UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

OR

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

For the transition period from _____ to _____

Commission file number 0-12305

KORU MEDICAL SYSTEMS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**13-3044880**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
100 Corporate Drive, Mahwah, New Jersey	**07430**
(Address of principal executive offices)	(Zip Code)

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

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

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

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

None
(Title of Class)

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No □

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files.) Yes ☒ No □

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer □	Accelerated filer □
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company □

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □

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

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. □

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). □

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes □ No ☒

Based on the closing sales price of June 30, 2023, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was $111,191,841.

As of March 13, 2024, 45,710,500 shares of common stock, $0.01 par value per share, were outstanding, which excludes 3,420,502 shares of Treasury Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2024 Annual Meeting of Shareholders are incorporated herein by reference in Part III of this Annual Report on Form 10-K to the extent stated herein. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2023.

INDEX TO FORM 10-K

PART I

Throughout this report, the "Company," "KORU Medical," "KORU," "we," "us" or "our" refer to KORU Medical Systems, Inc.

FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements can be identified by words such as: "mission," "believe," "plan," "goal," "intend," "seek," "expect," "will," and similar references to future periods. Examples of forward-looking statements include, among others, statements we make under "Our Strategy" in Business under Item 1 of this Form 10-K and "Liquidity and Capital Resources" in Management's Discussion and Analysis of Financial Condition and Results of Operations under Item 7 of this Form 10-K, and statements regarding success of our EU certification appeal, completion of a next-generation pump and consumable system, compliance with EU MDR, 2024 expenses, needs for additional capital, capital investments, plans for expansion of our share position and products, and increase in patient SCIg prescriptions. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on our current beliefs, expectations, and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and trends, the economy and other future conditions. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Our actual results and financial condition may differ materially from those indicated in the forward-looking statements. Therefore, readers should not rely on any of these forward-looking statements.

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

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

ITEM 1. BUSINESS

OUR BUSINESS

KORU Medical develops, manufactures and commercializes innovative and patient-centric large volume subcutaneous infusion solutions primarily for the subcutaneous drug delivery market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international standards for quality system management. Our focus is primarily concentrated on our mechanical infusion products, the FREEDOM Infusion Systems (which we refer to as the "FREEDOM System" when used with one or more accessories), which include the FREEDOM60® Syringe Driver, the FreedomEdge® Syringe Driver, HIgH-Flo Subcutaneous Safety Needle Sets™ and Precision Flow Rate Tubing™.

Our revenues are derived from three business sources: (i) domestic core (which consists of US and Canada), (ii) international core, and (iii) novel therapies. Our core domestic and international revenues consist of sales of our syringe drivers, tubing and needles ("Product Revenue") for the delivery of subcutaneous drugs that are FDA cleared for use with the FREEDOM System, with the primary delivery for immunoglobulin to treat Primary Immunodeficiency Diseases ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). Novel therapies revenues consist of Product Revenue for feasibility/clinical trials (pre-clinical studies, Phase I, Phase II, Phase III) of biopharmaceutical companies in the drug development process as well as non-recurring engineering services ("NRE") revenues (including product innovation, testing and registration services) received from biopharmaceutical companies to ready or customize the FREEDOM System for clinical and commercial use across multiple drug categories.

OUR MISSION

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

OUR STRATEGY

Our goal is to expand our position as a leading provider of large volume subcutaneous infusion systems (>10ml) self-administered in the home by the patient and/or delivered in an ambulatory infusion center by a healthcare professional. . We intend to accomplish this objective by increasing our leadership position and penetration in our domestic and international core subcutaneous immunoglobulin ("SCIg") market and extending this position into novel subcutaneous drug therapies. Both the Ig and novel therapy drugs, will use our Freedom Infusion system and new innovations that are in development for the Freedom Infusion system platform.

In the goal of increasing our leadership position in SCIg, we have identified multiple factors that we believe are driving growth of the SCIg market. These include:

- Increasing diagnoses of Primary Immunodeficiency Diseases ("PIDD"), which often require immunoglobulin ("Ig") treatment
- New on-label indications for SCIg drugs such as Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"), Secondary Immunodeficiency Diseases ("SIDD"), and others in clinical development.
- Increase in the number of available SCIg medications such as the introduction of Cutaquig® and Xembify® in the United States and Europe, and planned launches of Cuvitru® and HyQvia® in Japan
- Biopharmaceutical investment in SCIg products, such as prefilled syringe formats that make infusion easier for patients, which may make more patients eligible for SCIg therapy
- Increasing supply of donated plasma, which increases the global supply of Ig medications
- Favorable patient preference, side effect profile, and health economics for at-home SCIg compared with intravenous Ig therapy

We intend to maintain and extend our leadership position in the SCIg market through clinical and product innovation and commercial excellence. By improving our products, establishing thought leadership in subcutaneous therapy, partnering with drug manufacturers, expanding geographically, and executing commercially, we intend to increase our overall global share position and the number of patients prescribed SCIg over intravenous Ig.

In our goal to expand into novel therapies outside of SCIg, we estimate that at least 100 large-volume drugs are in clinical development utilizing subcutaneous infusion, with approximately 30% greater than 10ml. The pipeline is driven by the need to deliver high therapeutic doses, difficulty in formulating large molecules into small volumes, nursing shortage, pharmaceutical companies shifting development programs toward at-home subcutaneous therapy, and patient preference. Biopharmaceutical manufacturers seek device partners during the drug development process. We intend to partner with them during clinical development—generating non-recurring services revenues to prepare and customize our products for use during the clinical trial process and to obtain regulatory clearance for use with their drug. Post launch, we intend to commercialize our products for use with these drugs, working with our pharmaceutical partners, our distributors and our specialty pharmacy partners who distribute and train patients on the use of these products both in the home and in ambulatory infusion centers.

We believe our track record of regulatory clearance and successful patient use, combined with our channel access, position KORU to both maximize our growth in the core SCIg market and expand into new therapeutic areas.

OUR PRODUCTS

KORU's infusion devices work together as a system to deliver life-saving therapies to patients with chronic illnesses, such as PIDD and CIDP. The FREEDOM System comprises the FREEDOM60 Syringe Driver (standard 60/50ml syringe compatible) and FreedomEdge Syringe Driver (standard 30ml and 20ml syringe and prefilled syringe compatible), HIgH-Flo Subcutaneous Safety Needle Sets and Precision Flow Rate Tubing. The systems are portable, easy to operate, maintenance free and do not require batteries or electricity. The FREEDOM System operates at a lower pressure than an electrical, volumetric pump and maintains a balance between what a patient's subcutaneous tissues can tolerate what the system delivers.

Our FREEDOM System is cleared for several on-label subcutaneous indications including specific FDA clearance for: delivery of specific medications through subcutaneous and intravenous routes, including specific clearance for leading immune globulins Cutaquig ®, Cuvitru®, Hizentra®, Xembify, Empaveli® (branded Aspaveli® outside the United States), Gammagard Liquid®, and selected intravenously administered antibiotics. Outside of the U.S. our indications for use also include treatments for hydration and iron chelation.

Ambulatory infusion systems such as the FREEDOM System are most prevalent in the home care and alternate infusion site markets. The SCIg products administered with delivered by the FREEDOM System are indicated for a variety of conditions, including Primary Immunodeficiency (PIDD) and Chronic Inflammatory Demelinating Polyneuropathy (CIDP) in the United States and PIDD, CIDP and Secondary Immunodeficiency Disease ("SIDD") outside of the United States. Empaveli® is indicated for Paroxysmal Nocturnal Hemoglobinuria ("PNH"). The use of the FREEDOM System for SCIg drug delivery continues to increase, and it remains the market leading delivery system in the U.S. for these treatments. In recent years Hizentra® and HyQvia® has received an expanded indication for treatment of CIDP in the United States. Multiple SCIg drugs have received indications for SID outside of the United States. It is expected that patient access to SCIg will expand as new drugs are developed, existing drugs are approved and/or marketed in new countries, and existing drugs receive new indications.

HIgH-Flo Subcutaneous Safety Needle Sets are an important element of the FREEDOM System. The needle sets are available in 26- and 24-gauge sizes and feature unique design elements specific to subcutaneous self-administration.

Precision Flow Rate Tubing is designed for repeatable flow rates without allowing unrestricted flow. The tubing regulates the flow rate and infusion time for various applications when used with the FREEDOM System. Each tubing set provides a different level of flow restriction and consistently delivers medication with low residual volume to minimize drug waste.

SALES AND DISTRIBUTION

The FREEDOM System is sold through both direct sales and medical device distributors to pharmaceutical companies, specialty pharmacy customers and home infusion providers. Our products are sold principally through a small number of distributors so our specialty pharmacy customers receive the benefit of remote inventory management and one-stop shopping. We sell the majority of our products through three distributors in the U.S. and two distributors outside the U.S. As of December 31, 2023, these five distributors comprised approximately 74% of our net revenues with one of our U.S. distributors contributing approximately 41%.

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

MANUFACTURING AND RAW MATERIALS

We currently manufacture, assemble and package all of our pump products, assemble and complete final packaging of our consumables (which consist of needle and tubing sets), and perform calibration, pre- and post-assembly quality control inspection and testing at our Mahwah, NJ facility. Command Medical Products, Inc. ("Command"), a contract manufacturing organization with operations in Nicaragua, currently provides subassemblies, and manufactures, assembles and packages approximately 80% of our consumables..

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 on a single source basis. The Company uses single-source suppliers in part due to governmental approval and validation requirements. A change in supplier, or the use of multiple suppliers of the same materials, often would necessitate additional approvals and validations, which the Company seeks to avoid unless and until the need arises. The Company does not have any contracts with suppliers that impose material binding obligations on the Company or provide the Company with any material rights or benefits, other than the Company's agreement with Command. Command currently stores our finished goods in their warehouse located in Miami Florida once the products are released and shipped from Nicaragua.

RESEARCH AND DEVELOPMENT

We recognize the importance of innovation to our long-term success and are committed to research and new product development activities. Our product development team along with outside engineering resources are continuously engaged in improving existing product performance and innovating on new product opportunities to enhance our product portfolio. We spent $5.7 million and $5.0 million on research and development for the years ended December 31, 2023 and 2022, respectively. We intend to make additional investments in research and development over the next twelve months to support completing research and development for a "next-generation" infusion pump and consumable system.

REGULATORY

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

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

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

U.S. Device Classification and Clearance

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

Under the 510(k) process, applicants must demonstrate to the FDA that a device is as safe and effective as, or substantially equivalent to, a legally marketed device, known as the "predicate" device. Applicants must submit performance data to establish substantial equivalence. In some instances, data from human clinical trials must also be submitted in support of a 510(k), and this data must be collected in a manner that conforms to the applicable Investigational Device Exemption ("IDE") regulations. The FDA must issue a substantial equivalence determination before commercial distribution can occur. Changes to cleared devices that will not significantly affect the safety or effectiveness of the device can generally be made without additional 510(k) submissions. Changes that will significantly affect the safety or effectiveness of the device will require a new 510(k) prior to marketing of the modified device. We cannot predict with any certainty how future reforms to Federal regulations may impact our business. See "ITEM 1A. RISK FACTORS."

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

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

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

Post-Approval Regulation

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

Manufacturing Regulation

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

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

Other Healthcare Laws

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

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

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

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

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

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

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

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

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

Coverage and Reimbursement

Our profitability and operations are subject to changes in legislative, regulatory and reimbursement policies and decisions as well as changes in private payer reimbursement coverage and payment decisions and policies. Our products are purchased by specialty pharmacies and ambulatory service providers or hospitals that typically bill various third-party payors, such as governmental programs (e.g., Medicare, Medicaid, and comparable non-U.S. programs), private insurance plans and managed care plans, for the healthcare services and products provided to their patients. The ability of our customers to obtain appropriate coverage and reimbursement for our products and the drugs they administer is critical because it affects which products customers purchase and the price they are willing to pay. Third-party payors are increasingly reducing coverage and reimbursement for certain healthcare services and products and challenging prices charged for healthcare services and products.

Environmental Health and Safety Laws

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

COMPETITION AND THE MARKET

Competition for the FREEDOM System includes electronic (volumetric) pumps, elastomeric (infuser) pumps, and fully mechanical pumps as well as other types of pumps. Safety, ease of use, familiarity, cost effectiveness, accuracy, and sustainability are the principal driving influencers of pump selection. Electronic pumps deliver drugs at a programmed flow rate. They are more costly 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 and surgical wound site applications. Pharmacies are required to fill them with drugs and deliver them to the patient. They are easy to use from the patient point of view but can be more costly and time consuming to fill, are temperature sensitive and have larger residual volumes than other delivery systems.

