



# KORU Medical Systems

Q4 and Full Year 2021 Earnings  
March 2, 2022

# 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 CAGR, revenues, gross margin, 510(k) approvals, market share capture, SCIg adoption, and new novel therapies drugs. Forward-looking statements are neither historical facts nor assurances of future performance and are 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: impact of COVID-19 related to new SCIg patient starts, plasma supply, clinical trial activity, and supply chain; 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 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, 2021, which is available on the SEC website at [www.sec.gov](http://www.sec.gov) and on our website at [www.korumedical.com/investors](http://www.korumedical.com/investors). 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 otherwise.

This presentation includes certain non GAAP financial measures 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. In addition, 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 our reported results and, therefore, should not be relied upon as the sole financial measures to evaluate our financial results. The non GAAP financial measures are meant to supplement, and to be viewed in conjunction with, GAAP financial results. Reconciliations of our non-GAAP financial measures are included at the end of this presentation.

Revenue: All references to revenue(s) within the presentation refer to net revenue(s).



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# Q4 Highlights

Linda Tharby

*President and Chief Executive Officer*

# Well Positioned to Create Long-Term Value

**Market Leading  
Subcutaneous  
Immunoglobulin  
(SCIg) Home  
Infusion Platform**

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25k patients on  
platform

**Proven  
Pharmaceutical  
Partnership Model**

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11 commercialized  
drugs/indications on  
Koru Medical pump

**Attractive, Scalable  
Business Model**

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Recurring monthly  
consumables  
revenue

**Extending our  
Leadership in U.S.  
SCIg to Growing  
Subcutaneous  
Home Infusion  
Market**

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\$1.3B Total  
Addressable Market

# Strong Q4 Momentum

**\$6.5M**

Q4 2021 net revenues

- **60.0%** year-on-year revenue growth, **27.6%** on an adjusted basis
- 4 quarters of consecutive growth
- 4<sup>th</sup> quarter growth driven by strength across all 3 businesses

Quarterly Net Revenues; in Millions



Q4 Adjusted Net Revenues by Business; in Millions

	Q4 2021	Q4 2020	% Change
Domestic Core	\$5.0M	\$4.2M*	20.1%
International Core	\$1.3M	\$0.8M	51.3%
Novel Therapies	\$0.2M	\$0.1M	330.7%

\* Figures represent non-GAAP adjusted net revenues (early order/inventory stocking). See reconciliation to GAAP table in appendix.



# Vision 2026 - Our Plan for the Next Phase of Value Creation

## Increase Core SCIg Penetration – \$300M\* U.S. TAM



- New SCIg patient starts
- Win SCIg prefills
- Geographic expansion
- **2026 Milestones**
  - 8 new 510(k) clearances for products/indications

## Extend to Novel Therapies – \$1B\* U.S. TAM



- Focus on large volume >10ml
- **2026 Milestones**
  - 5 new novel therapy Phase III trials
  - 1 commercialized



## Building the Foundation – Strong Team/Innovation/Operational Excellence



• ~20% CAGR through 2026

• ~\$60M Revenue 2026

# New Clearances in Q4 2021



**CSL Behring**  
Hizentra<sup>®</sup>  
SCIg for PIDD

**CSL Behring**  
Hizentra<sup>®</sup>  
SCIg for CIPD

**Takeda**  
Cuvitru<sup>®</sup>  
SCIg for PIDD

**GRIFOLS**  
Xembify<sup>®</sup>  
510k Cleared

**CSL Behring**  
Hizentra<sup>®</sup>  
510k Cleared  
20 mL PFS

**octapharma**  
cutaquig<sup>®</sup>  
510k Cleared

**Apellis**  
EMPAVELI<sup>®</sup>  
510k Submitted

2010

2021

2022



**CSL Behring**  
Hizentra<sup>®</sup>  
SCIg for PIDD

**Takeda**  
HyQvia<sup>®</sup>  
SCIg for PIDD

**Takeda**  
Cuvitru<sup>®</sup>  
SCIg for PIDD

**octapharma**  
cutaquig<sup>®</sup>  
EU Label Addition

**Apellis** **sobi**  
EMPAVELI<sup>®</sup> (preparatoplan)  
EU Label Addition





# Building Momentum in Novel Therapies – Q4 Closed Agreements

Q4 2021

4

New Closes in Q4 2021

- Respiratory
- Oncology
- Immunology (2x)

