

## **KORU Medical Systems**

Q3 2023 Earnings Call November 8, 2023

### **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 501(k) clearance, Japan market launch, electronic pump trial completion, new novel therapies collaborations, new label indications on Freedom System, next generation Ig pump platform, next generation Novel Therapies pump platform, upcoming milestones in next six months, revenue, gross margin, operating expenses, cash, and cash flow. 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, 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, 2022 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 available on the SEC website at <a href="https://www.sec.gov">www.sec.gov</a> [sec.gov] and on our website at <a href="https://www.sec.gov">www.sec.gov</

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



## Third Quarter Financial Updates

- Third quarter net revenue 10% decline versus prior year
  - Novel Therapies impacted primarily by a large clinical trial order in the prior year and the timing of collaborations
  - Domestic Core impacted by slower than anticipated Subcutaneous Immunoglobulin (SCIg) market
- Revised full year 2023 revenue guidance, reaffirmed gross margin & raised cash guidance

## Continued Momentum with our Growth Strategy

- Solid Domestic Core business growth continues to outpace underlying market
- Continued to grow our Novel Therapies pipeline, winning a new Novel Therapies innovation collaboration
- Disciplined strategic operating expense management & gross margin expansion
- Appointed of Ken Miller as Chief Commercial Officer to drive global commercial execution
- Strong catalysts ahead including new product introductions, collaborations, and geographies



### Q3 Progress on Strategic Growth Pillars

### Grow Leadership Position in Domestic Core SCIg

#### Outperforming market in Domestic Core business

+6% YTD y/y growth +7% sequential q/q growth

+40% y/y pump growth

#### New 510k clearance

for Freedom60® Infusion System for use with the Hizentra® 50mL prefilled syringe

#### **Expand to Novel Therapies**

1 new collaboration closed in Q3 2023,

15 closed collaborations in total

On track to close 4-5 new collaborations

in 2023, 3 closed YTD

18 opportunities for new collaborations in the pipeline

3 new added in Q3 2023

#### **Geographic Expansion**

### +12% YTD y/y International Core growth

driven by deeper penetration into Secondary Immunodeficiency (SID) and in new countries

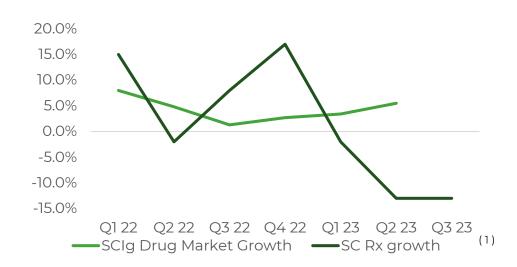
**Submitted Japan registration** market launch expected in 2024

Electronic pump trial completion expected in 1H24



# Market Trends Reaching Inflection – KRMD Outperforming the Domestic Core Market

#### **Ig Drug and Script Market Trends**



- New diagnoses had been declining due to decreased infection rates from '19-'21
- '22-'23 flu season strongest in 13 years, leading to increased diagnoses
- SCIg drug market up 4.9% YTD through Q2
   2023 +2.6% sequential growth from Q1 2023

#### **KRMD Domestic Core Growth & Trends**

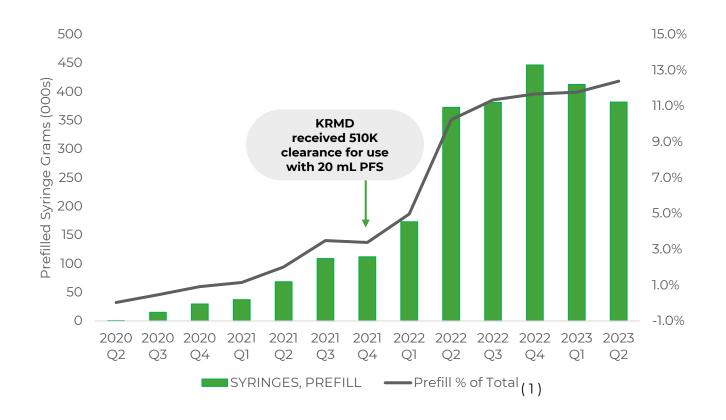


- Domestic Core y/y growth +6% YTD 2023
  - Sequential Q3 q/q growth +7%
- Pump growth Q3 y/y +40%
  - Sequential Q3 q/q pump growth +24%



# KORU PFS Leadership will Drive Increased Share and Potential for Higher Subcutaneous Penetration

KRMD earlier 510k clearance facilitated tripling of prefilled penetration



The Freedom System significantly improves the patient experience (2)