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

HUMAN CAPITAL RESOURCES

As of December 31, 2023, we had 82 full time employees, including 3 international employees. As of December 31, 2023, approximately 51% of the Company's workforce was female and approximately 37% of the Company's employees in managerial roles were female. Approximately 39% were minorities (non-White) in the Company workforce as of December 31, 2023. None of our employees are represented by a collective bargaining agreement.

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

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

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

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

PATENTS AND INTELLECTUAL PROPERTY

We have patents and other intellectual property that we believe protect the FREEDOM System, and we continue to file patent applications in connection with our research and development activities. As of December 31, 2023, we own 15 U.S. Patents and 60 foreign patents. In addition, we have 12 pending U.S. patent applications and 13 foreign patent applications. The fundamental patents protecting our drug delivery systems extend until 2039 and beyond.

EXECUTIVE OFFICERS

The following table sets forth certain information with respect to our executive officers as of March 13, 2024:

Name	Age	Position / Held Since
Linda Tharby	55	Chief Executive Officer and President (since April 2021)
Tom Adams	51	Chief Financial Officer, Secretary and Treasurer (since August 2023)
Brian Case	51	Chief Technology Officer (since April 2022)
Ken Miller	55	Chief Commercial Officer (since November 2023)

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

Ms. Tharby was appointed as President and CEO in April 2021. Ms. Tharby has over 25 years of executive leadership experience building and leading strong performing global organizations that develop and commercialize products and service innovations, while delivering solutions to patients in the home setting. Prior to joining KORU, Ms. Tharby spent 24 years working in various roles of increased responsibility at Becton Dickinson ("BD"). Ms. Tharby was a member of the Executive Leadership team of BD that transformed the company from an $8 billion medical supplies company to an $18 billion global medical technology company. Ms. Tharby's last role at BD was as Chief Customer Experience Officer from July 2018 through December 2020. Prior to that she served as BD's Chief Human Resources Officer, from October 2016 through July 2018. From 1998 to 2016, she held numerous senior global business leadership roles at BD, including Executive Vice President and President of Life Sciences, Group President of Pre-Analytical Systems and Biosciences, Worldwide President of Diabetes Care, and Vice President/General Manager of Pharmaceutical Systems. Ms. Tharby has an Honors Bachelor of Business Administration from Wilfrid Laurier University in Waterloo, Ontario Canada.

Mr. Adams joined KORU Medical in November 2021 as Vice President of Financial Planning and Analysis, was appointed Interim-Chief Financial Officer in July 2022 and Chief Financial Officer in August 2023. Mr. Adams has an extensive background in financial planning, corporate finance, commercial and supply chain finance, and mergers and acquisitions (M&A). Prior to joining KORU Medical, Mr. Adams spent 10 years at Integra Life Sciences in various leadership positions in Finance and Accounting Controllership with his most recent position as Senior Director of Finance. In this role, Mr. Adams was the head of finance for Integra's Tissue Technology Business where he served a leading role in supporting a $500 million business unit to high growth and profitability. Previous roles included Group Controller/Head of FP&A Global Supply and prior to Integra Life Sciences, Mr. Adams served as Director of Finance at Pfizer Inc serving in many domestic and international roles. Mr. Adams earned his Bachelor of Science in Business Administration-Accounting & Finance from the Ohio State University.

Mr. Case joined KORU Medical in April 2022 as Chief Technology Officer. Mr. Case has over 20 years of research and development experience working with a combination of large and small medical device companies. For the 16 years prior to joining KORU Medical, Mr. Case was an R&D leader with Fresenius Kabi, a global leader specializing in lifesaving medicines and technologies for infusion, transfusion, and clinical nutrition. As the Vice President of R&D for the Transfusion and Cell Technologies business, Mr. Case provided global business and technical leadership to drive the long-term product vitality of the business and promote entry into new business areas. During his time at Fresenius, Mr. Case's many accomplishments included bringing new products and technologies to market, leading to new business divisions, multiple international product approvals and value creation for the company. Mr. Case also led the Project Management office for the company, responsible for the identification and implementation of best practices and functional excellence. Prior to Fresenius, Mr. Case was the R&D Manager, Advanced Research at Cook Medical where he led a cross-functional team that developed and assessed new technologies to create a product portfolio to service the peripheral disease market. Mr. Case's work has been prolific with over 100 patents filed during his career. Mr. Case received his Master of Science in Engineering Management from Rose-Hulman Institute of Technology, and his Bachelor of Science in Engineering Mechanics, from University of Illinois.

Mr. Miller joined KORU Medical in November 2023 as Chief Commercial Officer. Mr. Miller has over 30 years of extensive expertise and experience in leading high-performing teams in commercialization and marketing strategy, international expansion, and driving sustainable growth and profitability. As Chief Commercial Officer, Mr. Miller has oversight of the global commercial function, including U.S. and International sales and marketing organizations. He was President & CEO of NASCO HealthCare from October 2018 through January 2023. At NASCO, he transformed sales & marketing, and led the consolidation of NASCO's manufacturing footprint which delivered year-over-year double digit revenue and EBITDA growth. Prior to NASCO, Ken spent 7 years at BD with his last role as the Worldwide President Diabetes Care where he led the transition from a product focus to a full-service diabetes management solution provider. Ken also held leadership roles in marketing, sales, and business development with Novo Nordisk, Adams Respiratory Therapeutics, and Roche Laboratories. He earned his Bachelor of Arts in Business Management from State University of New York at Albany and his Master of Business Administration from The University of Chicago, Booth School of Business.

ITEM 1A. RISK FACTORS

RISK FACTORS

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

Risks Related to Our Business

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

We need to successfully introduce new products to achieve our strategic business objectives. A significant element of our strategy is to increase revenue growth by investing in innovation and new product development, which will require substantial resources. Our successful product development will depend on many factors, including our ability to attract strong talent to lead our research and development efforts, properly anticipate and satisfy customer needs, adapt to new technologies, obtain regulatory concurrence on a timely basis, demonstrate satisfactory clinical results, manufacture products in an economical and timely manner, obtain appropriate intellectual property protection for our products, gain and maintain market acceptance of our products, and differentiate our products from those of our competitors. In addition, patents attained by others can preclude or delay our commercialization of a product. There can be no assurance that any products now in development or that we may seek to develop in the future will achieve technological feasibility, obtain regulatory concurrence or gain market acceptance. If we cannot successfully introduce new products or adapt to changing technologies, our products may become obsolete, and our revenue and profitability could suffer.

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 through our delivery system.. 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 with devices we do not offer or 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.

Our compliance with EU MDR regulations by December 2028 will require significant investment and, if we are not in compliance by that time, we will not be able to sell our products in the EU.

In the European Union (“EU”), we are required to comply with the new Medical Device Regulation (“MDR” or “EU MDR”) effective May 2021, which supersedes the prior Medical Device Directives. Medical devices which have a valid CE certificate to the current Medical Device Directives (issued before May 2021), as do all of our current products, can continue to be sold until December 2028 or until the CE certificate expires, whichever comes first, providing there are no significant changes as defined in Article 120 of EU MDR. The MDR was published in May 2017 with a 3-year transition period. That transition period was extended to May 2021 due to the COVID-19 pandemic. In early 2023, the transition period was further extended to December 2028 for class IIa products. The CE mark required to sell medical devices in the EU is affixed following conformity assessment and either approval from an appointed independent notified body or through self-certification by the manufacturer. The selected pathway to CE marking is based on product risk classification. CE marking indicates conformity to the applicable essential requirements of the relevant Medical Device Directives and in the future to the general safety and performance requirements for the new MDR. The MDR will change multiple aspects of the existing regulatory framework for CE marking, such as increased clinical evidence requirements and other new requirements, including Unique Device Identification (“UDI”) as well as many other post-market obligations. MDR also significantly modifies and increases the compliance requirements for the industry and will require significant investment by us in the near future to implement.

Our products are also subject to approval and regulation by foreign regulatory and safety agencies. For example, the EU has adopted the EU Medical Device Regulation (the “EU MDR”) and the In Vitro Diagnostic Regulation (the “EU IVDR”), each of which impose stricter requirements for the marketing and sale of medical devices, including in the area of clinical evaluation requirements, quality systems and post-market surveillance. Implementation of the compliance requirements of these regulations requires us to incur significant expenditures and utilize resources. Failure to continue to meet these requirements could adversely impact our business in the EU and other regions that tie their product registrations to the EU requirements.

If we are unable to comply with the MDR by December 2028, we will not be able to sell our products in the EU, which will materially impact our net revenues.

Interruption of our manufacturing or our contract manufacturing operations could adversely affect our business.

Command currently provides subassemblies for all of our consumables (needle and tubing sets), and manufactures, assembles and packages approximately substantially all of our consumables. In the event of any interruption in Command's operations or supply of goods, the Company may have to seek alternative sources of subassemblies, which may be not be readily available on commercially reasonable terms or at all, and increase its capacity for manufacturing finished goods in Mahwah, NJ, which could be time-consuming and costly.

The FDA and other U. S. and non-U.S. government agencies regulate our manufacturing and contract manufacturing operations for all of our products. Variations in our or Command's 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 currently manufactured in Nicaragua and Mahwah, NJ, and stored at our corporate headquarters in Mahwah, NJ. Loss or damage to our manufacturing or contract manufacturing and storage site due to weather, vandalism, terrorism, a natural disaster, issues in our manufacturing process, equipment failure or other factors, could adversely affect our ability to manufacture sufficient quantities of products or otherwise deliver products to meet customer demand or contractual requirements which may result in a loss of revenue and other adverse business consequences, including damage to our relationship with customers. Additionally, because Command manufactures and supplies the Company's subassemblies and finished goods for needle sets and tubing products in Nicaragua, there could be a delay in providing the products timely due to their climate and international boundaries. Command currently stores our finished goods in their warehouse located in Miami Florida once the products are released from Nicaragua.

We take precautions to safeguard our facility, 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 facility may harm our business, financial condition and operating results.

Public health crises, such as the COVID-19 pandemic, have had, and could in the future have, a negative effect on our business.

Pandemics or disease outbreaks, such as the COVID-19 pandemic, have created and may continue to create significant volatility, uncertainty and economic disruption in the markets we sell our products into and operate in, primarily the U.S., Europe, and Asia-Pacific and may negatively impact business and healthcare activity globally. In response to the COVID-19 pandemic, governments around the world have imposed measures designed to reduce the transmission of COVID-19 and individuals continue to respond to the fear of contracting COVID-19. In particular, elective procedures and exams were delayed or cancelled, there were significant reductions in physician office visits, and hospitals postponed or canceled capital purchases as well as limited or eliminated services. While elective procedures and exams and capital purchases have increased from initially depressed levels, the reduction in elective procedures, exams and capital purchases has had, and we believe may continue to have, a negative impact on the sales of our products. Additionally, governments and other third-party payors around the world facing tightening budgets could move to further reduce the reimbursement rates or the scope of coverage offered, which could further adversely affect sales of our products.

The extent to which fear of exposure to or actual effects of COVID-19, new variants, disease outbreak, epidemic or a similar widespread health concern impacts our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the speed and extent of geographic spread of the disease, the duration of the outbreak, travel restrictions, the efficacy of vaccination and treatment; impact on the U.S. and international healthcare systems, the U.S. economy and worldwide economy; the timing, scope and effectiveness of U.S. and international governmental response; and the impact on the health, well-being and productivity of our employees.

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

We operate in a single market – ambulatory infusion – and are dependent upon our success in that market. We face competition in our market from a wide range of international and domestic companies, including those that deliver electronic volumetric pumps, elastomeric infuser pumps, other mechanical devices, novel drug delivery devices and methodologies, and devices and formulation technologies that allow drugs to be delivered in volumes smaller than the FREEDOM System is designed to deliver. These include large medical device companies with multiple product lines, some of which may have greater financial and marketing resources than we do. We also face competition from companies that are even more specialized than ours with respect to particular markets or product lines. Some of those companies have greater financial and sales and marketing resources than we do or offer products at a lower price point than ours. In addition, former employees may develop products that are competitive with ours or capitalize on customer relationships developed while employed with us, subject to their continuing obligations under confidentiality agreements and

other restrictive covenants that may survive their employment. We face competition on the basis of product features, clinical or economic outcomes, product quality, availability, price, services, technological innovation and other factors. In addition, we face changing customer preferences and requirements, changes in the ways health care services are delivered, including the transition of high-acuity care to lower-acuity, and non-acute care settings.

Competition may increase further as additional companies begin to enter our market 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. Pharmaceutical manufacturers, health care systems, other health care companies and even retail pharmacies are also consolidating, resulting in greater purchasing power for these companies. As a result, competition among medical device suppliers to provide goods and services has increased. Group purchasing organizations and integrated health delivery networks have also served to concentrate purchasing decisions for some customers, which has led to downward pricing pressure for medical device suppliers. Further consolidation in the industry could intensify competition among medical device suppliers and exert additional pressure on the prices of our products.

