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, 2025

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, 2025, the aggregate market value of the voting and nonvoting common equity held by non-affiliates of the registrant was $119,084,035.

As of March 12, 2026, 46,370,432 shares of common stock, $0.01 par value per share, were outstanding, which excludes 3,438,526 shares of Treasury Stock.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's proxy statement for the 2026 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, 2025.

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, completion of a next-generation pump and consumable system, compliance with EU MDR, 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.

RISK FACTOR SUMMARY

Our business faces many risks and uncertainties. These risks and uncertainties could lead to events or circumstances that have a material adverse effect on our business, financial condition, results of operations and prospects. You should carefully review and consider the full discussion of our risk factors described under Item 1A, Risk Factors of this Annual Report together with other information in this Annual Report and our other filings with the SEC, before making an investment decision regarding our common stock.

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.
- Our business depends on an adequate supply of drugs to be administered by our products.
- The size of the markets for our products and any future products may be smaller than we estimate and may decline.
- We sell a majority of our products through a limited number of distributors on whom we depend, and our financial results depend on their purchasing patterns, as well as with end-user demand.
- 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.
- Interruption of our manufacturing or our contract manufacturing operations could adversely affect our business.
- If we are unable to compete successfully in our highly competitive industry, our business and financial condition may be adversely affected.
- Technological developments by others may disrupt our business and negatively impact our revenues.

Table of Contents

- If a cybersecurity incident was to occur, it could cause substantial disruption to our information systems and breaches of our security systems which could harm our business, customer relations and financial condition.
- 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.
- We need to attract and retain key employees to be competitive.
- Recent immigration enforcement actions in the U.S. could impact our operations or the operations of our suppliers and vendors, and the ability to retain talented personnel.

Risks Related to Our Industry

- Failure to obtain 510(k) clearance or PMA approval from the FDA for our new products or enhancements to our existing products may affect our ability to grow our business.
- Healthcare policy changes and industry cost-containment measures could result in downward pricing pressure for our products and limit our sales.
- 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.
- Defects or quality issues associated with our products could adversely affect the results of our operations.
- 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.
- 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.
- 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.

- If coverage and reimbursement from third-party payors for procedures utilizing our products are inadequate, adoption of our products will be adversely affected and our revenues and prospects for profitability will suffer.
- Most brand name injectable therapies will face future competition from generic or biosimilar therapies, which could significantly reduce their commercial viability.

Risks Related to Legal and Regulatory Compliance

- 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.
- 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 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 consumable products in the EU.
- Our failure to comply with laws and regulations relating to reimbursement of healthcare products may subject us to penalties and adversely impact our reputation, business, results of operations, financial condition and cash flows.

Risks Related to Economic Conditions

- Our distribution network and other operations outside the U.S. subject us to certain risks.
- Rising inflation increases economic uncertainty and may require us to raise prices in order to maintain our operating margins.
- We are subject to foreign currency exchange risk.
- A government shutdown may have a material adverse impact on our business and results of operations.
- A downturn in global economic conditions in government-sponsored healthcare systems could adversely affect our operations.
- Public health crises, such as the COVID-19 pandemic, have had, and could in the future have, a negative effect on our business.
- Brexit may impact our business in the United Kingdom.

Table of Contents

Risks Related to Our Financial Position

- 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.
- 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.
- We currently, and may in the future, have assets held at financial institutions that may exceed the insurance coverage offered by the Federal Deposit Insurance Corporation ("FDIC"), and the loss of such assets could have a negative effect on our operations and liquidity.
- Changes in tax or labor laws or exposure to additional income tax liabilities could increase our costs and reduce our margins.
- Changes in tariff and trade policies by the US administration, and uncertainties with respect to such policies, may have an adverse impact on our costs of goods and gross margin.
- Our operating results and financial condition may fluctuate.
- Future material impairments in the value of our long-lived assets could negatively affect our operating results.

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.
- We do not currently intend to pay dividends on our common stock.
- 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.
- There has been volatility in the price of shares of our common stock.
- 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.
- 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.

- 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.
- You may find it difficult to sell our common stock.
- Actions of activist stockholders could have an adverse effect on our business.

General Risk Factors

- Natural disasters, war and other events could adversely affect our suppliers and customers.
- 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.
- We are subject to lawsuits.
- Our insurance coverage may be inadequate to cover all the liabilities we may incur.

Table of Contents

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) pharma services and clinical trials. 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"). Pharma services and clinical trials 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.

The Company originally incorporated in March 1980.

OUR MISSION

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

OUR STRATEGY

Our goal is to strengthen our position as a leading provider of large-volume subcutaneous infusion systems (≥10ml) for self-administration in the home and for administration by healthcare professionals in infusion centers. We aim to achieve this by expanding our leadership and market penetration in the domestic and international subcutaneous immunoglobulin (SCIg) market while extending our expertise into emerging subcutaneous drug therapies. Both SCIg and novel drug therapies will leverage our FREEDOM System and upcoming innovations within the platform, supporting healthcare providers in delivering optimized, efficient, and patient-friendly infusion solutions.

To reinforce our leadership in SCIg, we have identified key market trends driving its continued growth, including:

- **Increasing diagnoses of Primary Immunodeficiency Diseases (PIDD)**, which frequently require immunoglobulin (Ig) treatment.
- **Expansion of on-label SCIg indications**, including Chronic Inflammatory Demyelinating Polyneuropathy (CIDP), Secondary Immunodeficiency Diseases (SIDD), and additional conditions currently in clinical development.

- **Growth in SCIg treatment options**; KORU is well positioned to lead the global transition to prefilled syringe delivery across major drug brands, with a focus on improving the SCIg patient experience.
- **Ongoing biopharmaceutical investment in SCIg therapies**, including prefilled syringe formats designed to enhance ease of use and expand patient eligibility for SCIg treatment.
- **Increasing availability of donated plasma**, which supports the growing global supply of Ig medications.
- **Patient preference and cost-effectiveness of at-home SCIg therapy**, which offers a favorable side effect profile and health economic advantages compared to intravenous Ig (IVIg) treatment.

As we continue to advance subcutaneous infusion therapy, we are focused on delivering solutions that not only improve patient outcomes but also enhance the overall infusion experience for both patients and caregivers. Our commitment to innovation extends beyond product development—we work closely with healthcare providers and specialty pharmacies to drive therapy optimization through advanced infusion solutions and evidence-based insights. By reducing the complexity of infusions, improving workflow efficiencies, and supporting economic sustainability for providers, we help ensure that SCIg therapy remains a viable and preferred option for a growing number of patients.

Table of Contents

Through ongoing clinical and product innovation, strategic partnerships, and commercial excellence, we will continue to expand our presence in the SCIg market. By improving treatment protocols, expanding geographic reach, and executing commercially, we aim to enhance our global market position and increase the number of patients benefiting from SCIg therapy over IVIg.

In our goal to expand into novel therapies outside of SCIg, we estimate that at least 170 large-volume drugs, greater than 2ml, are in clinical development utilizing subcutaneous infusion, with approximately 20% 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 and infusion clinic 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 infusion centers.

We believe our track record of achieving regulatory clearances 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 and what the system delivers.

Our FREEDOM System is FDA 510(k) cleared and certified outside the United States for delivery of several on-label subcutaneous indications including Cutaquig ®, Cuvitru®, Hizentra®, Xembify, Empaveli® (branded Aspaveli® outside the United States), and Gammagard Liquid®. Additionally, our FREEDOM System has specific FDA clearance for selected intravenously administered antibiotics.

Infusion systems such as the FREEDOM System are most prevalent in the home care and alternate infusion clinic markets. The SCIg products administered by the FREEDOM System are indicated for a variety of conditions, including Primary Immunodeficiency Disease (PIDD) and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) in the United States and PIDD, CIDP and Secondary Immunodeficiency Disorder ("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.

The FREEDOM System is also approved in the US for the administration by healthcare professionals of RYSTIGGO, a novel biologic, for the treatment of generalized myasthenia (gMG).

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 six distributors outside the U.S. As of December 31, 2025, these nine distributors comprised approximately 77% of our net revenues with one of our U.S. distributors contributing approximately 29%.

