

REPRO MED SYSTEMS, INC.

11,101,697 shares of common stock

This prospectus relates to the sale by the selling shareholders identified in this prospectus, or their assigns of up to an aggregate of 11,101,697 shares of our common stock (the "Shares").

We are registering the offer and sale of the Shares pursuant to registration rights we have granted pursuant to an agreement with the selling stockholders. We have agreed to bear all of the expenses incurred in connection with the registration of the Shares. The selling stockholders will pay or assume brokerage commission and similar charges, if any, incurred in the sale of the Shares.

We are not selling any Shares under this prospectus and will not receive any proceeds from the sale of the Shares by the selling stockholders.

The Shares to which this prospectus relates may be offered and sold from time to time directly by the selling stockholders or alternatively through underwriters, broker dealers, or agents. The selling stockholders will determine at what price they sell the Shares offered by this prospectus, and such sales may be made at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. For additional information on the methods of sale that may be used by the selling stockholders, see the section entitled "Plan of Distribution." For a list of the selling stockholders, see the section entitled "Selling Stockholders."

Our common stock is currently listed on the OTCQX under the symbol "REPR." The closing price of our common stock as reported on the OTCQX on February 27, 2019, was \$1.42.

The selling stockholders may be deemed "underwriters" within the meaning of the Securities Act of 1933, as amended (the "**Securities Act**"), in connection with the resale of the Shares.

This offering will terminate on the earlier of (i) the date when all the Shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act, (ii) the date that all of the Shares may be sold pursuant to Rule 144 under the Securities Act or any successor rule, or (iii) December 20, 2020.

Investing in our common stock involves risks, and you should not invest unless you can afford to lose your entire investment. See the section entitled "Risk Factors" beginning on page 6.

Neither the Securities and Exchange Commission (the "SEC") nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is March 8, 2019.

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ABOUT THIS PROSPECTUS

You should rely only on the information contained in this prospectus. We have not authorized any person to provide you with different or inconsistent information. If anyone provides you with different or inconsistent information, you should not rely on it. This is not an offer to sell or seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus is accurate only as of their respective dates. Our business, financial condition, results of operations and prospects may have changed since such dates.

We further note that the representations, warranties and covenants made by us in any document that is filed as an exhibit to the registration statement of which this prospectus is a part were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

Unless the context otherwise requires, the terms “RMS”, the “Company”, “we”, “us”, “our” and similar terms used in this prospectus refer to Repro Med Systems, Inc.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains “forward-looking statements” about our business, financial condition and prospects based on our current expectations, assumptions, estimates, and projections about us and our industry. All statements other than statements of historical fact are “forward-looking statements”, including, but not limited to, any projections of earnings, revenue or other financial items; any statements of the plans, strategies and objections of management for future operations; any statements concerning proposed new services or developments; any statements regarding future economic conditions or performance; any statements of belief; and any statements of assumptions underlying any of the foregoing.

Forward-looking statements may include the words “may,” “could,” “estimate,” “intend,” “continue,” “believe,” “expect” or “anticipate” or other similar words. These forward-looking statements present our estimates and assumptions only as of the date of this report. Unless otherwise required by law, we do not intend, and undertake no obligation, to update any forward-looking statement.

Although we believe that the expectations reflected in any of our forward-looking statements are reasonable, actual results could differ materially from those projected or assumed in any of our forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to change and inherent risks and uncertainties. The factors impacting these risks and uncertainties include, but are not limited to:

- introduction of competitive products;
- availability of insurance reimbursement;
- changes in United States Food and Drug Administration regulations;
- changes to health care policies;
- success of our research and development efforts;
- our ability to raise capital if or when needed;
- acceptance of and demand for new and existing products;
- expanded market acceptance of the FREEDOM System;
- our ability to obtain required governmental approvals;
- success in enforcing and obtaining patents;
- continued performance by principal suppliers;
- continued customer preference to work through distributors;
- continued service of key personnel and attracting and maintaining new personnel;
- the costs, duration and ultimate outcome of litigation; and
- general economic and business conditions.

You should read the matters described in the section entitled “*Risk Factors*” below and the other cautionary statements made in this prospectus as being applicable to all related forward-looking statements wherever they appear in this prospectus. We cannot assure you that the forward-looking statements in this prospectus will prove to be accurate and therefore prospective investors are encouraged not to place undue reliance on forward-looking statements.

PROSPECTUS SUMMARY

This summary highlights certain information described in greater detail elsewhere in this prospectus. Before deciding to invest in our securities you should read the entire prospectus carefully, including the "Risk Factors" section contained in this prospectus, our consolidated financial statements and the related notes, and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Company Overview

We design, manufacture and market proprietary and innovative portable medical devices and supplies, primarily for the ambulatory infusion market in compliance with the U.S. Food and Drug Administration 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 include the FREEDOM60® Syringe Driver, the FreedomEdge® Syringe Driver, HIgH-Flo Subcutaneous Safety Needle Sets™ and RMS Precision Flow Rate Tubing™. We were incorporated in the State of New York in March 1980.

Our principal office is located at 24 Carpenter Road, Chester, New York 10918. Our telephone number is (845) 469-2042.

Our common stock is traded on the OTCQX under the symbol "REPR."

The Offering

This prospectus relates to the resale of up to 11,101,697 shares of our common stock (the "Shares") that the selling stockholders purchased from various third parties in a private placement transaction pursuant to a Common Stock Purchase Agreement dated as of December 17, 2018. Pursuant to the purchase agreement, we agreed to file a resale registration statement under the Securities Act of 1933, as amended, at our expense covering the Shares within 45 days following the final closing of the transaction, which occurred on December 20, 2018. This prospectus forms a part of the registration statement.

Use of Proceeds

The Shares offered by this prospectus will be sold by the selling stockholders. We did not receive any proceeds from the purchase of the Shares by the selling stockholders and we will not receive any proceeds from the sale of the Shares by the selling stockholders.

Risk Factors

An investment in our securities involves a high degree of risk and could result in the loss of your entire investment. Prior to making an investment decision, you should carefully consider all of the information in this prospectus and, in particular, you should evaluate the risk factors set forth under the caption "Risk Factors" beginning on the next page of this prospectus.

RISK FACTORS

An investment in our common stock involves significant risks. Before making an investment in our common stock, you should carefully read all of the information contained in this prospectus and our other filings with the SEC. You should not make an investment in RMS unless you can afford to bear the loss of your entire investment. The following discussion provides information concerning the material risks and uncertainties that we have identified and believe may adversely affect our business, our financial condition and our results of operations. Before you decide whether to invest in our securities, you should carefully consider these risks and uncertainties, together with all of the other information in this prospectus. 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. In addition, please read "CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS" in this prospectus, where we describe additional uncertainties associated with our business and the forward-looking statements included in this prospectus.

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 electrically powered pumps, elastomeric infusers 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. 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 more care to non-acute 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.

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 (such as needle-free injection technology) 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 approvals 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 approval or gain market acceptance. If we cannot successfully introduce new products or adapt to changing technologies, our products may become obsolete and our revenue and profitability could suffer.

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

The United States (“U.S.”) Food and Drug Administration (the “FDA”) has announced its intention to pursue comprehensive reforms to its current 510(k) clearance pathway, which is used for clearance of low- to moderate-risk devices that are substantially equivalent to a device already on the market, and to its post-market safety monitoring process. The proposals, among other things, could prevent the use of certain older predicate devices as support for 510(k) clearance, provide for a “de novo” classification process to permit an evaluation of novel devices without a predicate device, establish an alternative 510(k) pathway for “well-understood” devices relying on objective safety and performance criteria, and expand post-market safety surveillance measures. These reforms could delay or prevent us from obtaining or maintaining 510(k) clearances or other premarket authorizations for our existing or new devices.

Compliance with the new rules could require us to undertake significant additional costs prior to and following commercialization of our products, which may reduce the profitability of those products.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We may need a new manufacturing facility in order to expand our operations.

We currently have six options to extend our current lease of our manufacturing facility, which is also our headquarters, through August 2022. Although we believe our current space is sufficient to significantly increase current production requirements, we may need to find a larger space for our manufacturing operations in order to expand our operations and carry out our business plan. There is no guaranty we will be able to find such space on favorable terms, or at all. If we do find appropriate space, we may need to expend significant resources to ensure it complies with applicable regulations for manufacturing. Moving our corporate headquarters and manufacturing facility 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 move.

We are subject to lawsuits.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Most of our customers prefer to purchase our products through distributors, rather than directly from us, because of one-stop shopping convenience and their ability to ship directly to patients. We sell most of our products through a small number of distributors, three in and two outside the U.S. As of December 31, 2018, these five distributors comprised approximately 75% of our gross revenues. Any decline in business with the distributors outside the U.S. could have an adverse impact on our business. If we were unable to sell through the distributors outside the U.S., we would have to find other distributors or broaden our customer base and expand direct relationships with customers. Other distributors may not be available or may not agree to arrangements that are commercially reasonable. In the U.S. we could transition to direct customer purchase; however, customers may not want to purchase directly from us and may decide to purchase competitors’ products through their distributors. Moreover, a transition from distributors to direct customer purchase would be time consuming and costly.

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

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

The price and supply of materials and components for our products may be impacted or disrupted for reasons beyond our control. While we work with suppliers to ensure continuity of supply, no assurance can be given that these efforts will be successful. Although we do carry strategic inventory and maintain insurance to help mitigate the potential risk related to any related 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, and our ability to make product sales.

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

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

The reinstatement of the Patient Protection and Affordable Care Act (“PPACA”)’s medical device tax may adversely affect our results of operations.

The PPACA imposes on medical device manufacturers, such as us, a 2.3% excise tax on U.S. sales of certain medical devices. While the excise tax has been suspended until the end of 2019, absent further legislative action, it will be reinstated in 2020, which would adversely affect our results of operations.

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 ultimately 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 for our products and the drugs they administer from third-party payers 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 as well as in some cases to all payers. In certain circumstances, insurance companies can attempt to bring a private cause of action against a manufacturer for causing a false claim to be filed under the Federal Racketeer Influenced and Corrupt Organizations Act. In addition, as a manufacturer of FDA-approved devices reimbursable by federal healthcare programs, we are subject to the Physician Payments Sunshine Act, which requires us to annually report certain payments and other transfers of value we make to U.S.-licensed physicians or U.S. teaching hospitals. Any failure to comply with these laws and regulations could subject us or our officers and employees to criminal and civil financial penalties. Similar reporting requirements applicable to medical device manufacturers have also been implemented by some states. Failure to comply with these state requirements could result in civil monetary penalties being assessed against us.

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

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

We may finance future cash needs through public or private equity offerings and may also use debt financings or strategic collaboration and licensing arrangements. We may seek to access the public or private equity markets whenever conditions are favorable, even if we do not have an immediate need for additional capital. To the extent that we raise additional funds by issuing equity securities, our shareholders may experience additional dilution, and debt financing, if available, may involve restrictive covenants and may result in high interest expense. If we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our product candidates, processes and technologies or our development projects or to grant 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 efforts or curtail some of our commercialization efforts of our operations.

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

Since July 2018, the composition of our executive team and Board of Directors has changed substantially. In addition, we have implemented a new management structure throughout the organization and are actively recruiting to fill these positions. 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 and will have had little or no experience with RMS prior to joining us, which may result in delays in our ability to implement our business plans. If we are unable to integrate, motivate and retain the services of our new executives and other managers and our directors, or if integration takes longer than we expect, it may have an adverse effect on our business and financial condition.

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

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

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

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 18% of our net sales in the twelve months ended December 31, 2018 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. relations with the governments of the foreign countries in which we operate, foreign regulatory requirements or changes in such requirements, local product preferences and product requirements, longer payment terms for accounts receivable than we experience in the U.S., difficulty in establishing, staffing and managing foreign operations, changes to international trade agreements and treaties, changes in tax laws, weakening or loss of the protection of intellectual property rights in some countries, and import or export licensing requirements.

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

Brexit may impact our business in the United Kingdom.

One of our two most significant international distributors is located in the United Kingdom (“UK”), and the other is in Finland, a member of the European Union (“EU”). The June 2016 referendum result in the UK to exit the EU (commonly known as “Brexit”), and the subsequent commencement of the official withdrawal process by the UK government in March 2017, has created uncertainties affecting business operations in the UK and the EU. Until the terms of the UK’s potential exit from the EU in March 2019 are determined, including any transition period, it is difficult to predict its impact. It is possible that the withdrawal could, among other things, affect the legal and regulatory environments to which our businesses 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 device changes to fix vulnerabilities and strengthen cybersecurity. Such changes could, in some cases, require reporting to and approval by the FDA prior to implementation, which could cause a delay in the continued marketing of the underlying product that will result in a loss of revenues to us. Furthermore, failure to adhere to good cybersecurity practices with regards to medical devices could result in enforcement action by the FDA including warning letters or other forms of enforcement.

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

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

Our operating results and financial condition may fluctuate.

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

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

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

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

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

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

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

Risks Related to this Offering

The price of our common stock may be volatile and may be affected by market conditions beyond our control, which could result in substantial losses for purchasers of our common stock in this offering.

The market price of our common stock may be influenced by many factors, including:

- our failure to achieve and maintain profitability;
- changes in earnings estimates and recommendations by financial analysts;
- actual or anticipated variations in our quarterly results of operations;
- changes in market valuations of similar companies;
- announcements by us or our competitors of significant contracts, new products, acquisitions, commercial relationships, or capital commitments;
- the loss of major customers or product or component suppliers;
- the loss of significant partnering relationships;
- general market, political and economic conditions;
- the emergence of new competitors;
- variations in our operating results and market conditions specific to companies in our industry;
- the success of competitive products or technologies;
- regulatory or legal developments in the U.S. and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- changes in our board or management;
- changes in the structure of healthcare payment systems;
- operating and market price performance of other companies that investors deem comparable;
- sales or purchases of our common stock by insiders;
- commencement of, or involvement in, litigation;
- changes in governmental regulations;
- general economic conditions and slow or negative growth of related markets;
- market conditions in the pharmaceutical and biotechnology sectors; and
- the other factors described in this “Risk Factors” section.