- Freedom60 with PFS is preferred by 78% of patients
- Up to 80% reduction in drug preparation tasks with PFS
- 89% of patients experienced faster setup times when using the Freedom60

KRMD 50mL 510k clearance will further accelerate penetration of PFS<sub>(2)</sub>

- 70% of patients are on >50 mL
- 86% patients prefer PFS vs. vials
- Expect 50% penetration of PFS by 2025



### Q3 Added One New 1 Collaboration

**\$2.5B** TAM<sub>(1)</sub> | **2M**<sub>(2)</sub> Global Patient 15 Total Collaborations | +1/-1 in Q3 2023 18 Open Opportunities | +3 in Q3 2023 Population **Expanded Indications to Patient Population Current Label (Ig)** (000's)Phase I Phase II Phase III **Launch Date** Immunology / Neurology 630 2024 2026 2026 2024 2024-2025 2027 2025 Immunology (New Pump Innovation) **Patient Population New Therapy Areas** (000's)Phase II Phase III **Launch Date** Phase I **G** EMPAVELI\* 15 Launched 2025 Nephrology 2 2027 Endocrinology 10 2027 Hematology 133 2028 Respiratory 239 5+ years Gastroenterology 393 5+ years Nephrology 540 Nephrology 2 5+ years 1,964 **Total** 



# Strong Recurring Revenue in Core Business, Future Growth Opportunities Through Novel Therapies



Revenue drivers 2023+

Hematology

GEMPAVELI\*

1-3 Years to Launch

5 collaborations

4 Immunology / Neurology (SCIg)

1 Nephrology

Revenue drivers 2023-2025

3+ Years to Launch

6 collaborations

3 Immunology (SCIg)

1 Hematology

1 Respiratory

1 Endocrinology

Revenue drivers 2026-2028

5+ Years to Launch

3 collaborations

1 Gastroenterology

2 Nephrology

Revenue drivers 2029+



### Q3 Progress on Geographic Expansion

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# Innovation Growing our Subcutaneous Leadership Position in Ig and Novel Therapies

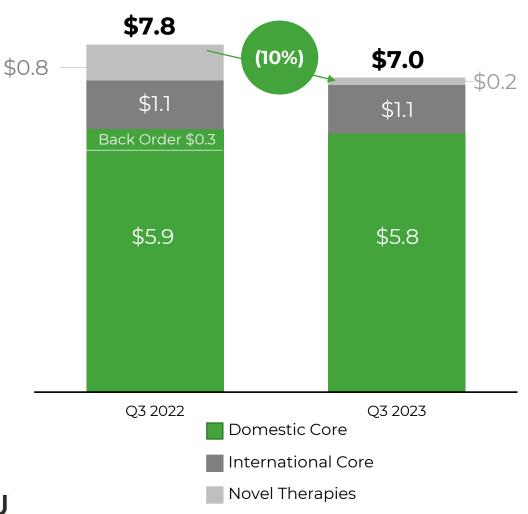
Value Proposition		2021-2022	2023	2024	2025-2026
No.S.	New Products (Comfort, Convenience, Connected)		Freedom60 pump line extension (Q4)	Next generation Ig pump platform	Next generation Novel Therapies pump platform
				Consumables 510k submission (Q2-3'24)	
<b>Q</b>	New Commercial Label Indications	HIZENTRA® 20mL PFS	Core SCIg indication – CSL Hizentra 50 mL PFS	Multiple new label indications on Freedom System	Multiple new label indications on Freedom System
		Core SCIg indications - XEMBIFY® and CUTAQUIG® approvals			
		Novel Therapies indications – EMPAVELI <sup>®</sup> and Aspaveli <sup>®</sup>			





### **Q3 YOY Revenue by Business**

#### Net Sales; In Millions



#### **Novel Therapies**

 Decreased 79% y/y related to a large clinical trial order in the prior year and timing of collaborations

#### **Domestic Core**

- Decreased 2% y/y, +6% YTD
- Lower consumable volumes as compared to prior year when a \$0.3M backorder was cleared.
- Outpaced U.S. Rx script declines driven by increased volume of pumps

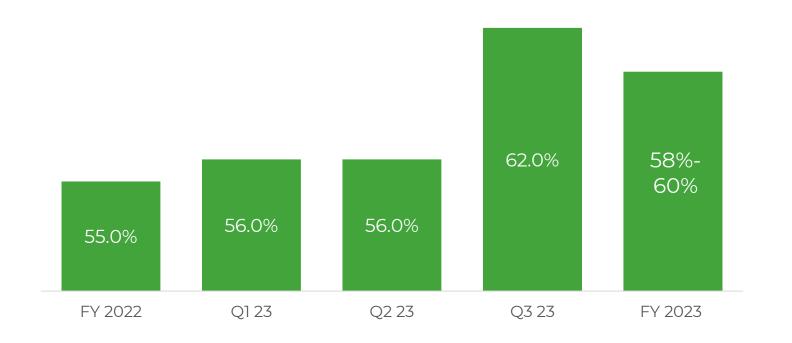
#### **International Core**

- Decreased 3% y/y growth, +12% YTD
- Lower volume driven by tender in prior period
- Growth in several countries expanding international footprint