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.

Table of Contents

MANUFACTURING AND RAW MATERIALS

We currently manufacture 100% of our pump product volume and a portion of our consumables volume at our Mahwah, NJ facility. The remaining amount of our consumable supply is sourced from Command Medical Products, Inc. (“Command”), a contract manufacturing organization with operations in Nicaragua.

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 $4.4 million and $5.3 million on research and development for the years ended December 31, 2025 and 2024, respectively. We intend to make ongoing investments in research and development for our infusion pumps, consumable systems, and accessories, as well as for future innovation.

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 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."

Table of Contents

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 many 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 three to 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 healthcare 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.

Table of Contents

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, 2025, we had 73 full time employees, including 4 international employees. As of December 31, 2025, approximately 48% of the Company's workforce was female and approximately 41% of the Company's employees in managerial roles were female. Approximately 38% were minorities (non-White) in the Company workforce as of December 31, 2025. 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, 2025, we own 15 U.S. Patents and 26 foreign patents. In addition, we have 8 pending U.S. patent applications and 18 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 12, 2026:

Table of Contents

Name	Age	Position / Held Since
Linda Tharby	57	Chief Executive Officer and President (since April 2021)
Tom Adams	53	Chief Financial Officer, Secretary and Treasurer (since August 2023)
Christopher Pazdan	43	Chief Operating Officer (since July 2024)
Adam Kalbermatten	42	Chief Commercial Officer (since July 2025)
Eric Schiller	52	Chief Technology Officer (since December 2025)

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. Pazdan joined KORU Medical in September 2021 as Vice President of Quality Assurance and Regulatory Affairs before being promoted to Senior Vice President of Operations in 2022, and subsequently to Chief Operating Officer in July 2024. As Chief Operating Officer, Mr. Pazdan oversees Manufacturing, Sourcing, Supply Chain, Quality, Regulatory and Project Management. Prior to joining KORU, Mr. Pazdan spent 17 years in various functions within the Medical Device industry, most recently serving as Vice President of Quality Assurance at Hillrom. In this role, Mr. Pazdan was head of quality for multiple business segments comprising $2 billion in annual revenue. Mr. Pazdan earned his Bachelor of Science in Engineering from the University of Illinois Urbana-Champaign.

Mr. Kalbermatten joined Koru Medical Systems as Chief Commercial Officer in July 2025, bringing more than 20 years of commercial leadership experience across the medical device and pharmaceutical industries. Adam has a proven track record of accelerating growth, scaling businesses, and building high-performing teams, all while delivering innovative, customer-centric solutions. Prior to Koru, Adam served as Vice President and General Manager of the Advanced Drug Delivery Systems business at Becton Dickinson ("BD") until 2025. He previously served as Chief Executive Officer of ZebraSci, a drug-device combination product development firm, between 2019-2022, where he led a successful turnaround and growth strategy, resulting in the company's acquisition by BD. Earlier in his career, Adam held global leadership and engineering roles at both Terumo Corporation and BD between 2005 and 2019. Adam holds a Bachelor of Engineering in Mechanical Engineering and a Master of Engineering in Engineering Management from Stevens Institute of Technology and an MBA from Columbia Business School.

Mr. Schiller joined Koru Medical Systems as Chief Technology Officer in December 2025, bringing more than 25 years of experience in medical devices and drug-device combination products. He has deep expertise across product development, engineering, supply chain, and lifecycle management. Prior to joining Koru, Eric held senior leadership roles at Sanofi between 2021 and 2025, most recently serving as Global Head of Device Development Portfolio, where he oversaw more than 80 pipeline assets across Specialty Care, General Medicine, and Vaccines, with approximately 40 planned launches by 2030. Earlier in his career, Eric held leadership positions at Bristol Myers Squibb, Celgene, Becton Dickinson, and Saint-Gobain, where he led global commercialization efforts and advanced innovative drug-delivery technologies. Eric holds an MBA from Seton Hall University and a Bachelor of Science in Mechanical Engineering from the New Jersey Institute of Technology and is a named inventor on multiple U.S. patents.

Table of Contents

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.

The size of the markets for our products and any future products may be smaller than we estimate and may decline.

Our estimates of the total addressable market for our products are based on a number of internal and third-party estimates and assumptions, including, without limitation, the assumed prices at which we can sell our products in those markets. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors.

As a result, our estimates of the annual total addressable market for our products may prove to be incorrect. If the actual number of patients with indications who would benefit from our products, the price at which we can sell our products or the annual total addressable market for our products is smaller than we have estimated, it may impair our prospective market and revenue opportunity.

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 six outside the U.S. As of December 31, 2025, these nine distributors comprised approximately 77% of our net revenues with one U.S. distributor contributing 29%. 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

Table of Contents

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.

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 an agreement with Command that expires December 31, 2026, subject to renewal. 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).

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 85% 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 in warehouse space 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.

Table of Contents

If we are unable to compete successfully in our highly competitive industry, our business and financial condition may be adversely affected.

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

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

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

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

If a cybersecurity incident was to occur, it could cause substantial disruption to our information systems and breaches of our security systems which could harm our business, customer relations and financial condition.

We collect and store sensitive data in the regular course of business on our networks and on third-party controlled applications. Such sensitive information includes our intellectual property and proprietary business information, information about our customers, suppliers and business partners, and personally identifiable information of our customers and employees. The secure processing, maintenance and transmission of this information is critical to our operations and business strategy. Our information technology and infrastructure may be subject to cybersecurity attacks by hackers or breached due to human error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, regulatory penalties, disruption of our operations and the services we provide to customers, and damage to our reputation and loss of confidence in our products and services, which could adversely affect our business, operating margins, revenues and competitive position. In addition, the regulatory environment regarding data security and privacy evolves frequently and has become increasingly restrictive.

We also use third-party information technology systems to store information, interface with customers, maintain financial accuracy, secure our data and accurately produce our financial statements. If our information technology systems do not effectively and securely collect, store, process and report relevant data for the operation of our business, whether due to equipment malfunction or constraints, software deficiencies, human error or cyber incident, our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations would be materially impaired. Any such impairment could have a material adverse effect on our results of operations, financial condition and the timeliness in which we report our operating results.

Table of Contents

Our insurance coverage related to information risks, breaches, and business interruption is subject to deductibles and coverage limitations. We may not be able to maintain our current insurance coverage on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against future claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against such information risks and breach claims, we could be exposed to significant liabilities.

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.

Table of Contents

Recent immigration enforcement actions in the U.S. could impact our operations or the operations of our suppliers and vendors, and the ability to retain talented personnel.

Recent immigration enforcement by the U.S. government has resulted in increased audits of our employment records, as well those of our suppliers and vendors, and the classification of employees, and may limit access to visa programs for employees. Such changes may affect our ability, and the ability of our suppliers and vendors, to retain talent, increase recruitment costs and affect innovation. We may be required to spend more time focusing on compliance with such immigration controls and spend more costs on employment and immigration attorneys and human resources specialists to ensure compliance with U.S. government requirements.

Risks Related to Our Industry

Failure to obtain 510(k) clearance or PMA approval from the FDA for our new products or enhancements to our existing products may affect our ability to grow our business.

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.

Such increased costs and delays or failures associated with the clearance and approval process and continuing review of approved products, could adversely affect our business, operating results and prospects. There is no assurance that future clearance or approval of our new products or enhancements to our existing products will be granted, or that we will be able to continue selling our products. Such failures could hurt our ability to maintain and grow our business.

Healthcare 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 healthcare costs to contain or reduce these costs and, more generally, to reform the healthcare 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.

Table of Contents

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.

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.

If coverage and reimbursement from third-party payors for procedures utilizing our products are inadequate, adoption of our products will be adversely affected and our revenues and prospects for profitability will suffer.

Purchasers of our products bill various third-party payors, including governmental healthcare programs, such as Medicare, and private insurance plans, for procedures in which our products are used. Reimbursement is a significant factor considered those purchasers in determining whether to acquire and utilize medical devices. Therefore, our ability to successfully commercialize our products depends significantly on the adequacy of coverage and reimbursement from these third-party payors.

