

# **KORU Medical Systems**

Q2 2025 Earnings Call August 6, 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.

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", "driver", "opportunity", "believe" and "will", and include without limitation expected clearance and launch dates for 510(k) submissions and new products, and 2025 2H and full year financial guidance (revenues, gross margin and cash usage and balance). 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, 2025 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 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 August 6, 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.



**Our Company** 

## KORU Medical: A Global Leader in Large Volume Subcutaneous Drug Delivery



KORU's Freedom Infusion System is a **leader in large-volume (>10mL) subcutaneous 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 10 current opportunities to bring **new drugs onto our Freedom Infusion System** 



# The Movement of Healthcare from Hospital to the Home Driving Large and Growing Subcutaneous Infusion Opportunity

Global Total Addressable Market for Large-Volume Subcutaneous >10ml Infusion

### **SCIg Opportunity**

#### \$450M1

Total global addressable market with <20% SCIg penetration: 7 launched SCIg drugs

### **Non-SCIg Opportunity**

#### 53

New Drugs in Development >10 mL<sup>2</sup>

## **KORU'S Strategic Growth Pillars**





**Expand Internationally** 



**Enable More Drugs, Reach More Patients** 



## Delivering Record Quarterly Revenues and Key Strategic Progress

- Record Q2 revenues of \$10.2 million, 21% growth over the prior year period
- 2 Strong strategic progress with global core business outperforming a growing SCIg market, acceleration in international expansion, and clinical trials driving Pharma Services and Clinical Trials (PST)
- Expanding patient base with SCIg growth, approval on expanded C3G/Primary IC-MPGN indication for Empaveli, and 510(k) submission for rare disease biologic
- Initiated pilot program for oncology opportunity; dosing 50+ patients with 4 oncology drugs at 6 infusion center sites
- Progressing towards profitability with second quarter cash usage of \$600K driven through combination of revenue growth, stable gross margins and improved operating leverage
- (6) Raising 2025 revenue guidance to \$39.5-\$40.5M, 18%-20% growth
- Adam Kalbermatten joins as Chief Commercial Officer, bringing 20 years of success leading drug delivery partnerships across pharma and biotech



# Strong Market and Strategic Progress Driving 19% Q2 Growth in Core Business



Domestic Core growth outpacing strong SCIg market growth

Expanding recurring revenue base with new patients

Share Capture in Key Accounts

New label expansion for C3G/Primary IC-MPGN indication with Empaveli



### **Expand Internationally**

International Core growth outpacing strong SCIg market growth

Gaining share with prefilled syringe (PFS) patient conversions

Continued geographic expansion in Middle East and North Africa (MENA)

**6 Collaborations/Opportunities** 

**4 Commercial Opportunities by 2026** 

\$450M Total Ig TAM<sup>2</sup>

#### New Ig Indications and Devices with 6 Pharma Collaborations Drive Share Gains and Geographic Expansion

Asset	Drug Trial Phase	Expected KRMD Clearance <sup>1</sup>	Details	_
Ig Device- Japan Launch	Launched	√ Phase I-'25 Phase II- '26	KRMD flow controller for use with launched drug	Completed Phase I Launch
Ig Device (Pump)	Launched	2026	KRMD next gen. pump for use with launched drug #1	
Ig Device (Pump)	Launched	2026	KRMD next gen. pump for use with launched drug #2	
Ig Device (Pump)	Launched	2026	KRMD next gen. pump for use with launched drug #3	
Ig Drug/Device	Phase III	2027/28	New drug launch using KRMD device	
Ig Drug/Device	Phase II/III	2027/28	New drug launch using KRMD device	Progressed to Phase II/III



# 5 New Drug Additions planned on KORU Freedom Infusion System by end of 2026

8 Collaborations/10 Opportunities

**5** Commercial Opportunities by 2026

\$1.8B Total TAM<sup>2</sup>

## 3 Enable More Drugs, Reach More Patients

Submitted 510(k) for Rare Disease Biologic in 2Q25

10 New Drugs in Pipeline

2 drugs being pursued for 510(k) independently by KRMD

8 drugs being pursued for 510(k) in pharmaceutical collaborations

New label expansion for C3G/Primary IC-MPGN indication with Empaveli

5 Commercial Opportunities by 2026

### KRMD Pursuing 510(k) Independently

Asset	Drug Trial Phase	Next Step	Clearance <sup>1</sup>	Annual Infusions <sup>2</sup>	Recent Update
Vancomycin	Launched	KRMD 510(k) Submission	2026	~900k	2025/2026 to 2026
Deferoxamine	Launched	KRMD 510(k) Submission	2026	~200k	2025/2026 to 2026