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

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

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

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

Our medical devices and technologies, as well as our business activities, are subject to a complex set of regulations and rigorous enforcement, principally by the FDA, numerous other federal, state, and non-U.S. governmental authorities and equivalent regulatory bodies of other countries. To varying degrees, each of these agencies requires us to comply with laws and regulations governing the design, development, and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, promotion, and distribution of our products; premarket clearance and approval; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market approval studies; and product import and export.

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

We cannot guarantee that we will be able to obtain or maintain FDA 510(k) clearance or premarket approval for our new products or enhancements or modifications to existing products (including the use of our FREEDOM System with therapies not covered by the existing FDA clearance), and the failure to maintain approvals or clearances, or obtain approval or clearance could have a material adverse effect on our business, results of operations, financial condition and cash flows. Even if we are able to obtain approval or clearance, it may:

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

Both before and after a product is commercially released, we have ongoing responsibilities under the FDA and other applicable non-U.S. government agency laws and regulations. The FDA and other worldwide regulatory agencies actively monitor compliance with local laws and regulations through review and inspection of design and manufacturing practices, recordkeeping, reporting of adverse events, labeling and promotional practices. The results of these inspections can include inspectional observations on the FDA's Form 483, warning letters, or other forms of enforcement. If the FDA or any state or foreign regulatory authorities were to conclude that we are not in compliance with any applicable laws or regulations, or that any of our medical products are ineffective or pose an unreasonable health risk, they could deem our products adulterated or misbranded, and take enforcement action against us. FDA and state and foreign regulatory authorities have broad enforcement powers. Possible enforcement actions include, but are not limited to: temporarily or permanently suspending the sale and/or distribution of such medical products; detaining or seizing all adulterated or misbranded medical products; ordering recall, repair, replacement, or refund of such products; refusing to grant pending pre-market approval or 510(k) clearance applications; and/or requiring us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health. In addition, the FDA prohibits device manufacturers from promoting their products for uses and indications other than those set forth in the approved product labeling, and failure to comply with this prohibition could subject us to significant civil or criminal exposure, administrative obligations and costs, and/or other potential penalties from, and/or agreements with, the federal government. The FDA and other non-U.S. government agencies may also assess civil or criminal penalties against us, our officers or employees and impose operating restrictions on a company-wide basis. The FDA may also recommend prosecution to the U.S. Department of Justice. Any adverse regulatory action, depending on its magnitude, may restrict us from effectively marketing and selling our products and limit our ability to obtain future pre-market clearances or approvals, and could result in a substantial modification to our business practices and operations.

Regulations regarding the development, manufacture and sale of medical devices are evolving and subject to future change and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. We cannot predict what impact, if any, those changes might have on our business; however, failure to comply with applicable regulatory requirements could have a material adverse effect on our business, financial condition, and results of operations. Later discovery of previously unknown problems with a product or manufacturer could result in fines, delays or suspensions of regulatory clearances or approvals, seizures or recalls of products, physician advisories or other field actions, operating restrictions and/or criminal prosecution. We may also initiate field actions as a result of a failure to strictly comply with our internal quality policies. The failure to receive product approval clearance on a timely basis, suspensions of regulatory clearances, seizures or recalls of products, physician advisories or other field actions, or the withdrawal of product approval by the FDA or by comparable agencies in foreign countries could have a material adverse effect on our business, financial condition or results of operations.

Governmental regulations outside the U.S. have also, and may continue to, become increasingly stringent and common. Penalties for regulatory non-compliance could be severe, including fines and revocation or suspension of a company's EU device approval, ability to distribute products and criminal sanctions. Future foreign governmental laws and regulations may have a material adverse effect on us.

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

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

If our EU device approval is suspended, it could have a material adverse effect on our business and financial results.

The Company's products are currently certified by its notified body, BSI, for sale in the EU. In March 2024, the Company received an assessment report from BSI stating that, following BSI's review of technical documentation submitted by the Company in connection with a prior audit nonconformance, a recommendation for continued certification cannot be made. The Company has filed an appeal to this determination. If the Company's appeal is denied, then its EU certification may be suspended with respect to some or all of the Company's products. Any such suspension would affect the Company's EU revenues, which effect could be material depending on the extent of the suspension.

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 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.

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

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

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

The design, manufacture and marketing of medical devices involve certain inherent risks. Manufacturing or design defects, component failures, unapproved or improper use of our products, or inadequate disclosure of risks or other information relating to the use of our products can lead to injury or other serious adverse events. We are subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances or approvals, seizure of our products, or delay in clearance or approval of future products.

These adverse events could also lead to safety alerts relating to our products or recalls (either voluntary or as required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of a product from the market. A recall could result in significant costs and lost sales and customers, enforcement actions and/or investigations by state and federal governments or other enforcement bodies, as well as negative publicity and damage to our reputation that could reduce future demand for our products. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Personal injuries relating to the use of our products can also result in significant product liability claims being brought against us. A product liability claim, regardless of its merit or outcome, could not only result in significant legal defense costs, but also have a material adverse effect on our business and reputation and ability to attract and retain customers for our products. In some circumstances, adverse events could also cause delays in regulatory approval of new products or the imposition of post-market approval requirements.

We are subject to lawsuits.

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

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

Patent and other proprietary rights are essential to our business. We own patents, trade secrets, trademarks and/or other intellectual property rights related to many of our products. Our success depends to a significant degree on our ability to obtain and enforce patents, both in the U.S. and in other countries. We can lose the protection afforded by these intellectual property assets through patent expirations, legal challenges or governmental action. Additionally, our intellectual property rights may be challenged or infringed upon by third parties, particularly in countries where property rights are not highly developed or protected, or we may be unable to enter into license agreements with third-party owners of intellectual property on reasonable terms. Unauthorized use of our intellectual property rights or inability to preserve existing intellectual property rights could adversely impact our competitive position and results of operations.

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

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

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

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

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

Our ability to compete effectively depends upon our ability to attract and retain executives and other key employees, including people in technical, marketing, sales, research and development, 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.

The failure to attract, integrate, motivate, and retain skilled and qualified personnel could have a material adverse effect on our business. We compete for such personnel against numerous companies, including larger, more established companies with significantly greater financial resources than we possess. Our ability to recruit such talent will depend on a number of factors, including compensation and benefits, work location and work environment. There can be no assurance that we will be successful in attracting or retaining such personnel and the failure to do so could have a material adverse effect on our business, financial condition and results of operations.

We sell a majority of our products through only a few distributors on whom we depend, and our financial results depend on their purchasing patterns.

Most of our customers prefer to purchase our products through distributors, rather than directly from us, because of "one-stop shopping" convenience and their ability to ship directly to patients. We sell most of our products through a small number of distributors, three in the U.S. and two outside the U.S. As of December 31, 2023, these five distributors comprised approximately 74% of our net revenues with one U.S. distributor contributing 41%. Purchasing patterns by these distributors cannot always be predicted and fluctuate from quarter to quarter and year to year based on, among other things, their expectations of customer demand. Any decline in business with the distributors outside the U.S. could have an adverse impact on our business. If we were unable to sell through the distributors outside the U.S., we would have to find other distributors or broaden our customer base and expand direct relationships with customers. Other distributors may not be available or may not agree to arrangements that are commercially reasonable. In the U.S. we could transition to direct customer purchase; however, customers may not want to purchase directly from us and may decide to purchase competitors' products through their distributors. Moreover, a transition from distributors to direct customer purchase would be time consuming and costly.

We and the biopharmaceutical companies with whom we do novel therapies business ("our biopharma customers") are subject to extensive regulation by governments around the world, and if these regulations are not complied with, existing and future operations may be curtailed, and we could be subject to liability.

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

In the European Union ("EU"), we are required to comply with the new Medical Device Regulation ("MDR" or "EU MDR") effective May 2021, which will supersedes the prior Medical Device Directives. Class IIa medical devices which have a valid CE certificate to the current Medical Device Directives can continue to be sold until December 2028 or until the CE certificate expires, whichever comes first, providing there are no significant changes as defined in Article 120 of EU MDR. The MDR was published in May 2017 with a 3-year transition period. That transition period was extended to May 2021 due to the COVID-19 pandemic. In 2023, the transition period was extended further to December 2028 for Class IIa products. The CE mark required to sell medical devices in the EU is affixed following conformity assessment and either approval from an appointed independent notified body or through self-certification by the manufacturer. The selected pathway to CE marking is based on product risk classification. CE marking indicates conformity to the applicable essential requirements of the relevant Medical Device Directives and in the future to the general safety and performance requirements for the new MDR. The MDR will change multiple aspects of the existing regulatory framework for CE marking, such as increased clinical evidence requirements and other new requirements, including Unique Device Identification ("UDI") as well as many other post-market obligations. MDR also significantly modifies and increases the compliance requirements for the industry and will require significant investment in the near future to implement.

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

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

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

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

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

We work with pharmaceutical and biotechnology companies who are targeting the use of our products with a variety of injectable therapies. When we collaborate with pharmaceutical developers, they may engage us in a variety of ways, including *in vitro* feasibility testing, product customization and validation ("development"), non-interventional user testing of our devices, animal or human clinical research using our devices, regulatory submissions, manufacturing development, and commercialization. Certain of those injectable therapies are not FDA approved and are in various phases of clinical development. The clinical development of these pipeline therapies can be terminated by their developers at any stage. Our biopharma customers may choose to continue their drug program without use of our devices. Use in one stage of work does not guarantee use in a future development stage or in commercialization. Furthermore, these pharmaceutical companies could obtain regulatory approval for their injectable therapies and decide for business reasons not to require or encourage utilization of our device. Prior investments we have made in manufacturing capacity or research and development will then not result in the generation of revenue that would have previously been anticipated.

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

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

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

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

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

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

Most of our components and raw materials, including all of our consumables subassemblies, are sourced from single suppliers. 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. A majority of the materials and components that go into the manufacturing of our products, including all of our consumables subassemblies. are single-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. A significant price increase from a single-source supplier could have a material impact on our financial results. While we work with suppliers to ensure continuity of supply, no assurance can be given that these efforts will be successful. Although we do carry strategic inventory and maintain insurance to help mitigate the potential risk related to any supply disruption, there can be no assurance that such measures will be sufficient or effective. The termination, reduction or interruption in supply of raw materials and components and an inability to quickly develop acceptable alternative sources for such supply, could adversely impact our ability to manufacture and sell our products in a timely or cost-effective manner.

We do not have long-term agreements in place with any of our suppliers, with the exception of a five- year agreement with Command which we entered in 2020. Due to regulatory requirements relating to the qualification of suppliers, we are not likely to be able to establish additional or replacement sources on a timely basis or without excessive cost. We are in the process of establishing alternative sources of supply for our raw materials and components, but there can be no assurance we will be able to do so.

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

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

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

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

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

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

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

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

We are required to comply with certain financial and operating covenants under our credit facility. Failure to comply with these covenants would prevent us from drawing on our facility and, once drawn, could cause amounts borrowed to become immediately due and payable.

If we want to draw on our credit facility, we must comply with specified financial and operating covenants under our credit facility and make payments, limiting our ability to operate our business as we otherwise might. Our failure to comply with any of these covenants or to meet any debt payment obligations could result in an event of default which, if not cured or waived, would result in any amounts outstanding, including any accrued interest and/or unpaid fees, becoming immediately due and payable. We might not have sufficient working capital or liquidity to satisfy any repayment obligations in the event of an acceleration of those obligations. In addition, if we are not in compliance with the financial and operating covenants under the credit facility at the time we wish to borrow funds, we will be unable to borrow funds. The financial and operating covenants under the credit facility may limit our ability to borrow funds or capital, including for general corporate purposes and strategic acquisitions.

We may experience difficulties resulting from our relatively new and evolving management structure and executive team.

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

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

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

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 and New Jersey will increase our costs for employees to support those operations, reduce our margins and negatively impact our profit.

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

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

We are subject to foreign currency exchange risk.

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

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

Approximately 17% of our net revenues in the year ended December 31, 2023, came from our operations outside the U.S., and we intend to continue to pursue growth opportunities in foreign markets. Our foreign operations subject us to certain risks, including, among others, the effects of fluctuations in foreign currency exchange, uncertainties with respect to local economic and political

conditions, competition from local companies, trade protectionism and restrictions on the transfer of goods across borders, U.S. diplomatic and trade relations with the governments of the foreign countries in which we operate, foreign regulatory requirements or changes in such requirements, local product preferences and product requirements, longer payment terms for accounts receivable than we experience in the U.S., difficulty in establishing, staffing and managing foreign operations, changes to international trade agreements and treaties, changes in tax laws, weakening or loss of the protection of intellectual property rights in some countries, and import or export licensing requirements.

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 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.

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

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

Our operating results and financial condition may fluctuate.

