

**Outset Medical Investor Presentation** November 2022



# Forward-looking statements and non-GAAP information

This presentation and the accompanying oral statements contain forward-looking statements within the meaning of the federal securities laws. All statements other than statements of historical fact are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expect," "plan," anticipate," "believe," "estimate," "predict," "intend," "potential," "would," "continue," "ongoing" or the negative of these terms or similar expressions. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect our business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties.

These forward-looking statements include, but are not limited to, statements about our possible or assumed future results of operations and financial position, including expectations regarding projected revenues, and revenue growth rate, gross margin, profitability and outlook, statements regarding our overall business strategy, plans and objectives of management, our expectations regarding the market sizes and growth potential for Tablo and the total addressable market opportunities for Tablo, our planned expansion within the home hemodialysis market, our expectations with respect to anticipated benefits of the TPNIES approval, as well as our expectations regarding the impact of the COVID-19 pandemic and other macroeconomic factors on us and our operations as well as the impact on our customers and suppliers. Forwardlooking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, which could cause actual results to differ materially from those expressed or implied in these forward-looking statements. These risks and

uncertainties include: our future financial performance, including our expectations regarding our revenues, cost of revenues, operating expenses, gross margin and our ability to achieve and maintain future profitability; continued execution of our initiatives designed to reduce the cost of producing and shipping Tablo devices and our ability to achieve projected cost reductions at the levels or within the timeframe we estimate; our ability to attain market acceptance among providers and patients; our ability to manage our growth; our expansion into the home hemodialysis market; our ability to ensure strong product performance and reliability; our relations with third-party suppliers, including contract manufacturers and single source suppliers; our ability to overcome manufacturing disruptions; the impact of COVID-19, natural or man-made disasters, and similar events, as well as the impact of macroeconomic factors, on our industry, business and results of operations; our ability to offer high-quality support for Tablo; our expectations of the sizes of the markets for Tablo; our ability to innovate and improve Tablo; our ability to effectively manage privacy, information and data security; concentration of our revenues in a single product and concentration of a large percentage of our revenues from a limited number of customers; our ability to compete effectively; our ability to accurately forecast customer demand and manage our inventory; our ability to ensure the proper training and use of Tablo; potential disruptions to our business and operations as a result of the prior Tablo home shipment hold; and our compliance with FDA and other regulations applicable to our products and business operations; as well as other risks and uncertainties described in the Risk Factors section of our public filings with the SEC, including our most recent annual and quarterly reports. Forward- looking statements should be considered in light of these risks and uncertainties, and you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of their date and we undertake no obligation to publicly update or revise any forward-

looking statement, whether as a result of new information, future developments or otherwise.

This presentation and the accompanying oral presentation also contain statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. This information involves many assumptions and limitations, and you are cautioned not to give undue weight to such information. We have not independently verified the accuracy or completeness of the information contained in the industry publications and other publicly available information. Accordingly, we make no representations as to the accuracy or completeness of that information nor do we undertake to update such information after the date of this presentation.

In addition to financial information presented in accordance with U.S. generally accepted accounting principles ("GAAP"), this presentation and the accompanying oral statements include certain non-GAAP financial measures, which may include Non-GAAP gross profit/loss, gross margin, operating expenses, net income/loss, and basic and diluted net income/loss per share. Any non-GAAP measure is presented for supplemental informational purposes only and should not be considered a substitute for or superior to financial information presented in accordance with GAAP. There are limitations related to the use of non-GAAP financial measures because they are not prepared in accordance with GAAP, may exclude significant expenses required by GAAP to be recognized in our financial statements, and may not be comparable to non-GAAP financial measures used by other companies. A reconciliation of these measures to the most directly comparable GAAP measures is included at the end of this presentation.

Tablo<sup>®</sup> is a disruptive, first-of-its-kind technology designed to reduce the cost and complexity of dialysis.



### **Investment highlights**



\$11.4B U.S. total addressable market<sup>1</sup>

1. Company estimates based on data contained in U.S. Renal Data System's 2021 Annual Data Report



Established footprint in \$2.5B U.S. acute care market is a strategic entry point for \$8.9B U.S. home market



**Revenue guidance of** \$111M-\$113M in 2022 and 50%+ gross margins

- over the longer-term
- 271% 3-year • revenue CAGR (2018–2021)
- Growth in recurring • revenue from higher-margin consumables and services

