UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported) **January 13, 2025**

KORU Medical Systems, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**0-12305**	**13-3044880**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

100 Corporate Drive, Mahwah, NJ	**07430**
(Address of principal executive offices)	(Zip Code)

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

_____
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[_] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[_] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[_] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[_] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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**

Indicate by check mark whether the registrant is an emerging growth company as defined in as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. [_]

ITEM 2.02. RESULTS OF OPERATIONS AND FINANCIAL CONDITION.

(a) Public Announcement or Release.

On January 13, 2025, KORU Medical Systems, Inc. (the "Company") issued a press release announcing certain preliminary financial results for the fiscal quarter and year ended December 31, 2024. The Company's press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The preliminary financial results included in the press release are based on the Company's current estimate of its results for the fiscal quarter and year ended December 31, 2024, and remain subject to change based on the completion of closing and review procedures.

The information contained in this Item 2.02 of the Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as expressly set forth by specific reference in such filing.

ITEM 7.01. REGULATION FD DISCLOSURE.

On January 13, 2025, the Company posted an investor presentation, which may be accessed through the Company's investor relations website. A copy of the presentation is furnished herewith as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein. The Company expects to use the investor presentation, in whole or in part, and possibly with modifications, in connection with presentations to investors, analysts and others. The information contained in the investor presentation is summary information that is intended to be considered in the context of the Company's Securities and Exchange Commission filings and other public announcements. The investor presentation speaks only as of the date of this Current Report on Form 8-K. The Company undertakes no duty or obligation to publicly update or revise this information, although it may do so from time to time. Any such updating may be made through the filing of other reports or documents with the SEC, through press releases or other public disclosure.

The information contained in this Item 7.01 of the Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that Section, nor shall it be deemed to be incorporated by reference into any filing of the Company under the Securities Act, or the Exchange Act, except as expressly set forth by specific reference in such filing.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release, dated January 13, 2025
99.2	Investor Presentation dated January 2025
104	Cover Page Interactive Data File (embedded within the inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KORU Medical Systems, Inc.

(Registrant)

Date: January 13, 2025

By: /s/ Linda Tharby
Linda Tharby

President and Chief Executive Officer

EXHIBIT 99.1

KORU Medical Systems Reports Preliminary Fourth Quarter and Full Year 2024 Results; Achieves Record Full Year and Quarterly Revenues; Positive Cash Flow for the Fourth Quarter

MAHWAH, NJ – January 13, 2025 – KORU Medical Systems (NASDAQ: KRMD) ("KORU Medical" or the "Company"), a leading medical technology company focused on the development, manufacturing, and commercialization of innovative and patient-centric large volume subcutaneous infusion solutions, today announced preliminary unaudited results for the fourth quarter and full year ended December 31, 2024.

Financial Results (unaudited)

- Preliminary, unaudited fourth quarter 2024 net revenues expected to be $8.9 million, representing growth of 23% over the prior year period

- Preliminary, unaudited full year 2024 net revenues expected to be $33.7 million, representing growth of 18% over the prior year

- Ending cash balance of $9.6 million, representing positive cash flow of $0.8 million for the fourth quarter and full year cash burn of $1.9 million, a 67% improvement over the prior year

"I am proud of the growth that we have achieved in our fourth quarter and 2024 finish," said Linda Tharby, President and CEO of KORU Medical. "We executed on all aspects of our strategic plan as we continued to win share in the US market, expanded our international footprint, and made meaningful progress towards adding new drug therapies to our label. We did this as we continued to improve margins and demonstrated a disciplined use of cash. We are excited by our fourth quarter momentum that we will carry into 2025 as we look to capitalize on near-term catalysts that will continue to transform KORU into a global leader in drug delivery."

KORU plans to release its fourth quarter and full year 2024 financial results in early March 2025. The quarterly and annual preliminary revenue figures included in this press release are subject to adjustment following the completion of review and audit procedures by the Company's independent registered public accountants.