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

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

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

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

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

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

Natural disasters (including pandemics), war, terrorism, labor disruptions and international conflicts, and actions taken by the U.S. and other governments or by our customers or suppliers in response to such events, could cause significant economic disruption and political and social instability in the U.S. and areas outside of the U.S. in which we operate. Most of our products are assembled and packaged 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.

Rising inflation increases economic uncertainty and may require us to raise prices in order to maintain our operating margins.

For much of the past two years, inflation rates have risen or held steady at rates not seen in a generation or more. Higher level of inflation not only reduces the real value of the profits we generate from our business (and in turn our returns to investors), but it also increases the costs of goods and services, including those from our single-source suppliers, that we need to run our business. Should such trends continue, it would not only have a destabilizing macroeconomic effect on the broader U.S. and global economy, but it may also require us to increase the price of our products in order to maintain sufficient operations margins. Any increase in the prices we charge our customers could reduce the demand for our products, perhaps significantly. We will continue to monitor inflation trends and will make adjustments to our business as necessary.

Brexit may impact our business in the United Kingdom.

One of our two most significant international distributors is located in the United Kingdom (“UK”), and the other is in Finland, a member of the European Union (“EU”). The June 2016 referendum result in the UK to exit the EU (commonly known as “Brexit”), and the subsequent commencement of the official withdrawal process by the UK government in March 2017, has created uncertainties affecting business operations in the UK and the EU. On January 31, 2020, the UK withdrew from the EU. Under the withdrawal agreement agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020 (the “Transition Period”) during which EU rules continued to apply. During the Transition Period, negotiations between the UK and the EU continued in relation to the future customs and trading relationship between the UK and the EU following the expiration of the Transition Period. Due to the current COVID-19 global pandemic, negotiations between the UK and the EU scheduled have either been postponed or occurred in a reduced forum via video conference. However, on December 24, 2020, the negotiators from the EU and UK reached an agreement on a new partnership. This agreement sets out the rules that apply between the EU and the UK as of January 1, 2021. New regulations require medical device registration with the Medicines and Healthcare Products Regulatory Agency (“MHRA") before being placed on the Great Britain market (England, Wales, and Scotland). Additionally, all medical devices will require a UK Conformity Assessment mark (“UKCA”) by December 31, 2024. CE marks issued by Notified Bodies will remain valid until this time. Therefore, we must be compliant with applicable legislation in order to identify our devices with the UKCA mark and continue to market and sell our devices in Great Britain beyond December 31, 2024.

We could be adversely affected, directly or indirectly, by the effects of an increased focus on environmental, social and governance issues.

Recently, shareholders generally have increased their focus on environmental, social and governance ("ESG") issues, specifically regarding how companies are addressing climate change, diversity, and human rights, among other ESG-related issues. Our failure to comply with shareholder expectations and standards regarding ESG issues, which are still evolving and can vary considerably, or the perception that we have not responded appropriately to ESG-related issues, could result in reputational harm, and could have an adverse effect on our business, results of operations and financial condition.

Climate change could present immediate and long-term risks to our industry and our customers. The potential for increased severe weather events could have a material adverse effect on our operations and infrastructure or the operations and infrastructure of our suppliers. In addition, the effects of climate change could include long-term changes in temperature levels and water availability, increased energy costs, and increased supply costs impacted by those increasing energy costs. The cost of mitigating or responding to ESG issues could be significant; however, these costs are too uncertain to predict. In addition, the approaches taken by the U.S. or foreign governments to regulate ESG issues, which may include legislative or regulatory changes, could adversely impact our business, results of operations, financial condition, and prospects, and are too uncertain to predict.

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.

Three stockholders, together with their respective affiliates, beneficially own approximately 17%, 11%, and 7% of our outstanding common stock, respectively. An affiliate of Horton Capital Management LLP. currently serves on our Board of Directors. Circumstances may arise in which these stockholders may have an interest in exerting influence to pursue or prevent acquisitions, divestitures or other transactions, including the issuance of additional shares or debt, that, in their judgment, could enhance their investment in us or another company in which they invest. Such transactions might adversely affect us or other holders of our common stock. Furthermore, our significant concentration of share ownership may adversely affect the trading price of our common stock because investors may perceive disadvantages in owning shares in companies with significant stockholders.

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

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

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

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

We provide and intend to continue to provide additional equity-based compensation to our employees, directors and consultants under our three equity compensation plans. We may issue equity-based compensation outside of our equity compensation plans as inducement for new employees. If our Board elects to issue additional stock options or other equity-based compensation, our stockholders may experience additional dilution, which could cause our stock price to decline. Because stock options granted under our equity compensation plans will generally only be exercised when the exercise price for such option is below the then market value of the common stock, the exercise of such options or the issuance of shares will cause dilution to the book value per share of our common stock and to existing and new investors.

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

Since our common stock was listed on the Nasdaq Capital Market on October 17, 2019, it has traded between $1.82 per share to $12.84 per share. Our stock price is subject to wide fluctuations in response to a variety of factors, including:

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

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

If we do not maintain compliance with the listing standards of the Nasdaq Capital Market, Nasdaq may delist our common stock from trading on its exchange.

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

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

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

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

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

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

You may find it difficult to sell our common stock.

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 1C. CYBERSECURITY

Management has responsibility for developing and coordinating the Company's cybersecurity policy and strategy, and for managing the prevention, detection, mitigation and remediation of cybersecurity incidents. We utilize various risk assessment tools and technologies to identify potential cyber and information security threats and risks, including engaging a third-party information technology services provider to perform risk evaluation and testing. In addition, the Company is in the process of implementing a program for all team members to participate in ongoing training and awareness programs that include periodic assessments to drive adoption and awareness of cybersecurity processes and controls.

We promote a company-wide culture of cybersecurity risk management intended to protect the confidentiality, integrity, and availability of our critical systems and the information contained therein. No risks from cybersecurity threats or previous cybersecurity incidents have materially affected, or are reasonably likely to materially affect, our business strategy, financial condition or results of operations. However, there can be no assurance that the controls and procedures in place to monitor and mitigate the risks of cyber threats will be successful or sufficient to avoid material losses or consequences in the future. Additionally, while we have insurance coverage in place that is designed to address certain aspects of cyber risks, such insurance coverage may be insufficient to cover all insured losses or all types of claims that may arise.

Our Board of Directors, as a whole and through its committees, oversees risk management, including cybersecurity risks. The Board has delegated risk management responsibilities, including but not limited to cybersecurity risk, to the Nominating and Governance Committee. Specifically, the Nominating and Governance Committee periodically reviews our cybersecurity policies, data security programs and plans that management has established to monitor compliance and assess preparedness.

ITEM 2. PROPERTIES

We currently rent 43,975 square feet of a building located at 100 Corporate Drive, Mahwah, New Jersey with the lease having commenced on March 1, 2022 and expiring August 31, 2032. This facility is used as our headquarters and for our in-house manufacturing operations.

ITEM 3. LEGAL PROCEEDINGS

None.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

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

We are authorized to issue 77,000,000 shares of capital stock, of which 75,000,000 are designated common stock, $0.01 par value per share, and 2,000,000 are designated preferred stock. As of March 13, 2024, 45,669,362 shares of our common stock were issued and outstanding held by approximately 471 stockholders of record. There were no shares of preferred stock issued and outstanding.

ITEM 6. SELECTED FINANCIAL DATA

Not applicable.

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

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

OVERVIEW

The Company develops, manufactures and commercializes innovative patient-centric large volume subcutaneous solutions primarily for the subcutaneous drug delivery market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international standards for quality system management.

Our revenues derive from three business sources: (i) domestic core (which consists of US and Canada), (ii) international core, and (iii) novel therapies. Our domestic core and international core revenues consist of sales of our products for the delivery of subcutaneous drugs that are FDA cleared for use with the FREEDOM Infusion System, with the primary delivery for immunoglobulin to treat Primary Immunodeficiency Diseases ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). Novel therapies revenues consist of product revenues from our infusion system (syringe drivers, tubing and needles) for feasibility/clinical trials (pre-clinical studies, Phase I, Phase II, Phase III) of biopharmaceutical companies in the drug development process as well as non-recurring engineering services revenues ("NRE") received from biopharmaceutical companies to ready or customize the FREEDOM System for clinical and commercial use.

The Company completed its transition of substantially all finished goods manufacturing of its needle and tubing sets to Command Medical Products, a third-party contract manufacturing organization which also provides subassemblies for all of the Company's products, in the second quarter of 2023.

The Company entered into a lease commencing March 1, 2022 for a new corporate headquarters and manufacturing facility located in Mahwah, NJ. During the quarter ended June 30, 2022, the Company completed the first phase of the move, the headquarters and office staff to the new location, and completed the move of its manufacturing facility at the end of the first quarter 2023.

The Company ended the 2023 fiscal year with $28.5 million in net revenues, a 2.2% increase compared with $27.9 million in the same period last year driven by volume growth in our core domestic and international business of 5.9% and 10.4% respectively, offset by a 41.6% decline in our novel therapies business.

Gross profit, for the year ended December 31, 2023, was $16.7 million, an increase of 8.7% or $1.3 million from the same period last year, and stated as a percentage of net revenues was 58.6%, an increase from 55.1% in the prior year.

Operating expenses for the year ended December 31, 2023, were $27 million, up from $26.1 million for the same period last year, the increase was driven primarily by research and development and depreciation, partially offset by selling, general and administrative expenses.

RESULTS OF OPERATIONS

Year Ended December 31, 2023 compared to Year Ended December 31, 2022

Net Revenues

The following table summarizes our net revenues for the years ended December 31, 2023 and 2022:

	Years Ended December 31,		Change from Prior Year		% of Net Revenues	
	2023	2022	$	%	2023	2022
Net Revenues						
Domestic Core	$ 22,446,519	$ 21,205,204	$ 1,241,315	5.9%	78.7%	76.0%
International Core	4,596,097	4,164,714	431,383	10.4%	16.1%	14.9%
Novel Therapies	1,475,050	2,526,119	(1,051,069)	(41.6%)	5.2%	9.1%
Total	$ 28,517,666	$ 27,896,037	$ 621,629	2.2%		

Total net revenues increased $0.6 million, or 2.2%, for the year ended December 31, 2023, as compared with the same period last year.

Domestic core growth of 5.9% was primarily driven by volume growth in pumps and consumables attributed to overall SCIG market growth and new account share gains. International core growth of 10.4% was driven by increased volume across several EU markets and the entry into multiple new geographic markets. Novel therapies net revenues declined by 41.6% driven primarily by lower NRE revenue of $0.9 million and fewer clinical trial supply shipments of $0.2 million than in the prior year.

Gross Profit

Our gross profit for the years ended December 31, 2023, and 2022 is as follows:

	Years Ended December 31,		Change from Prior Year	
	2023	2022	$	%
Gross Profit	$ 16,708,282	$ 15,368,986	$ 1,339,296	8.7%
Stated as a Percentage of Net Revenues	58.6%	55.1%		

Gross profit increased $1.3 million or 8.7% in the year ended December 31, 2023, compared to the same period in 2022 driven by the increase in net revenues of $0.6 million coupled with a favorable cost of goods sold impact of $0.7 million. Gross profit as a percentage of net revenues increased to 58.6% in the year ended 2023 compared to 55.1% for the year ended 2022 primarily driven by increased manufacturing productivity and product mix versus the prior year.

Operating Expenses

Our selling, general and administrative, research and development and depreciation and amortization costs for the years ended December 31, 2023, and 2022 are as follows:

	Years Ended December 31,		Change from Prior Year	
	2023	2022	$	%
Selling, general and administrative	$ 20,365,617	$ 20,606,507	$ (240,890)	(1.2%)
Research and development	5,742,254	4,956,215	786,039	15.9%
Depreciation and amortization	870,390	587,137	283,253	48.2%
Total Operating Expense	$ 26,978,261	$ 26,149,859	$ 828,402	3.2%

Selling, general and administrative expenses decreased $0.2 million, or 1.2%, during the year ended December 31, 2023 compared with the same period last year, primarily due to a $0.4 million decrease in compensation and benefits related to executive management restructuring costs that took place in the prior year, and a decrease in stock compensation costs of $0.2 million, partially offset by $0.4 million increase in compensation costs related to business development and medical affairs new hires.

Research and development expenses increased $0.8 million, or 15.9% during the year ended December 31, 2023 compared with the same period last year, primarily due to $0.5 million in compensation and benefits, $0.1 million in stock compensation and $0.1 million in expenses, to support acceleration and insourcing of our innovation efforts.

Depreciation and amortization expense increased by 48.2% to $0.9 million in the year ended December 31, 2023 compared with $0.6 million in the year ended December 31, 2022 resulting from prior year investments in our Mahwah, NJ facility which includes our corporate office, in-house manufacturing, and research and development labs and the associated annualized depreciation impact.