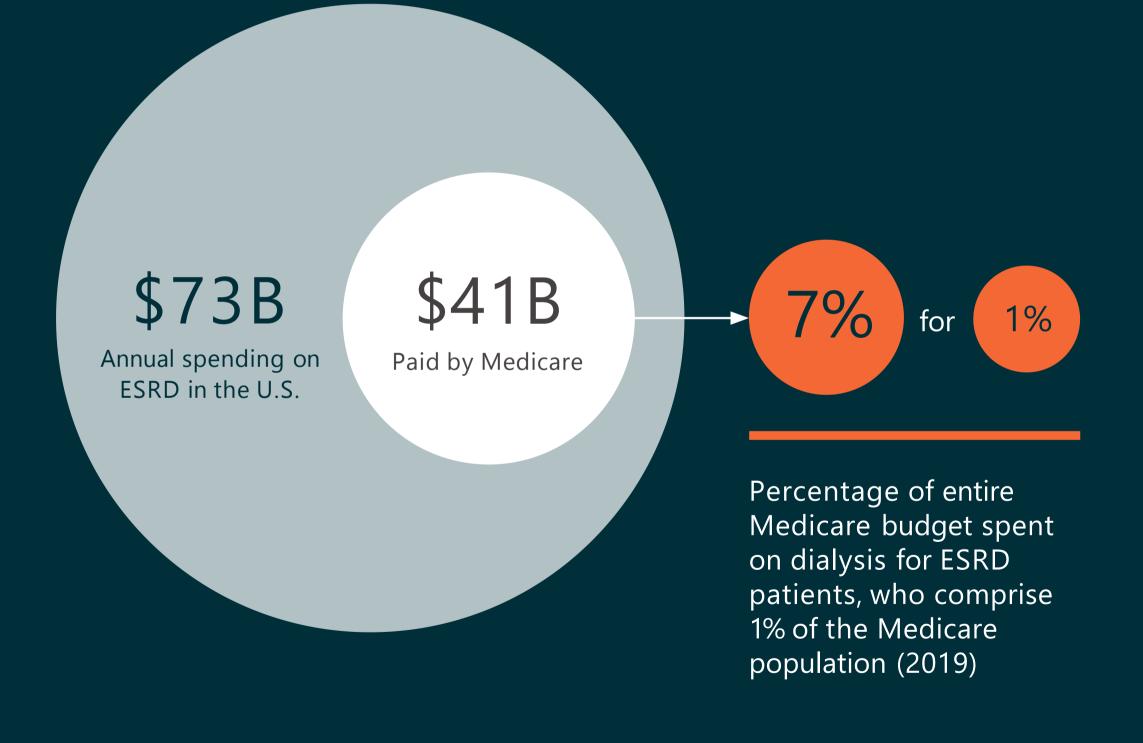
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**Recent reimbursement** tailwinds expected to drive home dialysis adoption

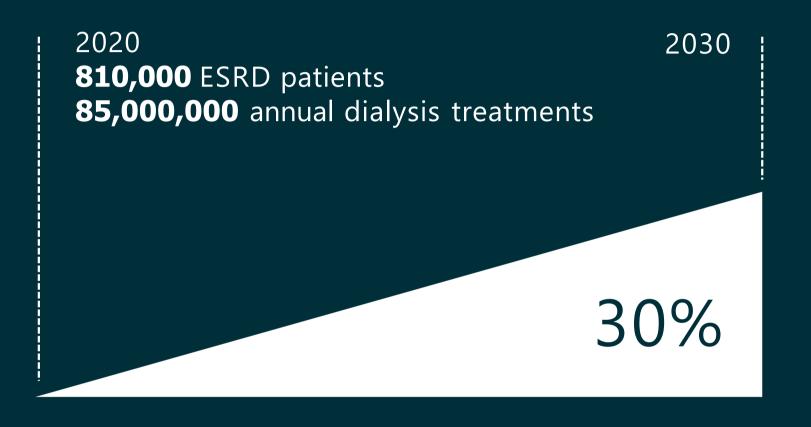


**Proven management** team with track record of execution

## Dialysis is one of the largest, most expensive, least-changed sectors of healthcare



Company estimates based on and data contained in U.S. Renal Data System's 2021 Annual Data Report



Expected ESRD patient population growth by 2030 as a result of **aging**, **diabetes**, hypertension and obesity

#### **CURRENT STATE**

## Patients are treated with dialysis across multiple settings of care

**ACUTE CARE** Hospital & sub-acute based dialysis

#### 4.5 million Treatments/year<sup>1</sup>

#### ~3% Annual growth rate

- 1. Company estimates based on 2020 Definitive Healthcare data
- 2. Company estimates based on data contained in U.S. Renal Data System's 2021 Annual Data Report