Now moves into Core Revenue

### KRMD Pursuing 510(k) through Pharmaceutical Collaborations

	Asset	Drug Trial Phase	Next Step	Expected KRMD Clearance <sup>1</sup>	Est. Global Total Annual Infusions <sup>2</sup>	Recent Update
<b>/</b>	Empaveli C3G/IC-MPGN	Launched	Commercialize	Complete	~100k	FDA Approved
	Rare Disease Biologic	Launched	KRMD 510(k) Clearance	2025	~270k	510(k) submitted
	Oncology Drug	Launched	KRMD 510(k) Submission	2026	~1,100k	
	KIRA (PNH)	Phase III	Entry to Phase III	2027/28	TBD	
	Endocrinology Drug	Phase III	Complete Phase III	2028	~1,000k	
	Respiratory Drug	Phase II	Complete Phase II	2028/29	TBD	
	KIRA (IgAN)	Phase II	Complete Phase II	2029/30	TBD	
	KIRA (C3G)	Phase II	Complete Phase II	2029/30	TBD	



## Strategic Product Development Captures Near Term Growth



## Flow Controller

### **Value Proposition**

Phase 1 Line extension: Improved COGS and capacity

Phase 2 Next Gen: Improved performance/ accuracy, expanded label indications in new markets

## **Timing**

Phase 1: Launched in Q2 ahead of schedule

Phase 2: 510(k) submission expected 1H26



## **Next Generation Pump**

## **Value Proposition**

- Accommodates all available PFS 5mL to 50mL and vial/syringe compatible
- Improved patient mobility, ease of use, and dosing feedback
- Opens new geographic markets

## **Timing**

510(k) submission expected 4Q25-1Q26



## **New Consumables Sets**

### **Value Proposition**

- Improved patient comfort and convenience
- Customizable platform for new drugs

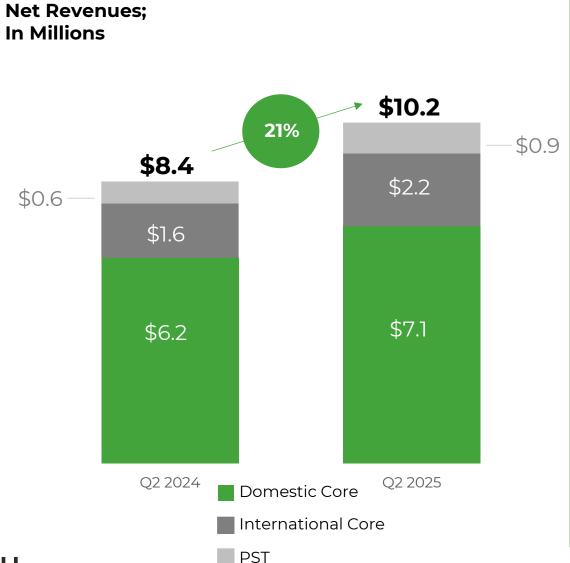
### **Timing**

510(k) submission expected 2H26



#### **Financials**

## Q2 Revenue Growth - Record \$10M+, 21% Growth



#### **Domestic Core**

- Increased 15% y/y
- Outpaced SCIg market growth
- Driven by new patient starts, market share gains, and strong consumables volumes

#### **International Core**

- Increased 34% y/y
- Expansion into new geographies
- PFS strategy in Europe

### **Pharma Services and Clinical Trials (PST)**

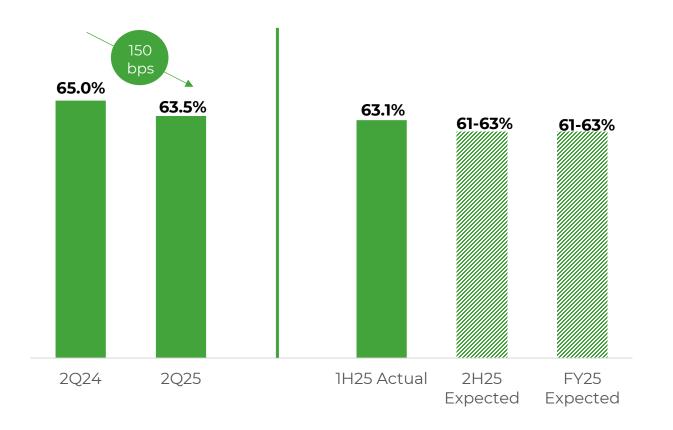
- Increased 42% y/y
- Strength in clinical trial orders from non-Ig partner