Net Loss

	Years Ended December 31,		Change from Prior Year	
	2023	2022	$	%
Net Loss	$ (13,741,062)	$ (8,661,142)	$ 5,079,920	58.7%
Stated as a Percentage of Net Revenues	(48.2%)	(31.0%)		

Our net loss increased $5.1 million in the year ended December 31, 2023 compared with the same period last year mostly driven by the establishment of an allowance for the nonrealization of deferred tax assets of $6.0 million offset by a higher gross profit of $1.3 million, an increase in other income of $0.4 million due to higher interest and dividend income from our treasury bill investments, which was partially offset by higher operating expenses of $0.8 million.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of $11.5 million as of December 31, 2023. Our principal source of operating cash inflows is from sales of our products and NRE services to customers. Our principal cash outflows relate to the purchase and production of inventory, funding of research and development, and selling, general and administrative expenses. To develop new products, support future growth, achieve operating efficiencies, and maintain product quality, we are continuing to invest in research and development, innovation, and equipment. Operating expenses for the 2023 fiscal year were $27.0 million.

Our inventory position was $3.5 million at December 31, 2023, which reflected a decrease of $2.9 million from December 31, 2022.

In October 2023, the Company received a payroll tax credit under the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") of $0.7 million. This credit was previously recorded as a receivable..

We expect that our cash on hand and cash flows from operations will be sufficient to meet our requirements at least through the next twelve months. Continued execution on our longer-term strategic plan may require the Company to draw on our new credit facility, take on additional debt or raise capital through issuance of equity, or a combination of both. Our future capital requirements may vary from those currently planned and will depend on many factors, including our rate of sales growth, the timing and extent of spending on various strategic initiatives including research and development, our international expansion, the timing of new product introductions, market acceptance of our solutions, and overall economic conditions including inflation and the potential impact of global supply imbalances on the global financial markets. To the extent that current and anticipated future sources of liquidity are or are expected to be insufficient to fund our future business activities and requirements, we may be required to draw on our existing credit facility, seek additional equity or debt financing sooner. There can be no assurance the Company will be able to obtain the financing or raise the capital required to fund its operations or planned expansion.

Cash Flows

The following table summarizes our cash flows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Net cash (used in) operating activities	$ (4,892,553)	$ (5,404,549)
Net cash (used in) investing activities	$ (814,597)	$ (2,801,568)
Net cash (used in)/ provided by financing activities	$ (218,867)	$ 279,485

Operating Activities

Net cash used in operating activities was $4.9 million for the year ended December 31, 2023. This net cash usage was primarily due to the net loss of $13.7, plus cash flows used to reduce accrued expenses of $1.2 million primarily from the payment of 2023 employee bonuses, and a decrease in accounts payable of $1.4 million. Partially offsetting these increases were cash flows generated from a decrease in inventory of $2.9 million, a decrease in accounts receivable of $0.5 million, and changes in working capital of $0.4 million.

Further contributing to this change were non-cash items including a deferred tax asset increase of $2.0 million partially offset by the establishment of an allowance for non-realization of deferred tax assets of $6.0 million, stock-based compensation expense of $2.8 million, depreciation and amortization expense of $0.9 million and a loss on disposal of fixed assets of $0.1 million.

Net cash used in operating activities of $5.4 million for the year ended December 31, 2022 was primarily due to the net loss of $8.7 million, working capital changes which included an increase in accounts payable and other liabilities of $1.3 million, an increase in accrued payroll of $0.4 million increase in inventory of $0.3 million, an increase in accrued expenses of $0.2 million. Further contributing were deferred tax assets of $2.0 million increased for book to tax differences related to stock option expense. Offsetting these were primarily non-cash charges for stock-based compensation of $3.1 million, and depreciation and amortization of $0.6 million.

Investing Activities

Net cash used in investing activities of $0.8 million for the year ended December 31, 2023, was for capital expenditures for research and development and manufacturing equipment.

Net cash used in investing activities of $2.8 million for the year ended December 31, 2022, was for capital expenditures for manufacturing space, research and development laboratories and office equipment for our corporate office and manufacturing facilities move.

Financing Activities

Net cash used in financing activities for the year ended December 31, 2023 of $0.2 million, was from a net between borrowings and payments on our note payable for insurance premium financing of $0.1 million, and $0.1 million for payments on our finance leases.

The $0.3 million provided by financing activities for the year ended December 31, 2022, was from $0.4 million in option exercises offset by $0.08 million in net borrowings on our indebtedness for a note payable for insurance premium financing and $0.05 million in equipment financing.

Debt and Borrowing Capacity

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

Lease Commitments

We have finance and operating leases for our corporate office and certain office and computer equipment. Our two operating leases have remaining lease terms of 8.6 years and 5 years, respectively. Our three finance leases have remaining lease terms of 3.4 years, 3 years, and 4.75 years, respectively.

Refer to "NOTE 5 — LEASES" in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K for further details regarding our operating and finance leases.

Subsequent Event

In March 2024, the Company received an assessment report from its notified body in the EU, BSI, stating that, following BSI's review of technical documentation submitted by the Company in connection with a prior audit nonconformance, a recommendation for continued certification cannot be made. The Company has filed an appeal to this determination. If the Company's appeal is denied, then its EU certification may be suspended with respect to some or all of the Company's products as determined by a BSI review panel. Management believes that the Company's appeal will be successful in limiting the scope of the suspension to have minimal impact on the Company's revenues, if any.

SIGNIFICANT ACCOUNTING POLICIES AND CRITICAL ACCOUNTING ESTIMATES

The preparation of financial statements in conformity with generally accepted accounting principles of the United States ("GAAP") requires estimates and assumptions that affect the reported amounts of assets and liabilities, revenues and expenses, and related disclosures of contingent liabilities in the financial statements and accompanying notes. The SEC has defined a company's critical accounting policies as the ones that are most important to the portrayal of the company's financial condition and results of operations, and which require the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified some of our more critical accounting estimates below. We also have other key accounting policies, which involve the use of estimates, judgments, and assumptions that are significant to understanding our results. For additional information, see "NOTE 1 — NATURE OF OPERATIONS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES" in the accompanying "Notes to Financial Statements" appearing in this Annual Report on Form 10-K. Although we believe that our estimates, assumptions, and judgments are reasonable, they are based upon information presently available. Actual results may differ significantly from these estimates under different assumptions, judgments, or conditions.

Revenue Recognition

Our revenues are derived from three business sources: (i) domestic core (which consists of US and Canada), (ii) international core, and (iii) novel therapies. Our core domestic and international revenues consist of sales of our syringe drivers, tubing and needles ("Product Revenue") for the delivery of subcutaneous drugs that are FDA cleared for use with the KORU Medical infusion system, with the primary delivery for immunoglobulin to treat Primary Immunodeficiency Diseases ("PIDD") and Chronic Inflammatory Demyelinating Polyneuropathy ("CIDP"). Novel therapies consist of Product Revenue for feasibility/clinical trials (pre-clinical studies, Phase I, Phase II, Phase III) of biopharmaceutical companies in the drug development process as well as non-recurring engineering services ("NRE") revenues (including testing and registration services) received from biopharmaceutical companies to ready or customize the FREEDOM System for clinical and commercial use across multiple drug categories.

For Product Revenue, 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 Product Revenue.

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.

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

We recognize NRE revenue under an input method, which recognizes revenue on the basis of our efforts or inputs (for example, resources consumed, labor hours expended, costs incurred, or time elapsed) to the satisfaction of a performance obligation relative to the total expected inputs to the satisfaction of that performance obligation (i.e. completion milestone). The input method that we use is based on costs incurred.

Contracts are often modified to account for changes in contract specifications and requirements. Contract modifications exist when the modification either creates new, or changes existing, enforceable rights and obligations. Generally, when contract modifications create new performance obligations, the modification is considered to be a separate contract and revenue is recognized prospectively. When contract modifications change existing performance obligations, the impact on the existing transaction price and measure of progress for the performance obligation to which it relates is generally recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) on a cumulative catch-up basis. Contract assets primarily represent revenue earnings over time that are not yet billable based on the terms of the contracts. Contract liabilities (i.e., deferred revenue) consist of fees invoiced or paid by the Company's customers for which the associated performance obligations have not been satisfied and revenue has not been recognized based on the Company's revenue recognition criteria described above. As of December 31, 2023, the Company has recognized a contract asset of zero which is included in other accounts receivable in the accompanying balance sheet.

Inventory

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

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

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

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

ACCOUNTING PRONOUNCEMENTS NOT YET ADOPTED

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

KORU MEDICAL SYSTEMS, INC.
INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors
KORU Medical Systems, Inc.
Mahwah, New Jersey

Opinion on the Financial Statements

We have audited the accompanying balance sheets of KORU Medical Systems, Inc. (the Company) as of December 31, 2023 and 2022, the related statements of operations, stockholders' equity and cash flows for the years then ended, and the related notes to the financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with 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.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Deferred Tax Valuation Allowance

Description of the Matter:

As discussed in Note 1 to the financial statements, the Company recorded a $6 million deferred tax valuation allowance during the year ended December 31, 2023. Management is required to evaluate deferred tax assets to determine if they are more likely than not to be realized.

We identified the valuation allowance as a critical audit matter. Management's estimate regarding the valuation allowance results in the application of a high degree of auditor judgment.

How We Addressed the Matter in Our Audit:

We applied auditor judgment to determine the nature and extent of procedures to be performed over the valuation allowance. We obtained an understanding of the Company's processes and controls in place for determining the qualitative factors used in the calculation of the allowance. We evaluated the valuation allowance by testing the completeness and accuracy of the data utilized in the determination of the qualitative factors and the reasonableness of management's judgments and significant assumptions used in the development of the qualitative factors.

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

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

Scranton, Pennsylvania
March 13, 2024

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS

	December 31, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 11,482,240	$ 17,408,257
Accounts receivable less allowance for doubtful accounts of $24,777 and $21,459 for December 31, 2023, and December 31, 2022, respectively	4,045,211	3,558,884
Inventory	3,481,301	6,404,867
Other receivables	28,889	972,396
Prepaid expenses and other	1,218,288	1,457,232
TOTAL CURRENT ASSETS	20,255,929	29,801,636
Property and equipment, net	3,837,657	3,886,975
Intangible assets, net of accumulated amortization of $390,341 and $325,872 at December 31, 2023 and December 31, 2022, respectively	754,361	787,182
Operating lease right-of-use assets	3,514,055	3,786,545
Deferred income tax assets, net allowance for non-realization of deferred tax assets of $6,002,777 and zero for December 31, 2023 and December 31, 2022, respectively	—	3,967,480
Other assets	98,970	102,625
TOTAL ASSETS	$ 28,460,972	$ 42,332,443
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 975,193	$ 2,391,799
Accrued expenses	1,711,427	2,889,941
Note Payable	314,344	433,295
Other liabilities	512,520	257,337
Accrued payroll and related taxes	462,941	542,399
Finance lease liability – current	109,540	98,335
Operating lease liability – current	368,313	345,834
TOTAL CURRENT LIABILITIES	4,454,278	6,958,940
Finance lease liability, net current portion	316,623	394,283
Operating lease liability, net of current portion	3,336,300	3,653,257
TOTAL LIABILITIES	8,107,201	11,006,480
Commitments and contingencies (Refer to Note 8)		
STOCKHOLDERS' EQUITY		
Common stock, $0.01 par value, 75,000,000 shares authorized, 49,089,864 and 48,861,891 shares issued; 45,669,362 and 45,441,389 shares outstanding at December 31, 2023, and December 31, 2022, respectively	490,899	488,619
Additional paid-in capital	47,018,707	44,252,117
Treasury stock, 3,420,502 shares at December 31, 2023 and December 31, 2022, at cost	(3,843,562)	(3,843,562)
Retained Deficit	(23,312,273)	(9,571,211)
TOTAL STOCKHOLDERS' EQUITY	20,353,771	31,325,963
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 28,460,972	$ 42,332,443

See accompanying Notes to Financial Statements.

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2023	**2022**
NET REVENUES	$ 28,517,666	$ 27,896,037
Cost of goods sold	11,809,384	12,527,051
Gross Profit	16,708,282	15,368,986
OPERATING EXPENSES		
Selling, general and administrative	20,365,617	20,606,507
Research and development	5,742,254	4,956,215
Depreciation and amortization	870,390	587,137
Total Operating Expenses	26,978,261	26,149,859
Net Operating Loss	(10,269,979)	(10,780,873)
Non-Operating Income		
Loss on foreign currency exchange	(5,124)	(39,874)
Loss on disposal of fixed assets	(59,807)	—
Interest income, net	561,328	145,587
TOTAL OTHER INCOME	496,397	105,713
LOSS BEFORE TAXES	(9,773,582)	(10,675,160)
Income (tax)/benefit	(3,967,480)	2,014,018
NET LOSS	$ (13,741,062)	$ (8,661,142)
NET LOSS PER SHARE		
Basic	$ (0.30)	$ (0.19)
Diluted	$ (0.30)	$ (0.19)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic	45,601,346	45,002,074
Diluted	45,601,346	45,002,074

See accompanying Notes to Financial Statements.