**CHRONIC CARE** In-center, transitional care & home hemodialysis

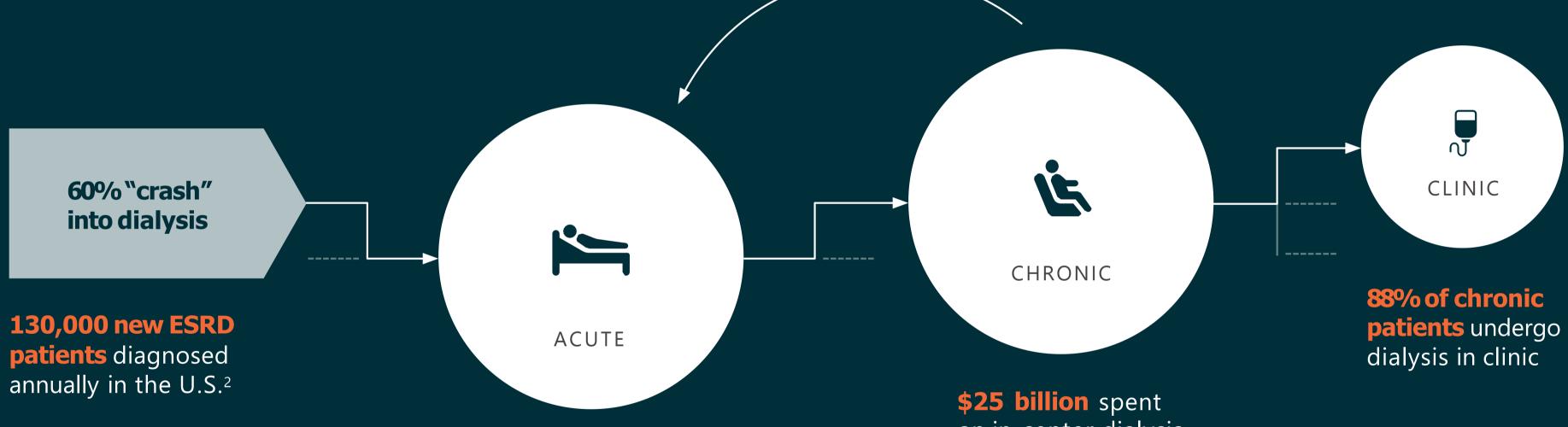
**81** million Treatments/year<sup>2</sup>

8-10%

## Annual growth rate for home dialysis

#### **CURRENT STATE**

# The result: hospitals lose money while patient outcomes remain poor



- 1. 2019 Medicare Claims data for MS-DRG 682 and MS-DRG 683
- 2. Company estimates based on, and data contained in, U.S. Renal Data System's 2021 Annual Data Report
- 3. Hickson LJ. et al. Nephron. 2018 ; 139(1): 1–12.

#### \$5,000-\$15,000

Average loss by hospital for each inpatient stay for renal failure with dialysis<sup>1</sup> **34% readmission** 30-day hospital readmission rate for hemodialysis patients<sup>3</sup>

on in-center dialysis treatments annually<sup>2</sup>

# Complicated

## Burdensome

## Inflexible

8

Expensive labor and supplies Operational inefficiency Low adoption and retention at home Innovation is desperately needed

## tablo®

A first-of-its-kind enterprise solution that replaces multiple machines and a water treatment room with a single device



#### Anywhere

An electrical outlet and tap water instead of costly fixed infrastructure

#### Anytime

Water purification and dialysate on demand, customized to the patient's prescription

#### Anyone

Sensors, data analytics and a touchscreen interface make Tablo easy to learn and use

## **Broad technology innovation drives execution against key strategic initiatives**

#### **Benefits to customers**

- EMR-integrated treatment data and Tablo fleet management
- Remote diagnostics and predictive maintenance
- Remote treatment monitoring and clinical analytics