In addition, if the market for stocks in our industry or the stock market in general, experiences a loss of investor confidence, the market price of our common stock could decline for reasons unrelated to our business, financial condition or results of operations. If any of the foregoing occurs, it could cause the price of our common stock to fall and may expose us to lawsuits that, even if unsuccessful, could be costly to defend and a distraction to the board of directors and management.

Sales of our common stock could exert downward pressure on the market price of our common stock and could encourage short selling that could exert further downward pressure.

The selling stockholders acquired shares of our common stock at a price less than the then current trading price of our common stock. To the extent their purchase price remains below the trading price of our common stock, they may have an incentive to immediately resell material amounts of such shares in the market that may, in turn, cause the trading price of our common stock to decline. Significant downward pressure on our stock price caused by such sales in the market could encourage short sales by other stockholders or third parties that would place further downward pressure on our stock price.

We may become obligated to pay liquidated damages if we fail to file, obtain effectiveness and maintain effectiveness of a registration statement under the Purchase Agreement we entered into with the selling stockholders.

We have granted to the selling stockholders resale registration rights pursuant to the terms of the Purchase Agreement. In addition to the registration rights, the selling stockholders are entitled to receive liquidated damages from us equal to 1% of the purchase price paid by the selling stockholders for the common stock per month (subject to proration) upon the occurrence of a number of events relating to filing the registration statement of which this prospectus forms a part, the registration statement becoming effective and maintaining an effective registration statement covering the securities being registered.

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.

Horton Freedom, L.P. and FirstLight Asset Management, LLC, together with their respective affiliates, beneficially own approximately 31% and 18%, of our outstanding common stock, respectively, after giving effect to the exercise of unexercised warrants. 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 not ever paid dividends on our common stock, and we do not intend to pay any dividends to holders of our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future.

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

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

We provide and intend to continue to provide additional equity-based compensation to our employees, officers, directors, consultants and independent contractors through a stock option plan. Under our stock option plan, 4,000,000 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. On February 20, 2019, our Board of Directors approved an increase to the number of shares authorized under the plan to 6,000,000, subject to stockholder approval at the 2019 Annual Meeting of Shareholders. If our Board elects to issue additional stock options under the plan, our stockholders may experience additional dilution, which could cause our stock price to decline. Because stock options granted under the plan will generally only be exercised when the exercise price for such option is below the then market value of the common stock, the exercise of such options or the issuance of shares will cause dilution to the book value per share of our common stock and to existing and new investors.

A limited public trading market may cause volatility in the price of shares of our common stock.

Our common stock is currently quoted on the OTCQX. The quotation of our common stock on the OTCQX does not assure that a meaningful, consistent and liquid trading market currently exists, and in recent years such market has experienced extreme price and volume fluctuations that have particularly affected the market prices of many smaller companies like us. Our common stock is subject to this volatility. Sales of substantial amounts of our common stock, 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.

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

We are currently a “smaller reporting company”, as defined in Rule 405 under the Securities Act. As a smaller reporting company, we take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “smaller reporting companies,” 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” 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 officers and directors can sell some of 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.

Our officers and directors beneficially own approximately 35% of our outstanding common stock as of February 27, 2019. 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. However, our officers and directors have entered into Lock-Up Agreements and have agreed to refrain from selling any shares of our common stock for 90 days after the effective date of the registration statement of which this prospectus forms a part.

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.

Historically, there has been a limited trading market in our common stock. We cannot assure you that an active trading market for our common stock will develop or 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.

Penny stock regulations may impose certain restrictions on marketability of our securities.

Our common stock is subject to penny stock rules, which may discourage broker-dealers from effecting transactions in our common stock or affect their ability to sell our securities. As a result, purchasers and current holders of our securities could find it more difficult to sell their securities. In addition, we may be subject to rules of the SEC that impose additional requirements on broker-dealers when selling penny stocks to persons other than established customers and accredited investors. In general, an accredited investor is a person with net worth in excess of \$1,000,000 or annual income exceeding \$200,000 individually, or \$300,000 together with his or her spouse. The relevant SEC regulations generally define penny stocks to include any equity security not traded on an exchange or the Nasdaq Stock Market with a market price (as defined in the regulations) of less than \$5 per share. Under the penny stock regulations, a broker-dealer must make a special suitability determination as to the purchaser and must have the purchaser's prior written consent to the transaction. Prior to any transaction in a penny stock covered by these rules, a broker-dealer must deliver a disclosure schedule about the penny stock market prepared by the SEC. Broker-dealers must also make disclosure concerning commissions payable to both the broker-dealer and any registered representative and provide current quotations for the securities. Finally, broker-dealers are required to send monthly statements disclosing recent price information for the penny stock held in an account and information on the limited market in penny stocks.

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USE OF PROCEEDS

The Shares offered by this prospectus will be sold by the selling stockholders. We did not receive any proceeds from the purchase of the Shares by the selling stockholders, and we will not receive any proceeds from the sale of the Shares by the selling stockholders in this offering.

SELLING STOCKHOLDERS

The Shares being offered by the selling stockholders pursuant to this prospectus were purchased by the selling stockholders from other existing stockholders in a private placement transaction pursuant to a Common Stock Purchase Agreement dated as of December 17, 2018 among us, the selling stockholders and the existing stockholders. For additional information regarding the purchases of common stock by the selling stockholders, see "Certain Relationships and Related Party Transactions" below. We have agreed, at our expense, to register all of the Shares for resale by the selling stockholders under the Securities Act. Except as indicated below, the selling stockholders have not had any material relationship with us within the past three years.

The selling stockholders are under no obligation to sell all or any portion of the Shares offered, nor are the selling stockholders obligated to sell such Shares immediately under this prospectus. Because each selling stockholder may sell all, some or none of the Shares that the selling stockholder holds, no estimate can be given as to the number of shares of our common stock that will be held by the selling stockholder upon termination of the offering.

The table below lists the selling stockholders and other information regarding the beneficial ownership of the shares of our common stock by the selling stockholders. As used in this prospectus, the term "selling stockholder" includes the selling stockholders named below and any donees, pledgees, transferees or other successors in interest selling shares received after the date of this prospectus from the selling stockholders as a gift, pledge, or other non-sale related transfer. The first column lists the number of shares of our common stock beneficially owned by the selling stockholders, based on their respective ownership of shares of our common stock as of February 27, 2019. The third column lists the shares of our common stock being offered under this prospectus by each selling stockholder. The fourth column lists the number of shares of our common stock that will be beneficially owned by each selling stockholder following the offering, assuming the sale of all of the Shares offered pursuant to this prospectus.

Name of Selling Stockholder	Number of Shares Beneficially Owned Before Offering	Percentage of Shares Beneficially Owned Before Offering	Number of Shares Being Offered	Number of Shares Beneficially Owned After Offering	Percentage of Shares Beneficially Owned After Offering
Horton Freedom, L.P. ⁽¹⁾	3,401,677	9%	3,201,697	199,980	*
Northern Valley Partners, LLC ⁽²⁾	100,000	*	100,000	0	*
Michael Potter ⁽³⁾	75,000	*	75,000	0	*
Sylvia Potter Family LTD Partnership ⁽⁴⁾	75,000	*	75,000	0	*
Brian L. Pessin	209,800	*	100,000	109,800	*
Sandra F. Pessin ⁽⁵⁾	1,527,295	4%	750,000	777,295	2%
First Asset Management, LLC ⁽⁶⁾	6,884,200	18%	6,800,000	84,200	*

*Less than 1%.

- (1) Based upon a Form 4 filed with the Securities and Exchange Commission on February 27, 2019, Horton Freedom, L.P., a Delaware limited partnership (“HFF”), owns directly, and has shared voting and investment power over, 3,401,677 shares. Pursuant to investment management agreements, Horton Capital Management, LLC, a Delaware limited liability company (“HCM”), maintains investment and voting power with respect to the shares held by HFF. Horton Capital Partners, LLC, a Delaware limited liability company (“HCP”), is the general partner of HFF. Joseph M. Manko, Jr. is the managing member of both HCM and HCP. By reason of the provisions of Rule 13d-3 promulgated under the Securities Exchange Act of 1934, as amended, each of HCM, HCP and Mr. Manko may be deemed to beneficially own the shares held by HFF. Mr. Manko has served as a director of the Company since May 2016.
- (2) Northern Valley Partners, LLC is a Delaware limited liability company (“Northern Valley Partners”). Michael Potter is the managing member of Northern Valley Partners and has voting and investment power with respect to the shares held by Northern Valley Partners.
- (3) The 75,000 shares do not include the 100,000 shares shown separately in the table above as being beneficially owned by Northern Valley Partners, of which Mr. Potter is the managing member. The 75,000 shares also do not include the 75,000 shares shown separately in the table above as being owned by the Sylvia Potter Family LTD Partnership, a Delaware limited partnership (the “Sylvia Potter Family LTD Partnership”), of which Mr. Potter is a general partner.
- (4) The general partners of the Sylvia Potter Family LTD Partnership are Michael Potter and Sylvia Potter, each of whom has voting and investment power with respect to the shares held by the Sylvia Potter Family LTD Partnership.
- (5) The 1,527,295 shares include 731,805 shares owned by Sandra F. Pessin’s spouse, Norman H. Pessin.
- (6) Based upon a Schedule 13G/A filed on February 14, 2019 with the Securities and Exchange Commission and additional information provided to us by First Light Asset Management, LLC, a Delaware limited liability company (the “Manager”), First Light Focus Fund, LP, a Delaware limited partnership (the “Fund”), is the direct holder of 6,800,000 shares. First Light Focus Fund GP, LLC, a Delaware limited liability company (the “General Partner”), may be deemed to be a beneficial owner of these shares because it is the sole general partner of the Fund. The Manager, may be deemed to be a beneficial owner of these shares because it acts as investment adviser to the Fund. Mathew P. Arens may also be deemed to be the beneficial owner of these shares because he controls the Manager in his position as the managing member and majority owner of the Manager. The Manager is an investment adviser registered under Section 203 of the Investment Adviser Act of 1940. Each of the Fund, the General Partner, the Manager and Mr. Arens has shared voting and investment power with respect to, and may be deemed to be the beneficial owner of, 6,884,200 shares of the Company.

PLAN OF DISTRIBUTION

We are registering for resale by the selling shareholders and certain transferees a total of 11,101,697 shares of common stock, all of which shares are issued and outstanding. We will not receive any of the proceeds from the sale by the selling shareholders of the shares of common stock. We will bear all fees and expenses incident to our obligation to register the shares of common stock. If the shares of common stock are sold through broker-dealers or agents, the selling shareholder will be responsible for any compensation to such broker-dealers or agents.

The selling shareholders may pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time pursuant to this prospectus.

The selling shareholders also may transfer and donate the shares of common stock in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling shareholders will sell their shares of common stock subject to the following:

- all of a portion of the shares of common stock beneficially owned by the selling shareholders or their perspective pledgees, donees, transferees or successors in interest, may be sold on the OTC Bulletin Board Market, any national securities exchange or quotation service on which the shares of our common stock may be listed or quoted at the time of sale, in the over-the counter market, in privately negotiated transactions, through the writing of options, whether such options are listed on an options exchange or otherwise, short sales or in a combination of such transactions;
- each sale may be made at market price prevailing at the time of such sale, at negotiated prices, at fixed prices or at carrying prices determined at the time of sale;
- some or all of the shares of common stock may be sold through one or more broker-dealers or agents and may involve crosses, block transactions or hedging transactions. The selling shareholders may enter into hedging transactions with broker-dealers or agents, which may in turn engage in short sales of the common stock in the course of hedging in positions they assume. The selling shareholders may also sell shares of common stock short and deliver shares of common stock to close out short positions or loan or pledge shares of common stock to broker-dealers or agents that in turn may sell such shares; and
- in connection with such sales through one or more broker-dealers or agents, such broker-dealers or agents may receive compensation in the form of discounts, concessions or commissions from the selling shareholders and may receive commissions from the purchasers of the shares of common stock for whom they act as broker-dealer or agent or to whom they sell as principal (which discounts, concessions or commissions as to particular broker-dealers or agents may be in excess of those customary in the types of transaction involved). Any broker-dealer or agent participating in any such sale may be deemed to be an "underwriter" within the meaning of the Securities Act and will be required to deliver a copy of this prospectus to any person who purchases any share of common stock from or through such broker-dealer or agent. We have been advised that, as of the date hereof, none of the selling shareholders have made any arrangements with any broker-dealer or agent for the sale of their shares of common stock.

The selling shareholder and any broker-dealer participating in the distribution of the shares of common stock may be deemed to be "underwriters" within the meaning of the Securities Act, and any profits realized by the selling shareholders and any commissions paid, or any discounts or concessions allowed to any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. In addition, any shares of common stock covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus. A selling shareholder may also transfer, devise or gift the shares of common stock by other means not covered in this prospectus in which case the transferee, devisee or giftee will be the selling shareholder under this prospectus.

If required at the time a particular offering of the shares of common stock is made, a prospectus supplement or, if appropriate, a post-effective amendment to the shelf registration statements of which this prospectus is a part, will be distributed which will set forth the aggregate amount of shares of common stock being offered and the terms of the offering, including the name or names of any broker-deals or agents, any discounts, commissions or concessions allowed or reallocated or paid to broker-dealers.

Under the securities laws of some states, the shares of common stock may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the shares of common stock may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with. There can be no assurance that any selling shareholder will sell any or all of the shares of common stock registered pursuant to the registration statement, of which this prospectus forms a part.

The selling shareholders and any other person participating in such distribution will be subject to applicable provisions of the Securities Exchange Act of 1934, as amended (the "Exchange Act") and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of common stock by the selling shareholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of common stock to engage in market-making activities with respect to the shares of common stock. All of the foregoing may affect the marketability of the shares of common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of common stock.