#### **Financials**

# Strong 1H Gross Margin Offset; 2H Expected Impact from International Mix and Tariffs

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



## **Gross Margin**

## **Second Quarter: 63.5% Gross Margin**

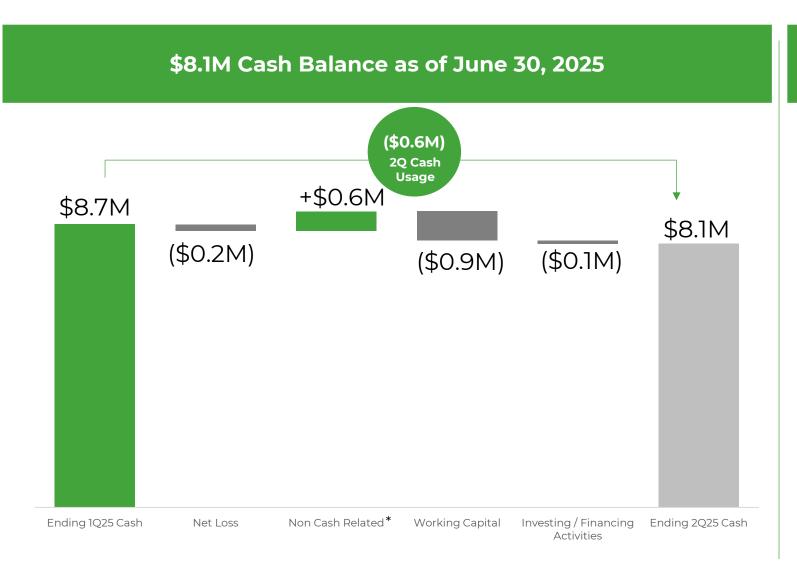
- 150 basis points decline y/y
  - Tariff impact of 90 bps and prior year favorable inventory revaluation adjustment of 90 bps
  - Offset by volume efficiencies and higher PST margins of 30 bps

## 2H: 61-63% Gross Margin

- Increased revenue in lower ASP markets and 2H tariff impact
- Reiterating Guidance of 61%-63% for FY25



## **Q2 Cash Usage Driving to Operational Cash Flow Positivity**



## **Key Drivers**

## Q2 cash usage of \$0.6M

- Lower net losses driven by higher revenues, sustained gross margins, and disciplined OpEx spending
- Non-cash related driven primarily by stock comp expenses and depreciation
- Working capital higher in the quarter driven by inventory replenishment and timing of AR collections
- Investments in manufacturing equipment for new products

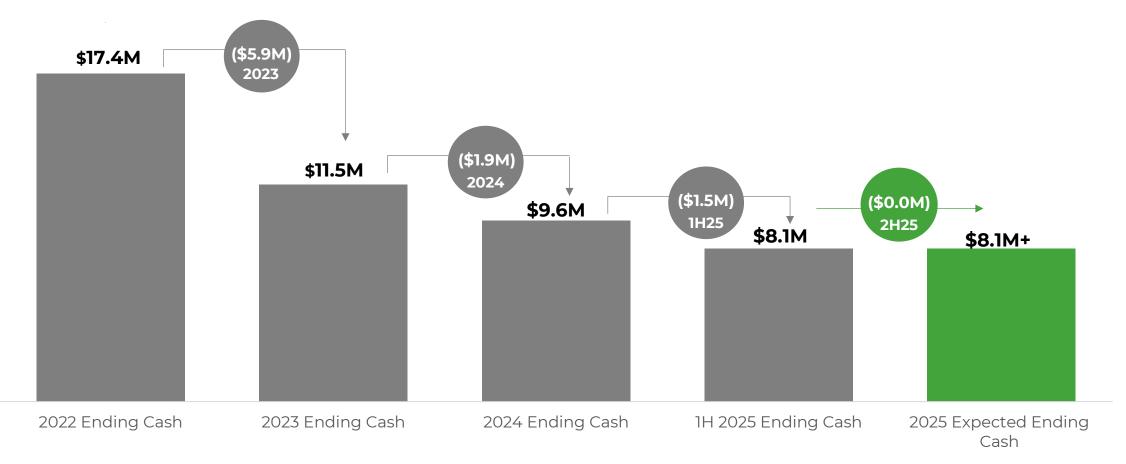


\* Refer to appendix slide 1

#### **Financials**

## Significant Reduction in Cash Usage over Last Three Years

## 2H Cash Usage Expected to be Neutral-to-Positive





# 1H 2025 Financial Highlights – Strength Across P&L

	1H25	1H24	Υ/Υ Δ
Revenue	\$19.8M	\$16.6M	+19% Growth
Gross Margin	63.1%	63.6%	-50bps
OpEx	\$14.1M	\$13.7M	+3% Increase
Net Loss	(\$1.4M)	(\$2.9M)	53% Improvement
Adj. EBITDA*	\$0.01M	(\$1.3M)	101% Improvement
Adj. EPS*	\$0.00	(\$0.02)	100% Improvement



\* Refer to appendix slide 1

## **Raising 2025 Revenue Guidance**

## Revenue Growth

Increased to **\$39.5-\$40.5M, 18-20% growth** 

#### **Key Drivers/Milestones**

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

# **Gross Margin Profile**

Reiterated between 61-63%

#### **Key Drivers/Milestones**

- 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 2H25 driven by R&D project work completion
- < \$2.0M of investing activities in CapEx for new production lines