2-way wireless data ecosystem

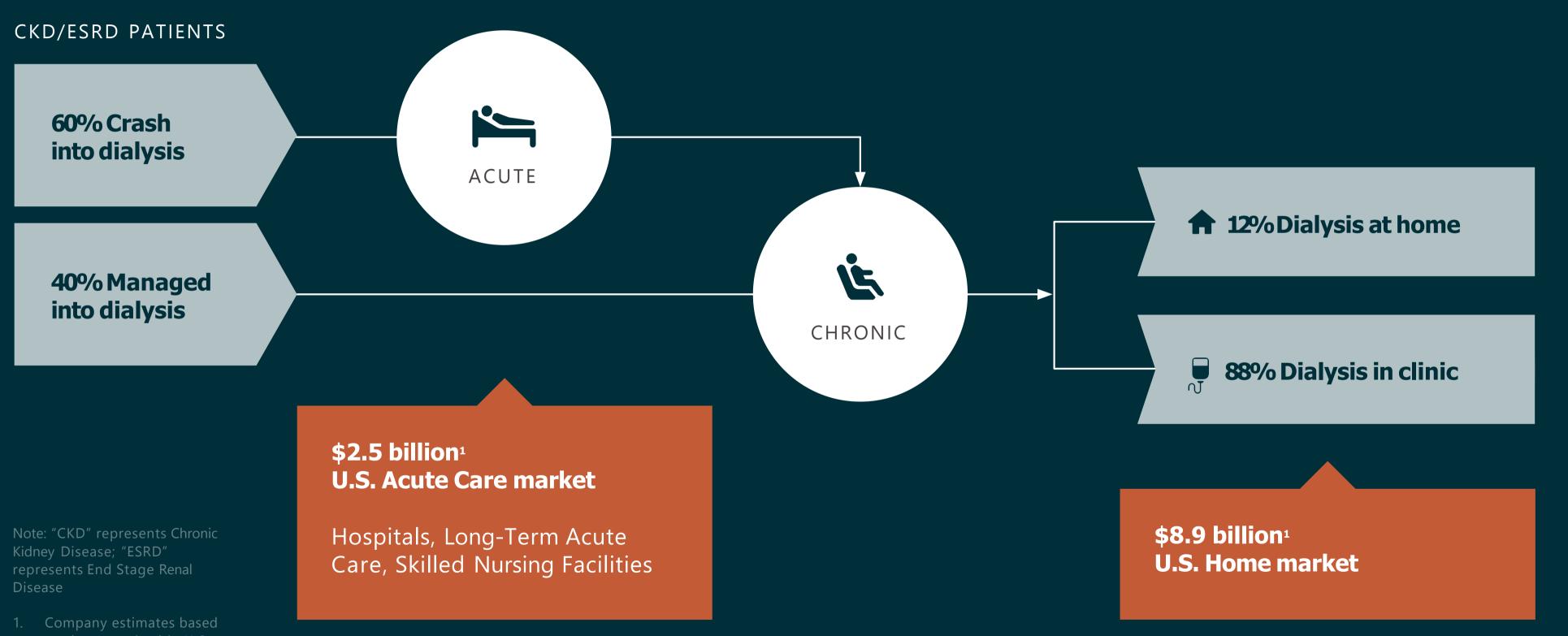
**Tablo Cloud** 



- Operating efficiencies and gross margin expansion
- State-of-the-art, cloud-based manufacturing and quality documentation system
- Digitized supply chain, virtual distribution and logistics tracking