About KORU Medical Systems

KORU Medical Systems develops, manufactures, and commercializes innovative and patient-centric large volume subcutaneous infusion solutions that improve quality of life for patients around the world. The FREEDOM Syringe Infusion System (the "Freedom System") currently includes the FREEDOM60® and FreedomEdge® Syringe Infusion Drivers, Precision Flow Rate Tubing™ and HIgH-Flo Subcutaneous Safety Needle Sets™. The Freedom System, which received its first FDA clearance in 1994, is used for self-administration in the home by the patient and/or delivery in an ambulatory infusion center by a healthcare professional. Through its Novel Therapies business, KORU Medical provides products for use by biopharmaceutical companies in feasibility/clinical trials during the drug development process and, as needed, is capable of customizing the Freedom System for clinical and commercial use across multiple drug categories. For more information, please visit www.korumedical.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties, including but not limited to sales expansion into new regions. Actual results may differ materially from these statements due to potential risks and uncertainties such as those risks and uncertainties included under the captions "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 which is on file with the SEC and available on our website at www.korumedical.com/investors and on the SEC website at www.sec.gov. All information provided in this release and in the attachments is as of April 11, 2024. Undue reliance should not be placed on the forward-looking statements in this press release, which are based on information available to us on the date hereof. We undertake no duty to update this information unless required by law.

Investor Contact:
Louisa Smith
investor@korumedical.com

Exhibit 99.1

Freedom to Live Life Fully

KORU MEDICAL SYSTEMS

A Global Leader in Large-Volume Subcutaneous Drug Delivery

Nasdaq: KRMD

Corporate Overview

January 2025

Forward-Looking Statements

This presentation contains "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995 regarding our expectations for future performance, including but not limited to our preliminary financial results for fourth quarter and full year 2024, the existence and timing of potential drug/indication launches, the success and timing of our novel therapies collaborations, our commercial revenue opportunity, our key 2025 milestones, expansion of products into infusion clinics, future financial performance (including but not limited to revenue, CAGR, EBITDA Margin, gross margin and operational cash flow), our future product launches, and meeting our Vision 2026 goals. Forward-looking statements are neither historical facts nor assurances of future performance and based only on our current beliefs, expectations and assumptions. Forward-looking statements 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, you 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, the following: new SCIg patient starts, growth of the SCIG market, plasma supply, clinical trial activity, new drug launches, market penetration of prefill syringes; supply chain and labor availability and pricing; third party contractor execution; timely receipt of other receivable credits; inflationary impacts; ability to reduce inventory; success of geographic expansion; effects of war and other global conflict; introduction of competitive products; availability of insurance reimbursement; changes in U.S. Food and Drug Administration regulations; changes to health care policies; success of our research and development efforts; our ability to obtain financing or raise capital if or when needed; acceptance of and demand for new and existing products; expanded market acceptance of the FREEDOM Syringe Infusion System and any new product we introduce; our ability to obtain required governmental approvals; success in enforcing and obtaining patents; continued performance by principal suppliers; continued customer preference to work through distributors; continued service of key personnel and attracting and maintaining new personnel; and general economic and business conditions, as well as those risks and uncertainties included under the captions "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023, available on the SEC website at www.sec.gov [sec.gov] and on our website at www.korumedical.com/investors [korumedical.com]. Any forward-looking statement made by us 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.

Revenues: All references to revenue(s) in this presentation refer to net revenues.

Our Company

We **enable, simplify**, and **enhance** the delivery **of large-volume subcutaneous (LVSC) drugs** in the home and in the clinic

More Time For What Matters Most

KORU's Freedom Infusion System is a **global leader in large-volume (>10mL) drug delivery**

Capitalizing on the ongoing shift from intravenous (IV) hospital settings to **subcutaneous (SC) therapy in the home and in infusion clinics**

Our subcutaneous Freedom Infusion System is, today, primarily used by **40,000 chronic, recurring** subcutaneous immunoglobulin (SCIg) drug therapy patients

Expanding our market beyond SCIg via 9 current collaborations with pharmaceutical companies to bring **new drug therapies** onto our label

Leveraging a low cost go-to-market model by serving pharmaceutical companies, specialty pharmacies, home care networks, and distributors

