

KORU Medical Systems

Q4 and FY 2022 Earnings Call March 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 future novel therapies pipeline, 510(k) filings, revenue, gross margin, operating expenses, 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 available on the SEC website at www.sec.gov [sec.gov] and on our website at www.sec.g

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





Q4 & FY 2022 Highlights

Linda Tharby

President and Chief Executive Officer

Vision 2026 Driven By Three Growth Pillars

Grow Our Leadership Position in Subcutaneous Immunoglobulin (SCIg)



- Increased SCIg drug market growth
- New Ig Label Indications
- New patient starts
- Win prefills

Expand to Novel Therapies Indications



- Focus on large volume >10ml
- Pipeline expansion
 - Clinical phase progression
 - New label indications

Geographic Expansion



- New patient starts
- Strengthen and expand distribution
- Electronic pump conversion

Building the Foundation

Innovation Focused on Comfort, Convenience, Connected

Quality and Regulatory Expertise

Operational Excellence





Significant 2022 Progress Towards Vision 2026



2022 Progress



19% full year 2022 revenue growth, 5 quarters of consecutive double-digit growth



Strength across all businesses, 11% growth in core business, outperforming underlying SCIg drug market



Novel Therapies pipeline growth totaling 14 collaborations across 7 drug classes, 1 new drug label indication, expanding TAM to +\$2.5B



\$17.4M ending cash balance



Growing Leadership Position in Subcutaneous Immunoglobulin Market

Continued strength from domestic core +11% year-over-year growth

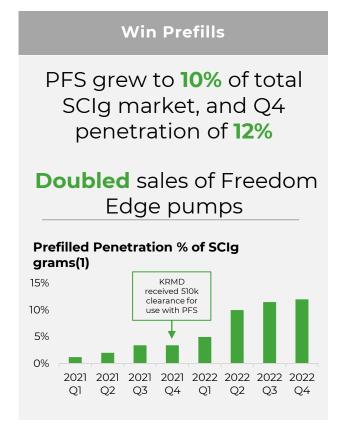
Underlying SCIg Drug Market Growth

FY 2022 SCIg drug market growth of **8%**(1)

Continued positive momentum heading into 2023, Q4 script growth of +17%, SCIg drug market growth of 12%₍₁₎

16%₍₁₎ SC Penetration

Win New Patient Starts CSL Behring octapharma **GRIFOLS** Apellis Takeda Broad label indications with 9 on-label drugs from 5 pharma companies 1 added in 2022, adding 15K patient TAM

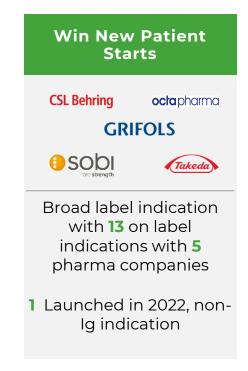


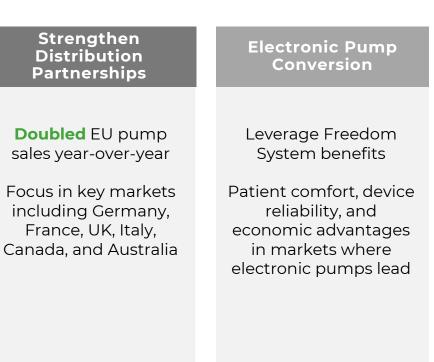


Geographic Expansion

+8% year-over-year growth in international core led by strong second half 2022 growth of +15%









Novel Therapies Pharmaceutical Collaborations

14 Total Collaborations | 7 Drug Classes

\$2.5B TAM₍₁₎ | 2.8M₍₂₎ Global Patient Population



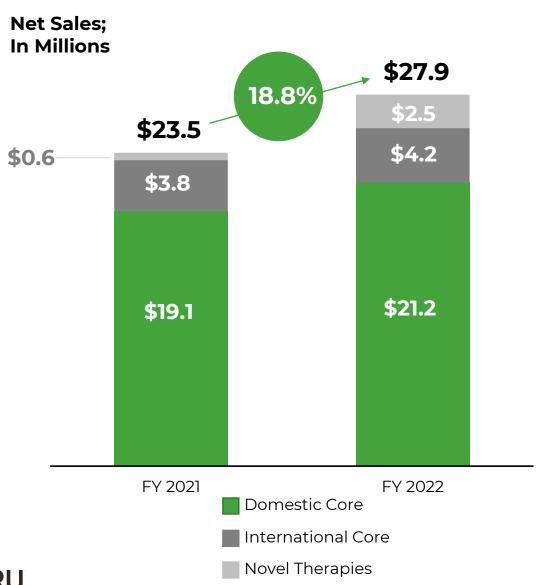




Financial Review

Tom Adams
Interim Chief Financial Officer

Full Year Strength Across All Three Businesses



Domestic Core

- Increased 11.3% year on year
- Driven by market, prefill patient growth and new account gains