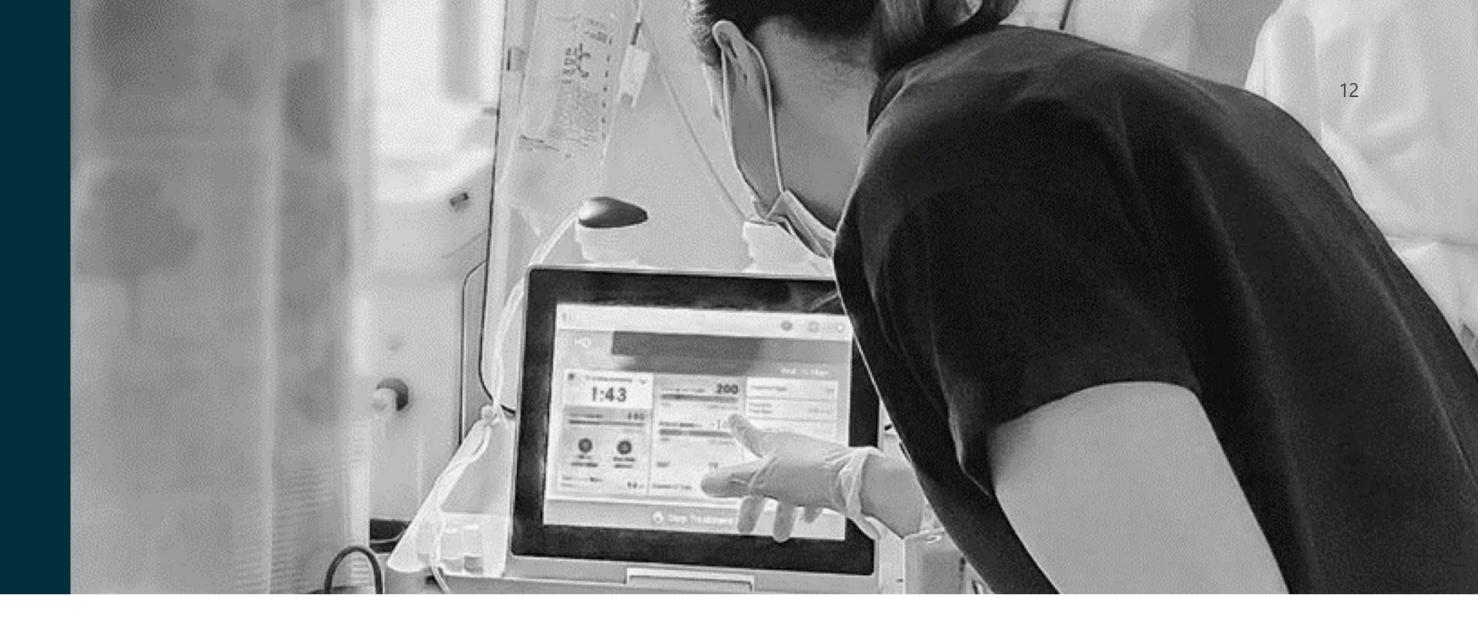
#### **DIALYSIS CARE LANDSCAPE**

## \$11.4B U.S. addressable market



on data contained in U.S. Renal Data System's 2021 Annual Data Report

## Dialysis is a cost center for hospitals



- No separate DRG for inpatient dialysis; ~600 DRGs involved dialysis in 2018
- 60% of hospitals stays involving dialysis resulted in negative operating margin, with average loss of \$5,000-\$15,000 per stay

Company estimates based on data contained in U.S. Renal Data System's 2021 Annual Data Report and 2020 Definitive Healthcare data; 2019 Medicare claims data for MS-DRG 682 and MS-DRG 68

