

# **KORU Medical Systems**

Q3 2024 Earnings Call November 13, 2024

# **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 the existence and timing of potential drug launches, the success and timing of our novel therapies collaborations, our future financial performance (including but not limited to CAGR, revenue growth, cash balances, cash flow and gross margin), our future product launches, 501(k) submissions, 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; continuation of our EU certification, 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 otherwi

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



# **Strong Third Quarter Execution**

- 1 17% y/y revenue growth for Q3, third consecutive quarter of double-digit growth
- Core business y/y growth of 11%, driven by outpacing SCIg market growth and new geographic entries
- **3** Strength in Novel Therapies driven by an increased number of new collaborations and clinical trial orders
- Gross profit y/y growth of 19% and gross margin improvement of 140 basis points
- 5 Ending cash balance of \$8.8M and YTD cash usage of \$2.7M, a 60% y/y improvement
- (6) Raising 2024 guidance for revenue, gross margin, and YE cash balance



## **Progress on Strategic Growth Pillars**

# Protect and Grow Domestic Core SCIg Business

#### **Domestic Core growth**

12% y/y growth; YTD 10% growth Record quarterly revenues

### Outpacing SCIg market<sup>1</sup>

Seven quarters of sequential market growth

#### **New accounts wins**

Continued Ig penetration and patient starts

### Updating new 510k submission

Expected Mid 2025

### **Expand Internationally**

#### **International Core growth**

5% y/y growth; YTD 38% growth Impacted by Q2 BSI stocking orders

#### Strong Ig growth

**Expanding indications** 

### Strong consumable volumes

Driven by new and existing geographies

Market share gains in new geographies

# Broaden our relevance with Novel Therapies

#### 16 collaborations in total

3 signed in 2024, 6 potential commercial launches by 2026

#### **Multiple Projects**

Initiated with collaboration partners for development and expansion

#### **Oncology Nursing Preference Study**

Demonstrated 97% preference for KORU FreedomEdge® over manual push

### **Updating 510k submission**

Rare disease biologic – infusion clinic entry expected 2025



1. Third party data source

## 6 New KORU Drug Collaboration Launches Expected by 2026

16 Total Collaborations		19 Open Opportunities			\$2.7B TAM <sub>(1)</sub> Across 2.1M Global Patient Population				
Novel Therapies	Patient Population (000's)	Phase I	Phase II	Phase III	Drug Launch Date <sub>(3)</sub>	KRMD Clearance			
SEMPAVELI" SASPAVELI™ (pegcetacoplan)	15				May 2021	May 2022			
Oncology	500				Launched	Expected 2025			
Rare Disease Biologic	65				Launched	Expected 2025			
Nephrology	2				2025	Expected 2025/26			
Hematology	133				2027	Expected 2027/28			
Endocrinology	10				2028	Expected 2028			
Respiratory	239				2028	Expected 2028/29			
Nephrology	540				2029	Expected 2029/30			
Nephrology	2				2029	Expected 2029/30			
Total Patient Pop.	1,506	_							
Core: Expanded Indications to L	.abel (Ig)				Drug Launch Date/New Indication				
CSL Hizentra 50mL PFS [device	e] <b>†</b>				Apr. 2023	December 2023			
Takeda Cuvitru Japan [device]					Sep. 2023	July 2024			
Immunology/Neurology [device	e]				Apr. 2023	Expected 2025			
Immunology [device]	630				2025	Expected 2025			
Immunology/Neurology					2026	Expected 2026/27			
Immunology/Neurology					2026	Expected 2028			
Immunology	1				2027	Expected 2027/28			



# 97% of Nurses Prefer KORU Freedom System For Subcutaneous Oncology Infusion<sup>1</sup>

### Nursing Preference Study: FreedomEdge® vs Manual Syringe Administration

Over 3,000 patients in 6 hospitals received KORU FreedomEdge® infusions from 33 nurses who had previously administered the same >10mL drug via manual push



97% of nurses reported increased patient interaction while using the FreedomEdge® Infusion System



81% of nurses
experienced **less hand pain** compared to
manual syringe
administration



91% of nurses found KORU FreedomEdge® Infusion System **easier to use** compared to manual syringe administration



73% of nurses

observed less patient

pain while using

FreedomEdge®

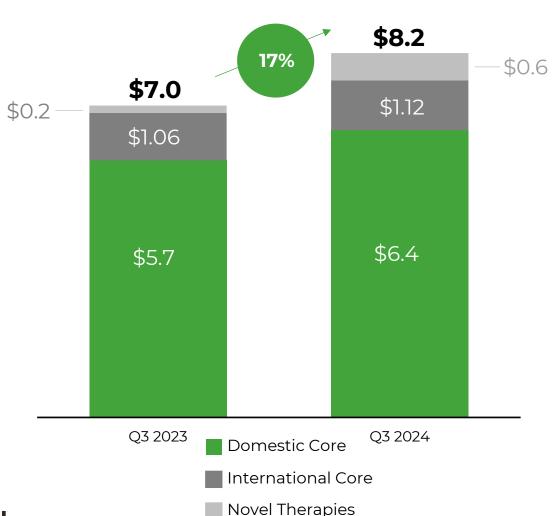
Infusion System

97% of nurses would recommend the KORU FreedomEdge® Infusion System over manual syringe in subcutaneous oncology infusions, citing ease of use and reduced discomfort as key reasons