Novel Therapies

- Increased 329.8% year on year
- Driven by non-recurring engineering services and pipeline expansion

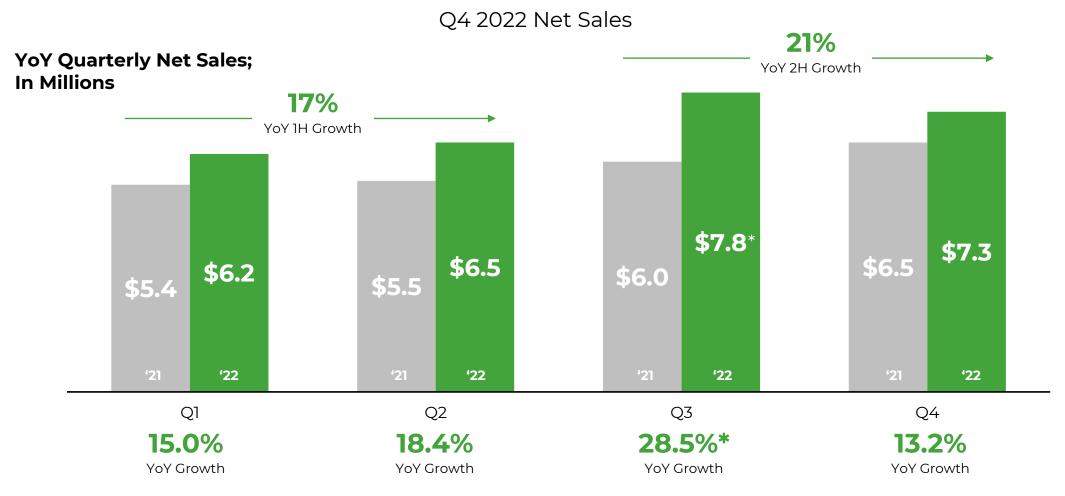
International Core

- Increased 8.0% year on year
- Strong 2H growth 15% led by new label indications across several countries



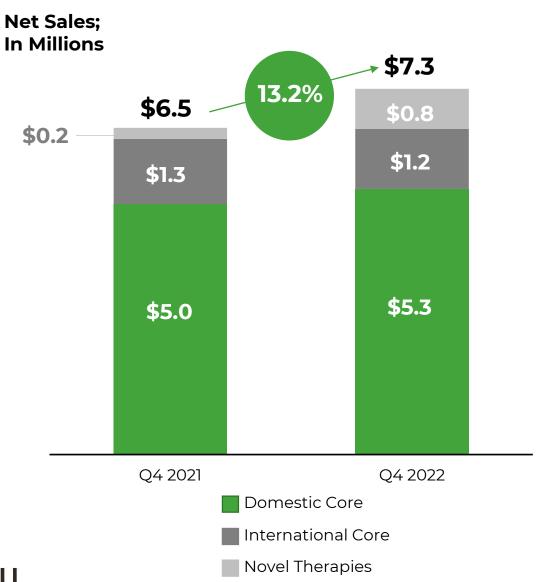
Net Sales Momentum Front Half to Back Half

\$7.3M





Q4 Growth Propelled by Novel Therapies



Novel Therapies

- Increased 260% Q4 year on year
- Significant progress on NRE innovation milestones and clinical service revenues

Domestic Core

- Increased 6.2% Q4 year on year; 2H 11% growth
- Driven by continued strength in prefilled syringe adoptions

International Core

- Decreased year on year 3.2%
- Revenue affected by prior year timing of orders in two countries
- 2H growth 15% driven by growth in Germany and in several markets for new label indications