We will bear all expenses of the registration of the shares of common stock including, without limitation, Securities and Exchange Commission filing fees and expenses of compliance with the state securities or "blue sky" laws. The selling shareholders will pay all underwriting discounts and selling commissions and expenses, brokerage fees and transfer taxes, as well as the fees and disbursements of counsel to and experts for the selling shareholders, if any. We will indemnify the selling shareholders against liabilities, including some liabilities under the Securities Act, in accordance with the registration rights agreement or the selling shareholders will be entitled to contribution.

We will be indemnified by the selling shareholders against civil liabilities, including liabilities under the Securities Act that may arise from any written information furnished to us by the selling shareholders for use in this prospectus, in accordance with the related securities purchase agreement or will be entitled to contribution. Once sold under this shelf registration statement, of which this prospectus forms a part, the shares of common stock will be freely tradable in the hands of persons other than our affiliates.

DESCRIPTION OF CAPITAL STOCK

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. As of the date of this prospectus, we had 38,204,594 shares of common stock and no shares of preferred stock issued and outstanding. Unless stated otherwise, the following discussion summarizes the terms and provisions of our restated certificate of incorporation and our amended and restated bylaws. This description is summarized from, and qualified in its entirety by reference to, our restated certificate of incorporation and amended and restated bylaws, copies of which have been publicly filed with the SEC.

Common Stock

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

Preferred Stock

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

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

Registration Rights

On December 17, 2018, RMS and certain of its existing stockholder and other parties named therein entered into a Common Stock Purchase Agreement providing for the sale in a private placement transaction of the Shares offered by this prospectus from the existing stockholders to the selling stockholders. The initial closing of the private placement occurred on December 18, 2018 and the final closing occurred on December 20, 2018. We did not issue any securities and did not receive any proceeds from sale of the Shares. Pursuant to the purchase agreement, we agreed to file a resale registration statement under the Securities Act covering the Shares within 45 days following the final closing. We will be obligated to pay liquidated damages in an amount of 1% of the purchase price paid for the Shares per month (subject to proration) if the registration statement is not declared effective within 105 days following the final closing, or 165 days if the registration statement is subject to a full review by the Securities and Exchange Commission.

All descriptions of the Common Stock Purchase Agreement herein are qualified in their entirety by reference to the text thereof filed as an exhibit hereto, which is incorporated herein by reference.

Anti-Takeover Effects of Provisions of Our Charter Documents

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

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

Limitations of Liability and Indemnification of Directors and Officers

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

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

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

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

Transfer Agent

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

MARKET INFORMATION

Our common stock is traded on the OTCQX market under the symbol, "REPR". Any quotations on the OTCQX reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions. As of February 27, 2019, 38,204,594 shares were issued and outstanding and there were approximately 771 stockholders of record. No shares of preferred stock have been issued. We are not issuing any securities in connection with this offering. 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.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The table below sets forth, as of February 27, 2019, the number of shares of common stock beneficially owned by each person owning more than 5% of the outstanding shares, by each named executive officer and director, and by all executive officers and directors as a group. Except as otherwise noted, the address of each person is c/o Repro Med Systems, Inc., 24 Carpenter Road, Chester, NY, 10918.

We have determined beneficial ownership in accordance with the rules of the Securities and Exchange Commission. Except as indicated by the footnotes below, we believe, based on the information furnished to us, that the persons and entities named in the table below have sole voting and investment power with respect to all shares of common stock that they beneficially own, subject to applicable community property laws.

Percentage ownership is based on 38,204,594 shares of common stock outstanding at February 27, 2019. In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of that person, except as indicated by the footnotes below, we also included options or warrants held by that person that are currently exercisable or exercisable within 60 days of February 27, 2019, as outstanding ignoring the withholding of shares of common stock to cover applicable taxes. We did not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person. We did not deem outstanding shares of common stock issuable as directors' fees within 60 days after February 27, 2019, as the number of shares is not able to be calculated at this time. Beneficial ownership representing less than 1% is denoted with an asterisk (*).

The information provided in the table is based on our records, information filed with the SEC, and information provided to us, except where otherwise noted.

Name of Principal Shareholders and Identity of Group	Number of Shares	Percent of Class	Notes:
Joseph M. Manko, Jr.	12,284,191	31%	(1)
Karen Fisher	500,000	1%	—
Mark Pastreich	451,561	1%	—
Arthur J. Radin	321,461	*	—
Manuel A. Marques	164,010	*	—
Daniel S. Goldberger	103,818	*	—
David W. Anderson	25,718	*	—
James M. Beck	556	*	—
Robert T. Allen	10,556	*	—
Donald B. Pettigrew	—	*	—
All Directors and Executive Officers as a Group	13,861,871	35%	(1)
Horton Capital Management, LLC	12,284,191	31%	(1)
First Asset Management, LLC	6,884,200	18%	(2)
Total of all Directors, Officers and 5% shareholders	20,746,071	53%	—

- (1) Based upon a Schedule Form 4 filed with the SEC on February 27, 2019 and other information provided to us by HCM, each of Mr. Manko and Horton Capital Management, LLC, a Delaware limited liability company (“HCM”), may be deemed to beneficially own 12,284,191 shares of common stock, including 6,759,404 shares of common stock held by Horton Capital Partners Fund, LP, a Delaware limited partnership (“HCPF”), 3,401,677 shares of common stock held by Horton Freedom, LP, a Delaware limited partnership (“HFF”) and 1,000,000 shares of common stock issuable upon the exercise of the Warrant, dated August 8, 2014, issued to HCPF. Pursuant to investment management agreements, HCM maintains investment and voting power with respect to shares of common stock held by HCPF and HFF. Despite the delegation of investment and voting power to HCM, Horton Capital Partners LLC, a Delaware limited liability company (“HCP”), may be also deemed to be the beneficial owner of shares of common stock held by HCPF and HFF because HCP has the right to acquire investment and voting power through termination of investment management agreements with HCM. In addition, HCM acts as an investment adviser to certain managed accounts. Under investment management agreements with managed account clients, HCM has investment and voting power with respect to 1,123,110 shares of common stock of the Company held in such managed accounts. HCP is the general partner of HCPF and HFF. Mr. Manko is the managing member of both HCM and HCP. The address of Mr. Manko, HCM, HCP, HCPF and HFF is 1717 Arch Street, 39th Floor, Philadelphia, PA 19103.
- (2) Based upon a Schedule 13G/A filed on February 14, 2019 with the Securities and Exchange Commission and additional information provided to us by First Light Asset Management, LLC, a Delaware limited liability company (the “Manager”), First Light Focus Fund, LP, a Delaware limited partnership (the “Fund”), is the direct holder of 6,800,000 shares. First Light Focus Fund GP, LLC, a Delaware limited liability company (the “General Partner”), may be deemed to be a beneficial owner of these shares because it is the sole general partner of the Fund. The Manager may be deemed to be a beneficial owner of these shares because it acts as investment adviser to the Fund. Mathew P. Arens may also be deemed to be the beneficial owner of these shares because he controls the Manager in his position as the managing member and majority owner of the Manager. The Manager is an investment adviser registered under Section 203 of the Investment Adviser Act of 1940. Each of the Fund, the General Partner, the Manager and Mr. Arens has shared voting and investment power with respect to, and may be deemed to be the beneficial owner of, 6,884,200 shares of the Company.

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 elsewhere in this prospectus. This discussion contains certain “forward-looking” statements (as such term is defined in the Private Securities Litigation Reform Act of 1995) about our business and operations and information relating to us that is based on the beliefs of the management, as well as assumptions made and information currently available. Our actual results may differ materially from those we currently anticipate as a result of many factors, including those described under “Cautionary Note Regarding Forward-Looking Statements” elsewhere in this prospectus. You should review the disclosure under the heading “Risk Factors” in this prospectus for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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

OVERVIEW

RMS went through some significant changes during 2018.

On July 25, 2018, Andrew I. Sealfon was terminated as President, Chief Executive Officer and Chairman of the Board, effective immediately. Consequently, Mr. Sealfon’s employment was terminated. Mr. Sealfon remained as a director until December 18, 2018. Also on July 25, 2018, Daniel S. Goldberger was appointed as President and Chief Executive Officer on an interim basis and as Chairman of the Board, and replaced as the Lead Director. The Board appointed Joseph M. Manko, Jr., a current RMS director, as Lead Director.

On September 4, 2018, the Company entered into an employment agreement with Donald B. Pettigrew to serve as its President and Chief Commercial Officer.

On September 17, 2018, the Board of Directors of the Company formed a special committee of the Board (the “Special Committee”) with authority to investigate, evaluate, make decisions, and take any and all action with respect to (a) a purported request (i) from Andrew I. Sealfon, Dr. Paul M. Baker and Andrea Baker, in their capacities as shareholders of the Company, to call a special shareholders’ meeting and (ii) from Mr. Sealfon and Dr. Baker, in their capacities as directors of the Company, to call a special meeting of the Board (collectively, the “Special Meetings Request”); and (b) issues of proper consideration for the Board raised by certain discoveries involving Mr. Sealfon prior to his termination from the Company. The Special Committee identified certain deficiencies in the Special Meetings Request based upon its review of the Special Meetings Request to date and communicated those to Mr. Sealfon and Dr. Baker. Shortly following the termination of Mr. Sealfon’s employment and service as President, Chief Executive Officer and Chairman of the Board, certain non-financial discoveries were made involving Mr. Sealfon prior to his termination from the Company. On the advice of and through Company counsel, the Company engaged Kroll, a division of Duff & Phelps Corporation, to perform an independent investigation of certain of Mr. Sealfon’s non-financial activities while employed by the Company. The Special Committee, through counsel, oversaw Kroll with respect to this investigation. The Special Committee retained Olshan Frome Wolosky LLP for legal advice. The Special Committee’s activities, including those with respect to the investigation, concluded effective with the entry into an Agreement Regarding Stock Sale dated as of December 17, 2018 between each of Mr. Sealfon and Mr. Baker and the Company in which the parties entered into mutual general releases with respect to all claims prior to that date.

Horton Capital Partners Fund, LP (“HCPF”) holds Warrants to purchase 1,000,000 shares of the Company’s common stock at an exercise price of \$0.45 per share, pursuant to a previously disclosed agreement with the Company dated August 8, 2014. The Warrant includes a conversion cap that precludes HCPF from exercising the Warrant to the extent that HCPF would, after such exercise, beneficially own (as determined in accordance with Section 13(d) of the Act) in excess of 9.99% of the shares of Common Stock then outstanding, unless HCPF elects to waive this provision with the agreement of the Company. As HCPF already owns in excess of 9.99% of the outstanding shares of Common Stock, this provision was waived by HCPF on August 31, 2018 and acknowledged by the Company on September 12, 2018. On September 13, 2018, HCPF notified the Company of its intention to exercise the warrant in full at a closing to take place no earlier than November 12, 2018, or 61 days from the Company’s acknowledgement. As of December 31, 2018, HCPF had not exercised its warrants which expire on August 8, 2019.

On December 17, 2018, the Company entered into a Common Stock Purchase Agreement (the “Agreement”) with Andrew I. Sealfon and other sellers set forth in the Agreement and purchasers listed in the Agreement in a private placement transaction. Pursuant to that agreement, we agreed to file a resale registration statement. The existing stockholders party to the agreement included Andrew I. Sealfon and Paul Mark Baker, then directors of RMS, together with certain members of their respective family members. Andrew I. Sealfon, Paul Mark Baker, Andrea Baker, Brad Sealfon and Mary Sealfon, existing stockholders party to the agreement, received an aggregate of \$12,218,977 in connection with the transaction. One of the purchasers was Horton Freedom, L.P., an affiliate of Horton Capital Partners, LLC, who paid \$3,842,036 in connection with the transaction. At the time of the purchase, Horton Capital Partners, LLC beneficially owned more than 5% of our outstanding common stock. Joseph M. Manko, Jr. is the managing member of Horton Capital Partners, LLC and has served as a director of the Company since May 2016.

In connection with the Agreement, also on December 17, 2018, we entered into an Agreement Regarding Stock Sale with Mr. Sealfon and a separate Agreement Regarding Stock Sale with Dr. Baker (the “Separation Agreements”). Pursuant to these Separation Agreements, Mr. Sealfon and Dr. Baker tendered their respective resignations from our Board of Directors effective with the first closing of the transaction under the purchase agreement, which occurred on December 18, 2018. Each of these separation agreements provides for the mutual general release by us, on the one hand, and each of Mr. Sealfon and Dr. Baker, on the other hand, of all claims against the other arising or occurring on or before the date thereof, subject to certain exceptions. Pursuant to the agreement with Mr. Sealfon, Mr. Sealfon agreed to certain non-competition and non-solicitation restrictions for a period of six months after the first closing.

Effective December 5, 2018, the Company added two new independent members to the Board of Directors, Robert T. Allen and James M. Beck. On December 6, 2018, the Company’s Vice President of Operations, Manuel Marques, was promoted to the position of Chief Operating Officer.

Effective December 20, 2018, we terminated the employment of Fred Ma, Ph.D., its Chief Medical Officer (“Employee”) and entered into a General Release and Confidentiality Agreement (the “Agreement”). Pursuant to the terms of the Agreement, RMS will pay Employee an aggregate \$225,000, payable bi-weekly commencing December 31, 2018. Pursuant to the Agreement, Employee has agreed to certain non-competition and non-solicitation restrictions for a period of six months.

We ended the year with record net sales of \$17.4 million for the twelve months ended December 31, 2018. We believe these record sales are in part due to increased penetration of the PIDD market for subcutaneous immunoglobulin, some early adoption of immunoglobulin for chronic inflammatory demyelinating polyneuropathy (“CIDP”) indication for the subcutaneous drug Hizentra®, and increased clinical trials with our pharmaceutical customers.

Higher sales and operating efficiencies improved our gross margins to 62.3% for 2018. Last year we had increased levels of scrap during quality inspections. In January 2018, we implemented a nondestructive testing protocol to reduce scrap which helped drive the improvement in margins.