Our Company

KORU at a Glance

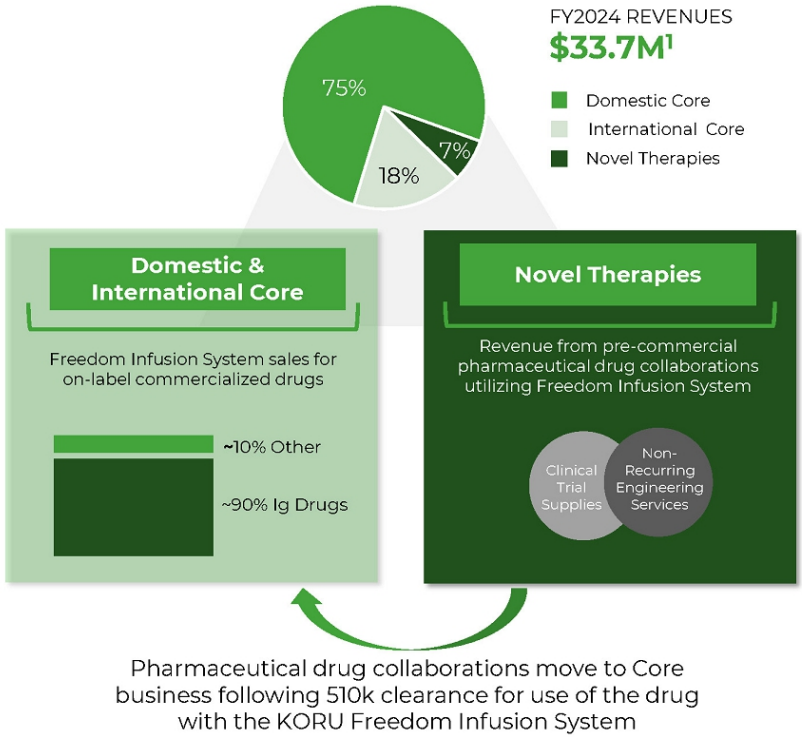
FREEDOM INTEGRATED INFUSION SYSTEM
70+ Global Patents

DRUG CLEARANCES / REGISTRATIONS
8 Drugs / 36 Countries
First Subcutaneous Drug Clearance 2010

FY 2024 REVENUES
$33.7M[1]; 18% y/y growth
75%+ Recurring

FY24 CASH BURN < $2M*, $10M UNDRAWN DEBT FACILITY IN PLACE
$9.6M Cash Balance[1]

HEADQUARTERS/MANUFACTURING
Mahwah, NJ



Pharmaceutical drug collaborations move to Core business following 510k clearance for use of the drug with the KORU Freedom Infusion System

KORU 1. As of Press Release published on January 13, 2025 with FY 2024 Preliminary Results, which are subject to change

Our Company

KORU's Freedom Infusion System

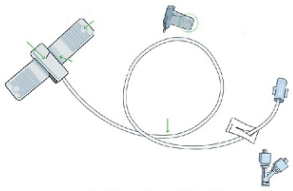
Mechanical Pumps
~20% of revenues

Freedom60® INFUSION SYSTEM

FreedomEDGE® INFUSION SYSTEM

Customizable Consumables
~80% of revenues

Precision™ FLOW RATE TUBING



High-Flo™ SUBQ NEEDLE SET

Simple, Easy-to-use, Reusable mechanical pump

8 On-label SC drugs[1]

2M+ annual infusions, 40k+ recurring chronic patients (ages 6-93)

97% Patient adherence rate[2]