Full Year Gross Margin

Gross Margin Change 2022 vs. 2021



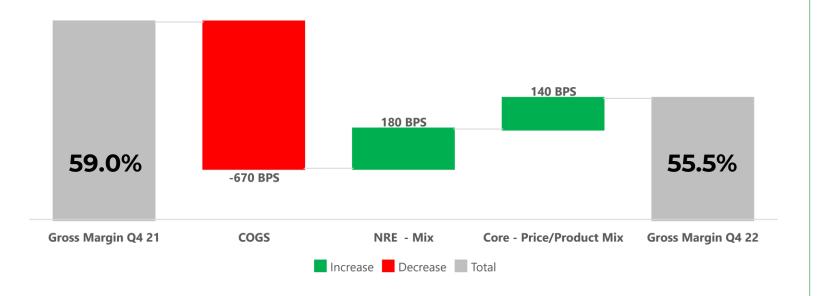
Full Year 2022

- Increase in COGS -400BPS
 - YOY cost increases for labor and materials - 210 BPS
 - Additional labor for backorder/inventory recovery - 140 BPS
 - Q4 transition expenses -50 BPS to support outsourced manufacturing
- -50 BPS NRE service revenue at a lower margin vs product
- +100 BPS Increases in Core ASP and product mix impact



Q4 Gross Margin

Gross Margin Change Q4 2022 vs. Q4 2021



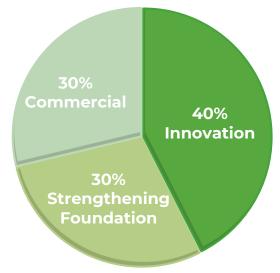
Q4 2022

- Increase in COGS -670 BPS
 - Year-year cost increases for labor and materials - 223 BPS
 - Additional labor for backorder/inventory recovery - 257 BPS
 - Ramp down of Chester MFG facility to support outsourced manufacturing and margin enhancements - 190 BPS
- +180 BPS Improved NRE mix
- +140 BPS Increase in Core average selling price and product mix impacts



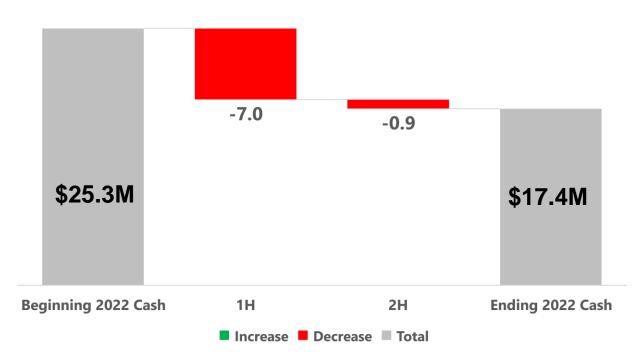
Strategic Use of Cash

Cash Balance at Year End 2022: \$17.4M



- Innovation investments in Novel Therapies
- Strengthening the foundation with new site (Mahwah) and Quality/Regulatory investments
- Commercial investments in Novel Therapies and US business

In millions



1H – New site investments, annual bonus, year-end accrual reversals, recruitment fees

2H – Higher gross profit, lower expenses, working capital improvements

Disciplined investment strategy to accelerate value creation





Guidance and Closing Comments

Linda Tharby

President and Chief Executive Officer

2023 Guidance

Revenue Growth

Revenue guidance in range 17%-20%, or \$32.5-\$33.5 million

Key Drivers/Milestones

- Core SCIg drug market growth of ~10%, prefilled syringe penetration 15-20%
- Expanded Novel Therapies pipeline with 6 new collaborations
- 2 new 510k filings in back half

Gross Margin Profile

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

Key Drivers/Milestones

- Completion of Manufacturing transition in 1H
 - Chester Site Closure Q1
 - 3rd Party Outsourcing Completion Q2
- 55-57% 1H, 60%+ margins in 2H

Cash & Cash Flow

Greater than **\$10M** ending cash balance

Key Drivers/Milestones

- Operating Expense of ~ \$30M, inclusive of stock compensation expense
- Working capital improvements
 - Inventory reduction of ~\$2M
- Higher cash burn in 1H driven by year end bonuses / accruals
- Estimated breakeven in 2H 2024 based on current strategic outlook



