

# **KORU Medical Systems**

Q1 2025 Earnings Call May 7, 2025

# **Forward Looking Statements**

This presentation contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve risks and uncertainties. All statements that are not historical fact are forward-looking statements, including, but not limited to, timing of 510(k) clearances and financial guidance for fiscal 2025.

Forward-looking statements discuss the Company's current expectations and projections relating to its financial position, results of operations, plans, objectives, future performance, and business. Forward-looking statements can be identified by words such as "guidance", "expect", "plan", "believe" and "will". Actual results may differ materially from the results predicted and reported results should not be considered as an indication of future performance.

The potential risks and uncertainties that could cause actual results to differ from the results predicted include, among others, uncertainties associated with SCIg market growth, prefilled syringe penetration, plasma supply, clinical trial activity and success, approval and commercialization of new drug indications, the shift to increased healthcare delivery in the home, new patient diagnoses, customer ordering patterns, global health crises, innovation and competition, labor and supply price increases, inflationary impacts, labor supply, tariffs and those risks and uncertainties included under the captions "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, which are 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 May 7, 2025. 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.

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



# Strong First Quarter Results Highlight Strategic Progress

- Q1 revenues of \$9.6 million, 18% growth over the prior year period
- Core business growth of 21% driven by recurring revenues, new patient starts, share expansion, and geographic expansion
- 3 Announcing plans to submit for FDA 510(k) clearance with 2 commercialized drugs on the Freedom Infusion System™ in 2025



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Improved gross margin to 62.8%, an increase of 50 basis points



Raising 2025 revenue guidance to \$38.5-\$39.5M, 15%-17% growth, reaffirming 61%-63% gross margins, and positive cash flow from operations for full year 2025



# **KORU's Vision for Accelerated Expansion**

## More Time For What Matters Most



### KORU's Freedom Infusion System is a **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 **45,000 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



# Strong Execution Across All Three Strategic Growth Pillars

Defend and Grow Leadership Position in Domestic SCIg Core

**Domestic Core performance** Q1 16% y/y revenue growth; 6 quarters of sequential growth

### Double digit SCIg market growth<sup>1</sup>

10% y/y SCIg growth 9 consecutive quarters of growth

#### **Expanding market share**

Capturing new chronic Ig patients and new accounts

**Expand Internationally** 

International Core performance Q1 36% y/y growth

**Strong SCIg growth** Continued new patient starts

New geographic entries Including MENA

Expanded prefilled syringe (PFS) opportunity Key PFS tender win in Q1; Ongoing market shift towards PFS in EU New Drugs on Label Through Pharmaceutical Services and Clinical Trials (PST)

**15 pharma collaborations in total** 2 added YTD in 2025

Announcing 2 new 510(k) submissions Iron chelation and antibiotic drug; 2025 expected submission

#### 9 upcoming opportunities

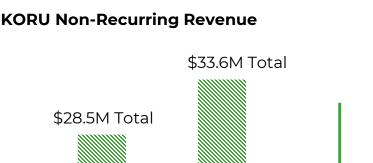
With potential to launch by end of 2026

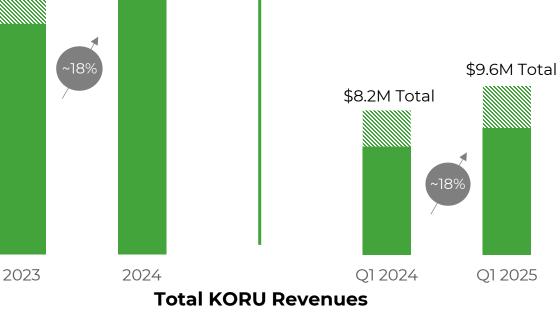


#### **Future Catalysts**

# **Recurring Revenues Supported by Strong Underlying SCIg Market Growth**







### Strong Recurring Base that is Expected to Grow

~75% of KORU's revenue is recurring Removing initial 1x sale of pumps and Novel Therapies service revenue

#### **Recurring SCIg patient base**

~45k+ KORU chronic SCIg patients ~2M+ KORU annual infusions

#### KORU outperforming market growth<sup>1</sup>

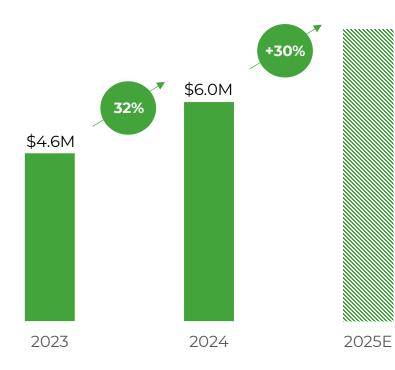
10-11% US SCIg Growth Outperformance driven by share gains and new market entries