## 536,000

#### **ESRD** annual admissions

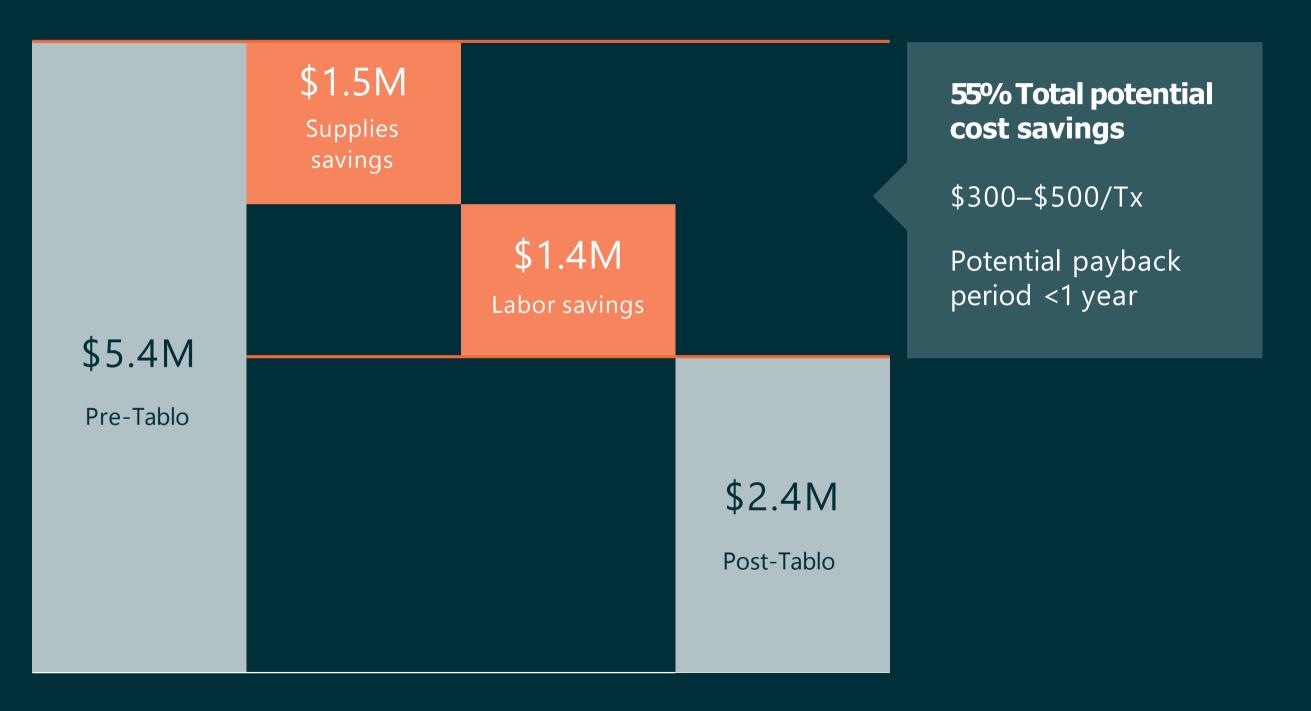
## 454,000

Additional Acute Kidney Injury annual admissions

## Significant cost savings generated for leading hospitals and health systems

#### Case Study

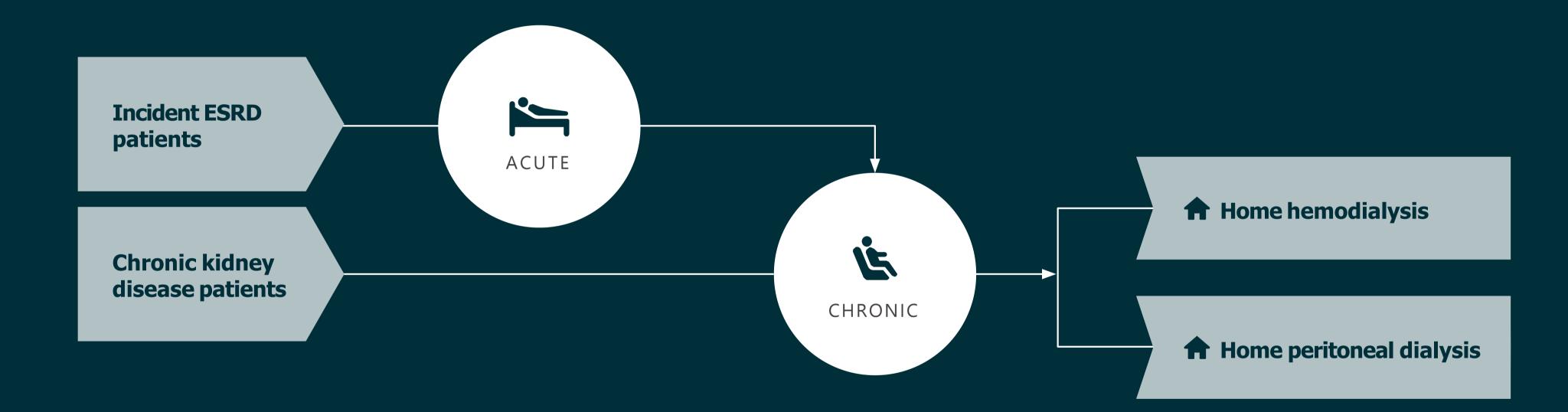
ICU Dialysis Cost Cut by 55% Cleveland Clinic



#### PROJECTED ANNUAL ICU DIALYSIS COST

Source: Cleveland Clinic; company estimates based on data provided by third party health system

# Tablo enables health systems to optimize patient care from the ICU to the home



- 1. Based on costs for dialysis in the ICU
- 2. Chan CT. et al. Kidney International (2019) 96, 37–47
- Based on 5-year calculation for Tablo
  Home program. Key assumptions:
  \$350 per treatment *X* 3.5 treatments
  per week

01

Reduce acute labor and supplies cost by **up to 80%**<sup>1</sup>

**02 Over 50%** of chronic dialysis patients managed at home<sup>2</sup> 03 Drive \$15,000–\$17,000 in annual profit per Tablo Home patient<sup>3</sup>

## The Tablo Home program brings economic opportunity

# \$15,000-\$17,000

Amount of annual profit each patient has the potential to generate for the provider<sup>1</sup>

- Based on 5-year calculation for Tablo Home program. Key assumptions: \$350 per treatment X 3.5 treatments per week
- 2. Key assumptions: \$350 per treatment, factoring in an estimated 65% Medicare payer mix from hospital cost report data for home-only programs

#### ESRD patients

1,000

Annual revenue outsourced to 3rd party dialysis operators<sup>2</sup>

 $\sim$ \$36 million

Converting 30% of ESRD patients to home program drives ~\$5 million in annual profit

## **Physicians and patients prefer Tablo**

NEPHROLOGISTS n=184 77%

Rated Tablo as a significant clinical improvement 98%

Said Tablo's benefits make them **more likely to recommend home dialysis** 

IN-CENTER & PERITONEAL DIALYSIS PATIENTS n=138

72%

Rated Tablo as a significant clinical improvement

77%

Rated Tablo's benefits as making them **more likely to try home dialysis** 

Company analysis undertaken with a third party. For additional clinical evidence, including from the XTEND and The First 1,000 Real-World Treatment studies, visit https://outsetmedical.com/clinical-evidence/

#### **XTEND Study Highlights**

50	Consecutive Tablo XT treatments
23.5 hrs	Median treatment time in the ICU setting
<b>4</b> %	Ended due to clotting
14 sec	Average alarm resolution time

#### The First 1,000 Real-World Treatments Study Highlights

<b>100</b> %	Patient retention, with no patients opting out of Home Hemodialysis (HHD)
93%	Treatment adherence
95%	Treatments completed within 10% of prescribed time

## The home market is significantly underpenetrated



Company estimates based on, and data contained in, U.S. Renal Data System's 2021 Annual Data Report

#### ~570,000

Chronic dialysis patients

#### 30%

Patients eligible for home hemodialysis

### 2%

Patients on home hemodialysis

alvsis

#### **Historical barriers**

- Medicare reimbursement misaligned with treatment frequency
- Inadequate provider payment incentives
- Cumbersome technology and training