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in Capital	Retained (Deficit)	Treasury Stock	Total Stockholders' Equity
	Shares	Amount				
BALANCE, DECEMBER 31, 2021	48,044,162	$ 480,441	$ 40,774,245	$ (910,069)	$ (3,843,562)	$ 36,501,055
Accrued compensation paid in shares	206,570	2,066	511,016	—	—	513,082
Compensation expense related to stock options	—	—	2,083,396	—	—	2,083,396
Compensation expense related to restricted stock awards	50,000	500	482,449	—	—	482,949
Issuance upon options exercised	561,159	5,612	401,011	—	—	406,623
Net loss	—	—	—	(8,661,142)	—	(8,661,142)
BALANCE, DECEMBER 31, 2022	48,861,891	$ 488,619	$ 44,252,117	$ (9,571,211)	$ (3,843,562)	$ 31,325,963
Accrued compensation paid in shares	127,973	1,280	445,069	—	—	446,349
Compensation expense related to stock options	—	—	1,940,720	—	—	1,940,720
Compensation expense related to restricted stock awards	100,000	1,000	380,801	—	—	381,801
Issuance upon options exercised	—	—	—	—	—	—
Net loss	—	—	—	(13,741,062)	—	(13,741,062)
BALANCE, DECEMBER 31, 2023	49,089,864	$ 490,899	$ 47,018,707	$ (23,312,273)	$ (3,843,562)	$ 20,353,771

See accompanying Notes to Financial Statements.

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2023	**2022**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (13,741,062)	$ (8,661,142)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	2,768,870	3,079,427
Depreciation and amortization	870,390	587,137
Loss on disposal of fixed assets	59,807	—
Deferred income taxes	(2,035,297)	(2,026,226)
Allowance for non-realization of deferred tax asset	6,002,777	—
ROU landlord credit	(21,988)	212,546
Changes in operating assets and liabilities:		
(Increase)/Decrease in accounts receivable	(486,327)	34,002
Decrease/(Increase) in inventory	2,923,566	(298,529)
Decrease/(Increase) in other receivables	943,507	(254,176)
Decrease in prepaid expenses and other assets	242,599	28,776
(Decrease)/Increase in accounts payable	(1,416,606)	1,164,266
(Decrease)/Increase in accrued payroll and related taxes	(79,458)	381,796
Increase in other liabilities	255,183	167,337
(Decrease)/Increase in accrued expenses	(1,178,514)	180,237
NET CASH USED IN OPERATING ACTIVITIES	(4,892,553)	(5,404,549)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(782,949)	(2,761,056)
Purchases of intangible assets	(31,648)	(40,512)
NET CASH USED IN INVESTING ACTIVITIES	(814,597)	(2,801,568)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of equity	—	406,623
Borrowings from indebtedness	565,172	783,799
Payments on indebtedness	(684,123)	(859,087)
Finance lease ROU asset	(33,461)	—
Payments on finance lease liability	(66,455)	(51,850)
NET CASH (USED IN) PROVIDED BY FINANCING ACTIVITIES	(218,867)	279,485
NET DECREASE IN CASH AND CASH EQUIVALENTS	(5,926,017)	(7,926,632)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	17,408,257	25,334,889
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 11,482,240	$ 17,408,257
Supplemental Information		
Cash paid during the years for:		
Interest	$ 50,832	$ 28,490
Income taxes	$ 3,160	$ —
Schedule of Non-Cash Operating, Investing and Financing Activities:		
Issuance of common stock as compensation	$ 446,349	$ 513,082

See accompanying Notes to Financial Statements.

KORU MEDICAL SYSTEMS, INC.
NOTES TO FINANCIAL STATEMENTS

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

NATURE OF OPERATIONS

KORU MEDICAL SYSTEMS, INC. (the "Company," "KORU Medical," "KORU," "we," "us" or "our") develops, manufactures and commercializes innovative and patient-centric large volume subcutaneous infusion solutions primarily for the subcutaneous drug delivery market as governed by the United States Food and Drug Administration (the "FDA") quality and regulatory system and international standards for quality system management. The Company operates as one segment.

BASIS OF PRESENTATION

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

CASH AND CASH EQUIVALENTS

For purposes of the statements 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 has historically held cash balances in excess of $250,000 at its primary commercial bank, which exceeds FDIC insurance limits. To reduce the risk of uninsured deposits, the Company entered an insured cash sweep program with KeyBank during the second quarter of 2023 to automatically invest its uninsured bank cash balances over $250,000 into FDIC insured banks so there is no more than $250,000 maintained at any one bank. Further, as of December 31, 2023 the Company had invested $10.2 million in a US Treasury bill that matures every 90 days.

INVENTORY

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

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

INTANGIBLE ASSETS

Certain of our identifiable intangible assets, including patents and trademarks, are amortized using the straight-line method over their estimated useful lives which range from 6 to 20 years. All of our intangible assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Our management is responsible for determining if impairment exists and considers various factors when making these determinations. Amortization expense related to intangible assets for the years ended December 31, 2023 and 2022 was $64,469 and $62,143, respectively.

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

Year Ending December 31,		
2024	$	65,869
2025		65,729
2026		64,674
2027		64,242
2028		64,242
Thereafter		429,605
Total amortization expense	$	754,361

INCOME TAXES

For interim income tax reporting, the Company estimates its annual effective tax rate and applies it to fiscal year-to-date pretax loss, excluding unusual or infrequently occurring discrete items. Tax jurisdictions with losses for which tax benefits cannot be realized are excluded. The Company reported an income tax expense of $4.0 million and income tax benefit of $2.0 million for the years ended December 31, 2023 and 2022, respectively.

We evaluate our deferred tax assets to determine if they are more likely than not to be realized by assessing both positive and negative evidence in accordance with ASC Topic 740, Income Taxes. After considering our cumulative pretax loss (the three-year period ending with the current year), as well as analyzing all available evidence, we have recorded a valuation allowance of $6.0 million against our net deferred tax assets during the year ended December 31, 2023. As we continue to assess the realizability of our deferred tax assets, reported pretax income and new evidence may result in a partial or full reduction of the valuation allowance in future periods.

Recurring items cause our effective tax rate to differ from the U.S. federal statutory rate of 21%, including U.S. federal R&D credits, U.S. state tax rates, and stock-based compensation.

Beginning in 2022, certain research and development costs are required to be capitalized and amortized over a five-year period under the Tax Cuts and Jobs Act enacted in December 2017. This change will impact the expected U.S. federal and state income tax expense and cash taxes to be paid for our fiscal 2023.

The Company files income tax returns in the U.S. federal jurisdiction and in various state jurisdictions. Income tax returns for years prior to fiscal 2019 are no longer subject to examination by tax authorities.

PROPERTY AND EQUIPMENT

Property and equipment are stated at original acquisition cost less accumulated depreciation. Additions and improvements are capitalized which increase the value or extend the life of an asset, while maintenance and repair costs are expensed as incurred. When assets are retired or otherwise disposed, the cost and related accumulated depreciation or amortization is removed from the respective accounts and any resulting gain or loss is included in income. Depreciation and amortization are calculated on the straight-line basis over the estimated useful lives of the assets which generally range from 3-10 years for furniture and office equipment, 3-12 years for manufacturing equipment and tooling and shorter of the lease term or their estimated useful lives for leasehold improvements. Depreciation and amortization expense related to property and equipment for the years ended December 31, 2023 and 2022 was $805,921 and $524,994, respectively.

STOCK-BASED COMPENSATION

The Company maintains a stock option plan and omnibus equity incentive plan under which it grants stock options to certain executives, key employees and consultants. It also has granted stock options outside of the plans as inducement awards. The fair value of each option grant is estimated on the date of the grant using the Black-Scholes option-pricing model. All options are charged against income at their fair value. The entire compensation expense of the award is recognized over the vesting period.

Shares of stock granted for director fees under the non-employee director compensation plan and under its omnibus equity incentive plan are recorded at the fair value of the shares at the grant date.

The Company issues restricted stock awards under its omnibus equity incentive plan and outside the plan as incentive awards. Restricted stock awards are equity classified and measured at the fair market value of the underlying stock at the grant date. The fair value of restricted stock awards vesting at certain market capitalization thresholds were estimated on the date of grant using the Brownian Motion Monte Carlo lattice model. The fair value of other restricted stock awards were estimated on the date of grant at the current stock price. We recognize restricted stock expense using the straight-line attribution method over the requisite service period and account for forfeitures as they occur.

NET LOSS PER COMMON SHARE

Basic net loss per common share is calculated by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common and common equivalent shares outstanding during the period. The Company's potentially dilutive common shares are those that result from diluted common stock options and unvested restricted stock awards. The calculation of diluted loss per share excluded stock options of 12,335 and zero in weighted-average shares for each of the years ended December 31, 2023 and 2022, respectively, as their effect was anti-dilutive as a result of the net loss incurred for those periods.

The calculation of diluted loss per share excluded performance-based restricted stock and time-based restricted stock of 904,496 and 950,000 in weighted-average shares for each of the years ended December 31, 2023 and 2022, respectively, as their effect was anti-dilutive as a result of the net loss incurred for those periods.

The following securities were not included in the computation of diluted shares outstanding for the years ended December 31, 2023, and 2022 because the effect would be anti-dilutive:

	Years Ended December 31,	
	2023	2022
Stock options	$ 12,335	$ —
Restricted stock	904,496	950,000
Total	$ 916,831	$ 950,000

	Years Ended	
	December 31, 2023	December 31, 2022
Net loss	$ (13,741,062)	$ (8,661,142)
Weighted Average Outstanding Shares:		
Basic weighted average shares outstanding	45,601,346	45,002,074
Dilutive effect of outstanding stock options and unvested restricted stock	—	—
Diluted weighted average shares outstanding	45,601,346	45,020,074
Net loss per share		
Basic	$ (0.30)	$ (0.19)
Diluted	$ (0.30)	$ (0.19)

Therefore, diluted weighted average number of shares outstanding and diluted net loss per share were the same as basic weighted average number of shares outstanding and net loss per share for the years ended December 31, 2023 and 2022. See “NOTE 4 — STOCK-BASED COMPENSATION” for further detail.

USE OF ESTIMATES IN THE FINANCIAL STATEMENTS

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

REVENUE RECOGNITION

The Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2014-09, *Revenue from Contracts with Customers*, which provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers.

Our revenues are derived from three business sources: (i) domestic core (which consists of US and Canada), (ii) international core, and (iii) novel therapies. Our core domestic and international revenues consist of sales of our syringe drivers, tubing and needles (“Product Revenue”) for the delivery of subcutaneous drugs that are FDA cleared for use with the KORU Medical infusion system, with the primary delivery for immunoglobulin to treat Primary Immunodeficiency Diseases (“PIDD”) and Chronic Inflammatory Demyelinating Polyneuropathy (“CIDP”). Novel therapies consist of Product Revenue for feasibility/clinical trials (pre-clinical studies, Phase I, Phase II, Phase III) of biopharmaceutical companies in the drug development process as well as non-recurring engineering services (“NRE”) revenues (including testing and registration services) received from biopharmaceutical companies to ready or customize the FREEDOM System for clinical and commercial use across multiple drug categories.

For Product Revenue, 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 Product Revenue.

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.

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

We recognize NRE revenue under an input method, which recognizes revenue on the basis of our efforts or inputs (for example, resources consumed, labor hours expended, costs incurred, or time elapsed) to the satisfaction of a performance obligation relative to the total expected inputs to the satisfaction of that performance obligation (i.e. completion milestone). The input method that we use is based on costs incurred.

Contracts are often modified to account for changes in contract specifications and requirements. Contract modifications exist when the modification either creates new, or changes existing, enforceable rights and obligations. Generally, when contract modifications create new performance obligations, the modification is considered to be a separate contract and revenue is recognized prospectively. When contract modifications change existing performance obligations, the impact on the existing transaction price and measure of progress for the performance obligation to which it relates is generally recognized as an adjustment to revenue (either as an increase in or a reduction of revenue) on a cumulative catch-up basis. Contract assets primarily represent revenue earnings over time that are not yet billable based on the terms of the contracts. Contract liabilities (i.e., deferred revenue) consist of fees invoiced or paid by the Company's customers for which the associated performance obligations have not been satisfied and revenue has not been recognized based on the Company's revenue recognition criteria described above. As of December 31, 2023, the Company has recognized a contract asset of zero which is included in other accounts receivable in the accompanying balance sheet.