#### **Outlook**

## **Key 2025 Milestones**

## **Financial Targets and Guidance**

- \$39.5-\$40.5M; ~20% growth
- Positive cash flow from operations for FY2025
- Adj. EBITDA growth, higher gross profit, increased operating leverage

# **Enable More Drugs, Reach More Patients**

- 3 new pharmaceutical collaborations (2 of 3 complete)
- 510(k) submission Deferoxamine (1H 2026)
- 510(k) submission Vancomycin (Q4 2025 Q1 2026)
- 510(k) submitted Rare Disease Drug for infusion clinic (2Q 2025)
- 510(k) submission Oncology Drug for infusion clinic (Q4 2025 Q1 2026)

## **Expand Internationally**

- Japan Commercial Sales Q3 2025
- Phase 1 flow controller launched Q2 2025
- 510(k) submission Phase 2 flow controller 1H 2026
- Further top-10 market penetration

# **Protect and Grow our Core Domestic Business**

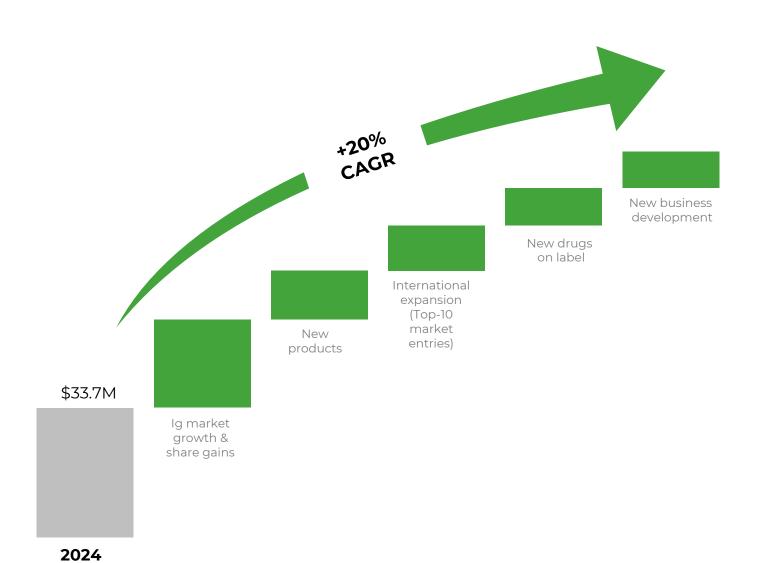
- Outpacing sustained 8-10% SCIg drug market growth lacksquare
- 510(k) submission new consumables (2H 2026)
- 510(k) submission next gen. pump (Q4 2025 Q1 2026)





#### **Outlook**

## **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

#### New business development

Adjacencies and other opportunities



#### **KORU Medical**

## **Strategic Highlights Summary**

- Macro tailwinds driving adoption of subcutaneous therapy; +50 large-volume (>10mL) SC drugs in development by major Pharma companies in multiple indications
- 19% growth in Core business with ~75% recurring revenues
- Strong underlying SCIg market; gaining greater market share domestically and expanding into top-ten global markets
- 10 non SCIg new drugs opportunities in pipeline; 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





# **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.

Reconciliation of GAAP Net Loss		Three Months Ended June 30,			Six Months Ended June 30,			
to Non-GAAP Adjusted EBITDA:		2025		2024		2025		2024
GAAP Net Loss	\$	(206,867)	\$	(988,715)	\$	(1,373,105)	\$	(2,924,673)
Reorganization Charges		_		_		_		99,329
Depreciation and Amortization*		209,487		217,864		426,844		449,233
Interest (Income)/Expense, Net		(78,951)		(213,999)		(152,130)		(251,186)
Stock-based Compensation Expense*		415,744		614,666		1,113,334		1,314,384
Non GAAP Adjusted EBITDA	\$	339,413	\$	(370,184)	\$	14,943	\$	(1,312,913)
Weighted average number common shares		46,193,709		45,811,373		46,088,353		45,761,799

Reconciliation of Reported Diluted EPS		Three Months Ended June 30,			Six Months Ended June 30,			
to Non-GAAP Adjusted Diluted EPS:		2025		2024	_	2025		2024
Reported Diluted Earnings Per Share	\$	_	\$	(0.02)	\$	(0.03)	\$	(0.06)
Depreciation and Amortization $^{st}$		_		_		0.01		0.01
Stock-Based Compensation Expense		0.01		0.01		0.02		0.03
Non GAAP Adjusted Diluted Earnings Per Share	\$_	0.01	\$	(0.01)	\$	0.00	\$	(0.02)