Third-party payors, whether foreign or domestic, governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the U.S., no uniform policy of coverage and reimbursement for medical device products exists among third-party payors. Therefore, coverage and reimbursement for medical device products can differ significantly from payor to payor. In addition, payors continually review new technologies for possible coverage and can, without notice, deny coverage for these new products. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained or maintained if obtained.

Reimbursement systems in international markets vary significantly by country and by region within some countries, and reimbursement approvals must be obtained on a country-by-country basis. In many international markets, a product must be approved for reimbursement before it can be approved for sale in that country. Further, many international markets have government-managed healthcare systems that control reimbursement for new devices and procedures. In most markets, there are private insurance systems as well as government-managed systems.

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.

Risks Related to Legal and Regulatory Compliance

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.

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.

Table of Contents

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 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.

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.

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.

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.

Table of Contents

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.

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.

Our failure to comply with laws and regulations relating to reimbursement of healthcare 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 healthcare goods and services, including laws and regulations related to kickbacks, false claims, self-referrals and healthcare 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.

Table of Contents

Risks Related to Economic Conditions

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

Approximately 26% of our net revenues in the year ended December 31, 2025, 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, including tariffs or other barriers to market participation, pricing pressure that we may experience internationally, 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.

There may be greater uncertainty and market volatility following U.S. and global elections, resulting from potential shifts in trade policies, tariffs or other trade protection measures, and the reaction of other countries thereto, or changes to international trade agreements, which could have a material adverse effect on our operations, including our ability to source and manufacture products in a timely and cost effective manner, financial condition, results of operations and/or liquidity. Geopolitical developments related to various global conflicts are sources of uncertainty and may cause disruptions to global or regional markets, supply chains or operations in the regions. Such global conflicts include, but are not limited to, Russia's invasion of Ukraine in 2022, uncertainty in the Middle East region, increasing tensions between China and Taiwan, and U.S. military operations in Venezuela. Sanctions and export restrictions may continue to proliferate, leading to greater uncertainty in emerging and growth markets. Any significant changes in the political, economic, financial, competitive, legal and regulatory or reimbursement conditions where we conduct, or plan to expand, our international operations may have a material impact on our business, financial condition or results of operations.

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.

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.

A government shutdown may have a material adverse impact on our business and results of operations.

The Company is subject to various federal regulations and various federal agency oversight. A government shutdown or understaffing at applicable federal agencies could result in unforeseen delays despite compliance with these regulations and federal agency requirements. Such a delay could materially and adversely affect the Company's results of operations, cash flows and liquidity.

A downturn in global economic conditions in government-sponsored healthcare systems 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, lower end-user demand through changes to payor reimbursement, 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. Further, sanctions, tariffs, or other measures that restrict international trade, as well as instability resulting from global conflicts, could negatively affect our business operations and 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 imposed measures designed to reduce the transmission of COVID-19 and individuals responded 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.

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 EU. The June 2016 referendum resulted in the UK’s decision 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 COVID-19 global pandemic, negotiations between the UK and the EU were delayed. 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 June 30, 2030. 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 June 30, 2030.

Risks Related to Our Financial Position

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.

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.

Changes in tariff and trade policies by the US administration, and uncertainties with respect to such policies, may have an adverse impact on our costs of goods and gross margin.

In February 2026, the Supreme Court of the United States held that tariffs imposed under the International Emergency Economic Powers Act (IEEPA) exceeded the President's statutory authority and were unlawful. As a result, previously implemented IEEPA-based reciprocal tariffs were terminated. Shortly thereafter, the Trump Administration announced and implemented a new across-the-board tariff of up to 15% on certain imports pursuant to Section 122 of the Trade Act of 1974. These actions have resulted in changes to applicable U.S. tariff rates and may continue to create uncertainty regarding U.S. trade policy, which could materially affect import costs, supply chains, pricing, and overall operating results.

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.

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 13%, 9%, and 8% 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. If we do not pay dividends, a return on our stockholders' investment will only occur if our stock price appreciates.

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.

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.

Table of Contents

General Risk Factors

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.

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 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.

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.

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.

Table of Contents

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

In the ordinary course of our business, we may be subject to various claims, pending and potential legal actions for damages, investigations relating to governmental laws and regulations and other matters arising out of the normal conduct of our business. We are not aware of any current material pending legal proceedings to which we are a party or of which any of our properties is the subject.

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 12, 2026, 46,370,432 shares of our common stock were issued and outstanding held by approximately 368 stockholders of record. There were no shares of preferred stock issued and outstanding.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all future earnings for the operation and expansion of our business and, therefore, do not anticipate declaring or paying cash dividends in the foreseeable future. The payment of dividends will be at the discretion of our Board of Directors and will depend on our results of operations, capital requirements, financial condition, prospects, contractual arrangements, any limitations on payments of dividends present in any of our future debt agreements and other factors our Board of Directors may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

Information relating to our equity compensation plans as of December 31, 2025, under which our equity securities were authorized for issuance, is included in Item 12 of Part III of this Annual Report and such information is incorporated herein by reference.

Table of Contents

ITEM 6. RESERVED

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 7 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) pharma services and clinical trials. 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"). Pharma services and clinical trials 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 Infusion System for clinical and commercial use.

The Company ended the 2025 fiscal year with $41.1 million in net revenues, a 22.2% increase compared with $33.6 million in the same period last year driven by growth in our domestic core and international core businesses of 11.0% and 80.0% respectively, partially offset by a 5.6% decrease in our pharma services and clinical trials business net revenues.

Gross profit for the year ended December 31, 2025, was $25.6 million, an increase of 20.0% or $4.3 million from the same period last year. Gross margin was 62.3% for the year ended December 31, 2025, a decrease from 63.4% from the prior year. We define gross margin as gross profit stated as a percentage of net revenues.

Operating expenses for the year ended December 31, 2025, were $28.6 million, up from $27.8 million from the same period last year.

RESULTS OF OPERATIONS

Year Ended December 31, 2025 compared to Year Ended December 31, 2024

Net Revenues

The following table summarizes our net revenues for the years ended December 31, 2025 and 2024:

	Years Ended December 31,		Change from Prior Year		% of Net Revenues	
	2025	2024	$	%	2025	2024
Net Revenues						
Domestic Core	$ 27,992,436	$ 25,214,613	$ 2,777,823	11.0%	68.1%	74.9%
International Core	10,881,183	6,043,979	4,837,204	80.0%	26.5%	18.0%
Total Core	38,873,619	31,258,592	7,615,027	24.4%	94.5%	92.9%
Pharma Services and Clinical Trials	2,253,747	2,387,871	(134,124)	(5.6)%	5.5%	7.1%
Total	$ 41,127,366	$ 33,646,463	$ 7,480,903	22.2%	100%	100%

Total net revenues increased $7.5 million, or 22.2%, to $41.1 million, for the year ended December 31, 2025, as compared with the same period last year. Domestic core growth of 11.0% was primarily driven by volume in consumables and pumps attributed to subcutaneous immunoglobulin (SCIg) market growth and new account share gains. International core growth of 80.0% was primarily driven by SCIg market growth, increased penetration in several established EU markets, and entry into multiple new geographic markets. Pharma services and clinical trials net revenues decreased $0.1 million, or 5.6%, driven by lower NRE collaborations revenues resulting from the timing of project milestones partially offset by higher clinical trial orders when compared to the prior year.

Table of Contents

Gross Profit

Our gross profit for the years ended December 31, 2025, and 2024 is as follows:

	Years Ended December 31,		Change from Prior Year	
	2025	2024	$	%
Gross Profit	$ 25,604,079	$ 21,331,858	$ 4,272,221	20.0%
Gross Margin	62.3%	63.4%		

Gross profit increased $4.3 million, or 20.0%, to $25.6 million, in the year ended December 31, 2025, compared to the same period in 2024 driven by the increase in net revenues of $7.5 million partially offset by an increase in manufacturing costs. Gross margin decreased to 62.3% in the year ended 2025 compared to 63.4% for the year ended 2024, primarily driven by higher materials costs, tariff-related charges, and geographic sales mix from outside the United States, partially offset by higher average selling prices in the US market.