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

The following table summarizes net revenues by geography for the years ended December 31, 2023 and 2022:

	Years Ended December 31,	
	2023	**2022**
Net Revenues		
Domestic	$ 23,676,039	$ 23,586,254
International	4,841,627	4,309,783
Total	$ 28,517,666	$ 27,896,037

LEASES

In February 2016, the FASB issued a standard related to leases to increase transparency and comparability among organizations by requiring the recognition of right-of-use ("ROU") assets and lease liabilities on the balance sheet. Most prominent among the changes in the standard is the recognition of ROU assets and lease liabilities by the Company for those leases classified as operating leases under current GAAP, while our accounting for capital leases remains substantially unchanged. Under the standard, disclosures are required to meet the objective of enabling users of financial statements to assess the amount, timing, and uncertainty of cash flows arising from leases. The standard became effective for us on January 1, 2019. The standard had a material impact on our balance sheets but did not have a material impact on our statements of operations. See "NOTE 5 — LEASES" for further detail.

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which amends guidance on reporting credit losses for assets held at amortized cost basis and available for sale debt securities. For assets held at amortized cost basis, Topic 326 eliminates the probable initial recognition threshold in current GAAP and, instead, requires an entity to reflect its current estimate of all expected credit losses. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial assets to present the net amount expected to be collected. For available for sale debt securities, credit losses should be measured in a manner similar to current GAAP, however Topic 326 will require that credit losses be presented as an allowance rather than as a write-down. This ASU affects entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off balance sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in this update are effective for fiscal years beginning after December 15, 2022, including interim periods within those fiscal years. The Company adopted this standard on January 1, 2023, and it did not have a significant impact on our financial statements.

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

FAIR VALUE MEASUREMENTS

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

- Level 1 – Quoted prices in active markets for identical assets or liabilities.

- Level 2 – Inputs other than Level 1 that are observable for the asset or liability, either directly or indirectly, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets or liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data by correlation or other means.

- Level 3 – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Value is determined using pricing models, discounted cash flow methodologies, or similar techniques and includes instruments for which the determination of fair value requires significant judgment or estimation.

The carrying amounts of cash and cash equivalents, accounts receivable, prepaid expenses, accounts payable and accrued expenses are considered to be representative of their fair values because of the short-term nature of those instruments. There were no transfers between levels in the fair value hierarchy during the year ended December 31, 2023.

IMPAIRMENT OF LONG-LIVED ASSETS

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of the asset and its eventual disposition are less than the carrying amount. The impairment loss, if recognized, would be based on the excess of the carrying value of the impaired asset over its respective fair value. No impairment losses have been recorded through December 31, 2023.

NOTE 2 — INVENTORY

Inventory consists of:

	December 31, 2023	December 31, 2022
Raw materials and work-in-process	$ 1,869,356	$ 3,853,034
Finished goods	1,862,525	2,611,951
Total	3,731,881	6,464,985
Less: reserve for obsolete inventory	(250,580)	(60,118)
Inventory, net	$ 3,481,301	$ 6,404,867

NOTE 3 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	December 31, 2023	December 31, 2022
Furniture and office equipment	$ 1,412,164	$ 1,456,745
Leasehold improvements	1,953,653	2,413,820
Manufacturing equipment and tooling	3,193,113	2,810,813
Total property and equipment	6,558,930	6,681,378
Less: accumulated depreciation and amortization	(2,721,273)	(2,794,403)
Property and equipment, net	$ 3,837,657	$ 3,886,975

NOTE 4 — STOCK-BASED COMPENSATION

The Company has three equity incentive plans: the 2015 Stock Option Plan, as amended (the "2015 Plan"), the 2021 Omnibus Equity Incentive Plan (the "2021 Plan"), and the Non-Employee Director Compensation Plan. The Company has also issued restricted stock and stock options as employment inducement awards to its Chief Executive Officer and Chief Commercial Officer, respectively.

The 2015 plan provides for the grant of up to 6,000,000 incentive stock options and nonqualified stock options. As of December 31, 2023, there were options to purchase 2,436,250 shares of the Company's common stock outstanding to certain executives, key employees and consultants under the 2015 Plan, of which 85,000 were issued during the year ended December 31, 2023 and 445,000 were issued during the year ended December 31, 2022. Additional options may be issued under the 2015 Plan as outstanding options are forfeited. As of December 31, 2023, there were 2,724,250 shares reserved for outstanding awards and available for issuance under the 2015 Plan.

The 2021 Plan provides for the grant of up to 1,000,000 incentive stock options, nonqualified stock options, stock awards, restricted stock awards, restricted stock units and/or stock appreciation rights to employees, consultants and directors. During the years ended December 31, 2023 and 2022, there were awards with respect to 21,100 and 97,100 shares of common stock, respectively, issued under the 2021 Plan. Additional awards may be issued under the 2021 Plan as outstanding awards are forfeited. As of December 31, 2023, there were 822,142 shares reserved for outstanding awards and available for issuance under the 2021 Plan.

Each non-employee director of the Company (other than the Chairman of the Board) is eligible to receive $110,000 annually, to be paid quarterly $12,500 in cash and $15,000 in common stock. The Chairman of the Board is eligible to receive $140,000 annually, to be paid quarterly $12,500 in cash and $22,500 in common stock. From May 18, 2021 to May 6, 2022, non-employee director compensation was paid pursuant to the 2021 Plan. Since May 6, 2022, non-employee director compensation has been paid pursuant to the Non-Employee Director Compensation Plan. All payments were and are pro-rated for partial service.

The per share weighted average fair value of stock options granted during the year ended December 31, 2023 and December 31, 2022 was $1.84 and $1.98, respectively. The fair value of each award is estimated on the grant date using the Black-Scholes option pricing model with the following weighted average assumptions used for grants in the year ended December 31, 2023 and December 31, 2022. 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. We have recognized tax benefits associated with stock-based compensation of $256,315 and $231,341 for the year ended December 31, 2023 and 2022, respectively.

Time Based Stock Options

The following table summarizes the activities for our stock options with time based vesting for the years ended December 31, 2023, and 2022.

	December 31,	
	2023	2022
Dividend yield	0.00%	0.00%
Expected Volatility	51.9% - 61.3%	65.29% - 77.5%
Weighted-average volatility	—	—
Expected dividends	—	—
Expected term (in years)	10	10
Risk-free rate	3.50% - 4.53%	1.81% - 4.02%

The following table summarizes the status of the time-based stock options:

	Years Ended December 31,			
	2023		2022	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Outstanding at January 1	3,035,000	$ 3.93	3,672,500	$ 3.42
Granted	430,000	$ 2.66	920,000	$ 2.62
Exercised	—	$ —	1,031,250	$ 1.57
Forfeited	208,750	$ 5.45	526,250	$ 2.73
Outstanding at December 31	3,256,250	$ 3.66	3,035,000	$ 3.93
Options exercisable at December 31	1,458,750	$ 4.42	737,500	$ 4.93
Weighted average fair value of options granted during the period	—	$ 1.84	—	$ 1.99
Stock-based compensation expense	—	$ 1,940,720	—	$ 2,083,397

Total stock-based compensation expense was $1,940,720 and $2,083,397 for the years ended December 31, 2023, and 2022, respectively. Net cash received from option exercises for the years ended December 31, 2023, and 2022 was zero and $406,623, respectively.

The weighted-average grant-date fair value of options granted during the years ended December 31, 2023, and 2022 was $0.8 million and $1.8 million, respectively. There were no options exercised during the year ended December 31,2023 and 1,031,250 options exercised during the year ended December 31, 2022.

The following table presents information pertaining to time- based stock options outstanding at December 31, 2023:

Range of Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$2.18-$9.49	3,256,250	8.3 years	$ 3.66	1,458,750	$ 4.42

As of December 31, 2023, there was $3,145,616 of total unrecognized compensation cost related to non-vested time- based stock options granted under the Company's plans. That cost is expected to be recognized over a weighted-average period of 46 months. The total fair value of shares vested as of December 31, 2023, and December 31, 2022, was $4,819,658 and $2,703,002, respectively.

Performance Based Stock Options

Pursuant to an employment agreement entered into on November 6, 2023, with the Company's Chief Commercial Officer, and as an inducement to his employment, the Company issued a non-qualified option to purchase 200,000 shares of common stock that vest upon achievement of sales growth milestones. The following table summarizes the activities for our unvested performance stock option awards for the twelve months ended December 31, 2023, and 2022.

	Twelve Months Ended December 31,			
	2023		2022	
	Shares	Weighted Average Grant-Date Fair Value	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	—	$ —	—	$ —
Granted	200,000	$ 1.48	—	$ —
Vested	—	$ —	—	$ —
Forfeited/canceled	—	$ —	—	$ —
Unvested at December 31	200,000	$ 1.48	—	$ —

As of December 31, 2023, there was $176,345 of unrecognized compensation cost related to unvested employee performance options. This amount is expected to be recognized over a weighted-average period of 36 months. We have recognized tax benefits associated with restricted stock award compensation of $1,137 and zero for the twelve months ended December 31, 2023 and 2022, respectively.

RESTRICTED STOCK AWARDS

The following table summarizes the activities for our unvested restricted stock awards for the twelve months ended December 31, 2023, and 2022.

	Twelve Months Ended December 31,			
	2023		2022	
	Shares	Weighted Average Grant-Date Fair Value	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	950,000	$ 3.04	1,000,000	$ 3.01
Granted	54,496	$ 3.68	—	$ —
Vested	100,000	$ 3.31	50,000	$ 3.31
Forfeited/canceled	—	$ —	—	$ —
Unvested at December 31	904,496	$ 2.77	950,000	$ 3.04

As of December 31, 2023, there was $1,076,664 of unrecognized compensation cost related to unvested employee restricted shares. This amount is expected to be recognized over a weighted-average period of 21 months. We have recognized tax benefits associated with restricted stock award compensation of $79,326 and $101,419 for the twelve months ended December 31, 2023 and 2022, respectively.

NOTE 5 — LEASES

We have finance and operating leases for our corporate office and certain office and computer equipment. Our two operating leases have remaining lease terms of 8.6 years and 5 years, respectively. Our three finance leases have remaining lease terms of 3.4 years, 3 years, and 4.75 years, respectively.

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

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

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

The components of lease expense were as follows:

	Years Ended December 31,	
	2023	**2022**
Operating lease cost	$ 448,630	$ 514,294
Short-term lease cost	130,483	131,490
Total lease cost	$ 579,113	$ 645,784
Finance lease cost:		
Amortization of right-of-use assets	$ 110,566	$ 50,895
Interest on lease liabilities	25,343	5,393
Total finance lease cost	$ 135,909	$ 56,288

Supplemental cash flow information related to leases was as follows:

	Years Ended December 31,	
	2023	**2022**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 464,104	$ 247,504
Financing cash flows from finance leases	$ 125,259	$ 57,243

Supplemental balance sheet information related to leases was as follows:

	December 31, 2023	December 31, 2022
Operating Leases		
Operating lease right-of-use assets	$ 3,514,055	$ 3,786,545
Operating lease liability – current	368,313	345,834
Operating lease liability, net of current portion	3,336,300	3,653,257
Total operating lease liabilities	$ 3,704,613	$ 3,999,091
Finance Leases		
Property and equipment, at cost	$ 577,929	$ 544,468
Accumulated depreciation	(161,461)	(50,895)
Property and equipment, net	$ 416,468	$ 493,573
Finance lease liability – current	109,540	98,335
Finance lease liability, net of current portion	316,623	394,283
Total finance lease liabilities	$ 426,163	$ 492,618

	December 31, 2023	December 31, 2022
Weighted Average Remaining Lease Term		
Operating leases	6.9 Years	9.7 Years
Finance leases	3.7 Years	4.6 Years
Weighted Average Discount Rate		
Operating leases	5.76%	4.00%
Finance leases	6.19%	4.25%

Maturities of lease liabilities are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
2024	512,055	131,437
2025	512,055	131,437
2026	512,055	131,437
2027	512,055	74,194
2028	512,055	6,181
Thereafter	1,832,557	—
Total undiscounted lease payments	4,392,832	474,686
Less: imputed interest	(688,220)	(48,523)
Total lease liabilities	$ 3,704,613	$ 426,163

NOTE 6 — FEDERAL AND STATE INCOME TAXES

Income tax expense consisted of the following:

	Year Ended December 31, 2023	Year Ended December 31, 2022
State income tax:		
Current, net of refund	$ 0	$ 0
Federal income tax:		
Deferred	2,035,297	2,014,018
Current	—	—
Write-off of deferred tax asset	(6,002,777)	—
Income tax benefit/(expense)	$ (3,967,480)	$ 2,014,018

The reconciliation of income taxes shown in the financial statements and amounts computed by applying the Federal expected tax rate of 21% for year 2023 and 2022 is as follows:

	Year Ended December 31, 2023	Year Ended December 31, 2022
Loss before taxes	$ (9,773,582)	$ (10,675,160)
Income taxes computed at the federal statutory rate	$ 2,052,452	$ 2,241,784
State income and franchise tax	—	—
Permanent differences and other	(17,155)	(227,766)
Write-off of deferred tax asset	(6,002,777)	—
Income tax benefit/(expense)	$ (3,967,480)	$ 2,014,018

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

	December 31, 2023	December 31, 2022
Deferred compensation cost	$ 1,047,608	$ 557,931
Depreciation and amortization	(913,671)	(624,184)
R&D credit	142,030	142,030
NOL	3,566,630	2,956,685
Allowance for bad debts and other	2,160,180	935,018
Allowance for non-realization of deferred tax asset	(6,002,777)	—
Deferred income tax assets, net	$ —	$ 3,967,480

Our U.S. federal and state income tax returns remain open to examination for the tax years 2020 through 2022.