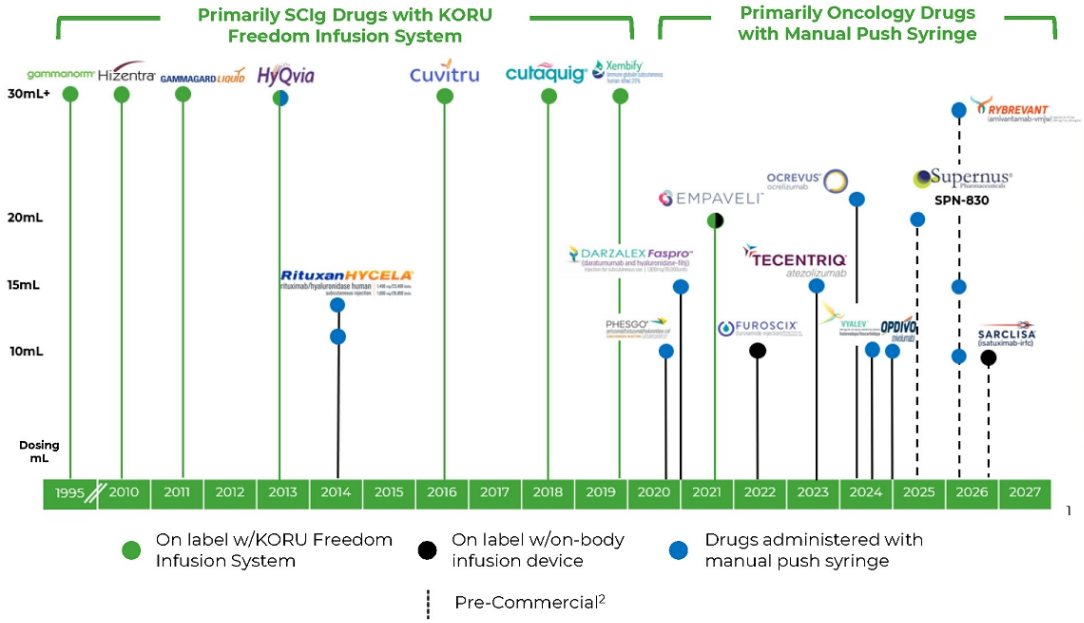
Customizable platform for use with LVSC drugs

Registered in 36 countries

1. Includes CSL Hizentra, Octapharma Cutaquig and Gammanorm, Takeda Cuvitru, Hyqvia and Gammagard Liquid, Grifols Xembify, and Apellis Empaveli 2. Rutland B, Basshard J, Southworth C. Enhancing Drug Adherence and Patient Outcomes: The Role of SCIG Pump Selection in Subcutaneous Immunoglobulin Therapy for Primary Immunodeficiency Disease. Poster presented at: National Home Infusion Association Annual Conference; March 23-27, 2024; Austin TX.

SC Landscape

Shift from IV to SC is Driving a Sizeable and Growing Market of Large-Volume Subcutaneous (LVSC) Opportunities



7 LVSC drugs have launched between 2010-2019, 6 of which were in the Ig drug class and approved with the KORU Freedom Infusion System

Between 2020-2025, 8 drugs have launched, and the LVSC market has diversified, primarily in oncology

There are multiple new drugs in the clinical pipeline as pharma companies are increasingly adding SC formulations

1. Third Party Data on File 2. Timing based on pharma company estimates

KORU's Opportunity

KORU is Well Positioned to Capitalize on the Expanding SC Market Opportunity

Market Proven Freedom Infusion System

Proven system with 15+ years on market; 2M+ infusions annually, underlying market growing 8-9%[1]

Simple, reusable and fully reimbursed system with 97% adherence rate and 8 on-label SC drugs

Thousands of trained healthcare professionals to enable transition from hospital to home

Efficient, Scalable Go-to-Market Strategy

SC drug prescriptions driven by pharma companies; allows efficient scaling without related spend for KORU

KORU manufactures and sells to distributors who market directly to specialty pharmacies and homecare networks

Razor-Razor Blade Model; 75%+ Recurring Revenue

Pump hardware lasts 3+ years; disposable SC infusion consumable sets used weekly and drive recurring revenue

Consumables compatible with mechanical and e-pumps

$2.7B TAM with Ig and New Drug Indications

Fully customizable system to accommodate any SC drug above 10ml with proven safety and commercial success