The organizational changes described above included expenses related to the termination and replacement of C-suite executives and senior management, legal expenses related to activities under the purview of the Special Committee, the recruitment of new directors replacing exiting directors and investment banking and legal fees for the Agreement, all in aggregate, increased operating expenses by \$0.6 million for the fourth quarter and \$1.0 million for the twelve months ended December 31, 2018.

Despite the large reorganization charges, we ended the year with \$0.9 million in net income and \$5.3 million of cash on hand, including a certificate of deposit of \$1.5 million.

Fiscal Year End

In order to conform to industry norms and to facilitate financial analysis for investors, on March 22, 2017, the Board of Directors approved a change in the Company’s fiscal year end from February 28 to December 31. For the fiscal year ended December 31, 2017, RMS filed a Transition Report on Form 10-KT for the ten months ended December 31, 2017 and the twelve months ended February 28, 2017. For fiscal year ending December 31, 2018, twelve months are compared to the transition year ten months ended December 31, 2017. For comparison purposes, RMS is also presenting the twelve months ending December 31, 2017 within this management discussion and analysis below.

RESULTS OF OPERATIONS

Twelve Months Ended December 31, 2018 compared to the Ten Months Ended December 31, 2017

Net Sales

The following table summarizes our net sales for the twelve months ended December 31, 2018 and the ten months ended December 31, 2017.

	Twelve Months Ended		Ten Months Ended		Change from Prior Year		% of Net Sales		
	December 31, 2018	December 31, 2017	\$	%	December 31, 2018	December 31, 2017			
Net Sales									
Domestic	\$ 14,235,689	\$ 10,885,446	\$ 3,350,243	30.8%	82.0%	81.8%			
International	3,118,048	2,428,448	689,600	28.4%	18.0%	18.2%			
Total	\$ 17,353,737	\$ 13,313,894	\$ 4,039,843	30.3%					

Net sales for the twelve months ended December 31, 2018 were 30.3% greater than net sales for the ten months ended December 31, 2017 due to the twelve month versus ten month period comparison. Also contributing to the increase were higher needle set sales we believe is in part due to increased penetration of the PIDD market for subcutaneous immunoglobulin, some early adoption of immunoglobulin for CIDP indication for the subcutaneous drug Hizentra®, and increased clinical trials with our pharmaceutical customers.

The following table summarizes our net sales for the twelve months ended December 31, 2018 and 2017.

	Twelve Months Ended December 31,		Change from Prior Year		% of Net Sales	
	2018	2017	\$	%	2018	2017
Net Sales						
Domestic	\$ 14,235,689	\$ 12,615,121	\$ 1,620,568	12.9%	82.0%	81.7%
International	3,118,048	2,827,591	290,457	10.3%	18.0%	18.3%
Total	\$ 17,353,737	\$ 15,442,712	\$ 1,911,025	12.4%		

Net sales increased \$1.9 million or 12.4% compared with the twelve month period last year, driven primarily by increased needle set sales, which we believe is in part due to increased penetration of the PIDD market for subcutaneous immunoglobulin, some early adoption of immunoglobulin for CIDP indication for the subcutaneous drug Hizentra®, and increased clinical trials with our pharmaceutical customers.

Gross Profit

Our gross profit for the twelve months ended December 31, 2018 and the ten months ended December 31, 2017 is as follows:

	Twelve Months Ended		Ten Months Ended		Change from Prior Year	
	December 31, 2018	December 31, 2017	\$	%	\$	%
Gross Profit	\$ 10,810,488	\$ 8,138,948	\$ 2,671,540	32.8%		
Stated as a Percentage of Net Sales	62.3%	61.1%				

The increase in gross profit of \$2.7 million or 32.8% is due to the twelve month versus ten month period comparison, as well as due to operating efficiencies. Last year we had increased levels of scrap during quality inspections. In January 2018, we implemented a nondestructive testing protocol to reduce scrap which helped drive the improvement in margins.

Our gross profit for the twelve months ended December 31, 2018 and 2017 is as follows:

	Twelve Months Ended December 31,		Change from Prior Year	
	2018	2017	\$	%
Gross Profit	\$ 10,810,488	\$ 9,268,107	\$ 1,542,381	16.6%
Stated as a Percentage of Net Sales	62.3%	60.0%		

Gross profit for the twelve months ended December 31, 2018 increased \$1.5 million or 16.6% compared to the same period last year, driven by increased net sales and operating efficiencies described above.

Selling, general and administrative and Research and development

Our selling, general and administrative expenses and research and development costs for the twelve months ended December 31, 2018 and the ten months ended December 31, 2017 are as follows:

	Twelve Months Ended		Change from Prior Year	
	December 31, 2018	December 31, 2017	\$	%
Selling, general and administrative	\$ 9,095,565	\$ 6,594,570	\$ 2,500,995	37.9%
Research and development	241,124	50,587	190,537	376.7%
	<u>\$ 9,336,689</u>	<u>\$ 6,645,157</u>	<u>\$ 2,691,532</u>	<u>40.5%</u>
Stated as a Percentage of Net Sales	53.8%	49.9%		

Selling, general and administrative expenses increased \$2.5 million for the twelve months ended December 31, 2018, up 37.9% from the ten month period ended December 31, 2017 due in part to the twelve month period versus the ten month period comparison. Additionally, legal expenses increased related to the activities under the purview of the Special Committee, the Common Stock Purchase Agreement executed on December 17, 2018, continued litigation efforts and increased general counsel support for corporate matters, totaling \$0.8 million. Our reorganization efforts included costs associated with C-suite, senior management and board changes, resulting in severance expense, sign on bonuses, stock option issuances and recruiting fees in aggregate totaling \$0.6 million. We added a clinical and medical affairs associate and had higher regulatory salary and benefits, consulting fees for FDA submissions and international registrations totaling in aggregate \$0.3 million and we spent more for consulting and investor and public relations services totaling \$0.2 million. Offsetting some of these expenses were lower salary and benefits in selling and marketing and in executive department due to management changes and attrition, lowering expense year over year by \$0.6 million.

Research and development expenses increased by \$0.2 million for the twelve months ended December 31, 2018 compared to the ten month period ended December 31, 2017 due to an increase in headcount and expanded product development initiatives compared with last year.

Our selling, general and administrative expenses and research and development costs for the twelve months ended December 31, 2018 and 2017 are as follows:

	Twelve Months Ended December 31,		Change from Prior Year	
	2018	2017	\$	%
Selling, general and administrative	\$ 9,095,565	\$ 7,731,972	\$ 1,363,593	17.6%
Research and development	241,124	88,621	152,503	172.1%
	<u>\$ 9,336,689</u>	<u>\$ 7,820,593</u>	<u>\$ 1,516,096</u>	<u>19.4%</u>
Stated as a Percentage of Net Sales	53.8%	50.6%		

Selling, general and administrative expenses increased \$1.4 million, or 17.6%, for the twelve months ended December 31, 2018, compared with the same period last year, primarily due to increased legal fees related to the activities under the purview of the Special Committee, the Common Stock Purchase Agreement executed on December 17, 2018, continued litigation efforts and increased general counsel support for corporate matters, totaling \$0.8 million. Our reorganization efforts included costs associated with C-suite, senior management and board changes, resulting in severance expense, sign on bonuses, stock option issuances and recruiting fees in aggregate totaling \$0.6 million. We added a clinical and medical affairs associate and had higher regulatory salary and benefits, consulting fees for FDA submissions and international registrations totaling in aggregate \$0.3 million and we spent more for consulting and investor and public relations services totaling \$0.2 million. Offsetting some of these expenses were lower salary and benefits in selling and marketing and in executive department due to management changes and attrition, lowering expense year over year by \$0.6 million.

Research and development costs increased \$0.2 million, or 172.1%, due to an increase in headcount and expanded product development initiatives compared with last year.

Depreciation and amortization

Depreciation and amortization expense was \$52,006, or 20.2%, higher in the twelve months ended December 31, 2018 compared with the ten month period ended December 31, 2017 due principally to the twelve month versus ten month comparison.

For the twelve months ended December 31, 2018, depreciation and amortization expense increased \$2,701, or 0.9%, compared with the same period last year. We continued to invest in capital assets, mostly related to production, and in patent applications and their maintenance. Amortization increased and was offset by a reduction in depreciation expense as a significant number of assets become fully depreciated over the course of the year compared with last year.

Net Income

	Twelve Months Ended December 31, 2018		Ten Months Ended December 31, 2017		Change from Prior Year		
	\$		\$		\$	%	
Net Income	\$	910,570	\$	904,957	\$	5,613	0.6%
Stated as a Percentage of Net Sales		5.2%		6.8%			

Our net income for the twelve months ended December 31, 2018 was \$0.9 million, unchanged from the ten months ended December 31, 2017. Although we had two additional months of net sales in 2018, our expenses were significantly higher for the reasons described above, as well as due to the additional two months in the period compared with December 31, 2017. Partially offsetting the expenses was the favorable tax rate compared with last year.

	Twelve Months Ended December 31,		Change from Prior Year				
	2018	2017	\$	%			
Net Income	\$	910,570	\$	819,547	\$	91,023	11.1%
Stated as a Percentage of Net Sales		5.2%		5.3%			

Our net income for the twelve months ended December 31, 2018 was \$0.9 million, as compared to net income of \$0.8 million for the twelve months ended December 31, 2017. This increase was the result of increased net sales, improved gross margin and the lower tax rate compared with last year. Partially offsetting these were expenses the Company incurred related to legal fees, severance, sign on bonuses and recruiting fees as described above.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash of \$3.7 million as of December 31, 2018. Additionally, we have a \$1.5 million certificate of deposit that matures in May 2019 and a \$1.5 million line of credit with no outstanding amounts against it. Our principal source of operating cash inflows is from sales of our products to customers. Our principal cash outflows relate to the purchase and production of inventory and related costs, selling, general and administrative expenses, legal fees, capital expenditures and patent costs.

We believe that as of December 31, 2018, cash on hand and cash expected to be generated from future operating activities will be sufficient to fund our operations, including further research and development and capital expenditures for the next 12 months. We believe the FREEDOM System continues to find a solid following in the SCIG market, and this market is expected to continue to increase both domestically and internationally.

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

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

Cash Flows

The following table summarizes our cash flows:

	Twelve Months Ended December 31, 2018	Ten Months Ended December 31, 2017
Net cash provided by operating activities	\$ 1,479,662	\$ 899,912
Net cash used in investing activities	\$ (1,729,824)	\$ (219,281)
Net cash provided by/(used in) financing activities	\$ 14,429	\$ (19,360)

Operating Activities

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

Net cash provided by operating activities of \$0.9 million for the ten months ended December 31, 2017 was primarily attributable to our net income of \$0.9 million, non-cash charges in earnings of \$0.3 million for depreciation and amortization of long lived tangible and intangible assets, stock based compensation of \$0.1 million and an increase in accrued expenses of \$0.2 million due to increased bonus accrual. Further adding to the net cash provided by operating activities was an increase in accrued income tax liability of \$0.3 million due to increased profitability and an increase in accrued payroll and related taxes of \$0.2 million related to a severance accrual for the former Chief Operating Officer. Partially offsetting these were increases in accounts receivable of \$0.4 million, an increase in inventory of \$0.3 million as we build inventory and a decrease in accounts payable of \$0.3 million related to the payment of legal fees accrued at February 28, 2017.

Investing Activities

Our net cash used in investing activities of \$1.7 million for the fiscal year ended December 31, 2018 was from the purchase of a certificate of deposit for \$1.5 million as well as continued investment in capital assets and patent applications of \$0.5 million, all partially offset by net proceeds from certificates of deposits of \$0.2 million.

Net cash used in investing activities of \$0.2 million for the ten months ended December 31, 2017, was primarily attributable to our investment in capital assets, mostly related to production and computer equipment, and for new patent applications and maintenance of existing patents.

Financing Activities

Net cash provided by financing activities was \$14,429 for the twelve months ended December 31, 2018 resulting mostly from the exercise of options less payment for cancelled shares. Net cash used in financing activities was \$19,360 for the ten months ended December 31, 2017 and was attributable to the payment for cancellation of shares.

LEASE COMMITMENTS

We currently lease 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, for manufacturing operations and research & development. We are in year twenty of a twenty-year lease and are responsible for all repairs, maintenance, and upkeep of the space occupied. The terms of the lease call for a monthly lease payment of \$11,042 per month. We also contribute payments of 65% of the building's annual property taxes, amounting to \$50,512 for the fiscal year ended December 31, 2018. On November 14, 2017, we executed a lease extension with our current landlord, which calls for six month extensions beginning March 1, 2019 with the option to renew six times, with monthly lease payments of \$12,088.

We also lease 2,500 square feet of storage space in a nearby industrial park on a year-to-year basis. In the twelve months ended December 31, 2018, we paid \$20,921 in rent and common charges for this space.

ACCOUNTING POLICIES

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

NON-GAAP FINANCIAL MEASURES

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

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

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

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

A reconciliation of our non-GAAP measures is below:

Reconciliation of GAAP Net (Loss)/Income to Non-GAAP Adjusted EBITDA:	Twelve Months Ending	
	December 31,	
	2018	2017
GAAP Net Income	\$ 910,570	\$ 819,547
Tax (Benefit)/Expense	266,380	390,799
Depreciation/Amortization	309,263	306,562
Interest Income	(28,104)	(3,743)
Reorganization Charges	996,447	—
Stock Compensation Expense	293,040	66,947
Non-GAAP Adjusted EBITDA	\$ 2,747,596	\$ 1,580,112

Reconciliation of GAAP Net (Loss)/Income To Non-GAAP Normalized Net Income:	Twelve Months Ending	
	December 31,	
	2018	2017
GAAP Net (Loss)/Income	\$ 910,570	\$ 819,547
Reorganization Charges	996,447	—
Tax (Expense) adjustment	(209,254)	—
Non-GAAP Normalized Net Income	\$ 1,697,763	\$ 819,547

Reorganization Charges. Reorganization charges include costs related to the termination and replacement of C-suite executives and senior management, legal expenses related to activities under the purview of the special committee formed by the Board as previously disclosed, the recruitment of new directors replacing exiting directors and investment banking and legal fees for the recent Common Stock Purchase Agreement the Company executed on December 17, 2018.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The main difference between the current requirement under GAAP and this ASU is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases. This ASU requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). Classification will be based on criteria that are largely similar to those applied in current lease accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. This is effective for annual and interim periods beginning after December 15, 2018 and early adoption is permitted. This ASU must be adopted using a modified retrospective transition, and provides for certain practical expedients. Transition will require application of the new guidance at the beginning of the earliest comparative period presented. We believe the adoption of this ASU may have a material impact on our assets and liabilities, but not a material impact on the results of operations on our financial statements, disclosure requirements and methods of adoption.