Operating Expenses

Our selling, general and administrative, research and development and depreciation and amortization expenses for the years ended December 31, 2025, and 2024 are as follows:

	Years Ended December 31,		Change from Prior Year	
	2025	2024	$	%
Selling, general and administrative	$ 23,378,807	$ 21,631,674	$ 1,747,133	8.1%
Research and development	4,387,214	5,257,942	(870,728)	(16.6)%
Depreciation and amortization	810,500	888,473	(77,973)	(8.8)%
Total Operating Expense	$ 28,576,521	$ 27,778,089	$ 798,432	2.9%

Selling, general and administrative expenses increased $1.7 million, or 8.1%, to $23.4 million, during the year ended December 31, 2025 compared with the same period last year, primarily due to an increase in compensation and benefits-related bonus accrual, sales commission related to year over year company performance, and legal fees, partially offset by lower consulting expenses.

Research and development expenses decreased $0.9 million, or 16.6%, to $4.4 million, during the year ended December 31, 2025 compared with the same period last year, primarily due to lower compensation and benefit expense and CTO severance expenses from the prior year, partially offset by higher temporary labor expenses for product development.

Depreciation and amortization expense decreased $0.1 million, or 8.8%, to $0.8 million, during the year ended December 31, 2025, as compared with the same period last year, primarily driven by asset retirement and decreased capital spending.

Net Loss

	Years Ended December 31,		Change from Prior Year	
	2025	2024	$	%
Net Loss	$ (2,637,926)	$ (6,066,633)	$ 3,428,707	56.5%

Our net loss decreased $3.4 million or 56.5% in the year ended December 31, 2025 compared with the same period last year, driven by higher gross profit of $4.3 million, partially offset by an increase in operating expense of $0.8 million.

LIQUIDITY AND CAPITAL RESOURCES

Our principal source of liquidity is our cash on hand of $8.9 million as of December 31, 2025. Our principal source of operating cash inflows is from sales of our products in our core business, clinical trial products, and NRE services to our customers. Our principal cash outflows relate to the purchase and production of inventory, selling, general and administrative expenses, and funding of research and development, 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 2025 fiscal year were $28.6 million.

Our inventory position was $3.7 million at December 31, 2025, which reflects an increase of $0.9 million from December 31, 2024.

Table of Contents

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 credit facility, take on additional debt, raise capital through issuance of equity, or utilize a combination of the above. 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, tariffs, 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 credit facility or 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 growth opportunities.

Cash Flows

The following table summarizes our cash flows:

	Year Ended December 31, 2025	Year Ended December 31, 2024
Net cash used in operating activities	$ 462,405	$ (319,718)
Net cash used in investing activities	$ (949,790)	$ (1,333,042)
Net cash used in financing activities	$ (221,350)	$ (248,533)

Operating Activities

Net cash produced from operating activities was $0.5 million for the year ended December 31, 2025. This net cash produced was primarily due to the net loss of $2.6 million, an increase in inventory of $0.9 million, an increase in accounts receivable of $0.5 million, and an increase in prepaids and other assets of $0.2 million, offset by an increase in accrued expenses for 2025 bonuses and payroll of $0.6 million, and an increase in accounts payable of $0.6 million.

Further contributing to this change were non-cash items of $3.4 million including stock-based compensation expense of $2.7 million, depreciation and amortization expense of $0.8 million, and partially offset by a $0.1 million decrease in non-cash leasing liabilities.

Net cash used in operating activities was $0.3 million for the year ended December 31, 2024. This net cash usage was primarily due to the net loss of $6.1 million, offset by a $2.6 million increase in accrued expenses for 2024 bonuses and payroll, $0.7 million in lower inventories, and $0.7 million in increased accounts payable, partially offset by a higher accounts receivable balance of $1.7 million, and $0.2 million of changes in other liabilities, prepaids, and other assets.

Further contributing to this change were non-cash items of $3.8 million including stock-based compensation expense of $2.6 million, depreciation and amortization expense of $0.9 million, and $0.3 million for non-cash leasing charges and losses on disposals of fixed assets.

Investing Activities

Net cash used in investing activities of $0.9 million for the year ended December 31, 2025, was driven by capital expenditures for manufacturing equipment related to our production line for our next generation consumables and infusion pumps.

Net cash used in investing activities of $1.3 million for the year ended December 31, 2024, was driven by capital expenditures for manufacturing equipment related to our production line for our next generation consumables.

Financing Activities

Net cash used in financing activities of $0.2 million for the year ended December 31, 2025 was primarily due to payments on our note payable for insurance premium financing, partially offset by new borrowings for a subsequent insurance premium financing agreement. The insurance premium financing note was also paid off early, without penalty, during the period.

Net cash used in financing activities of $0.2 million for the year ended December 31, 2024 was primarily due to payments on our note payable for insurance premium financing, partially offset by new borrowings for a subsequent insurance premium financing agreement. In addition, we had payments for taxes related to net share settlement of equity awards of $0.1 million.

Table of Contents

Debt and Borrowing Capacity

Refer to "NOTE 5 — DEBT OBLIGATIONS" 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 three operating leases have remaining lease terms of 6.7 years, 3.1 years, and 2.4 years, respectively. Our three finance leases have remaining lease terms of 1.4 years, 1.0 years, and 2.8 years, respectively.

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

SIGNIFICANT ACCOUNTING POLICIES AND CRITICAL ACCOUNTING ESTIMATES

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

Revenue Recognition

Our revenues are derived from three business sources: (i) domestic core (which consists of US and Canada), (ii) international core, and (iii) pharma services and clinical trials. 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"). Pharma services and clinical trials 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.

Table of Contents

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, 2025, the Company has recognized a contract asset of $319,955 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

Financial Statements

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
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, 2025 and 2024, and the related statements of operations, stockholders' equity, and cash flows for the years ended December 31, 2025 and 2024, and the related notes. In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years ended December 31, 2025 and 2024, in conformity with accounting principles generally accepted in the United States of America.

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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
Critical audit matters 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 judgements. We determined that there were no critical audit matters.

/s/ Cherry Bekaert LLP

We have served as the Company's auditor since 2024.

Tampa, Florida
March 12, 2026

KORU MEDICAL SYSTEMS, INC.
BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 8,872,212	$ 9,580,947
Accounts receivable, net	6,209,950	5,720,750
Inventory, net	3,678,131	2,803,669
Other receivables	319,955	277,193
Prepaid expenses and other current assets	908,542	749,851
TOTAL CURRENT ASSETS	19,988,790	19,132,410
Property and equipment, net	4,471,386	4,290,515
Intangible assets, net of accumulated amortization of $527,949 and $458,538 at December 31, 2025 and December 31, 2024, respectively	684,841	730,279
Operating lease right-of-use assets	2,956,192	2,966,341
Other assets	98,970	98,970
TOTAL ASSETS	$ 28,200,179	$ 27,218,515
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	$ 2,267,473	$ 1,649,969
Accrued expenses	4,828,830	3,924,184
Note payable	—	271,152
Other liabilities	27,722	29,269
Accrued payroll and related taxes	531,972	811,401
Finance lease liability	124,913	115,587
Operating lease liability	413,448	400,258
TOTAL CURRENT LIABILITIES	8,194,358	7,201,820
Finance lease liability, net current portion	78,675	202,613
Operating lease liability, net of current portion	2,879,224	3,000,403
TOTAL LIABILITIES	11,152,257	10,404,836
Commitments and contingencies (Refer to Note 9)		
STOCKHOLDERS' EQUITY		
Common stock, $0.01 par value, 75,000,000 shares authorized, 49,790,934 and 49,377,617 shares issued; 46,370,432 and 45,957,115 shares outstanding at December 31, 2025, and December 31, 2024, respectively	497,909	493,776
Additional paid-in capital	52,449,339	49,581,303
Treasury stock, 3,438,526 and 3,438,526 shares at December 31, 2025 and December 31, 2024, respectively, at cost	(3,882,494)	(3,882,494)
Accumulated Deficit	(32,016,832)	(29,378,906)
TOTAL STOCKHOLDERS' EQUITY	17,047,922	16,813,679
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 28,200,179	$ 27,218,515

See accompanying Notes to Financial Statements.