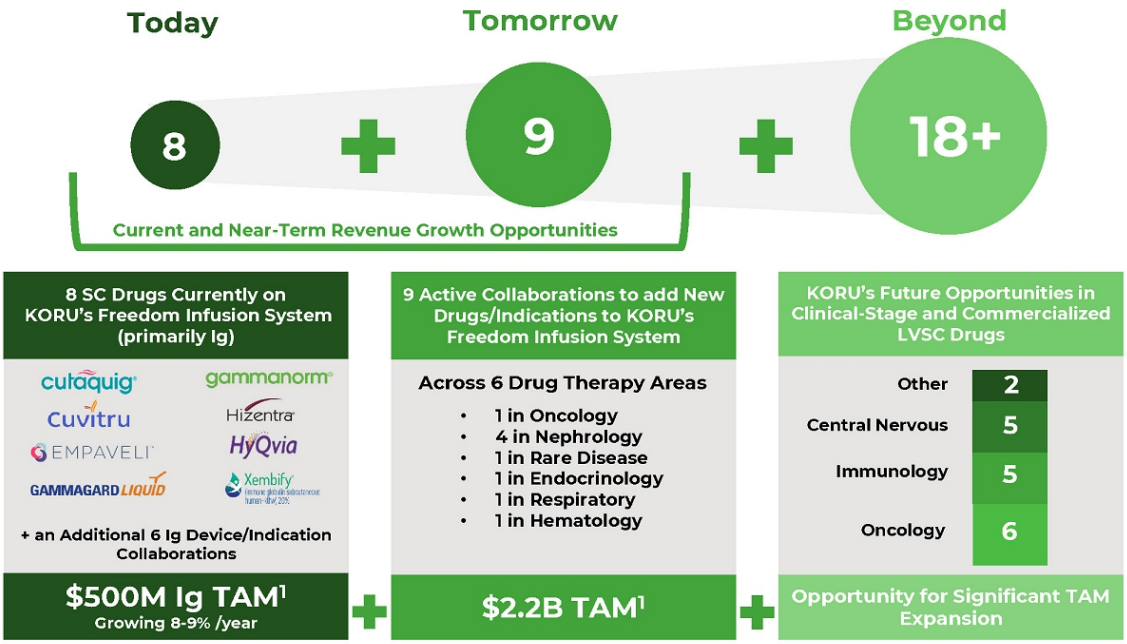
Expanding beyond $500M global Ig market with new drug therapy areas adding additional $2.2B in TAM[2]

5 launched oncology infusion clinic drugs using manual syringe push method of delivery present further opportunity

1. KORU Medical Estimates and Third-Party Data on File 2. TAM based on patient population, expected treatment frequency. Not adjusted for clinical risk

KORU's Opportunity

$2.7B[1] Total Addressable Market Opportunity with Growing SCIg Market and Expansion to New Drug Therapies



KORU

1.TAM based on patient population, expected treatment frequency. Not adjusted for clinical risk

KORU's Opportunity

Strategic Growth Pillars

		Key Drivers
3 ~$2.2B TAM[1]	**Add New Drugs on Label Through Novel Therapies Pipeline** **5 new SC Drugs expected to be commercialized and added to KRMD label by 2027**	**Novel Therapies Pipeline** • 5 new drug approvals expected by 2027 • 9 current new drug collaborations • Entering infusion clinics in 2025 • 15 pipeline opportunities
2 ~$265M TAM[1]	**Expand Internationally** **10% market share, growing at or above market rates (8-9%)[2] with multiple opportunities for growth**	**International Ig** • Multiple top-10 new market entries and increased market penetration • Increased SCIg new patient starts • Pre-filled syringe launches • Next-gen pump and consumables launch • Pharmaceutical partnerships for new indications/devices driving share expansion • Broader partnerships
1 ~$235M TAM[1]	**Defend & Grow Leadership Position in Domestic Subcutaneous Ig** **Strong base business with leading market share[1], growing at or above market rates (8-9%)[2] targeting additional market share capture**	**Domestic Ig** • Increased SCIg new patient starts • Continued shift towards pre-filled syringes • Next-gen pump and consumables launch • Pharmaceutical partnerships for new indications/devices driving share expansion • New market entries

KORU's Opportunity

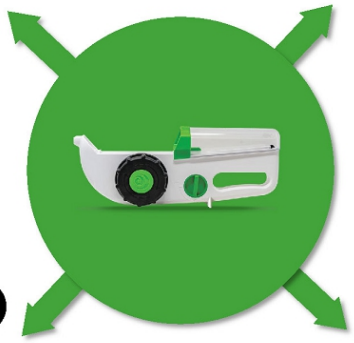
Global Ig Business Drives Annual Recurring Revenue Base

Global Patient Base

40k Patients using the KORU Freedom Infusion System today, representing 2M+ annual recurring infusions

Current 510k Clearances

8 SCIg drugs from 5 major pharmaceutical manufacturers cleared for use on the KORU Freedom Infusion System



Chronic Disease with Weekly Recurring Treatments

Chronic disease (PIDD, CIDP, etc.) patients receive SCIg doses 1-2x per week for the remainder of their lives