In July 2018, the FASB issued ASU No. 2018-10 Codification Improvements to Topic 842, Leases. The amendments in this ASU affect narrow aspects of the guidance issued in the amendments in ASU 2016-02. The amendments in this ASU related to transition do not include amendments from proposed ASU, Leases (Topic 842): Targeted Improvements, specific to a new and optional transition method to adopt the new lease requirements in ASU 2016-02. That additional transition method will be issued as part of a forthcoming and separate ASU that will result in additional amendments to transition paragraphs included in this ASU to conform with the additional transition method. The amendments in this ASU affect the amendments in ASU 2016-02, which are not yet effective, but for which early adoption upon issuance is permitted. For entities that early adopted Topic 842, the amendments are effective upon issuance of this ASU, and the transition requirements are the same as those in Topic 842. For entities that have not adopted Topic 842, the effective date and transition requirements will be the same as the effective date and transition requirements in Topic 842. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements. The amendments in this ASU affect narrow aspects of the guidance issued in the amendments in ASU 2016-02. The amendments in this ASU related to transition do not include amendments from proposed ASU, Leases (Topic 842): Targeted Improvements, specific to a new and optional transition method to adopt the new lease requirements in ASU 2016-02. That additional transition method will be issued as part of a forthcoming and separate ASU that will result in additional amendments to transition paragraphs included in this ASU to conform with the additional transition method.

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

In August 2018, the FASB issued ASU No. 2018-15 Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this ASU align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this ASU. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption of the amendments in this ASU is permitted, including adoption in any interim period, for all entities. The amendments in this ASU should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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

DESCRIPTION OF OUR BUSINESS

We design, manufacture and market proprietary and innovative portable medical devices, primarily for the ambulatory infusion market in compliance with 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 RMS Precision Flow Rate Tubing™. We were incorporated in the State of New York in March 1980.

Our mission is to improve the quality of life of patients around the world through the development and delivery of high quality, innovative and easy to use therapeutic solutions.

We strive to be the best specialty infusion system partner providing a proprietary drug and fluid delivery system for home or alternate site settings where performance, reliability, ease of use and cost effectiveness are driving influencers. Our easy-to-use, lightweight and portable FREEDOM System allows the patient to continue with their daily activities while receiving infusion therapy. The patient experiences optimal therapy delivery using the innovative FREEDOM System with dynamic equilibrium (“DynEq™”), HIGH-Flo Subcutaneous Safety Needle Sets and RMS Precision Flow Rate Tubing.

OUR STRATEGY

In January 2019, the Board of Directors approved our strategic plan to become the preferred drug delivery partner for specific infusion therapies in select markets.

The financial goals for our strategic plan through 2022 are:

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

We are committed to delivering simple, effective, drug delivery systems to the home health care environment. We believe our Freedom Infusion Systems using DynEq™ technology is superbly positioned for Immunoglobulin therapy and we plan to build on that platform. We plan to drive revenue by supporting the accelerating adoption of Hizentra®, Cuvitru® and other formulations for immunoglobulin therapy and participating in the migration of other therapeutics into the home health marketplace globally. We expect to leverage our specialty pharmacy customer base by bringing additional products and services to our channel.

FREEDOM System

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

The FDA issued a 510(k) clearance for the RMS "Integrated Catch-Up Freedom Syringe Driver Infusion System," which is our FREEDOM System, effective August 31, 2017, which includes the RMS Precision Flow Tubing and our HIgH-Flo Subcutaneous Safety Needle Sets. The FREEDOM System is cleared by the FDA for a wide range of flow rates and certain medications for subcutaneous and intravenous indications, including specific clearance for leading immune globulins that include Hizentra® and Cuvitru® and a variety of antibiotics. The FDA clearance includes the following Caution Statement, "In order to achieve specific and repeatable flow rate performance with the FREEDOM Syringe Infusion Systems' unique constant force mechanism, use only Freedom System accessories manufactured by RMS Medical Products ..." and "For use with subcutaneous immune globulin products, use only RMS flow control devices and HIgH-Flo Subcutaneous Safety Needle Sets, as use of generic products may result in unknown flow rates and additional site complications such as pain, swelling and redness."

Ambulatory infusion systems are most prevalent in the home care and alternate site markets. The use of the FREEDOM System for treatment of primary immune deficiencies through subcutaneous immune globulin ("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 chronic inflammatory demyelinating polyneuropathy (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 pump is easily configured for this application;
- it is the best value infusion system available in a heavily cost constrained market; and
- it has demonstrated ultimate effectiveness and an impeccable safety profile.

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

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

We have available online our RMS Freedom Flow Rate Calculator, a tool designed to help providers determine which of the RMS Precision Flow Rate Tubing and HIgH-Flo Subcutaneous Safety Needle Sets to use based on the medication being administered and desired flow rate/time of infusion.

Sales and Distribution

The FREEDOM System is sold through both direct sales and medical device distributors, where the majority of our sales are generated. We sell most of our products through a small number of distributors, three in and two outside the U.S. As of December 31, 2018, these five distributors comprised approximately 75% of our gross revenues. One distributor in the U.S. provides approximately 58% of our gross revenues. Specialty pharmacy customers purchase FREEDOM System products through distributors for inventory management and one-stop shopping convenience. In the U.S., physician's prescriptions for SCIG are filled by specialty pharmacies and home infusion providers who also provide patient care and training in the patient's home or home infusion facility via a network of nurses. We continue our efforts to expand internationally with the majority of current international sales in the European market and the United Kingdom where our products are sold via distributors. We have two distributors outside the U.S., one in the United Kingdom and one in Finland, that accounted for approximately 11% of our gross revenues for the twelve months ended December 31, 2018.

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

Manufacturing and Raw Materials

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

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

Research and Development

We recognize the importance of innovation and renovation to our long-term success and are committed to research and new product development activities. Our product development team along with outside engineering resources is engaged in continuously improving existing product performance and researching new product opportunities to increase our pipeline. We spent \$0.2 million on research and development for the year ending December 31, 2018 and \$0.1 million for the year ending December 31, 2017. We intend to make additional investments in research and development over the next twelve months.

Regulatory

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

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

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

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

Employees

As of February 27, 2019, we had 76 full time employees and 2 part time employees.

Patents and Trademarks

We have filed and received U.S. and foreign protection for many of our products relating to infusion systems and related components. We currently have twelve pending applications and four issued with expiration dates ranging from 2021 to 2031. 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 “Legal Proceedings” for details regarding our patent litigation.

DESCRIPTION OF PROPERTY

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, for manufacturing operations and for research and development.

Currently, we are in year twenty of a twenty-year lease that expires in February 2019 and are responsible for all repairs, maintenance, and upkeep of the space occupied. The terms of the lease call for monthly lease payments of \$11,042, and we contribute payments of 65% of the building’s annual property taxes. We have entered into a lease extension with our current landlord, which calls for six month extensions beginning March 1, 2019 with the option to renew six times through August 2022, with monthly lease payments of \$12,088. Our current landlord is a director of RMS. See “*CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS*.”

We also lease 2,500 square feet of storage space in a nearby industrial park on a month-to-month basis. The monthly payments are \$1,583 with aggregate annual payments of \$18,992.

We own a residence adjacent to our headquarters facility for use as additional office space. We intend to list that property for sale as we believe it is no longer useful.

LEGAL PROCEEDINGS

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

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

On August 22, 2017, we filed a motion in this California case seeking a Preliminary Injunction prohibiting EMED from making false statements and claims regarding the products of both companies. The motion has now been fully briefed, and the parties are awaiting action by the Court.

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

The second court case was filed by EMED in the United States District Court for the Eastern District of Texas on June 25, 2015, claiming patent infringement of Claim 1 of another of its patents (US 8,961,476 – "'476'"), by our needle sets, and seeking unspecified monetary damages ("ED Texas '476 matter"). This '476 patent is related to the '703 patent.

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

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

The SDNY '576 matter is proceeding with preliminary matters and although a fixed trial date has not been set it is expected to be in the fourth quarter of 2019 or the first quarter of 2020.

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

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

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

As is required by the respective Courts in both the SDNY '576 matter and the ED Texas '476 matter, the parties are engaging in settlement discussions and have scheduled mediation sessions.

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

MANAGEMENT

The following table sets forth certain information with respect to our executive officers and directors as of March 5, 2019:

<u>Name</u>	<u>Age</u>	<u>Position / Held Since</u>
Donald B. Pettigrew	50	Chief Executive Officer (since February 2019) President and Chief Commercial Officer (since August 2018)
Karen Fisher	52	Chief Financial Officer and Treasurer (since 2015)
Manuel Marques	46	Chief Operating Officer (since December 2018)
Daniel S. Goldberger	60	Executive Chairman (since February 2019) Chairman of the Board (since July 2018) Director (since April 2018)
Robert T. Allen	63	Director (since December 2018)
David W. Anderson	66	Director (since 2016)
James M. Beck	71	Director (since December 2018)
Joseph M. Manko, Jr.	53	Director (since 2016) Lead Director (since July 2018)
Mark L. Pastreich	89	Director (since 2011)
Arthur J. Radin	81	Director (since 2015)

All directors hold office until the next annual meeting of shareholders or until their successors are elected. Executive officers hold office at the discretion of the Board of Directors.

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

Ms. Fisher has more than 25 years of financial experience at a variety of industries. Prior to joining RMS 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 has served as our Vice President of Operations and Engineering since February 2016, and joined RMS as Director of Manufacturing and Manufacturing Engineering in July 2015. Prior to joining RMS, 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 RMS. Mr. Marques has over 23 years of experience within the dental, medical device, and automotive industries, and holds two U.S. patents for cardiovascular medical devices. Mr. Marques obtained a B.S. in Mechanical Engineering Technology and also an M.S. in Engineering Management from the New Jersey Institute of Technology.

Mr. Goldberger has over 35 years of experience within the biotech, medical technology, and high tech industries. His areas of expertise include mergers and acquisitions, capital formation, intellectual property, product development, supply chain, business analytics, and turnarounds. Since January 2018, Mr. Goldberger has been the Chief Executive Officer of Synergy Disc Replacement Inc., a private company commercializing a proprietary total disc implant for cervical spine therapy. From October 2017 to January

2018, Mr. Goldberger served as Chief Executive Officer of Milestone Medical, Inc. Prior to this he served as the Chief Executive Officer of Xtant Medical Holdings, Inc. from August 2013 to January 2017. He also served as the Chief Executive Officer of Sound Surgical Technologies LLC from April 2007 to February 2013. Mr. Goldberger served on the boards of Xtant Medical Holdings, Inc., Sound Surgical, Xcorporeal and Glucon. He currently serves as an advisor to investment funds Meridian Capital and Wellfleet Capital. Mr. Goldberger earned his B.S. in Mechanical Engineering from M.I.T, his M.S. in Mechanical Engineering from Stanford University and attended the Stanford Directors College.

Mr. Allen is a certified public accountant and seasoned executive with 38 years of operating and financial experience focused on the healthcare services sector. He is currently a principal at RLA Advisors, which provides advisory services to leadership teams in rapidly expanding organizations and turnaround situations. Mr. Allen most recently served as President of Coram/CVS Infusion Services, from 2013 to 2014. Prior to serving as President, he held positions of COO and CFO at Coram between 2006 and 2013. Prior to Coram, Mr. Allen held leadership roles at Titan Health Corporation and American Medical Response. Mr. Allen also currently sits on the board of Oceans Healthcare, an operator of hospitals in the Southeast.

Mr. Anderson has been in the medical (device) industry for over 23 years and since 2017 has served as the Chief Executive Officer for Brain Temp, Inc. Previously, he held the role of Chief Executive Officer for Orteq Sports Medicine from 2014 to 2017 and Gentis, Inc. from 2004 through 2014. He also serves on the board for ACell Inc., (Regenerative Medicine for Woundcare), as well as serves on several advisory committees. Mr. Anderson received a B.S. in Chemical Engineering from Cornell University and attended University of Minnesota for Graduate Studies in Microbiology.

Mr. Beck has more than 30 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, Mr. Beck 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. Manko has been the Senior Principal in Horton Capital Management LLC, the investment manager for the Horton Capital Partners Fund, LP (“Horton Fund”) since 2013. The Horton Fund is a significant shareholder in the Company. Mr. Manko has over 20 years of investment experience in the asset management, investment banking, private equity and corporate securities markets. From 2005 to 2010 Mr. Manko was a Partner and Chief Executive Officer of Switzerland-based BZ Fund Management Limited, where he was responsible for corporate finance, private equity investments, three public equity funds and the firm’s Special Situations and Event-Driven strategies. Prior to that Mr. Manko was a Managing Director with Deutsche Bank in London. He began his investment banking career at Merrill Lynch as a Vice President in Hong Kong and prior to that, Mr. Manko was a corporate finance attorney at Skadden, Arps, Slate, Meagher & Flom LLP. Mr. Manko has served on the board of several companies in the bio-pharmaceutical industry and has advised numerous companies in the pharmaceutical, biotech and medtech industries. Mr. Manko earned both his B.A. and Juris Doctor from the University of Pennsylvania.

Mr. Pastreich has been a partner in Casper Creek LLC, a real estate company that owns the building leased by us, where he has been for the last 18 years. Mr. Pastreich has also held various positions in businesses and real estate ventures.