Tablo addresses key barriers to home dialysis adoption and retention



## tablo®

3x

Treatments per week

<25 hours Training per patient

0 hours Dialysate prep time



#### **Historical device**

5-6

Treatments per week

100 hours Training per patient

16–24 hours Dialysate prep time per week

# **IDE trial demonstrated Tablo's safety and effectiveness in the home**

Trial partici	pants
26–71	Years of age
43%	Black / Hispanic
27%	Latino
60%	History of diabetes
96%	History of hypertension

Met efficacy endpoints

Achieved weekly Std Kt/V  $\geq$  2.1

**In-Center** % weeks that met primary endpoint

2.8 Avg

99.5%

**In-Home** % weeks that met primary endpoint

2.8 Avg

98.3%

For additional clinical evidence, visit https://www.outsetmedical.com/clinical-evidence/

#### Met safety endpoints

1.8 Overall incidence of adverse events (0 pre-specified adverse events related to Tablo)

High home retention rate and treatment compliance

0%

Drop-out during in-home period 99%

Adherence to prescribed home treatment frequency

### **Positive Tablo patient experience**

#### Patients prefer Tablo for home<sup>1</sup>

Surveyed 13 patients in the IDE previously at home using the incumbent HHD machine

Preferred Tablo Preferred prior system

#### Patients report fewer symptoms on Tablo<sup>2</sup>

Patient-reported outcomes survey comparing in-clinic treatments on Tablo vs. their previous dialysis machine

#### PATIENT PREFERENCE RESULTS—TABLO VS PRIOR HOME SYSTEM

<b>100%</b> (	0%		Felt mor
<b>89.3%</b> 1	10.7%		Reported
<b>86.4%</b> 1	13.6%		Felt mor
<b>85.3%</b> 1	14.7%		Experier
<b>84%</b>	16%		Reported
<b>83.7%</b>	16.3%		
<b>83.7</b> %	16.3%		
<b>80.6%</b> 1	19.4%		
<b>78.3%</b> 2	21.7%		
<b>75.8%</b> 2	24.2%		
<b>85.6%</b> 1	14.4%		
	89.3% 86.4% 85.3% 84% 83.7% 83.7% 80.6% 78.3% 75.8%	100%89.3%10.7%86.4%13.6%85.3%14.7%84%16%83.7%16.3%83.7%16.3%80.6%19.4%75.8%24.2%85.6%14.4%	89.3%       10.7%         86.4%       13.6%         85.3%       14.7%         84%       16%         83.7%       16.3%         83.7%       16.3%         80.6%       19.4%         78.3%       21.7%         75.8%       24.2%

1. Outset 2019 IDE trial

2. Alvarez L, May Y, Chertow G. Early Patient Experience with the Tablo Hemodialysis System

ore energized after dialysis34%red less cramping during treatment61%ore relaxed during treatment48%enced fewer headaches after dialysis47%red fewer alarms during treatment78%

## **Reimbursement tailwinds for** home dialysis on Tablo

## 2022-2023

#### **TPNIES**

- ~\$23-25/treatment on top of the Medicare base rate for each Tablo home treatment over 2 years
- CMS determined Tablo to be a substantial clinical improvement over incumbent device
- Payment is per treatment, irrespective of number of treatments per week

#### CMS methodology: Price of console/5 yr useful life = X/156treatments per year = $Y/Tx \times 0.65 = Z/Tx - 9.50/Tx$ to account for what CMS already pays for equipment/Tx

## 2024-2027

#### **ESRD Treatment Choices Model (ETC)**

- ETC provides for additional payments (up to ~8%) or for reductions in payments (down by ~10%) depending on ability to drive home dialysis adoption and transplant wait list additions
- Biden Administration further strengthened the ETC for 2022 by further elevating the home dialysis rates providers must achieve to receive the incremental improvement and/or avoid penalties

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New Health Equity Incentive (HEI) starts July 2022 and rewards providers for a 2.5% increase in home dialysis and transplant adoption by low-income patients

# Outset's highly efficient business model

#### INITIAL CONSOLE PURCHASE



#### SINGLE PLATFORM

Optimizes commercial outreach and manufacturing



#### DATA ECOSYSTEM

Streamlines service and support

#### ONGOING REVENUE

Initial console purchase generates recurring and predictable consumable and service revenue



CONSOLE UTILIZATION

Leads to higher treatment revenue mix

# Integrated commercial strategy drives acute growth and home expansion

ACUTE STRATEGY

Top-down installed base growth through national and regional customers Expand within each location and across the system

> SAME CUSTOMERS, PHYSICIANS, TRAINING AND SUPPORT



CLINICAL SALES REPS

Utilization and fleet expansion



CAPITAL SALES TEAM

System-wide console adoption

#### HOME STRATEGY

Target health systems and innovative care providers Grow patient adoption, retention and cost of care evidence base