A Stronger Team Delivering on 2022 – With Clear Pathway to 2026 Milestones



Fifth consecutive quarter of double-digit growth, and FY 2022 delivered 19% y/y growth



U.S. and International growth driven by strength of **prefill syringes**, **new indications**, and a **strengthening** global subcutaneous **Ig drug market**



Novel Therapies business finished the year with **14 total collaborations** – delivering \$2.0M in incremental revenues for FY 2022 and **increasing TAM to \$2.5B**



Innovation and strategic investments supporting **2 new 510k filings**, **+ 5 Novel Therapies collaborations** in 2023



FY 2023 revenue guidance in a range of 17%-20%, and gross margin exiting the year at +60%



On track to **+\$60M by 2026** and **multiple new Novel Therapies drug label indications**





GAAP Reconciliation

| Reconciliation of GAAP Net (Loss) | Three Months Ended December 31, | | | | | Twelve Months Ended December 31, | | | | |
|-----------------------------------|------------------------------------|-------------|----|------------|----|-------------------------------------|-------------|--|--|--|
| to Non-GAAP Adjusted EBITDA: | | 2022 | | 2021 | | 2022 | 2021 | | | |
| GAAP Net Loss | \$ | (1,976,728) | (| 1,068,358) | \$ | (8,661,142) \$ | (4,562,823) | | | |
| Tax (Benefit)/Expense | | (434,659) | | (375,837) | | (2,014,018) | (1,801,618) | | | |
| Depreciation and Amortization | | 187,658 | | 113,308 | | 587,137 | 463,130 | | | |
| Interest (Income)/Expense, Net | | (101,009) | | 3,800 | | (145,587) | (13,083) | | | |
| Reorganization Charges | | ` <u> </u> | | _ | | 765,433 | 1,192,618 | | | |
| Manufacturing Initiative Expenses | | 184,343 | | 1,883 | | 293,229 | 239,216 | | | |
| Stock-based Compensation Expense | | 588,654 | | 739,922 | | 3,079,426 | 2,707,544 | | | |
| Non-GAAP Adjusted EBITDA | \$ | (1,551,741) | \$ | (585,282) | \$ | (6,095,522) \$ | (1,775,016) | | | |

| Reconciliation of Reported Diluted EPS | Three Months Ended December 31, | | | | Twelve Months Ended December 31, | | | | |
|--|------------------------------------|--------|----|--------|-------------------------------------|--------|----|--------|--|
| to Non-GAAP Adjusted Diluted EPS: | | 2022 | | 2021 | | 2022 | | 2021 | |
| Reported Diluted Earnings Per Share | \$ | (0.04) | \$ | (0.02) | \$ | (0.19) | \$ | (0.10) | |
| Reorganization Charges | | _ | | _ | | 0.02 | | 0.03 | |
| Manufacturing Initiative Expenses | | _ | | _ | | 0.01 | | 0.01 | |
| Stock-based Compensation Expense | | _ | | _ | | _ | | 0.01 | |
| Tax (Expense) Adjustment | | _ | | _ | | | | (0.01) | |
| Non-GAAP Adjusted Diluted Earnings Per | | | | _ | \$ | | \$ | | |
| Share | \$ | (0.04) | \$ | (0.02) | | (0.16) | | (0.06) | |



GAAP Reconciliation

Reorganization Charges. We have excluded the effect of reorganization charges in calculating our non-GAAP measures. In 2021 we incurred significant expenses in connection with the departure and replacement of our chief executive officer and the recruiting of two new board members, which we would not have otherwise incurred in periods presented as part of our continuing operations. In 2022 we incurred further severance expense related to the reorganization of the leadership team and the departure of our chief financial officer, which we would not have otherwise incurred in periods presented as part of continuing operations.

Manufacturing Initiative Expenses. We have excluded the effect of expenses related to creating manufacturing efficiencies, in calculating our non-GAAP measures. We incurred expenses in connection with these initiatives which we would not have otherwise incurred in periods presented as part of our continuing operations. We expect to incur related expenses for the next three to six months.

Stock-based Compensation Expense. We have excluded the effect of stock-based compensation expense in calculating our non-GAAP measures. We record non-cash compensation expense related to grants of options and restricted shares for executives, employees and consultants, and grants of shares to our board of directors. Depending upon the size, timing and the terms of the grants, the non-cash compensation expense may vary significantly but will recur in future periods.