Mr. Radin, who started his career at Touche Ross & Co., has been a partner in public accounting firms for 45 years. He was a Partner with Radin, Glass & Co., our former independent auditors, from 1998 until January 2015 when he joined Janover LLC, a certified public accounting firm. Mr. Radin retired as a Partner as of January 2017 and remains a consultant at Janover LLC. He is a member of the New York State Society of Certified Public Accountants Editorial Board. Mr. Radin received a B.A. degree from Columbia College and an M.B.A. in Business Administration from New York University.

Director Independence

We are not currently subject to corporate governance standards of companies listed on a national securities exchange or inter-dealer quotation system, which require, among other things, that the majority of the Board of Directors be independent and define the independence of directors. However, we have chosen to define an “independent” director in accordance with the NASDAQ Global Market’s requirements for independent directors. The Board of Directors, in applying these standards, has affirmatively determined that its current “independent” directors are Messrs. Allen, Anderson, Beck, Manko, and Radin. The Board of Directors, in applying these standards, previously affirmatively determined that Paul Mark Baker, who was a director during the last completed fiscal year, was “independent” under these standards.

Our Governance and Nomination Committee, which acts as our compensation committee, consists of five directors, all of which are independent under the NASDAQ Global Market’s definition.

EXECUTIVE COMPENSATION

The following table summarizes all compensation paid by us in the last two completed fiscal years for our “named executive officers”, which are:

- our Chief Executive Officer;
- our two most highly compensated executive officers other than our Chief Executive Officer who were serving as executive officers at December 31, 2018 as that term is defined under Rule 3b-7 of the Securities Exchange Act of 1934, as amended; and
- up to two additional individuals for whom disclosure would have been required but for the fact that the individual was not serving as an executive officer at December 31, 2018.

Summary Compensation Table

Name and Position	Year*	Nonequity						Total
		Salary	Bonus	Incentive Plan	Stock	Option	All Other	
		\$	\$	\$	\$	\$	\$	\$
Daniel S. Goldberger Executive Chairman ⁽¹⁾	2018	77,769	75,000	—	5,843	112,517	5,843	276,972
Karen Fisher Chief Financial Officer ⁽²⁾⁽⁶⁾	2018	208,000	—	65,000	—	—	—	273,000
	2017	166,731	—	33,346	—	—	—	200,077
Donald B. Pettigrew Chief Executive Officer, President & Chief Commercial Officer ⁽³⁾⁽⁶⁾	2018	106,041	—	54,167	—	—	—	160,208
Andrew I. Sealfon Former Chief Executive Officer ⁽⁴⁾	2018	253,016	—	—	2,083	—	23,615	278,714
	2017	354,167	—	60,833	—	—	—	415,000
Fred Ma Former Chief Medical Officer ⁽⁵⁾	2018	303,800	—	—	45,000	—	225,000	573,800
	2017	250,000	—	60,000	65,000	—	—	375,000

* 2018 represents the twelve month period ending December 31, 2018 and, due to the change in our fiscal year end, 2017 represents the ten month period ending December 31, 2017.

(1) Mr. Goldberger entered into an employment agreement with us on October 12, 2018. The agreement provides for a monthly base salary of \$30,000 and a signing bonus of \$75,000. Mr. Goldberger will receive a performance bonus based upon amounts payable to the person who first succeeds Mr. Goldberger as our chief executive officer, which performance bonus will equal 50% of the initial annual base salary and 50% of the initial target bonus payable to such successor. Effective February 1, 2019, Mr. Pettigrew has succeeded Mr. Goldberger as Chief Executive Officer. Mr. Goldberger’s performance bonus will be paid in a combination of cash and/or shares of common stock, as may be determined in the sole discretion of the Board, on April 2, 2019. Upon execution of the employment agreement, Mr. Goldberger received a 10-year non-qualified option to purchase up to 500,000 shares of our common stock at a per share exercise price of \$1.57. Of the option shares, 100,000 vested immediately, and the remaining 400,000 vest at the rate of 25,000 shares per completed quarter. The option will immediately vest and be exercisable in full upon a change in control within the meaning of the Company’s 2015 Stock Option Plan. Prior to the effective date of Mr. Goldberger’s employment agreement and while serving on the Board, he received \$5,843 in cash and 5,843 shares of common stock in accordance with the Board-approved director compensation plan. Effective February 1, 2019, Mr. Goldberger resigned as interim Chief Executive Officer and was appointed Executive Chairman. As Executive Chairman, Mr. Goldberger will receive an annual salary of \$120,000 and be eligible for an annual performance bonus of 50% of his annual salary in accordance with our policy and procedure for granting of a specified executive bonus based on achievement of goals. The performance bonus is payable in cash or shares of our common stock, at the discretion of the Board of Directors.

- (2) Ms. Fisher entered into an employment agreement with us on January 15, 2015. Pursuant to this agreement and our 2015 Stock Option Plan, Ms. Fisher was awarded incentive stock options to purchase up to 500,000 shares of our common stock. The options vested on November 3, 2016 and are exercisable for \$0.38 per share. The employment agreement has no fixed term, provided that if Ms. Fisher is terminated without “good cause” (as further defined in the agreement), she is entitled to receive her then current base annual salary for a period of six months following termination. Under the employment agreement, Ms. Fisher receives an annual base salary, plus a minimum performance bonus of 20% of the base annual salary based on our policy and procedure for granting of a specified executive bonus, which is based on achievement of objectives set by us as part of the annual budget process. Effective January 1, 2019, Ms. Fisher’s annual base salary is \$250,000.
- (3) Mr. Pettigrew entered into an employment agreement with us on September 4, 2018. Pursuant to this agreement, Mr. Pettigrew receives an annual base salary of \$325,000 and is eligible to earn an annual bonus in accordance with our policy and procedure for granting of a specified executive bonus, which is equivalent to 50% of annual base salary based on achievement of objectives set by us as part of the annual budget process. Under the agreement, Mr. Pettigrew received non-qualified stock options to purchase up to 1,000,000 shares of common stock at a per share exercise price of \$1.23 that vest 25% on September 4, 2019 and 12.5% every six months thereafter until fully vested. Mr. Pettigrew will also receive reimbursement for commuting expenses to and from the corporate offices until September 4, 2019. Upon termination of Mr. Pettigrew’s employment by us without Cause or for Good Reason (as defined in the agreement), subject to his execution of a customary general release of claims in favor of us and our affiliates, Mr. Pettigrew will be entitled to receive an amount equal to 12 months of Mr. Pettigrew’s then-current annual base salary, to be paid in accordance with our normal payroll practices after the termination date. Mr. Pettigrew will further be entitled to payment of his annual bonus, if earned. For the same 12-month period after the termination date, we will also pay premiums for Mr. Pettigrew’s health insurance as currently enrolled on the termination date. Effective February 1, 2019, Mr. Pettigrew was appointed President and Chief Executive Officer, and his annual base salary increased to \$360,000.
- (4) Mr. Sealfon’s employment terminated effective July 25, 2018. Upon termination Mr. Sealfon was paid his accrued vacation of \$21,532. Mr. Sealfon served on the Board of Directors from termination until December 17, 2018, for which he received \$2,083 in cash and 2,083 shares of our common stock pursuant to the Board-approved director compensation plan.
- (5) Dr. Ma resigned effective December 20, 2018. In connection with such resignation, we entered into a General Release and Confidentiality Agreement with Dr. Ma dated as of his resignation date, which superseded his employment agreement dated as of November 1, 2016. Pursuant to the terms of the new agreement, we will pay Dr. Ma an aggregate \$225,000, payable in accordance with our normal payroll practices commencing December 31, 2018. Under the old employment agreement, Dr. Ma received an annual base salary of \$300,000, plus he was eligible to earn an annual bonus in accordance with our policy and procedure for granting of bonuses to management and executives. The old agreement further called for the quarterly issuance of a number of shares of common stock determined by dividing \$15,000 by the closing bid price of our common stock as reported by the OTC Markets Inc. as of the last working day of such quarter. Dr. Ma also received a housing allowance of \$8,000.
- (6) On November 8, 2018, we entered into a Conditional Severance Agreement dated as of November 8, 2018 with each of Karen Fisher and Donald Pettigrew. If the employment of the executive is terminated by us without Cause (as defined in the conditional severance agreement) or the executive terminates his or her employment with us for Good Reason (as defined in the conditional severance agreement), in each case within six months following the date of our next annual or special meeting of shareholders that results in a majority of our Board of Directors consisting of persons not recommended for election, and/or persons recommended to be removed as a current director, by our current Board of Directors, then we will pay the executive an amount equaling twelve months of the executive’s then current base salary, plus an amount equal to his or her full minimum annual bonus, less any severance and bonus amounts otherwise paid by us to the executive pursuant to an employment agreement. If, prior to that shareholders’ meeting, (i) the executive resigns his or her employment for any reason; or (ii) we terminate the executive’s employment for any reason, then no payments will be made under this agreement. This agreement will automatically terminate in the event a shareholder’s meeting resulting in a change of control as described above does not take place by July 9, 2019.

Officers and directors are reimbursed for travel and other expenses incurred on our behalf. We offer an optional 401(k) savings plan with a company matching component to all full-time employees with 90 days of service.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth information regarding the outstanding equity awards held by our named executive officers as of December 31, 2018.

2018 OUTSTANDING EQUITY AWARDS AT FISCAL YEAR END

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Option Exercise Price (\$)	Option Expiration Date
Karen Fisher	500,000 ⁽¹⁾	—	0.38	11/02/2020
Daniel S. Goldberger	100,000 ⁽³⁾	400,000	1.57	10/11/2028
Manuel A. Marques	95,000 ⁽¹⁾	—	0.36	11/16/2020
Manuel A. Marques	—	50,000 ⁽⁴⁾	0.46	07/27/2022
Manuel A. Marques	69,010 ⁽⁵⁾	180,990	0.50	10/10/2022
Donald B. Pettigrew	—	1,000,000 ⁽²⁾	1.23	09/03/2023

(1) Incentive stock options granted under the 2015 Stock Option Plan that are fully vested and subject to early termination as provided in the option agreement, immediately prior to a change of control of the Company.

(2) Non-qualified stock options granted under the 2015 Stock Option Plan that vest 25% on September 4, 2019 and 12.5% every six months thereafter until fully vested.

(3) Non-qualified stock options granted under the 2015 Stock Option Plan, of which 100,000 vested on October 12, 2018, and the remaining 400,000 will vest at the rate of 25,000 shares per completed quarter commencing with the three month period beginning on the first day of the month following October 12, 2018. These options will immediately vest and be exercisable in full upon a Change in Control within the meaning of the Company's 2015 Stock Option Plan.

(4) Incentive stock options granted under the 2015 Stock Option Plan that vest on July 27, 2019.

(5) Incentive stock options granted under the 2015 Stock Option Plan that vest 15,625 shares quarterly, commencing October 11, 2017.

Director Compensation

The following table provides compensation paid information for the year ended December 31, 2018 for each non-employee member of our Board of Directors who served during that year, except Daniel Goldberger and Andrew Sealfon, whose compensation for service as directors is presented under "Summary Compensation Table":

2018 DIRECTOR COMPENSATION TABLE

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$)	All Other Compensation (\$)	Total (\$)
Robert T. Allen	917	917	—	1,834
David W. Anderson	12,500	12,500	—	25,000
Paul M. Baker	12,500	12,500	—	25,000
James M. Beck	917	917	—	1,834
Joseph M. Manko, Jr. ⁽¹⁾	12,500	12,500	—	25,000
Mark L. Pastreich	12,500	12,500	—	25,000
Arthur J. Radin	12,500	12,500	—	25,000
Brad A. Sealfon	3,906	3,906	—	7,812

(1) The stock awards were issued to Horton Capital Partners Fund L.P., an affiliate of Mr. Manko.

Non-employee members of the Board of Directors receive \$25,000 each annually, to be paid quarterly half in cash and half in common stock. We pay no additional remuneration to our employees serving as directors in their capacities as such. All directors, including our employee directors (if any), are reimbursed for reasonable out-of-pocket expenses incurred in connection with their attendance at meetings of the Board of Directors and committee meetings. On February 20, 2019, the Board of Directors increased non-employee director compensation to an annual retainer of \$50,000 plus \$10,000 for chairing a Board committee, all to be paid half in cash and half in common stock of the Company. The director compensation increase was effective January 1, 2019 and the chairman compensation was effective February 20, 2019.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The Shares subject to this prospectus were purchased by the selling stockholders from certain existing stockholders in a private placement transaction pursuant to a Common Stock Purchase Agreement dated as of December 17, 2018. Pursuant to that agreement, we agreed to file the resale registration statement of which this prospectus forms a part. The existing stockholders party to that agreement included Andrew I. Sealfon and Paul Mark Baker, then directors of RMS, together with certain members of their respective family members. Andrew I. Sealfon, Paul Mark Baker, Andrea Baker, Brad Sealfon and Mary Sealfon, existing stockholders party to the agreement, received an aggregate approximately \$12,218,977 in connection with the transaction. One of the purchasers from those existing stockholders (now a selling stockholder under this prospectus) was Horton Freedom, L.P., an affiliate of Horton Capital Partners, LLC, who paid approximately \$3,842,036 in connection with the transaction. At the time of the purchase, Horton Capital Partners, LLC beneficially owned more than 5% of our outstanding common stock. Joseph M. Manko, Jr. is the managing member of Horton Capital Partners, LLC and has served as a director of the Company since May 2016.

In connection with the purchase agreement, also on December 17, 2018, we entered into an Agreement Regarding Stock Sale with Mr. Sealfon and a separate Agreement Regarding Stock Sale with Dr. Baker. Pursuant to these Separation Agreements, Mr. Sealfon and Dr. Baker tendered their respective resignations from our Board of Directors effective with the first closing of the transaction under the purchase agreement, which occurred on December 18, 2018. Each of these separation agreements provides for the mutual general release by us, on the one hand, and each of Mr. Sealfon and Dr. Baker, on the other hand, of all claims against the other arising or occurring on or before the date thereof, subject to certain exceptions. Pursuant to the agreement with Mr. Sealfon, Mr. Sealfon has agreed to certain non-competition and non-solicitation restrictions for a period of six months after the first closing.