# Rapidly Expanding International Business

**Robust Growth Since Inception of International Core Strategy** 

Net International Revenues; In Millions



\$60M

Estimated international SCIg TAM<sup>1</sup>

10%

Estimated KORU international market share<sup>1</sup>

**30-40%** KORU international market

share goal

## Rapidly Expanding International Market Opportunity

#### Top-10 markets remain under penetrated

Significant growth potential in key regions Additional opportunity in MENA

### **Expanding opportunities**

KORU needle sets used with electronic pumps Global PFS expansion

#### Strategic Ig partnerships

Multi-year Ig collaborations driving accelerated market penetration



## Future Catalysts Robust Pipeline With Multiple Near-Term Opportunities

17 Opportunities / 15 Collaborations

9 Commercial Opportunities by 2026

\$2.7B<sup>1</sup> Addressable Market Combined

Immunology New Indications/New Devices					
Asset	Drug Trial Phase	Next Step	Expected KRMD Clearance <sup>2</sup>	Patient Population (000s)	
Freedom Japan Clearance	Launched	Commercialization	2025	Ť	
Ig Device	Launched	KRMD 510k	2026	630	
Ig Device	Launched	KRMD 510k	2026		
Ig Device	Launched	KRMD 510k	2026		
lg Drug		Complete Phase III	2027/28		
lg Drug		Entry to Phase II	2027/28	¥	

### Opportunity for Increased Market Share and Geographic Penetration in Ig

#### New Drug Potential Launches

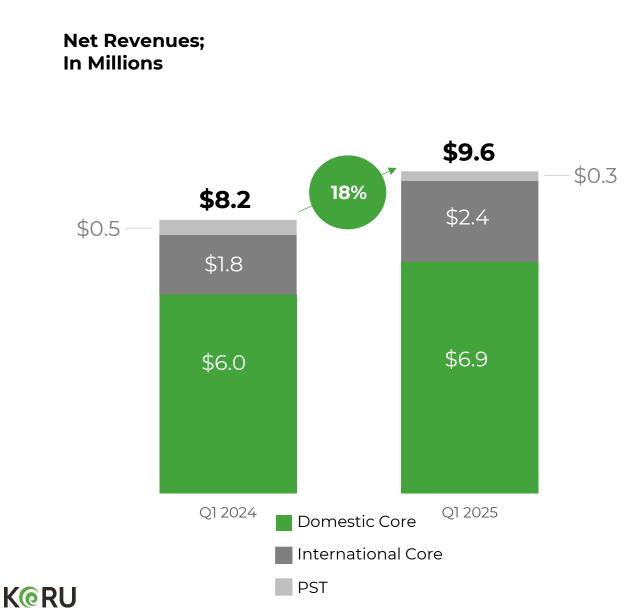
	new Diug Poteitia	Launches					
	Asset	Drug Trial Phase	Next Step	Expected KRMD Clearance <sup>2</sup>	Patient Population (000s)	Est. Total Annual Infusions <sup>3</sup>	
	Rare Disease Biologic	Launched	KRMD 510k	2025	65	~100k	
	Nephrology Drug		FDA Approval	2025	3	~20k	
Pipeline Jpdates	Iron Chelation Drug	Launched	KRMD 510k	2025/26	TBD	TBD	
	Antibiotic Drug	Launched	KRMD 510k	2025/26	TBD	TBD	
	Oncology Drug	Launched	KRMD 510k	2026	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

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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

# Q1 Y/Y Revenue by Business



#### **Domestic Core**

- Increased 16% y/y
- Outpaced SCIg market growth
- Driven by new patient starts, market share gains, and strong pump volumes

### **International Core**

- Increased 36% y/y
- Expanded into new geographies
- Prefilled tender win in an established market
- Included \$0.1M of incremental distributor stocking y/y