	Development Stage	Ig	New Drugs	Total
Closed	Phase III	2	0	2
	Earlier	0	2	2
Total Closed		2	2	4

FY 2021

6

New Closes in 2021

- Respiratory
- Oncology
- Immunology (2x)
- Hematology
- Neurology

	Development Stage	Ig	New Drugs	Total
Closed	Phase III	2	1	3
	Earlier	1	2	3
Total Closed		3	3	6

- Earlier – Indicates Feasibility through Phase II
- Phase III is Pharma company final clinical trial prior to FDA approval
- Revenues for Novel Therapies include product sale for use in clinical trial, and/or services revenue
- Pursuing over 15 new opportunities – with the majority of these in NT

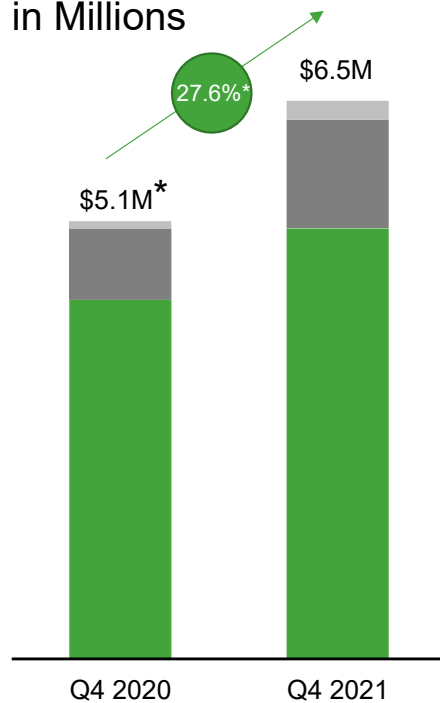


# Financial Review

Karen Fisher  
*Chief Financial Officer*

# Q4 2021

Adjusted Net Revenues\*;  
in Millions



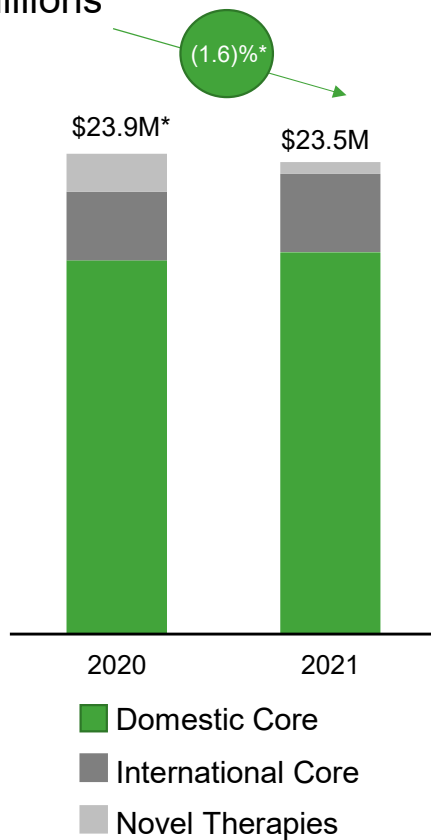
- Domestic Core
- International Core
- Novel Therapies

	Q4 2020	Q4 2021
Gross Margin	56.6%	59.0%
Operating Expenses	\$3.5M	\$5.9M
Net Loss	(\$0.8)M	\$(1.1)M
Adjusted EBITDA*	(\$0.3)M	\$(0.6)M

\*Figures represent non-GAAP adjusted net revenues (early order/inventory stocking), and non-GAAP adjusted EBITDA. See reconciliation to GAAP table in appendix.