From 1992 to 2018, we leased an aircraft from AMI Aviation, Inc., of which our former President and Chief Executive Officer, Andrew Sealfon, was a majority shareholder. The lease expenses paid were \$13,421 for the ten months ended December 31, 2017 and \$9,045 for the nine months ended September 30, 2018. The lease expired in December 2018.

In February 2011, Mark Pastreich joined our board of directors. Mr. Pastreich is a principal in the company that owns the building leased by us for our corporate headquarters and manufacturing facility at 24 Carpenter Road, Chester, New York 10918. We are in year twenty of a twenty-year lease. Our current lease payments for the ten months ended December 31, 2017 were approximately \$152,379 (including apportioned property taxes), and for the nine months ended September 30, 2018 were approximately \$137,241 (including apportioned property taxes). 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.

LEGAL MATTERS

Certain legal matters relating to the validity of our securities offered by this prospectus will be passed upon for us by Royer Cooper Cohen Braunfeld LLC, Philadelphia, Pennsylvania.

EXPERTS

Our consolidated financial statements as of December 31, 2017 and February 28, 2017 and for the years then ended included in this prospectus have been audited by McGrail Merkel Quinn & Associates, P.C., an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

AVAILABLE INFORMATION

We are filing with the SEC this registration statement on Form S-1 under the Securities Act with respect to the common stock offered hereby. This prospectus, which constitutes part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedule thereto, certain parts of which are omitted in accordance with the rules and regulations of the SEC. For further information regarding our common stock and our company, please review the registration statement, including exhibits, schedules and reports filed as a part thereof. Statements in this prospectus as to the contents of any contract or other document filed as an exhibit to the registration statement, set forth the material terms of such contract or other document but are not necessarily complete, and in each instance reference is made to the copy of such document filed as an exhibit to the registration statement, each such statement being qualified in all respects by such reference.

We file annual, quarterly, and current reports, proxy statements and other information with the SEC. Our SEC filings are available to the public over the Internet at the SEC's web site at www.sec.gov and on the investor relations page of our website at www.rmsmedicalproducts.com. Information on our web site is not part of this prospectus. You may also read and copy any document we file with the SEC at its public reference facilities at 100 F Street N.E., Washington, D.C. 20549. You can also obtain copies of the documents upon the payment of a duplicating fee to the SEC. Please call the SEC at 1-800-SEC-0330 for further information on the operation of the public reference facilities.

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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, 2018 and December 31, 2017, the related statements of operations, changes in equity, and cash flows for the twelve months ended December 31, 2018 and the ten months ended December 31, 2017, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and December 31, 2017 and the results of its operations and its cash flows for the twelve months ended December 31, 2018 and the ten months ended December 31, 2017, 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 5, 2019

REPRO MED SYSTEMS, INC.
BALANCE SHEETS

	<u>December 31,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	\$ 3,738,803	\$ 3,974,536
Certificates of deposit	1,517,927	263,269
Accounts receivable less allowance for doubtful accounts of \$37,500 and \$77,067 for December 31, 2018, and December 31, 2017, respectively	1,425,854	1,861,949
Inventory	2,103,879	1,658,681
Prepaid expenses	246,591	170,739
TOTAL CURRENT ASSETS	<u>9,033,054</u>	<u>7,929,174</u>
Property and equipment, net	858,781	836,283
Patents, net of accumulated amortization of \$239,581 and \$203,768 at December 31, 2018 and December 31, 2017, respectively	632,156	483,821
Deferred tax asset	1,466	—
Other assets	19,582	31,582
TOTAL ASSETS	<u>\$ 10,545,039</u>	<u>\$ 9,280,860</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Deferred capital gain - current	\$ 3,763	\$ 22,481
Accounts payable	453,498	454,398
Accrued expenses	688,649	658,060
Accrued payroll and related taxes	421,714	334,903
Accrued tax liability	16,608	115,854
TOTAL CURRENT LIABILITIES	<u>1,584,232</u>	<u>1,585,696</u>
Deferred capital gain – long term	—	3,762
Deferred tax liability	—	21,675
TOTAL LIABILITIES	<u>1,584,232</u>	<u>1,611,133</u>
STOCKHOLDERS' EQUITY		
Common stock, \$0.01 par value, 75,000,000 shares authorized, 40,932,911 and 40,731,529 shares issued; 38,195,680 and 37,994,298 shares outstanding at December 31, 2018, and December 31, 2017, respectively	409,329	407,315
Additional paid-in capital	4,595,214	4,216,718
Retained earnings	4,300,468	3,389,898
	9,305,011	8,013,931
Less: Treasury stock, 2,737,231 shares at December 31, 2018 and December 31, 2017, respectively, at cost	(344,204)	(344,204)
TOTAL STOCKHOLDERS' EQUITY	<u>8,960,807</u>	<u>7,669,727</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 10,545,039</u>	<u>\$ 9,280,860</u>

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

REPRO MED SYSTEMS, INC.
STATEMENTS OF OPERATIONS

	For the	
	Twelve Months Ended December 31, 2018	Ten Months Ended December 31 2017
NET SALES	\$ 17,353,737	\$ 13,313,894
Cost of goods sold	6,543,249	5,174,946
Gross Profit	10,810,488	8,138,948
OPERATING EXPENSES		
Selling, general and administrative	9,095,565	6,594,570
Research and development	241,124	50,587
Depreciation and amortization	309,263	257,257
Total Operating Expenses	9,645,952	6,902,414
Net Operating Profit	1,164,536	1,236,534
Non-Operating Income/(Expense)		
Gain on sale of fixed asset	4,930	—
(Loss)/Gain on foreign currency exchange	(20,620)	68,566
Interest income	28,104	2,420
INCOME BEFORE TAXES	1,176,950	1,307,520
Income tax expense	266,380	402,563
NET INCOME	\$ 910,570	\$ 904,957
NET INCOME PER SHARE		
Basic	\$ 0.02	\$ 0.02
Diluted	\$ 0.02	\$ 0.02
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic	38,128,260	37,897,632
Diluted	38,921,622	38,445,482

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

REPRO MED SYSTEMS, INC.
STATEMENT OF STOCKHOLDERS' EQUITY
FOR THE TWELVE MONTHS ENDED DECEMBER 31, 2018 AND THE TEN MONTHS ENDED DECEMBER 31, 2017

	Common Stock		Additional Paid-in Capital	Retained Earnings	Treasury Stock	Total Stockholders' Equity
	Shares	Amount				
BALANCE,						
FEBRUARY 28, 2017	40,558,429	\$ 405,584	\$ 4,129,726	\$ 2,484,941	\$ (344,204)	\$ 6,676,047
Issuance of stock based compensation	217,100	2,171	110,329	—	—	112,500
Compensation expense related to stock options	—	—	(4,417)	—	—	(4,417)
Cancellation of common stock	(44,000)	(440)	(18,920)	—	—	(19,360)
Net income for the year ended December 31, 2017	—	—	—	904,957	—	904,957
BALANCE,						
DECEMBER 31, 2017	40,731,529	\$ 407,315	\$ 4,216,718	\$ 3,389,898	\$ (344,204)	\$ 7,669,727
Issuance of stock based compensation	99,134	991	117,050	—	—	118,041
Compensation expense related to stock options	—	—	248,040	—	—	248,040
Cancellation of common stock	(22,752)	(227)	(36,594)	—	—	(36,821)
Issuance of Option Exercised	125,000	1,250	50,000	—	—	51,250
Net income for the year ended December 31, 2018	—	—	—	910,570	—	910,570
BALANCE,						
DECEMBER 31, 2018	<u>40,932,911</u>	<u>\$ 409,329</u>	<u>\$ 4,595,214</u>	<u>\$ 4,300,468</u>	<u>\$ (344,204)</u>	<u>\$ 8,960,807</u>

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

REPRO MED SYSTEMS, INC.
STATEMENTS OF CASH FLOWS

	For the	
	Twelve Months Ended December 31, 2018	Ten Months Ended December 31, 2017
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Income	\$ 910,570	\$ 904,957
Adjustments to reconcile net income to net cash provided by operating activities:		
Stock based compensation expense	366,081	108,083
Depreciation and amortization	309,263	257,257
Gain on sale of fixed asset	(4,930)	—
Deferred capital gain – building lease	(22,480)	(18,734)
Deferred taxes	(23,141)	(60,747)
Provision for returns and doubtful accounts	(39,567)	58,941
Changes in operating assets and liabilities:		
Decrease/(Increase) in accounts receivable	475,662	(418,860)
Increase in inventory	(445,198)	(304,978)
(Increase)/Decrease in prepaid expense	(75,852)	5,217
Decrease/(Increase) in other assets	12,000	(93)
Decrease in accounts payable	(900)	(318,030)
Increase in accrued payroll and related taxes	86,811	157,885
Increase in accrued expense	30,589	240,703
(Decrease)/Increase in accrued tax liability	(99,246)	288,311
NET CASH PROVIDED BY OPERATING ACTIVITIES	1,479,662	899,912
CASH FLOWS FROM INVESTING ACTIVITIES		
Payments for capital expenditures	(297,018)	(137,817)
Payments for patents	(184,148)	(80,509)
Purchase of certificate of deposit	(1,500,000)	(955)
Proceeds from certificates of deposit	245,342	—
Proceeds on sale of fixed assets	6,000	—
NET CASH USED IN INVESTING ACTIVITIES	(1,729,824)	(219,281)
CASH FLOWS FROM FINANCING ACTIVITIES		
Stock issuances	51,250	—
Payment for cancelled shares	(36,821)	(19,360)
NET CASH PROVIDED BY FINANCING ACTIVITIES	14,429	(19,360)
Net (Decrease) Increase in CASH AND CASH EQUIVALENTS	(235,733)	661,271
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	3,974,536	3,313,265
CASH AND CASH EQUIVALENTS, END OF YEAR	<u>\$ 3,738,803</u>	<u>\$ 3,974,536</u>
Supplemental Information		
Cash paid during the years for:		
Interest	\$ —	\$ —
Taxes	\$ 378,000	\$ 175,000
NON-CASH FINANCING AND INVESTING ACTIVITIES		
Issuance of common stock as compensation	<u>\$ 118,041</u>	<u>\$ 112,500</u>

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

REPRO MED SYSTEMS, INC.
NOTES TO FINANCIAL STATEMENTS
DECEMBER 31, 2018 AND DECEMBER 31, 2017

NOTE 1 NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

NATURE OF OPERATIONS

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

CASH AND CASH EQUIVALENTS

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

CERTIFICATES OF DEPOSIT

The certificate of deposit is recorded at cost plus accrued interest. The certificate of deposit earns interest at a rate of 1.73% and matures in May 2019.

INVENTORY

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

PATENTS

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

INCOME TAXES

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

The Company believes that it has no uncertain tax positions requiring disclosure or adjustment. Generally, tax years starting with 2016 are subject to examination by income tax authorities.

PROPERTY, EQUIPMENT, AND DEPRECIATION

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

STOCK-BASED COMPENSATION

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

NET INCOME PER COMMON SHARE

Basic earnings per share are computed on the weighted average of common shares outstanding during each year. Diluted earnings per share include only an increase in the weighted average shares by the common shares issuable upon exercise of employee, director and consultant stock options (See Note 6).

	Fiscal Year Ended	
	Twelve Months December 31, 2018	Ten Months December 31, 2017
Net income	\$ 910,570	\$ 904,957
Weighted Average Outstanding Shares:		
Outstanding shares	38,128,260	37,897,632
Option shares includable	793,362	547,850
	<u>38,921,622</u>	<u>38,445,482</u>
Net income per share		
Basic	\$ 0.02	\$ 0.02
Diluted	\$ 0.02	\$ 0.02

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

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

REVENUE RECOGNITION

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

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

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

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

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In June 2016, the 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, 2019, including interim periods within those fiscal years. The Company is assessing the impact of the adoption of this ASU on its financial statements, disclosure requirements and methods of adoption.

In February 2016, the FASB issued ASU No. 2016-02, Leases (Topic 842). The main difference between the current requirement under GAAP and this ASU is the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases. This ASU requires that a lessee recognize in the statement of financial position a liability to make lease payments (the lease liability) and a right-of-use asset representing its right to use the underlying asset for the lease term (other than leases that meet the definition of a short-term lease). The liability will be equal to the present value of lease payments. The asset will be based on the liability, subject to adjustment, such as for initial direct costs. For income statement purposes, the FASB retained a dual model, requiring leases to be classified as either operating or finance. Operating leases will result in straight-line expense (similar to current operating leases) while finance leases will result in a front-loaded expense pattern (similar to current capital leases). Classification will be based on criteria that are largely similar to those applied in current lease accounting. For lessors, the guidance modifies the classification criteria and the accounting for sales-type and direct financing leases. This is effective for annual and interim periods beginning after December 15, 2018 and early adoption is permitted. This ASU must be adopted using a modified retrospective transition, and provides for certain practical expedients. Transition will require application of the new guidance at the beginning of the earliest comparative period presented. We believe the adoption of this ASU may have a material impact on our assets and liabilities, but not a material impact on the results of operations on our financial statements, disclosure requirements and methods of adoption. In July 2018, the FASB issued ASU No. 2018-10 Codification Improvements to Topic 842, Leases. The amendments in this ASU affect narrow aspects of the guidance issued in the amendments in ASU 2016-02. The amendments in this ASU related to transition do not include amendments from proposed ASU, Leases (Topic 842): Targeted Improvements, specific to a new and optional transition method to adopt the new lease requirements in ASU 2016-02. That additional transition method will be issued as part of a forthcoming and separate ASU that will result in additional amendments to transition paragraphs included in this ASU to conform with the additional transition method. The amendments in this ASU affect the amendments in ASU 2016-02, which are not yet effective, but for which early adoption upon issuance is permitted. For entities that early adopted Topic 842, the amendments are effective upon issuance of this ASU, and the transition requirements are the same as those in Topic 842. For entities that have not adopted Topic 842, the effective date and transition requirements will be the same as the effective date and transition requirements in Topic 842. In July 2018, the FASB issued ASU No. 2018-11, Leases (Topic 842): Targeted Improvements. The amendments in this ASU affect narrow aspects of the guidance issued in the amendments in ASU 2016-02. The amendments in this ASU related to transition do not include amendments from proposed ASU, Leases (Topic 842): Targeted Improvements, specific to a new and optional transition method to adopt the new lease requirements in ASU 2016-02. That additional transition method will be issued as part of a forthcoming and separate ASU that will result in additional amendments to transition paragraphs included in this ASU to conform with the additional transition method.