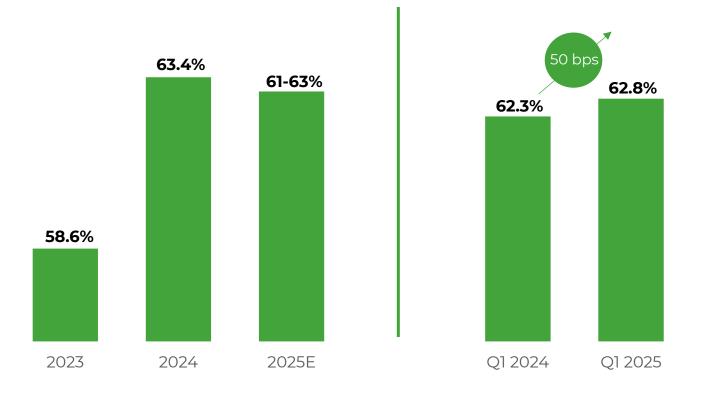
### Pharmaceutical Services and Clinical Trials

- Decreased 39% y/y
- Driven by lower clinical trial orders
  - Timing of Q1 order pushed to Q2

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# **Ql Gross Margin Profile**

Driving y/y Margin Improvement with Consistent Performance >60%



### Gross Margin

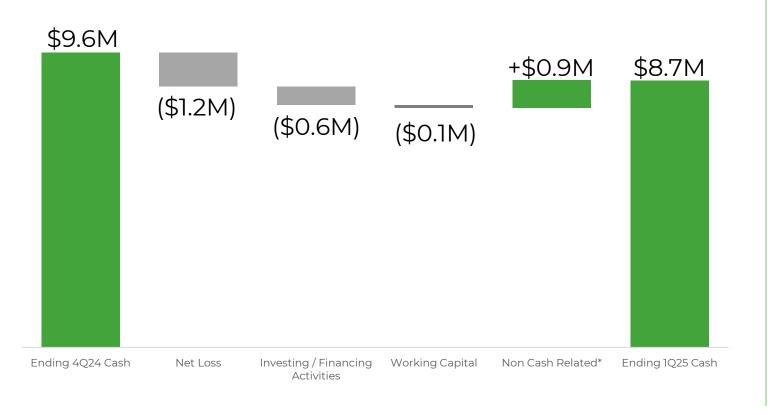
## First Quarter: 62.8%

- 50 basis points improvement y/y
  - Driven by favorable product sales mix
  - Continue to implement operational excellence programs to expand future margins
  - Reiterating Guidance of 61%-63% for FY25; inclusive of current COGS tariff impacts



# Q1 Cash Balance

Cash Balance as of March 31, 2025: \$8.7M



## Key Drivers

## Q1 cash usage of \$0.8M

- Net loss of ~(\$1.2M)/ 36% improvement
- Investments (\$0.4M) in capex for next generation consumables production line, and insurance premium financing (\$0.2M).
- Working Capital changes of (\$0.1M) driven primarily by higher inventory, higher accounts receivables, offset by higher accounts payable and accrued expenses.
- Non-cash items\* of \$0.9M, for stock compensation, depreciation and amortization



# Raising 2025 Revenue Guidance

# Revenue Growth

## Increased to \$38.5-\$39.5M, 15-17% growth

#### Key Drivers/Milestones

- Sustained 8-10% SCIg drug market growth
- Continued US and International share gains
- Flow controller line extension
- Japan market entry
- NRE revenue from 3 new Novel Therapies collaborations

# Gross Margin Profile

Reiterated between 61-63%

#### Key Drivers/Milestones

- One-time new product startup costs in 2H
- Higher mix of growth in international markets with lower ASPs
- Supply chain inflationary and tariff pressures
- Pricing and manufacturing efficiencies planned to maintain gross margin profile

# Cash Flow Generation

Reiterated positive cash flow from operations for the **full year 2025** 

#### Key Drivers/Milestones

- Operating Expense of ~\$26-\$27M, exclusive of stock compensation expense
- Higher OpEx spend to occur in 1H25 driven by R&D project work completion
- < \$2.0M of investing activities in CapEx for new production lines

# Key 2025 Milestones

## **Financial Targets and Guidance**

- \$38.5-39.5M ; mid teens growth
- Positive cash flow from operations for FY2025
- Adj. EBITDA growth, higher gross profit, increased operating leverage

## Add New Drugs to Label through Novel Therapies Pipeline

- 3 new pharmaceutical collaborations (2 of 3 complete)
- 510(k) submission Iron Chelation Drug (2H 2025)
- 510(k) submission Antibiotic Drug (2H 2025)
- 510(k) submission Rare Disease Drug for infusion clinic (2H 2025)
- 510(k) submission Oncology Drug for infusion clinic (Q4 2025 Q1 2026)