# Full Year 2021

Adjusted Net Revenues\*;  
in Millions



	2020	2021
Gross Margin	61.8%	58.6%
Operating Expenses	\$16.2M	\$20.8M
Net Loss	(\$1.2)M	(\$4.6)M
Adjusted EBITDA*	\$3.7M	(\$1.8)M

\*Figures represent non-GAAP adjusted net revenues (early order/inventory stocking), and non-GAAP adjusted EBITDA. See reconciliation to GAAP table in appendix.



# Guidance and Closing Comments

Linda Tharby

*President and Chief Executive Officer*

# 2022 Guidance

## Revenue Growth

Outlook of **\$26 to \$27** million net revenues in 2022

### Key Drivers/Phasing:

- U.S. SCIg market growth in the high single digits
- New novel therapies closed agreements
- Expect double digit year-on-year growth with a slower Q1 2022 start due to Q4 2021 Omicron impact

## Gross Margin Profile

Outlook of **60%** run rate to exit 2022

### Key Drivers/Phasing:

- Gross margin will be impacted through Q3 2022 by manufacturing transition
- Expect first half 2022 to be consistent with Q4 2021

## Operating Expenses

Outlook of **\$27 to \$28** million in 2022

### Key Drivers/Phasing:

- Operating expenses include investment in
  - R&D for product innovation
  - Expanding novel therapies pipeline
  - Building the foundation [team/facility move]
- Growth off Q4 2021 run rate of 10-15% to hold through the year 2022



# Well Capitalized to Drive Shareholder Value

\$25.3M cash as of December 31<sup>st</sup>, 2021

## Use of Funds



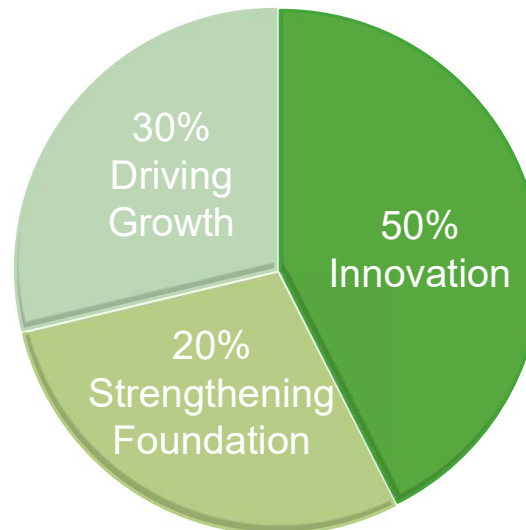
Innovation



Driving growth



Strengthening foundation



Disciplined investment strategy to drive KORU Medical to the next phase of value creation

# Q4 2021 Highlights



Q4 2021 marked a return to double-digit growth



3 new 510(k) clearances Hizentra<sup>®</sup> for 20mL prefilled syringes, and two additional SCIg drugs, Cutaquig and Xembify



Expanded novel therapies pipeline with 4 new closed agreements – 2 non-IG



Pathway to ~20% CAGR through 2026 with \$1.3B U.S. TAM



Strengthened leadership team positioned to execute and drive growth

# Appendix

# Non-GAAP Net Revenues Reconciliation

## Reconciliation of Reported Net Revenues to Non-GAAP Net Revenues

	Three Months Ended December 31,		Change from Prior Year	
	2021	2020	\$	%
Reported Net Revenues	\$ 6,490,507	\$ 4,057,220	\$ 2,433,287	60.0%
Early Order/Inventory Stocking	—	1,031,000	(1,031,000)	100.0%
Non-GAAP Adjusted Net Revenues	\$ 6,490,507	\$ 5,088,220	\$ 1,402,287	27.6%