6 New Ig Pharmaceutical Collaborations

New indications and devices give us opportunity to expand our market share and geographic reach

- **$500M TAM[1]** — Global Ig market totals $500M TAM; 20% penetrated by SC (vs 80% IV)
- **8-9% Market growth[2]** — SCIg Market is growing 8-9% year; an additional 4k patients begin treatment protocol annually
- **≈$750-$1,000 Annual revenue per patient** — Recurring revenue generated by each Ig patient on the KORU Freedom Infusion System; based on 1x pump sales + weekly consumables

KORU

1. TAM based on patient population, expected treatment frequency. Not adjusted for clinical risk 2. KORU Medical Estimates and Third-Party Data on File

KORU's Opportunity

Active Pharmaceutical Collaborations Lead to $2.7B[1] TAM

15 Total Opportunities | **6** Commercial Opportunities by 2026 | **$2.7B**[1] Addressable Market Combined

Immunology New Indications/New Devices

Asset	Drug Trial Phase	Next Step	Expected KRMD Clearance[2]	Patient Population (000s)
Ig Device	Launched	KRMD 510k	2026	
Ig Device	Launched	KRMD 510k	2026	
Ig Device	Launched	KRMD 510k	2026	
Ig Drug	●●●	Complete Phase III	2026	630
Ig Drug	●●●	Complete Phase III	2027	
Ig Drug	●○○	Entry to Phase II	2027/28	

Opportunity for Increased Market Share and Geographic Penetration in Ig

New Drug Potential Launches

Asset	Drug Trial Phase	Next Step	Expected KRMD Clearance[2]	Patient Population (000s)	Est. Total Annual Infusions[3]
Rare Disease Biologic	Launched	KRMD 510k	2025	65	~100k
Nephrology Drug	●●●	Complete Phase III	2025	3	~20k
Oncology Drug	Launched	KRMD 510k	2025/26	500	~800k
Nephrology Drug	●●●	Complete Phase III	2027	30	~300k
KIRA (PNH)	●●●	Entry to Phase III	2027/28	133	TBD
Endocrinology Drug	●●●	Complete Phase III	2028	10	TBD
Respiratory Drug	●●○	Complete Phase II	2028/29	239	TBD
KIRA (IgAN)	●●○	Complete Phase II	2029/30	540	TBD
KIRA (C3G)	●●○	Complete Phase II	2029/30	2	TBD

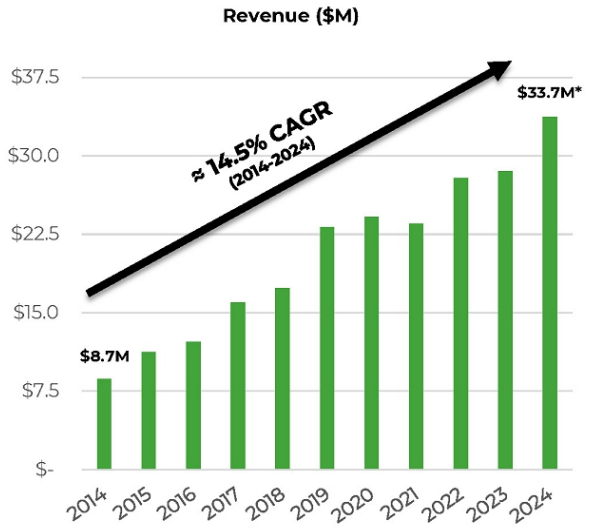
Commercial Revenue Opportunity from New Drugs and Indications on our Label

KORU

1.TAM based on patient population, expected treatment frequency. Not adjusted for clinical risk 2. Clearance and launch dates are based on most recent estimation and are subject to change 3. Annual infusions are estimates at 3 years post drug launch

Financials & Outlook

Financial Highlights



2024 Revenue*
$33.7M; 18% y/y growth

14.5% Revenue CAGR*
More than tripled size of Company in 10 years

Cash Flow Positive in Q4 2024*
FY24 cash burn of <$2M, a 67% improvement from '23-'24