STATEMENTS OF OPERATIONS

	For the Years Ended December 31,	
	2025	2024
NET REVENUES	$ 41,127,366	$ 33,646,463
Cost of goods sold	15,523,287	12,314,605
Gross Profit	25,604,079	21,331,858
OPERATING EXPENSES		
Selling, general and administrative	23,378,807	21,631,674
Research and development	4,387,214	5,257,942
Depreciation and amortization	810,500	888,473
Total Operating Expenses	28,576,521	27,778,089
Net Operating Loss	(2,972,442)	(6,446,231)
Non-Operating Income/(Expense)		
Income/(loss) on foreign currency exchange	53,097	(45,991)
Other income/(expense)	9,906	(16,160)
Interest income, net	293,403	444,642
TOTAL OTHER INCOME	356,406	382,491
LOSS BEFORE TAXES	(2,616,036)	(6,063,740)
Income tax expense	(21,890)	(2,893)
NET LOSS	$ (2,637,926)	$ (6,066,633)
NET LOSS PER SHARE		
Basic	$ (0.06)	$ (0.13)
Diluted	$ (0.06)	$ (0.13)
WEIGHTED AVERAGE COMMON SHARES OUTSTANDING		
Basic	46,187,077	45,802,701
Diluted	46,187,077	45,802,701

See accompanying Notes to Financial Statements.

Index to Financial Statements

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY

	Common Stock		Additional Paid-in	Retained	Treasury	Total Stockholders'
	Shares	Amount	Capital	(Deficit)	Stock	Equity
BALANCE, DECEMBER 31, 2023	49,089,864	$ 490,899	$ 47,018,707	$ (23,312,273)	$ (3,843,562)	$ 20,353,771
Accrued compensation paid in shares	191,946	1,919	452,909	—	—	454,828
Compensation expense related to stock options	—	—	1,509,544	—	—	1,509,544
Compensation expense related to restricted stock awards	55,061	551	567,369	—	(38,932)	528,988
Issuance upon options exercised	40,746	407	—	—	—	407

Payments for taxes related to net share settlement of equity awards	—	—	(58,447)	—	—	(58,447)
Issuance of warrants	—	—	91,221	—	—	91,221
Net loss	—	—	—	(6,066,633)	—	(6,066,633)
BALANCE, DECEMBER 31, 2024	49,377,617	$493,776	$49,581,303	$(29,378,906)	$(3,882,494)	$ 16,813,679
Accrued compensation paid in shares	137,079	1,371	506,710	—	—	508,081
Compensation expense related to stock options	—	—	988,427	—	—	988,427
Compensation expense related to restricted stock awards	195,725	1,957	1,201,875	—	—	1,203,832
Issuance upon options exercised	80,513	805	185,528	—	—	186,333
Payments for taxes related to net share settlement of equity awards	—	—	(27,536)	—	—	(27,536)
Issuance of warrants	—	—	13,032	—	—	13,032
Net loss	—	—	—	(2,637,926)	—	(2,637,926)
BALANCE, DECEMBER 31, 2025	49,790,934	$497,909	$52,449,339	$(32,016,832)	$(3,882,494)	$ 17,047,922

See accompanying Notes to Financial Statements.

Index to Financial Statements

KORU MEDICAL SYSTEMS, INC.
STATEMENTS OF CASH FLOWS

	For the Years Ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net Loss	$ (2,637,926)	$ (6,066,633)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense and warrant expense	2,713,539	2,623,920
Depreciation and amortization	810,500	888,473
Loss/(Gain) on disposal of fixed assets	(6,700)	16,160
Non-cash leasing charges	(97,840)	243,394
Changes in operating assets and liabilities:		
Increase in accounts receivable	(489,199)	(1,675,540)
Decrease/(Increase) in inventory	(874,462)	677,632
Decrease/(Increase) in prepaid expenses and other assets	(196,682)	220,133
Increase in accounts payable	617,504	674,776
Increase/(Increase) in accrued payroll and related taxes	(279,429)	348,460
Decrease in other liabilities	(1,547)	(483,250)
Increase in accrued expenses	904,647	2,212,757
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	462,405	(319,718)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property and equipment	(932,517)	(1,297,427)
Proceeds on disposals of property and equipment	6,700	8,500
Purchases of intangible assets	(23,973)	(44,115)
NET CASH USED IN INVESTING ACTIVITIES	(949,790)	(1,333,042)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of employee stock options	186,165	—
Borrowings from insurance finance indebtedness	406,751	487,516
Payments on insurance finance indebtedness	(677,903)	(530,707)
Payments for taxes related to net share settlement of equity awards	(27,536)	(97,379)
Payments on finance lease liability, net of asset	(108,827)	(107,963)
NET CASH USED IN FINANCING ACTIVITIES	(221,350)	(248,533)

NET DECREASE IN CASH AND CASH EQUIVALENTS	(708,735)	(1,901,293)
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	9,580,947	11,482,240
CASH AND CASH EQUIVALENTS, END OF YEAR	$ 8,872,212	$ 9,580,947
Supplemental Information		
Cash paid during the years for:		
Interest	$ 55,546	$ 71,934
Income taxes	$ 14,850	$ —

See accompanying Notes to Financial Statements.

Index 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").

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. As of December 31, 2025 the Company held cash and cash-equivalents of $8.9 million, the majority of which was held in a secured US-treasury money market mutual fund.

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, 2025 and 2024 was $69,411 and $68,197, respectively.

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

Year Ending December 31,		
2026	$	65,969
2027		65,620
2028		65,620
2029		65,620
2030		62,000
Thereafter		360,012
Total amortization expense	$	684,841

Index to Financial Statements

INCOME TAXES

The Company accounts for deferred income taxes using the asset and liability method. Under this method, deferred income taxes arise from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements, which will result in taxable or deductible amounts in the future. Temporary differences are then measured using the enacted tax rates and laws. Determining the appropriate amount of valuation allowance requires management to exercise judgement about future operations.

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 a recorded valuation allowance of $7.1 million against our net deferred tax assets as of the year ended December 31, 2025. 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, stock-based compensation and changes in our valuation allowance.

We account for uncertain tax positions in accordance with authoritative guidance which prescribes a minimum recognition threshold a tax position is required to meet before being recognized in the financial statements. Our evaluations of tax positions consider various factors including, but not limited to, changes in tax law, the measurement of tax positions taken or expected to be taken in tax returns, the effective settlement of matters subject to audit, information obtained during in-process audit activities and changes in facts or circumstances related to a tax position. We accrue interest and penalties related to unrecognized tax benefits as a component of income tax expense recorded in continuing operations.

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 2022 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, 2025 and 2024 was $639,908 and $704,690, 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 recognized as compensation expense at their grant date fair value. The entire compensation expense of the award is recognized over the vesting period.

Shares of stock previously granted for director fees under the non-employee director compensation plan, as well as shares of stock granted 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 restricted stock awards with time-based vesting were estimated on the date of grant at the current stock price. The fair value of restricted stock awards vesting at certain annual sales growth thresholds were estimated as of the date of Board acknowledgement of the achievement, 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.

Index to Financial Statements

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

Our revenues are derived from three business sources: (i) domestic core (which consists of US and Canada), (ii) international core, and (iii) pharma services and clinical trials. 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"). Pharma services and clinical trials 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 are included as a component of cost of goods sold in the accompanying statements of operations and are generally billed to customers, and 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 comprise a standalone 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, 2025, 2024, and 2023, the Company has recognized a contract asset of $319,955, $222,623, $0, respectively, which is included in other accounts receivable in the accompanying balance sheets.

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 and (b) They arose from the sale of goods or services.