# Q3 Y/Y Revenue by Business

#### Net Revenues; In Millions



#### **Domestic Core**

- Increased 12% y/y; 10% YTD growth
- Outpaced Ig market growth
- Driven by higher consumable and pump volumes, new patient starts, and continued account penetration

#### **International Core**

- Increased 5% y/y; 38% YTD growth
- Consumable growth in new and existing markets
- Strong performance in new geographies
- Customers consumed excess BSI inventory and are expected to return to regular order patterns in Q4

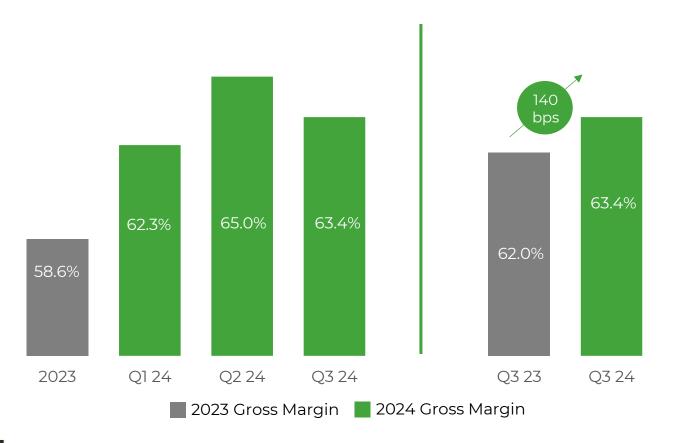
#### **Novel Therapies**

- Increased 276% y/y; 46% YTD
- Progress on NRE work for six collaborations vs. two last year
- Strong product sales in support of customer clinical trials



# **Improved Gross Margin Profile**

Driving y/y margin improvement with consistent performance >60%



### **Gross Margin**

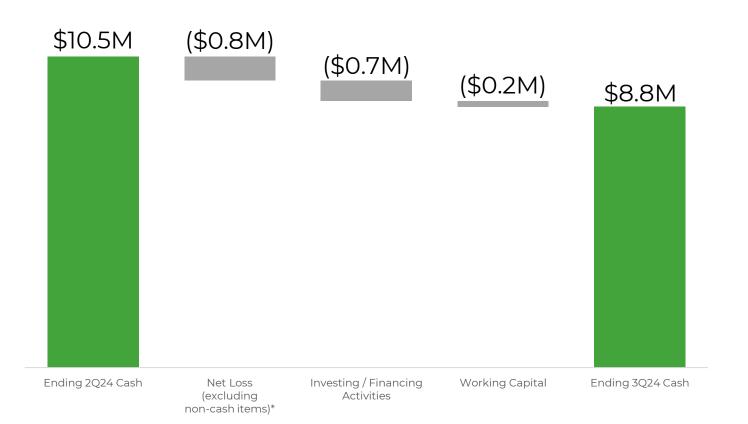
Third Quarter: 63.4%

- Gross margins consistently >60%
- 140 basis points improvement y/y
  - Driven by improved NRE margins from insourcing engineering activities
  - Increase in ASPs
  - Partially offset by changes in product sales mix



# Improved Cash Management/Operating Leverage

Cash Balance as of September 30, 2024: \$8.8M



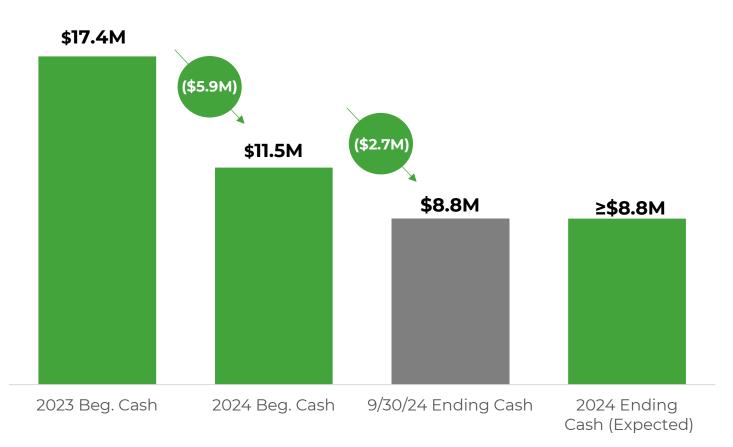
### **Key Drivers**

- Cash usage of \$1.7M, in line with expectations
  - Net loss of ~(\$0.8M), excluding non-cash items\*
  - Investing / Financing Activities driven by capital purchases for new consumables product line
  - Working Capital driven
     primarily by higher inventory
     due to timing of raw materials
     purchases and supply chain
     events, partially offset by an
     increase in expense accruals