Cash & Cash Equivalents*
$9.6M cash on hand, $10M undrawn debt facility in place

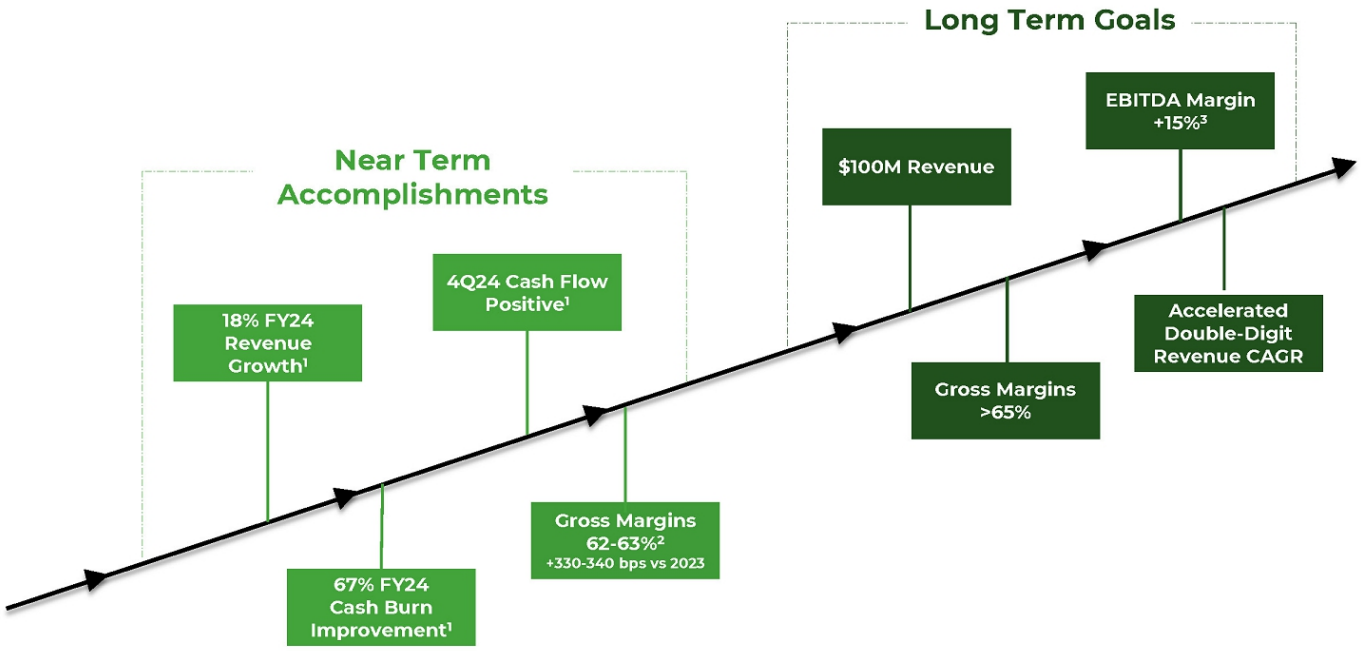
Q3 2024 Financial Highlights

	YTD 3Q24	YTD 3Q23	Y/Y Δ
Revenue	$24.8M	$21.3M	16.3% growth
Gross Margin	63.6%	58%	560bps growth
OpEx	$20.6M	$20.4M	1% increase
Net Loss	($4.5M)	($6.3M)	28% improvement
EPS	($0.10)	($0.14)	29% improvement
Cash Burn	($2.7M)	($6.6M)	60% improvement

* As of Press Release published on January 13, 2025 with FY 2024 Preliminary Results, which are subject to change