The following table summarizes net revenues by geography for the years ended December 31, 2025 and 2024:

	Years Ended December 31,	
	2025	2024
Net Revenues		
Domestic	$ 30,238,333	$ 27,506,682
International	10,889,033	6,139,781
Total	$ 41,127,366	$ 33,646,463

Index to Financial Statements

ACCOUNTING PRONOUNCEMENTS RECENTLY ADOPTED

In December 2023 the FASB issued ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures which expands the existing rules on income tax disclosures. This update requires entities to disclose specific categories in the tax rate reconciliation, provide additional information for reconciling items that meet a quantitative threshold and disclose additional information about income taxes paid on an annual basis. The new disclosure requirements are effective for fiscal years beginning after December 15, 2024. We adopted this ASU for the annual period ended December 31, 2025 and the amendments have been applied prospectively in the financial statements. The adoption of this ASU did not have a significant impact on our financial statements.

In November 2023 the FASB issued ASU 2023-07, Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures which expands disclosure requirements to require entities to disclose significant segment expenses that are regularly provided to or easily computed from information regularly provided to the chief operating decision maker. This update also requires all annual disclosures currently required by Topic 280 to be disclosed in interim periods. The new disclosure requirements are effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. We adopted this ASU for the annual period ended December 31, 2024 and the amendments have been applied retrospectively to all prior periods presented in the financial statements. The adoption of this ASU 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, 2025.

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 for the years ended December 31, 2025 and 2024.

Index to Financial Statements

NOTE 2 — INVENTORY

Inventory consists of:

	December 31, 2025	December 31, 2024
Raw materials and work-in-process	$ 732,506	$ 827,768
Finished goods	2,949,645	1,979,887
Total	3,682,151	2,807,655
Less: reserve for obsolete inventory	(4,020)	(3,986)
Inventory, net	$ 3,678,131	$ 2,803,669

NOTE 3 — PROPERTY AND EQUIPMENT

Property and equipment consists of the following at:

	December 31, 2025	December 31, 2024
Furniture and office equipment	$ 1,407,636	$ 1,433,622
Leasehold improvements	1,959,045	1,953,653
Manufacturing equipment and tooling	5,171,898	4,376,147
Total property and equipment	8,538,579	7,763,422
Less: accumulated depreciation and amortization	(4,067,193)	(3,472,907)
Property and equipment, net	$ 4,471,386	$ 4,290,515

NOTE 4 — STOCK-BASED COMPENSATION

The Company maintains 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 2024 Omnibus Equity Incentive Plan (the "2024 Plan"). All equity awards issued to employees, consultants, and non-employee directors on or after May 9, 2024 are issued from the 2024 Plan. The Company has also issued restricted stock and stock options as employment inducement awards outside of these plans to its Chief Executive Officer, Chief Commercial Officer, and Chief Technology Officer.

The 2015 Plan provides for the grant of incentive stock options and nonqualified stock options. As of December 31, 2025, there were 1,958,000 shares reserved for outstanding awards under the 2015 Plan.

The 2021 Plan provides for the grant of incentive stock options, nonqualified stock options, stock awards, restricted stock awards, restricted stock units, performance share units, stock appreciation rights, and/or other equity-based awards to employees, consultants and directors. As of December 31, 2025, there were 100,000 shares reserved for outstanding awards under the 2021 Plan.

The 2024 Plan provides for the grant of incentive stock options, nonqualified stock options, stock awards, restricted stock awards, restricted stock units, performance share units, stock appreciation rights and/or other equity-based awards to employees, consultants and directors. Awards previously made under the 2015 Plan and the 2021 Plan that are forfeited or cancelled after May 9, 2024 will be available for issuance under the 2024 Plan. As of December 31, 2025, there were 1,290,951 shares reserved for outstanding awards and 1,632,381 shares available for issuance under the 2024 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 in arrears of $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 in arrears of $12,500 in cash and $22,500 in common stock. Prior to May 9, 2024 in the periods presented in this report, non-employee director equity compensation was issued from the Non-Employee Director Compensation Plan. From and after May 9, 2024 non-employee director equity compensation is issued from the 2024 Plan. All payments were and are pro-rated for partial service.

Restricted stock units ("RSUs") and performance share units ("PSUs") are equity classified and measured at the fair value of the underlying stock at the grant date.

Index to Financial Statements

In 2025 the Company issued PSU's to certain employees and measured the fair value of the PSUs using a Monte Carlo simulation valuation model. The risk-free interest rate used was 3.93%, which was based on the US treasury yield consistent with the contractual term of the awards. The expected volatility was a blended volatility rate of 48.78%, which incorporated both the Company's observed equity volatility and the relevant guideline company volatility.

Shares of stock granted for non-employee director fees are recorded at the fair value of the shares at the grant date.

The per share weighted average fair value of stock options granted during the years ended December 31, 2025 and December 31, 2024 was $2.21 and $1.44, 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, 2025 and December 31, 2024. 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.

Time-Vesting Stock Options

The following table summarizes the inputs into the Black-Scholes model for all time-vesting stock options granted during the year ended December 31, 2025.

	December 31, 2025
Dividend yield	0.00%
Expected Volatility	60.50% - 68.95%
Expected dividends	—
Expected term (in years)	6.25
Risk-free rate	3.90% - 4.16%

The following table summarizes the status of the time-based stock options outstanding at December 31, 2025:

	Shares	**Weighted Average Exercise Price**
Outstanding at January 1	2,687,024	3.07
Granted	834,445	3.38
Exercised	(126,783)	2.57
Forfeited	(274,508)	2.25
Outstanding at December 31	3,120,178	3.25
Options exercisable at December 31	1,878,721	3.38

Total stock-based compensation expense for time-vested stock options was $1,002,555 and $1,530,446 for the years ended December 31, 2025, and 2024, respectively. $186,165 and zero was received from option exercises for the years ended December 31, 2025, and 2024, respectively. As of December 31, 2025, the intrinsic value of all outstanding time-based stock options was $8,222,085.

The following table presents information pertaining to time-based stock options outstanding at December 31, 2025:

Range of Exercise Price	**Number Outstanding**	**Weighted Average**	**Weighted Average**	**Number Exercisable**	**Weighted Average**

		Remaining Contractual Life	Exercise Price		Exercise Price
$2.08 - $3.98	3,120,178	7.1 years	$ 3.25	1,878,721	$ 3.38

As of December 31, 2025, there was $2,157,602 of total unrecognized compensation cost related to time-vested stock option awards granted under the Plans. That cost is expected to be recognized over a weighted-average period of 24 months.

Performance-Vesting Stock Options

The following table summarizes the activities for our unvested performance-vesting stock option awards for the year ended December 31, 2025.

	Shares	Weighted Average Grant-Date Fair Value
Outstanding at January 1	155,334	$ 1.48
Granted	—	—
Exercised	(22,000)	1.48
Vested	—	—
Forfeited/canceled	(133,334)	1.48
Unvested at December 31	—	$ —

Total stock-based compensation expense for performance-vesting stock options was $0 and $21,778 for the years ended December 31, 2025, and 2024, respectively. No cash was received from the exercise of performance-vesting stock options for the years ended December 31, 2025, and 2024.

As of December 31, 2025, there was $0 of unrecognized compensation cost related to unvested employee performance options.

Restricted Stock Awards, RSUs, and PSUs

The following table summarizes the activities for our unvested restricted stock awards, RSUs, and PSUs for the year ended December 31, 2025.

	Shares	Weighted Average Grant-Date Fair Value
Unvested at January 1	1,269,937	$ 2.54
Granted	745,399	3.59
Vested	(199,750)	3.06
Forfeited/canceled	(93,439)	2.30
Unvested at December 31	1,722,147	$ 2.99

Total stock-based compensation expense for restricted stock awards, RSUs, and PSUs was $1,201,874 and $579,519 for the years ended December 31, 2025, and 2024, respectively.

As of December 31, 2025, there was $2,582,766 of unrecognized compensation cost related to unvested employee restricted stock awards, RSUs, and PSUs. This amount is expected to be recognized over a weighted-average period of 25 months.