### On Track to Reach Cash Flow Breakeven

Cash burn improving with expected 2024 ending cash balance of ≥\$8.8M



### **Key Drivers**

- Substantially reduced y/y cash burn with YTD cash usage of \$2.7M, a 60% improvement over 2023
- Key contributors:
  - Lower net losses driven by higher revenues
  - Higher gross margin
  - Improved operating leverage
  - Improvements in working capital
- Expected Q4 cash flow breakeven
- 2024 ending cash balance of at least \$8.8M
- Long-term \$10M credit facility remains unused



# Strong Year-To-Date Execution Down the P&L

### YTD Q3 Financial Highlights

Metric	YTD '24	YTD <b>'23</b>	Υ/Υ Δ		
Revenue	\$24.8M	\$21.3M	16.3% growth		
Gross Margin	63.6%	58%	560bps growth		
OpEx	<b>Ex</b> \$20.6M		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		



## Raising 2024 Guidance

### Revenue Growth

Increased to \$32.75-\$33.25M, 15-17% growth

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

- SCIg drug market growth of mid-to-high single digits
- 3 new Novel Therapies collaborations
- Prefill syringe market penetration of approx. 20-25%

# **Gross Margin Profile**

Increased to **62-63**%<sup>2</sup>

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

- Favorable manufacturing efficiencies
- Improved Novel Therapies sales mix
- Supply chain inflationary pressures

# Cash & Cash Flow

Increased to greater than **\$8.8M** ending cash balance<sup>3</sup>

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

- Operating Expense of **~\$24.5**-**\$25.0M,** exclusive of stock compensation expense
- Cash flow breakeven in Q4 2024, and cash flow positive for full year 2025
- Ending cash balance is exclusive of unused credit facility



## **Continued Progress on Vision 26 Key Milestones**



Double-digit revenue growth versus FY2023



**Accelerating Core growth** with new patient starts, share gains, and continued International expansion



**Progressing Novel Therapies pipeline** with 6 potential commercial launches by 2026 – continued focus on late-stage drug candidates and entering the infusion clinic market



**Expecting multiple 510k submissions in 2025** for new products and new drug launches on FREEDOM® Infusion System



Continued operating leverage driving cash flow breakeven in Q4 2024 and cash flow positive for the full year 2025





### **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.

	Three Months Ended					Nine Months Ended				
Reconciliation of GAAP Net (Loss)		September 30,				September 30,				
to Non-GAAP Adjusted EBITDA:		2024		2023		2024		2023		
GAAP Net Loss	\$	(1,580,817)	\$	(1,368,262)	\$	(4,505,490)	\$	(6,275,033)		
Tax Benefit *		(314,095)		(300,247)		(892,524)		(1,477,642)		
Allowance for Tax Benefit *		314,095		_		892,524		_		
Reorganization Charges		396,926				496,255				
Depreciation and Amortization*		227,785		216,014		677,019		642,050		
Interest Income, Net		(112,997)		(135,429)		(364,183)		(392,098)		
Manufacturing Initiative Expense		_		_		_		55,361		
Stock-based Compensation Expense*		634,608		697,658		1,948,992		2,379,613		
Non-GAAP Adjusted EBITDA	\$	(434,495)	\$	(890,266)	\$	(1,747,407)	\$	(5,067,749)		
Weighted average number of common shares		45,851,019		45,606,603		45,791,756		45,547,427		

Reconciliation of Reported Diluted EPS		Three Months Ended September 30,				Nine Months Ended September 30,				
to Non-GAAP Adjusted Diluted EPS:		2024	2023		2024		2023			
Reported Diluted Earnings Per Share	\$	(0.03)	\$	(0.03)	\$	(0.10)	\$	(0.14)		
Tax Benefit*		(0.01)		(0.01)		(0.02)		(0.03)		
Allowance for Tax Benefit *		0.01		_		0.02		_		
Reorganization Charges		0.01		_		0.01		_		
Depreciation and Amortization *		_		_		0.01		0.01		
Interest Income, Net						(0.01)		(0.01)		
Manufacturing Initiative Expense		_		_		_		_		
Stock-based Compensation Expense *		0.01		0.02		0.04		0.05		
Non-GAAP Adjusted Diluted Earnings Per Share	\$	(0.01)	\$	(0.02)	\$	(0.05)	\$	(0.12)		



\*Non-cash items