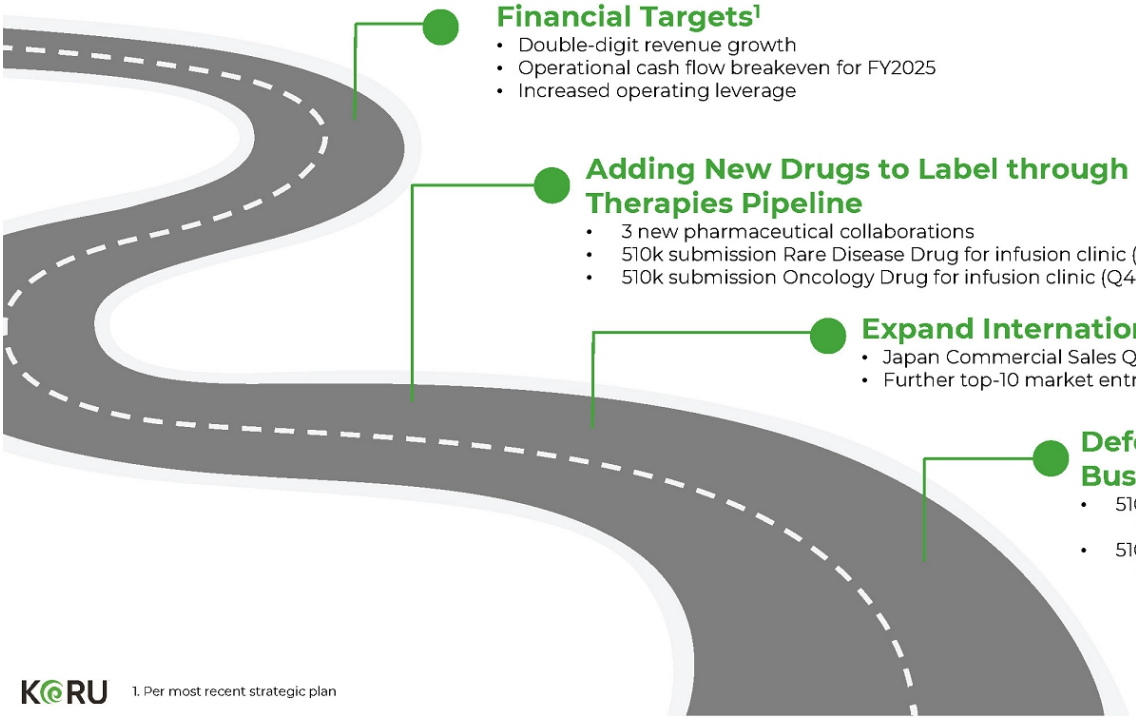
Financials & Outlook

Financial Profile



Financials & Outlook

Key 2025 Milestones



Financial Targets[1]

- Double-digit revenue growth
- Operational cash flow breakeven for FY2025
- Increased operating leverage

Adding New Drugs to Label through Novel Therapies Pipeline

- 3 new pharmaceutical collaborations
- 510k submission Rare Disease Drug for infusion clinic (Q2 – Q4 2025)
- 510k submission Oncology Drug for infusion clinic (Q4 2025 – Q1 2026)

Expand Internationally

- Japan Commercial Sales Q1 2025
- Further top-10 market entries

Defend and Grow Core SCIg Business

- 510k submission new consumables
  - (Q2 – Q4 2025)
- 510k submission new pump
  - (Q4 2025 – Q1 2026)

KORU

1. Per most recent strategic plan

Our Company

Strong Foundation; Experienced Pharma and MedTech Leadership Team Focused on Execution

- 44,000 sq. ft. Facility:
  - Class 8 cleanrooms
  - Controlled manufacturing environment
  - R&D laboratory space
  - In-house distribution center
- ISO 13485/MDSAP/EU MDR Certified Quality Management Systems
- Successful Notified Body and Pharmaceutical customer audit outcomes

LINDA THARBY
Chief Executive Officer & President

TOM ADAMS
Chief Financial Officer

KEN MILLER
Chief Commercial Officer

CHRIS PAZDAN
Chief Operating Officer

BRENT RUTLAND
Vice President of Medical Affairs

BRIAN HERTZOG
Vice President of Biopharma Business Development

Baxter BD Pfizer Roche Nemera McKESSON La Jolla Pharmaceutical

KORU Medical

Investment Highlights

1. **Macro tailwinds** driving adoption of subcutaneous therapy; 18+ large-volume SC drugs in development by major Pharma companies in multiple indications
2. **Double-digit growth** across all businesses; Domestic Core, International Core, and Novel Therapies
3. **Strong underlying SCIg market**; gaining greater market share domestically and **expanding into other top-ten global markets**
4. **6 potential commercial opportunities (drugs, indications, and devices) by 2026**; oncology and rare disease indications will **expand our presence outside of the home and into infusion clinics**
5. **Cash flow positive in 4Q24**; operational cash flow positive in 2025