NOTE 5 — DEBT OBLIGATIONS

On March 8, 2024, the Company entered into a loan and security agreement with a large domestic banking institution, 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. On March 31, 2025 the loan and security agreement was amended to extend the maturity of the revolving credit facility to December 31, 2026 and the interest-only portion of the term loan facility to October 1, 2026. In addition, certain other covenants were also modified. On December 24, 2025, the loan and security agreement was further amended to extend the term loan availability date through March 31, 2026 with a new maturity date of December 1, 2028. As of December 31, 2025, there were no outstanding borrowings under the term loan nor the revolving credit facility.

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 October 1, 2026, followed by 27 equal monthly payments of principal plus interest.

In connection with our loan financings agreement dated March 8, 2024, the Company issued common stock warrants to the lender. The fair value of each warrant was estimated on the date of the grant using the Black-Scholes option-pricing model. All options and warrants were charged against income at their fair value. The entire compensation expense of the grant was recognized over the vesting period.

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), which was modified in 2025, of not less than 1.25 to 1.00 tested on the last day of each calendar quarter.

On July 16, 2025, the Company renewed its commercial insurance premium finance and security agreement with its insurance provider, with an aggregate principal amount of the note of $406,751, for the insurance period covering July 1, 2025 through June 30, 2026. On December 28, 2025 the Company executed its option to repay the remaining balance of note, without penalty, in the amount of $262,584.

NOTE 6 — LEASES

We have finance and operating leases for our corporate office and certain office, vehicles, and computer equipment.

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" 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" 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,	
	2025	**2024**
Operating lease cost	$ 533,979	$ 487,960
Short-term lease cost	6,086	5,952
Total lease cost	$ 540,065	$ 493,912

Finance lease cost:		
Amortization of right-of-use assets	$ 117,898	$ 115,585
Interest on lease liabilities	12,001	21,896
Total finance lease cost	$ 129,899	$ 137,481

Supplemental cash flow information related to leases was as follows:

	Years Ended December 31,	
	2025	**2024**
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 524,625	$ 501,214
Financing cash flows from finance leases	$ 131,437	$ 131,437

Index to Financial Statements

Supplemental information related to leases was as follows:

	December 31, 2025	**December 31, 2024**
Weighted Average Remaining Lease Term		
Operating leases	6.57 Years	5.1 Years
Finance leases	1.67 Years	2.7 Years
Weighted Average Discount Rate		
Operating leases	4.13%	6.52%
Finance leases	4.74%	6.34%

Maturities of lease liabilities are as follows:

Year Ending December 31,	**Operating Leases**	**Finance Leases**
2026	539,329	131,437
2027	554,475	74,194
2028	557,286	6,178
2029	553,759	—
Thereafter	1,554,382	—
Total undiscounted lease payments	3,759,231	211,809
Less: imputed interest	(466,559)	(8,221)
Total lease liabilities	$ 3,292,672	$ 203,588

NOTE 7 — FEDERAL AND STATE INCOME TAXES

Domestic and international pre-tax income/(loss) consists of the following:

	Year Ended December 31, 2025	**Year Ended December 31, 2024**
United States	$ (2,616,036)	$ (6,063,740)
Loss before income taxes	$ (2,616,036)	$ (6,063,740)

Income tax expense attributable to operations is comprised of the following:

	Year Ended December 31, 2025	**Year Ended December 31, 2024**

Current:		
Federal	$ (1,276)	$ —
State	(20,614)	(2,893)
International	—	—
Total Current	(21,890)	(2,893)
Deferred:		
Federal	—	—
State	—	—
International	—	—
Total Deferred	—	—
Income Tax Expense	$ (21,890)	$ (2,893)

Index to Financial Statements

Deferred income taxes reflect the net tax effects of temporary differences between carrying amounts of assets and liabilities for financial reporting purposes and the amounts for income tax purposes. Significant components of our deferred tax assets and liabilities are as follows:

	December 31, 2025	December 31, 2024
Deferred Tax Assets:		
Net Operating Loss	$ 4,984,118	$ 4,025,905
Credits	113,204	129,598
Capitalized Research Costs	1,276,364	2,451,496
NQO & RSA Stock Options	517,418	350,484
Deferred Lease Liability	830,800	647,446
Accruals & Reserves	694,279	712,058
Other	—	48
Gross Deferred Tax Asset	8,416,183	8,317,035
Valuation allowance	(7,053,948)	(7,080,843)
Total Deferred Tax Asset	$ 1,362,235	$ 1,236,192
Deferred Tax Liabilities:		
Intangibles	(61,596)	(58,170)
ROU Assets	(747,412)	(538,632)
Fixed Assets	(553,227)	(639,390)
Total Deferred Tax Liabilities	(1,362,235)	(1,236,192)
Net Deferred Tax Asset	$ —	$ —

Management regularly assesses the ability to realize deferred tax assets recorded based upon the weight of available evidence, including such factors as recent earnings history and expected future taxable income on a jurisdiction by jurisdiction basis. In the event that the Company changes its determination as to the amount of realizable deferred tax assets, the Company will adjust its valuation allowance with a corresponding impact to the provision for income taxes in the period in which such determination is made. The Company's management believes that, based on a number of factors, it is more likely than not, that all or some portion of the deferred tax assets will not be realized; and accordingly, for the year ended December 31, 2025 the Company has provided a full valuation allowance against the Company's U.S. net deferred tax assets. The net change in the valuation allowance for the year ended December 31, 2025 was a decrease of $26,895.

As of December 31, 2025, the Company had net operating loss carryforwards for federal and state income tax purposes of approximately $22,514,225 and $4,393,561, respectively. The state net operating loss carryforwards will begin to expire in 2041 and our federal net operating loss carryforward will last indefinitely.

As of December 31, 2025, the Company had federal and state research credit carryforwards of approximately $113,204 and $0 respectively. The federal research credit carryforwards will begin to expire in 2036.

As of December 31, 2025, and 2024 the Company had no gross unrecognized tax benefits. The Company's policy is to recognize accrued interest and penalties related to unrecognized income tax benefits in the Provision for income taxes should such amounts

occur in future periods.

The Company files income tax returns in the US federal and various state jurisdictions with varying statutes of limitations. Tax years 2022 through 2024 are open to examination by major taxing jurisdictions to which the Company is subject.

Index to Financial Statements

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes for years prior to the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2024
Federal tax at statutory rate	$ 1,272,820
State income taxes	184,595
Valuation allowance	(1,078,066)
Deferred tax true ups	(352,653)
Other items	(29,589)
Total	(2,893)

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to income before income taxes for years after the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2025	Percent
Federal tax at statutory rate	$ 549,368	21.0%
State and Local Income Taxes (1)	(20,614)	(0.8%)
Nontaxable or Nondeductible Items		
Stock Based Compensation	(41,305)	(1.6%)
Other	(99,899)	(3.8%)
Change in Valuation Allowance	(146,633)	(5.6%)
Deferred tax true ups	(262,807)	(10.0%)
Total	**(21,890)**	**(0.8%)**

(1) State Taxes in Texas made up the majority (greater than 50%) of the tax effect in this category

The amount of cash income taxes paid by the Company were as follows:

	Year Ended December 31, 2025
Federal	**$** 5,000
State and Local	
Pennsylvania	9,200
All other State and Local	650
Total	14,850

The Company did not pay any income tax during the year ended December 31, 2024.

NOTE 8 — MAJOR CUSTOMERS

For the years ended December 31, 2025 and December 31, 2024, approximately 56% and 64%, respectively, of the Company's net product revenues were derived from three major customers that are distributors. As of December 31, 2025 and December 31, 2024, accounts receivable due from the three major customers was $3.7 million and $3.6 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.

Index to Financial Statements

NOTE 9 — COMMITMENTS AND CONTINGENCIES

LEGAL PROCEEDINGS

The Company has been and may again become involved in legal proceedings, claims and litigation arising in the ordinary course of business. 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 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.