## Expand Internationally

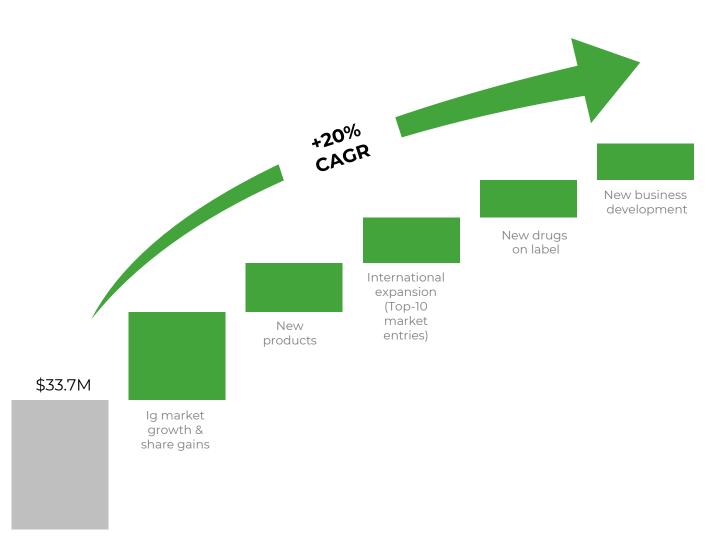
- Japan Commercial Sales 1H 2025
- Phase 1 flow controller launch Q3 2025
- 510(k) submission Phase 2 flow controller Q1 2026
- Further top-10 market entries

# **Defend & Grow Domestic SCIg**

- Sustained 8-10% SCIg drug market growth
- 510(k) submission new consumables (2H 2025)
- 510(k) submission next gen. pump (Q4 2025 Q1 2026)



# Sustained pathway to +20% growth



### **Key Growth Drivers**

Sustained share of SCIg market growth and share gains 8-10% annual growth

#### **New product launches & innovation** 2<sup>nd</sup> generation consumables, new PFS pump, and flow controller

# Entry into new SCIg markets & expansion of established markets

Japan, Canada, Western EU

#### New drugs on label

Includes current pipeline collaborations

#### New business development

Adjacencies and other opportunities

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## KORU Medical Strategic Highlights Summary



**Macro tailwinds** driving **adoption of subcutaneous therapy**; many large-volume SC drugs in development by major Pharma companies in multiple indications



21% growth in Core business with **75% recurring revenues** 



Strong underlying SCIg market; gaining greater market share domestically and expanding into other top-ten global markets



9 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



**Raising 2025 revenue guidance,** maintaining gross margin and positive cash flow from operations targets





# Appendix

# **Non-GAAP Financial Measures**

This presentation includes the non-GAAP financial measures "adjusted EPS", "adjusted diluted EPS", and "adjusted EBITDA" that are not in accordance with, nor an alternate to, generally accepted accounting principles and may be different from non-GAAP measures used by other companies. These non-GAAP measures are not based on any comprehensive set of accounting rules or principles. Non-GAAP financial measures should not be considered a substitute for, or superior to, measures of financial performance prepared in accordance with GAAP. They are limited in value because they exclude charges that have a material effect on KORU Medical's reported results and, therefore, should not be relied upon as the sole financial measures to evaluate the Company's financial results. Non-GAAP financial measures are meant to supplement, and to be viewed in conjunction with, GAAP financial results. Reconciliations of the Company's non-GAAP measures are included at the end of this presentation.

Reconciliation of GAAP Net Loss	Three Months Ended March 31,		March 31,	
to Non-GAAP Adjusted EBITDA:		2025		2024
GAAP Net Loss	\$	(1,166,237)	\$	(1,935,958)
Depreciation and Amortization*		217,357		231,369
Interest (Income), Net		(73,180)		(37,187)
Reorganization Charges				99,329
Litigation Expense		133,411		
Stock-based Compensation Expense *		697,590		699,718
Non GAAP Adjusted EBITDA	\$	(191,059)	\$	(942,729)
Weighted average number common shares		45,981,826		45,712,224
Reconciliation of Reported Diluted EPS	1	Three Months Ended March 31,		
to Non-GAAP Adjusted Diluted EPS		2025		2024

2025		2024	
(0.03)	\$	(0.04)	
_		0.01	
_		—	
0.02	_	0.02	
0.00	\$	(0.02)	
	(0.03) — — — — — — — — — — — — — —	(0.03) \$ 	