## Reconciliation of Reported Net Revenues to Non-GAAP Net Revenues

	Twelve Months Ended December 31,		Change from Prior Year	
	2021	2020	\$	%
Reported Net Revenues	\$ 23,490,175	\$ 24,176,448	\$ (686,273)	(2.8%)
Early Order/Inventory Stocking	—	(304,000)	304,000	100.0%
Non-GAAP Adjusted Net Revenues	\$ 23,490,175	\$ 23,872,448	\$ (382,273)	(1.6%)

*Early Order/Inventory Stocking.* For the quarter, we included the effect of an early order and covid related inventory stocking in calculating our non-GAAP measure. We had an early order from our largest distributor in the three months ended September 30, 2020, which would have otherwise been placed in the three months ended December 31, 2020, as well as higher purchases in the first half of the year that we believe would have been made in the second half of 2020, had it not been for the pandemic. For the twelve months ended December 31, 2020, we excluded what we believe to still be inventory stocking purchased in the first half of the year, had it not been for the pandemic.

# Non-GAAP Adjusted EBITDA & EPS Reconciliation

Reconciliation of GAAP Net Loss to Non-GAAP Adjusted EBITDA:	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
GAAP Net Loss	\$ (1,068,358)	\$ (834,628)	\$ (4,562,823)	\$ (1,212,063)
Tax (Benefit)/Expense	(375,837)	(298,400)	(1,801,618)	17,800
Depreciation and Amortization	113,308	120,794	463,130	418,595
Interest Expense/(Income), Net	3,800	(18,705)	(13,083)	(42,395)
Reorganization Charges	—	95,700	1,192,618	95,700
Discontinued Product Expenses	—	(459)	—	70,859
Litigation Expenses	—	466	—	2,447,213
Manufacturing Initiative Expenses	1,883	51,723	239,216	246,527
Stock-based Compensation Expense	739,922	607,592	2,707,554	1,618,732
Non-GAAP Adjusted EBITDA	<u>\$ (585,282)</u>	<u>\$ (275,917)</u>	<u>\$ (1,775,006)</u>	<u>\$ 3,660,968</u>

Reconciliation of Reported Diluted EPS to Non-GAAP Adjusted Diluted EPS*:	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2021	2020	2021	2020
Reported Diluted Earnings Per Share	\$ (0.02)	\$ (0.02)	\$ (0.10)	\$ (0.03)
Reorganization Charges	—	—	0.03	—
Discontinued Product Expense	—	—	—	—
Litigation Expenses	—	—	—	0.06
Manufacturing Initiative Expenses	—	—	—	0.01
Stock-based Compensation Expense	—	—	0.01	—
Tax (Expense) Adjustment	—	—	(0.01)	(0.02)
Non-GAAP Adjusted Diluted Earnings Per Share	<u>\$ (0.02)</u>	<u>\$ (0.02)</u>	<u>\$ (0.07)</u>	<u>\$ 0.02</u>

\* Numbers presented are rounded to the nearest whole cent

# Non-GAAP Adjusted EBITDA & EPS Reconciliation (Cont.)

*Reorganization Charges.* We have excluded the effect of reorganization charges in calculating our non-GAAP measures. 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.

*Discontinued Product Expense.* We have excluded the effect of expenses related to a discontinued product line in calculating our non-GAAP measures. We did not incur any related expense in 2021.

*Litigation.* We have excluded litigation expenses in calculating our non-GAAP measures. Litigation expenses in 2020 included professional fees associated with our litigation with EMED, which discontinued as a result of the settlement on May 20, 2020.

*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 six to nine 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 for executives, employees and consultants, and grants of common stock to our board of directors and our CEO. 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. Adjusted EBITDA for the twelve months ended December 31, 2021 included stock-based compensation expense of \$0.4 million related to the departure and replacement of our chief executive officer. This expense is the only amount included in Stock-based Compensation Expense in calculating Adjusted Diluted EPS .