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

In August 2018, the FASB issued ASU No. 2018-15 Intangibles – Goodwill and Other – Internal-Use Software (Subtopic 350-40): Customer’s Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract. The amendments in this ASU align the requirements for capitalizing implementation costs incurred in a hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal use software license). The accounting for the service element of a hosting arrangement that is a service contract is not affected by the amendments in this ASU. The amendments in this ASU are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption of the amendments in this ASU is permitted, including adoption in any interim period, for all entities. The amendments in this ASU should be applied either retrospectively or prospectively to all implementation costs incurred after the date of adoption. The Company is assessing the impact of the adoption of the ASU on its financial statements, disclosure requirements and methods of adoption.

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

FAIR VALUE OF FINANCIAL INSTRUMENTS

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

ACCOUNTING FOR LONG-LIVED ASSETS

The Company reviews its long-lived assets for impairment at least annually or whenever the circumstances and situations change such that there is an indication that the carrying amounts may not be recoverable. As of December 31, 2018, the Company does not believe that any of its assets are impaired.

NOTE 2 INVENTORY

Inventory consists of:

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Raw materials and Work-in-process	\$ 1,155,632	\$ 1,042,367
Finished goods	1,020,930	677,762
Total	<u>2,176,562</u>	<u>1,720,129</u>
Less: reserve for obsolete inventory	72,683	61,448
Inventory, net	<u>\$ 2,103,879</u>	<u>\$ 1,658,681</u>

NOTE 3 PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	<u>December 31, 2018</u>	<u>December 31, 2017</u>	<u>Estimated Useful Lives</u>
Land	\$ 54,030	\$ 54,030	
Building	171,094	171,094	20 years
Furniture, office equipment, and leasehold improvements	1,058,507	1,052,501	3-10 years
Manufacturing equipment and tooling	1,279,865	1,075,471	3-12 years
Total	<u>2,563,496</u>	<u>2,353,096</u>	
Less: accumulated depreciation	1,704,715	1,516,813	
Property and equipment, net	<u>\$ 858,781</u>	<u>\$ 836,283</u>	

Depreciation expense was \$273,450 and \$233,626 for the twelve months ended December 31, 2018, and the ten months ended December 31, 2017, respectively.

NOTE 4 RELATED PARTY TRANSACTIONS

On December 17, 2018, the Company entered into a Common Stock Purchase Agreement (the "Agreement") with Andrew I. Sealfon and other sellers set forth in the Agreement and purchasers listed in the Agreement in a private placement transaction. Pursuant to that agreement, we agreed to file a resale registration statement. The existing stockholders party to the agreement included Andrew I. Sealfon and Paul Mark Baker, then directors of RMS, together with certain members of their respective family members. Andrew I. Sealfon, Paul Mark Baker, Andrea Baker, Brad Sealfon and Mary Sealfon, existing stockholders party to the agreement, received an aggregate of \$12,218,977 in connection with the transaction. One of the purchasers was Horton Freedom, L.P., an affiliate of Horton Capital Partners, LLC, who paid \$3,842,036 in connection with the transaction. At the time of the purchase, Horton Capital Partners, LLC beneficially owned more than 5% of our outstanding common stock. Joseph M. Manko, Jr. is the managing member of Horton Capital Partners, LLC and has served as a director of the Company since May 2016.

In connection with the purchase agreement, also on December 17, 2018, we entered into an Agreement Regarding Stock Sale with Mr. Sealfon and a separate Agreement Regarding Stock Sale with Dr. Baker. Pursuant to these Separation Agreements, Mr. Sealfon and Dr. Baker tendered their respective resignations from our Board of Directors effective with the first closing of the transaction under the purchase agreement, which occurred on December 18, 2018. Each of these separation agreements provides for the mutual general release by us, on the one hand, and each of Mr. Sealfon and Dr. Baker, on the other hand, of all claims against the other arising or occurring on or before the date thereof, subject to certain exceptions. Pursuant to the agreement with Mr. Sealfon, Mr. Sealfon has agreed to certain non-competition and non-solicitation restrictions for a period of six months after the first closing.

LEASED AIRCRAFT

From 1992 to 2018, we leased an aircraft from AMI Aviation, Inc., of which our former President and Chief Executive Officer, Andrew Sealfon, was a majority shareholder. The lease payments were \$9,045 for the year ended December 31, 2018 and \$13,421 for the ten months ended December 31, 2017. Upon the termination of Mr. Sealfon as President and Chief Executive Officer on July 25, 2018, the Company ceased leasing this aircraft.

BUILDING LEASE

In February 2011, Mark Pastreich joined our board of directors. Mr. Pastreich 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. We are in year twenty of a twenty-year lease. With a monthly lease amount of \$11,042, the lease payments were \$132,504 for the twelve months ended December 31, 2018, and \$110,420 for the ten months ended December 31, 2017. The Company also paid property taxes for the twelve months ended December 31, 2018 in the amount of \$50,072 and \$41,959 for the ten months ended December 31, 2017. 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 monthly lease amount of \$12,088.

NOTE 5 STOCKHOLDERS' EQUITY

On June 29, 2016, RMS's Board of Directors authorized the Company to make open market purchases of up to 2,000,000 shares of the Company's outstanding Common Stock. The purchases are made through a broker designated by the Company, with price, timing and volume restrictions based on average daily trading volume, consistent with the rules of the Securities and Exchange Commission for such repurchases. As of September 30, 2018, the Company had repurchased 396,606 shares at an average price of \$0.45. In June 2017, management of the Company decided to discontinue repurchasing its outstanding common stock under the program for an undetermined period of time to utilize cash for capital investments needed to expand the business.

NOTE 6 STOCK-BASED COMPENSATION

On June 29, 2016, the Board of Directors amended the 2015 Stock Option Plan authorizing the Company to grant awards to certain executives, key employees, and consultants under the plan, which was approved by shareholders at the Annual Meeting held on September 6, 2016. Currently, the total number of shares of Common Stock, with respect to which awards may be granted pursuant to the Plan, may not exceed 4,000,000. On February 20, 2019, our Board of Directors approved an increase to the number of shares authorized under the plan to 6,000,000, subject to shareholder approval at the 2019 Annual Meeting of Shareholders.

As of December 31, 2018, the Company had 2,419,000 options outstanding to certain executives, key employees and consultants under the Plan.

On October 21, 2015, the Board of Directors of the Company approved non-employee director compensation of \$25,000 each annually, to be paid quarterly half in cash and half in common stock, beginning September 1, 2015.

The per share weighted average fair value of stock options granted during the fiscal year ended December 31, 2018 and December 31, 2017 was \$0.83 and \$0.29, 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 fiscal year ended December 31, 2018 and December 31, 2017. 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.

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Dividend yield	0.00%	0.00%
Expected Volatility	61.1-65.2%	70.1%-72.2%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	5-10 Years	5 Years
Risk-free rate	2.8-3.15%	2.3%-2.36%

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

	<u>December 31, 2018</u>		<u>December 31, 2017</u>	
	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding at January 1	1,038,000	\$ 0.41	1,345,000	\$ 0.39
Granted	1,518,000	\$ 1.34	318,000	\$ 0.49
Exercised	125,000	\$ 0.41	—	\$ —
Forfeited	12,000	\$ 0.87	625,000	\$ 0.39
Outstanding at year end	2,419,000	\$ 1.00	1,038,000	\$ 0.41
Options exercisable	785,094	\$ 0.55	737,010	\$ 0.38
Weighted average fair value of options granted during the period		\$ 0.83	—	\$ 0.29
Stock-based compensation expense		\$ 248,040	—	\$ (4,417)

Total stock-based compensation expense, net of forfeitures, for stock option awards totaled \$248,040 and \$(4,417) for the fiscal year ended December 31, 2018 and December 31, 2017, respectively.

The weighted-average grant-date fair value of options granted during twelve months ended December 31, 2018 and the ten months ended December 31, 2017 was \$1,255,234 and \$93,115 respectively. The total intrinsic value of options exercised during the twelve months ended December 31, 2018 and the ten months ended December 31, 2017, was \$51,250 and zero respectively.

The following table presents information pertaining to options outstanding at December 31, 2018:

<u>Range of Exercise Price</u>	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life</u>	<u>Weighted Average Exercise Price</u>	<u>Number Exercisable</u>	<u>Weighted Average Exercise Price</u>
\$0.36-1.57	2,419,000	5 years	\$ 1.00	785,094	\$ 0.55

As of December 31, 2018, there was \$1,078,843 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 34 months. The total fair value of vested options was \$258,666 and \$150,820 at December 31, 2018 and December 31, 2017, respectively.

NOTE 7 SALE-LEASEBACK TRANSACTION - OPERATING LEASE

On February 25, 1999, the Company entered into a sale-leaseback arrangement whereby the Company sold its land and building at 24 Carpenter Road in Chester, New York and leased it back for a period of twenty years. The leaseback is accounted for as an operating lease. The gain of \$0.5 million realized in this transaction has been deferred and is amortized to income in proportion to rental expense over the term of the related 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 at monthly lease amount of \$12,088.

Rent expense for the twelve months ending December 31, 2018 was \$132,504 and ten months ended December 31, 2017 was \$110,420.

NOTE 8 FEDERAL AND STATE INCOME TAXES

The provision (benefit) for income taxes at December 31, 2018, and December 31, 2017 consisted of:

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
State income tax:		
Current, net of refund	\$ 12,391	\$ 1,670
Federal income tax:		
Deferred	23,141	(47,327)
Current	230,848	448,220
Total	<u>\$ 266,380</u>	<u>\$ 402,563</u>

The reconciliation of income taxes shown in the financial statements and amounts computed by applying the Federal expected tax rate of 21% for fiscal year 2018 and 34% for fiscal year 2017 is as follows:

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Income before tax	\$ 1,176,950	\$ 1,307,520
Computed expected tax	\$ 247,160	\$ 444,557
State income and franchise tax	12,391	1,670
Reduction in deferred tax from change in tax rate	—	(13,420)
Other	6,829	(30,244)
Provision for taxes	<u>\$ 266,380</u>	<u>\$ 402,563</u>

The components of deferred tax assets/(liabilities) at December 31, 2018, and December 31, 2017, respectively, are as follows:

	<u>December 31, 2018</u>	<u>December 31, 2017</u>
Deferred compensation cost	\$ 79,632	\$ 33,987
Depreciation and amortization	(79,640)	(69,550)
Allowance for bad debts and other	1,474	13,888
Deferred tax asset/(liabilities)	<u>\$ 1,466</u>	<u>\$ (21,675)</u>

New Tax Legislation

On December 22, 2017, the President of the United States (“U.S.”) signed into law the Tax Cuts and Jobs Act tax reform legislation. This legislation makes significant change in U.S tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the highest U.S corporate tax rate from the current rate of 35% to 21%, effective January 1, 2018. As a result of the enacted law, the Company was required to revalue deferred tax assets and liabilities at the enacted rate. This revaluation resulted in an additional benefit of \$13,420 included in income tax expense and corresponding reduction in the net deferred tax liabilities at December 31, 2017. The other provisions of the Tax Cuts and Jobs Act did not have a material impact on the 2017 financial statements.

NOTE 9 MAJOR CUSTOMERS

For the twelve months ended December 31, 2018, and the ten months ended December 31, 2017, approximately, 58% and 56%, respectively, of the Company's gross product revenues were derived from one major customer. At December 31, 2018 and December 31, 2017, accounts receivable due from this customer were \$0.8 million and \$0.9 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 10 LEGAL PROCEEDINGS

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

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

On August 22, 2017, we filed a motion in this California case seeking a Preliminary Injunction prohibiting EMED from making false statements and claims regarding the products of both companies. The motion has now been fully briefed, and the parties are awaiting action by the Court.

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

The second court case was filed by EMED in the United States District Court for the Eastern District of Texas on June 25, 2015, claiming patent infringement of Claim 1 of another of its patents (US 8,961,476 – "'476"), by our needle sets, and seeking unspecified monetary damages ("ED Texas '476 matter"). This '476 patent is related to the '703 patent.

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

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

The SDNY '576 matter is proceeding with preliminary matters and although a fixed trial date has not been set it is expected to be in the fourth quarter of 2019 or the first quarter of 2020.

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

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

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

As is required by the respective Courts in both the SDNY ‘576 matter and the ED Texas ‘476 matter, the parties are engaging in settlement discussions and have scheduled mediation sessions.

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

NOTE 11 EMPLOYEE BENEFITS

We provide a safe harbor 401(k) plan for our employees that allows for employee elective contributions, Company matching contributions and discretionary profit sharing contributions. Employee elective contributions are funded through voluntary payroll deductions. The Company makes safe harbor matching contributions in an amount equal to 100% of the employee’s contribution not to exceed 3% of employee’s compensation plus 50% of employee’s pay contributed between 3% and 5% of employee’s compensation. Company matching expense for the period ended December 31, 2018 and December 31, 2017 was \$121,834 and \$64,881, respectively. The Company has not provided for a discretionary profit sharing contribution.

NOTE 12 SUBSEQUENT EVENTS

On February 1, 2019, Mr. Donald B. Pettigrew, the Company’s President and Chief Commercial Officer, was promoted to President and Chief Executive Officer, replacing Mr. Daniel S. Goldberger as interim Chief Executive Officer. Mr. Goldberger remains our Chairman of the Board and, effective February 1, 2019, was appointed Executive Chairman.

Dealer Prospectus Delivery Obligation

Until (*), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.