NOTE 7 — MAJOR CUSTOMERS

For the years ended December 31, 2023 and December 31, 2022, approximately 66% and 64%, respectively, of the Company's net product revenues were derived from three major customers that are distributors. As of December 31, 2023 and December 31, 2022, accounts receivable due from the three major customers was $2.6 million and $2.2 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 8 — COMMITMENTS AND CONTINGENCIES

LEGAL PROCEEDINGS

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

OTHER

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

The Manufacturing and Supply Agreement provides for a term of five years from the Effective Date. Either party may terminate the Manufacturing and Supply Agreement upon a material breach by the other Party that has not been cured within 90 days, upon the bankruptcy or insolvency of the other Party or as expressly set forth elsewhere in the Agreement.

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

NOTE 9 — EMPLOYEE BENEFITS

We provide a safe harbor 401(k) plan for our employees that allows for employee elective contributions, Company matching contributions and discretionary profit-sharing contributions. Employee elective contributions are funded through voluntary payroll deductions. The Company makes safe harbor matching contributions in an amount equal to 100% of the employee's contribution, not to exceed 3% of employee's compensation plus 50% of employee's pay contributed between 3% and 5% of employee's compensation. Company matching expense for the years ended December 31, 2023 and December 31, 2022 was $227,447 and $214,931, respectively. The Company has not provided for a discretionary profit-sharing contribution.

NOTE 10 — DEBT OBLIGATIONS

On July 28, 2023, the Company entered into a commercial insurance premium finance and security agreement with AON Premium Finance, LLC in the aggregate principal amount of $0.57 million bearing an annual percentage rate of 9.5%, to finance its insurance premiums. Monthly payments are due on the first of each month beginning August 1, 2023 through June 1, 2024. The balance of AON note was $314,344 as of December 31, 2023 and $433,295 as of December 31, 2022, respectively.

NOTE 11 — SUBSEQUENT EVENT

On March 8, 2024, the Company entered into a loan and security agreement with HSBC Ventures USA Inc., as lender, providing for a $5,000,000 revolving credit facility and a $5,000,000 term loan facility. Borrowings are secured by a first-priority lien on substantially all of the assets of the Company, subject to customary exceptions. The revolving credit facility matures on December 31, 2025 and the term loan matures on December 1, 2028. Our former revolving credit facility with Key Bank expired during the quarter ended September 30, 2023.

Borrowings under the revolving credit facility will bear interest at the greater of Prime or 6.50%, payable in arrears on a monthly basis and at maturity. Borrowings under the term loan will bear interest at the greater of Prime minus 0.50% or 6.50% and will be interest-only through December 31, 2025, followed by 24 equal monthly payments of principal plus interest.

The loan and security agreement contains customary affirmative covenants a financial maintenance covenant that requires the Company to maintain a minimum Adjusted Quick Ratio (defined as the ratio of the Company's (i) unrestricted and unencumbered cash and cash equivalents maintained with the lender and its affiliates, plus eligible accounts receivable, to (ii) current liabilities) of not less than 1.50 to 1.00 tested on the last day of each month.

There are no outstanding borrowings under the facility as of March 13, 2024.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES

An evaluation was performed under the supervision and with the participation of our management, including our principal executive officer or CEO, and principal financial officer or CFO, of the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of December 31, 2023. Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2023, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our CEO and CFO, to allow timely decisions regarding required disclosure.

MANAGEMENT'S REPORT ON INTERNAL CONTROL OVER FINANCIAL REPORTING

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

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

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2023. This assessment was based on criteria for effective internal control over financial reporting described in "Internal Control - Integrated Framework," issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on this assessment, management determined that, as of December 31, 2023, the Company maintained effective internal control over financial reporting.

CHANGES IN INTERNAL CONTROL OVER FINANCIAL REPORTING

There has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the year ended December 31, 2023, that has materially affected, or that is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Information regarding our executive officers required by Item 10 of Part III is set forth in Item 1 of Part I "Business — Executive Officers." Information required by Item 10 of Part III regarding our directors and any material changes to the process by which security holders may recommend nominees to the Board of Directors is included in our Proxy Statement relating to our 2024 Annual Meeting of Shareholders, and is incorporated herein by reference. Information relating to our Code of Ethics and to compliance with Section 16(a) of the 1934 Act is set forth in our Proxy Statement relating to our 2024 Annual Meeting of Shareholders and is incorporated herein by reference. We intend to disclose amendments to our Code of Ethics, as well as waivers of the provisions thereof, on our website under the heading "Investors - Governance" at www.korumedical.com.

ITEM 11. EXECUTIVE COMPENSATION

Information required by Item 11 of Part III is included in our Proxy Statement relating to our 2024 Annual Meeting of Shareholders and is incorporated herein by reference.

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

Information required by Item 12 of Part III is included in our Proxy Statement relating to our 2024 Annual Meeting of Shareholders and is incorporated herein by reference.

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

Information required by Item 13 of Part III is included in our Proxy Statement relating to our 2024 Annual Meeting of Shareholders and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information required by Item 14 of Part III is included in our Proxy Statement relating to our 2024 Annual Meeting of Shareholders and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

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

Exhibit No.	Description
2.1	Agreement and Plan of Merger by and between KORU Medical Systems, Inc., a New York corporation, and KORU Medical Systems, Inc., a Delaware corporation (incorporated by reference to our Form 8-K filed with the SEC on May 17, 2023).
3.1(i)	Certificate of Incorporation of KORU Medical Systems, Inc. effective May 16, 2023 (incorporated by reference to our Form 8-K filed with the SEC on May 17, 2023).
3.1(ii)	Bylaws of KORU Medical Systems, Inc. (incorporated by reference to our Form 8-K filed with the SEC on May 17, 2023).
4.1	Description of Securities (incorporated by reference to the Company's Form 10-K filed with the SEC on March 23, 2021).
10.1	2015 Stock Option Plan, as amended (incorporated by reference to the Company's Proxy Statement on Schedule 14A filed with the SEC on July 28, 2016).
10.2	2021 Omnibus Equity Incentive Plan (incorporated by reference to the Company's Proxy Statement on Schedule 14A filed with the SEC on April 5, 2021).
10.3	Form of Non-Qualified Stock Option (incorporated by reference to the Company's Form 10-K filed with the SEC on March 23, 2021).
10.4	Form of Incentive Stock Option (incorporated by reference to the Company's Form 10-K filed with the SEC on March 23, 2021).
10.5	Non-Employee Director Compensation Plan (incorporated by reference to the Company's Proxy Statement on Schedule 14A filed with the SEC on March 18, 2022).
10.6	Manufacturing and Supply Agreement dated as of November 11, 2020 between KORU Medical Systems, Inc. and Command Medical Products (incorporated by reference to the Company's Form 10-Q filed with the SEC on November 12, 2020). Certain information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.
10.7	Employment Agreement effective as of March 15, 2021 between KORU Medical Systems, Inc. and Linda Tharby (incorporated by reference to the Company's Form 10-K filed with the SEC on March 23, 2021).* †
10.8	Employment Agreement effective as of March 18, 2022 between KORU Medical Systems, Inc. and Brian Case (incorporated by reference to the Company's Form 10-K filed with the SEC on March 8, 2023).*
10.9	Employment Agreement effective as of October 20, 2021 between KORU Medical Systems, Inc. and Thomas Adams (incorporated by reference to the Company's Form 10-Q filed with the SEC on August 3, 2022).*
10.10	First Amendment to Employment Agreement effective as of August 1, 2023 between Thomas Adams and KORU Medical Systems, Inc. (incorporated by reference to the Company's Form 8-K filed with the SEC on August 2, 2023).*

continued

Exhibit No.	Description
10.11	Employment Agreement effective as of November 6, 2023 between KORU Medical Systems, Inc. and Kenneth Miller (incorporated by reference to the Company's Form 8-K filed with the SEC on November 8, 2023).*
10.12	Lease dated as of January 21, 2022 between the Company and Breit Industrial Canyon NJ1W05 LLC (incorporated by reference to the Company's Form 10-K filed with the SEC on March 2, 2022).
10.13	Loan and Security Agreement dated as of March 8, 2024 by and between KORU Medical Systems, Inc. and HSBC Ventures USA Inc. (incorporated by reference to the Company's Form 8-K filed with the SEC on March 13, 2024).+
10.14	Stock Purchase Warrant issued to HSBC Ventures USA Inc. issued on March 8, 2024 (incorporated by reference to the Company's Form 8-K filed with the SEC on March 13, 2024).
23.1	Consent of Independent Auditors (filed herewith).
31.1	Certification of the Principal Executive Officer of registrant required under Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Certification of the Principal Financial Officer of registrant required under Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.1	Certification of the Principal Executive Officer of registrant required under Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32.2	Certification of the Principal Financial Officer of registrant required under Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
101.INS	Inline XBRL Instance Document - the XBRL Instance Document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document.
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

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

* Denotes management compensatory agreement or arrangement.

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

ITEM 16. FORM 10-K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on March 13, 2024.

KORU MEDICAL SYSTEMS, INC.

/s/ Linda Tharby
Linda Tharby, President and Chief Executive Officer

/s/ Thomas Adams
Thomas Adams, Chief Financial Officer and Treasurer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities indicated on March 13, 2024.

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

/s/ Edward Wholihan
Edward Wholihan, Director

/s/ Robert A. Casella
Robert A. Casella, Director

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

/s/ Shahriar Matin
Shahriar Matin, Director

/s/ Donna French
Donna French, Director

/s/ Linda Tharby
Linda Tharby, Director

EXHIBIT 23.1

McGrail Merkel Quinn & Associates, P.C.
CERTIFIED PUBLIC ACCOUNTANTS & CONSULTANTS

Clay Avenue Professional Plaza
1173 Clay Avenue
Scranton, PA 18510
570 961-0345
Fax: 570 961-8650
mmq.com

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-1 (No. 333-229498), Registration Statement on Form S-3 (No. 333-238242), Registration Statement on Form S-3 (No. 333-272026), Registration Statement on form S-8 (No. 333-265943), Registration Statement on Form S-8 (No. 333-273300) and related Prospectuses of KORU Medical Systems, Inc. of our report dated March 13, 2024, with respect to the financial statements of KORU Medical Systems, Inc., appearing in this Annual Report on Form 10-K for the fiscal year ended December 31, 2023.

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

Scranton, Pennsylvania
March 13, 2024

EXHIBIT 31.1

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

I, Linda Tharby, Principal Executive Officer, certify that:

1) I have reviewed this Annual Report on Form 10-K of KORU MEDICAL SYSTEMS, INC.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Linda Tharby
Linda Tharby
President and Chief Executive Officer
Date: March 13, 2024

EXHIBIT 31.2

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

I, Thomas Adams, Principal Financial Officer, certify that:

1) I have reviewed this Annual Report on Form 10-K of KORU MEDICAL SYSTEMS, INC.;

2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3) Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations, and cash flows of the registrant as of, and for, the periods presented in this report;

4) The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5) The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors:

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

/s/ Thomas Adams
Thomas Adams
Chief Financial Officer and Treasurer
Date: March 13, 2024

EXHIBIT 32.1

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

In connection with the Annual Report of KORU MEDICAL SYSTEMS, INC. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Linda Tharby, Principal Executive Officer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

/s/ Linda Tharby
Linda Tharby
Chief Executive Officer and President
Date: March 13, 2024

EXHIBIT 32.2

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

In connection with the Annual Report of KORU MEDICAL SYSTEMS, INC. (the "Company") on Form 10-K for the year ended December 31, 2023 as filed with the Securities and Exchange Commission (the "Report"), I, Thomas Adams, Principal Financial Officer and Treasurer, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company as of the dates and for the periods expressed in the Report.

/s/ Thomas Adams
Thomas Adams
Chief Financial Officer and Treasurer
Date: March 13, 2024