### **Improving Gross Margin Profile**

Maintaining Gross Margin Guidance:
Exit 60-62%
Full Year 58-60%



#### Q3 62.0%

- Margin improvement driven by increased manufacturing efficiencies from site closure and outsourcing.
- Achieved high end of 2H '23 Gross margin guidance

#### Exit Q4 60-62%

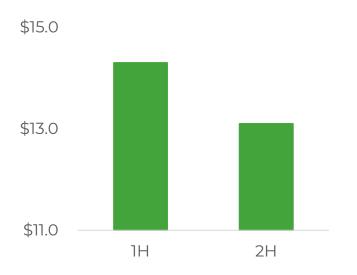
- Full 2 quarters of outsourced manufacturing (+400 BPS)
- 2H Pricing & Volume mix (+100 BPS)



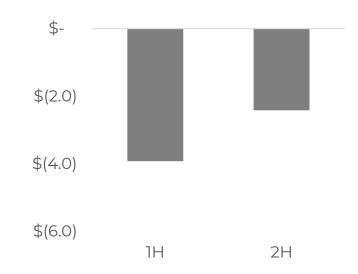
# Strategic Operating Expense Discipline to Achieve Breakeven

Applying operating expense discipline to ensure runaway toward cash flow break even

### Operating Expenses In Millions



### Net Loss (excluding non-cash items) In Millions

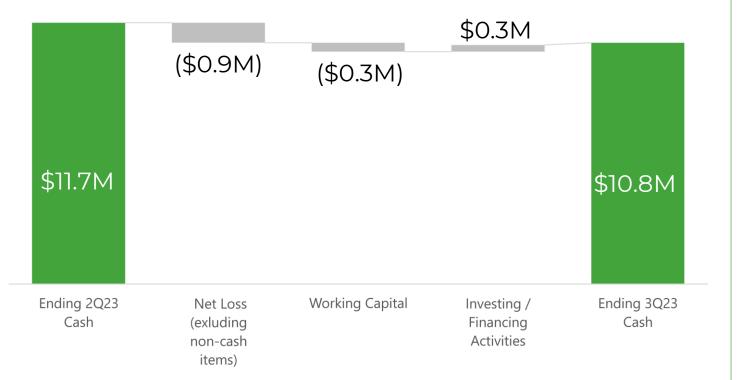


- Disciplined strategic spending on operating expense through short term revenue decline
- Net losses in 2H of the year improving driven by gross margin expansion and operating expense control
- Expecting Cash Flow Break even in Q4 2024



### Q3 2023 Cash





#### **Key Drivers:**

- Q3 cash burn of \$0.9M
- Net loss of \$0.9M: lower by \$1.1M versus
   Q2 driven by operating expense control and improved gross margin
- Working Capital (\$0.3M): continued inventory reduction progress \$0.6M offset by timing in higher AR of (\$0.3M), and lower AP (\$0.6M)
- Increasing end of year cash balance to greater than \$10.5M

Cash Burn:

- 1H \$5.7
- 2H <\$1.2M</li>



### **Revising 2023 Guidance**

### Revenue Growth

Revenue guidance \$28.0-\$28.5 million

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

- Q4 Core SCIg drug market growth of ~3-4%
- Prefilled syringe penetration~11-12%
- Expanded Novel Therapies pipeline with 4-5 total new collaborations
  - 3 completed
- 1 new 510k in back half
  - Completed

# **Gross Margin Profile**

Gross margins between **58-60%**, and **60-62%** exit rate

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

- Completion of Manufacturing transition in 1H
- 55-57% 1H 56% 1H actual
- 60-62% margins in 2H
  - 62% in Q3

## Cash & Cash Flow

Greater than \$10.5M ending cash balance

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

- Operating Expense of < \$28M, inclusive of stock compensation expense ~\$3.1M
- Working capital improvements
  - Inventory reduction of ~ \$2M, +75% completed YTD
- Estimated **breakeven in Q4 2024** based on current strategic outlook



### **Catalysts to Capture Growth**

#### **Key Upcoming Milestones**

New Product Launches

Launch Freedom60 for use with the 50mL PFS

Submissions

New Product & drug indications





## **Upcoming Investor Day**



