE:

_____
Linda Tharby

COMPANY:

Repro Med Systems, Inc.

By: _____
R. John Fletcher
Chairman of the Board

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), Registration Statement on Form S-3 (No. 333-238242) and related Prospectuses of Repro Med Systems, Inc. of our reports dated March 23, 2021, 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, 2020.

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

Scranton, Pennsylvania
March 23, 2021

EXHIBIT 31.1

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

I, James M. Beck, 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/ James M. Beck
James M. Beck
Interim Chief Executive Officer
Date: March 23, 2021

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 23, 2021

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, 2020 as filed with the Securities and Exchange Commission (the "Report"), I, James M. Beck, 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/ James M. Beck
James M. Beck
Interim Chief Executive Officer
Date: March 23, 2021

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, 2020 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 23, 2021