The Manufacturing and Supply Agreement originally provided for a term of five years from the Effective Date. On November 19, 2025, the Manufacturing and Supply Agreement was amended and restated effective January 1, 2024. The amended and restated agreement expires by its terms on December 31, 2026, and will automatically renew for successive one-year periods unless one party elects not to renew in accordance with the terms of the agreement. Either party may terminate the agreement upon a material breach by the other party that has not been cured within 45 days, upon the bankruptcy or insolvency of the other party or as otherwise expressly set forth in the agreement. The other terms of the amended and restated agreement are substantially the same as the original agreement, but now include a rebate for the Company based on annual qualified purchases from Command.

NOTE 10 — EMPLOYEE BENEFITS

We provide a safe harbor 401(k) plan for our employees that allows for employee elective contributions, Company matching contributions and discretionary profit-sharing contributions. Employee elective contributions are funded through voluntary payroll deductions. The Company makes safe harbor matching contributions in an amount equal to 100% of the employee's contribution, not to exceed 3% of employee's compensation plus 50% of employee's pay contributed between 3% and 5% of employee's compensation. Company matching expense for the years ended December 31, 2025 and December 31, 2024 was $330,014 and $262,915, respectively. The Company has not provided for a discretionary profit-sharing contribution.

NOTE 11 — SEGMENT DISCLOSURE

The Company's operations are based in, and revenues are predominately derived from, the United States, and business activities are managed on a consolidated basis. The Company operates in one reportable segment.

The Company's Chief Executive Officer is the Chief Operating Decision Maker ("CODM"). The CODM regularly reviews disaggregated revenue data by product line. However, consolidated net income is utilized as a measure of profit and loss to assess the performance of the business and to determine how to allocate resources. Significant expenses within net income include cost of goods sold, selling, general and administrative, research and development, and depreciation and amortization, which are each separately presented on the Company's Statements of Operations. Segment asset information is not used by the CODM to allocate resources.

NOTE 12 — SUBSEQUENT EVENTS

The Company imports certain materials and products that are subject to U.S. government tariffs and import duties. Subsequent to year-end, a federal court ordered the U.S. government to begin refunding certain tariffs. The Company believes that some of the tariffs it has paid may be eligible for refund; however, the amount and timing of any potential refunds are uncertain. Accordingly, the Company has not recorded, nor plans to record, any benefit related to possible tariff refunds at this time.

Table of Contents

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, 2025. Based on that evaluation, our management, including our CEO and CFO, concluded that as of December 31, 2025, 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 (as defined in Rule 13a-15(f) under the Exchange Act). 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, 2025. 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, 2025, 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, 2025, 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 under the caption "2026 Annual Meeting of Shareholders" relating to our 2026 Annual Meeting of Shareholders ("2026 Proxy Statement"), which is to be filed no later than 120 days after December 31, 2025, and is incorporated herein by reference. Information concerning the composition of the Audit Committee and our Audit Committee financial expert is contained in our 2026 Proxy Statement under the caption "The Board and Committees of the Board – Committee Membership and Function – Audit Committee" and is incorporated herein by reference. Information on beneficial ownership reporting compliance will be contained under the caption "Delinquent Section 16(a) Reports", if applicable, in our 2026 Proxy Statement 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 2026 Proxy Statement relating to our 2026 Annual Meeting of Shareholders and is incorporated herein by reference. Our Code of Ethics is posted on our website at www.korumedical.com under the heading "Investors – Governance". Printed copies of the Code of Ethics may be obtained, without charge, by contacting the Corporate Secretary, KORU Medical Systems, Inc., 100 Corporate Drive, Mahwah, NJ 07430; telephone 800-624-9600. 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. Information about the Company's insider trading policy is contained in our 2026 Proxy Statement under the caption "Corporate Governance – Insider Trading Policy" and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information required by Item 11 of Part III is included in our Proxy Statement relating to our 2026 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 2026 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 2026 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 2026 Annual Meeting of Shareholders and is incorporated herein by reference.

Table of Contents

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)	Amended and Restated By-laws of KORU Medical Systems, Inc., effective February 5, 2026 (incorporated by reference to our Form 8-K filed with the SEC on February 10, 2026).
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 pursuant to the 2015 Stock Option Plan and the 2021 Omnibus Equity Incentive Plan (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 pursuant to the 2015 Stock Option Plan and the 2021 Omnibus Equity Incentive Plan (incorporated by reference to the Company's Form 10-K filed with the SEC on March 23, 2021).
10.5	2024 Omnibus Equity Incentive Plan (incorporated by reference to the Company's Proxy Statement on Schedule 14A filed with the SEC on March 28, 2024).
10.6	Long-Term Incentive Program (incorporated by reference to the Company's Form 8-K filed with the SEC on August 21, 2024).
10.7	Form of Performance Share Unit Award Agreement pursuant to the 2024 Omnibus Equity Incentive Plan.**
10.8	Form of Restricted Stock Unit Award Agreement pursuant to the 2024 Omnibus Equity Incentive Plan.**
10.9	Form of Non-Qualified Stock Option Award Agreement pursuant to the 2024 Omnibus Equity Incentive Plan.**
10.10	Non-Employee Director Compensation (incorporated by reference to the Company's Proxy Statement on Schedule 14A filed with the SEC on March 18, 2022).
10.11	Amended and Restated Manufacturing and Supply Agreement dated as of November 17, 2025 between KORU Medical Systems, Inc. and Command Medical Products (incorporated by reference to the Company's Form 8-K filed with the SEC on November 25, 2025). Certain information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.
10.12	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).* †
10.13	Amended and Restated Employment Agreement effective as of July 18, 2024 between KORU Medical Systems, Inc. and Christopher Pazdan (incorporated by reference to the Company's Form 8-K filed with the SEC on July 24, 2024).* †

Table of Contents

Exhibit No.	Description
10.14	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).*
10.15	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).* †
10.16	Employment Agreement effective as of June 30, 2025 between KORU Medical Systems, Inc. and Adam Kalbermatten (incorporated by reference to the Company's Form 10-Q filed with the SEC on August 6, 2025).*
10.17	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).
10.18	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).+
10.19	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).

19	KORU Medical Systems, Inc. Amended and Restated Insider Trading Policy.**
23.1	Consent of Cherry Bekaert LLP.**
24.1	Power of Attorney (included on the signature pages hereto)
31.1	Certification of the Principal Executive Officer of registrant required under Section 302 of the Sarbanes-Oxley Act of 2002.**
31.2	Certification of the Principal Financial Officer of registrant required under Section 302 of the Sarbanes-Oxley Act of 2002.**
32.1	Certification of the Principal Executive Officer of registrant required under Section 906 of the Sarbanes-Oxley Act of 2002.**
32.2	Certification of the Principal Financial Officer of registrant required under Section 906 of the Sarbanes-Oxley Act of 2002.**
97	Clawback Policy (incorporated by reference to the Company's Form 10-K filed with the SEC on March 12, 2025).
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.

+ 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.
** Filed herewith.

ITEM 16. FORM 10-K SUMMARY

None.

Table of Contents

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.

KORU MEDICAL SYSTEMS, INC.

Dated: March 12, 2026

/s/ Linda Tharby
Linda Tharby
President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENT, that each person whose signature appears below constitutes and appoints Linda Tharby and Thomas Adams, and each of them, acting individually, as her or his attorney-in-fact, each with full power of substitution

and resubstitution, for her or him and in her or his name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as she or he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or her or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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 and on the dates indicated.

Signature	**Title**	**Date**
/s/ Linda Tharby Linda Tharby	*President, Chief Executive Officer, Director* *(Principal Executive Officer)*	March 12, 2026
/s/ Thomas Adams Thomas Adams	*Chief Financial Officer and Treasurer* *(Principal Financial Officer and Principal Accounting Officer)*	March 12, 2026
/s/ R. John Fletcher R. John Fletcher	*Chairman of the Board and Director*	March 12, 2026
/s/ Edward Wholihan Edward Wholihan	*Director*	March 12, 2026
/s/ Robert A. Casella Robert A. Casella	*Director*	March 12, 2026
/s/ Joseph M. Manko, Jr. Joseph M. Manko, Jr.	*Director*	March 12, 2026
/s/ Shahriar Matin Shahriar Matin	*Director*	March 12, 2026
/s/ Donna French Donna French	*Director*	March 12, 2026