FIELD SERVICE ENGINEERS

Technical support

### **Strong financials**

#### as of Sept. 30, 2022

#### Acute

Continued demand from both new and existing customers; macroeconomic headwinds have persisted for provider customers, but stable since August

#### Home

Focused on regaining momentum following release of a temporary shipment hold on new Tablo consoles for home use

#### **Gross margin**<sup>2</sup>

Continued improvement from ongoing costdown programs, +50 basis points Q/Q; +500 bps Y/Y

#### Total cash

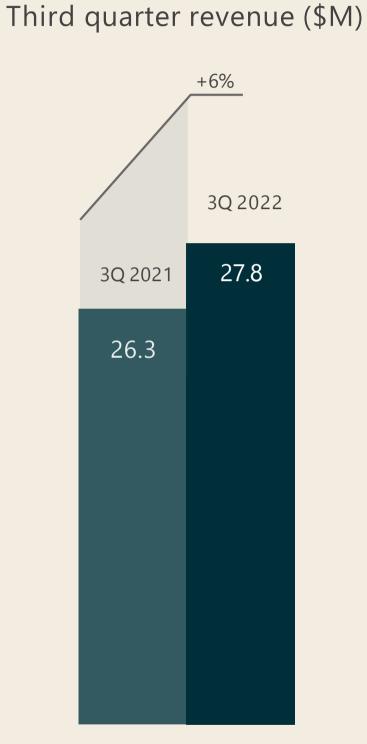
\$260.8<sup>1</sup> million

#### as of Dec 31, 2021

#### Units **deployed** Total: ~2,600 Acute Care: 2,000 Sub-Acute: 300 Clinics & Home: 300

#### Year-end backlog 2020: 551

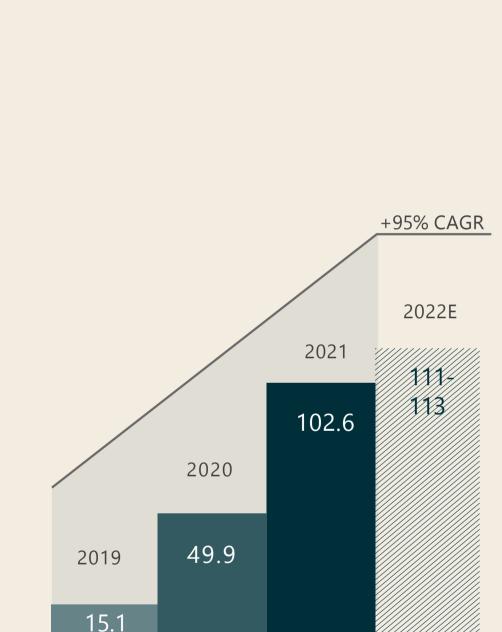
2021: 1,251



#### **11.4%** GM%<sup>2</sup> **16.4%**

- 1. Includes restricted cash and short-term investments
- 2. Non-GAAP; see GAAP to non-GAAP reconciliation in the appendix





Annual revenue (\$M)

### **Strategic focus and key 2022** priorities

#### **Revenue growth**

- Revenue guidance of \$111M-\$113M, 8% - 10% growth in 2022
- Enterprise solution sold through ongoing land-and-expand model into national and regional health systems
- Continued focus on rebuilding commercial momentum in the home setting

#### **Gross margin improvement**

- Guidance of gross margin expansion to roughly mid-teens as a % of revenue for the full year 2022
- Deliver on ongoing cost reduction roadmap
- Drive Tablo treatment utilization

#### Home expansion

- Reengage with home providers and continue to establish new home programs
- Targeting 100 home programs with both health systems and specialty providers
- Maintain highly differentiated patient retention rate



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## **Non-GAAP reconciliations**

(in thousands, except per share amounts)

#### Reconciliation between GAAP and non-GAAP net loss per share:

		Three Months Ended September 30,			
		2022		2021	
GAAP net loss per share, diluted	\$	(0.85)	\$	(0.65)	
Stock-based compensation expense		0.15		0.06	
Non-GAAP net loss per share, diluted	\$	(0.70)	\$	(0.59)	

#### **Reconciliation between GAAP and non-GAAP net loss:**

	Three Months Ended September 30,			N
	 2022		2021	C
GAAP net loss, diluted	\$ (40,781)	\$	(30,470)	
Stock-based compensation expense	7,430		2,864	N
Non-GAAP net loss, diluted	\$ (33,351)	\$	(27,606)	-

#### Reconciliation between GAAP and non-GAAP results of operations:

AAP gross p Stock-based co Ion-GAAP gro

GAAP gross m Stock-based co

Non-GAAP gro

#### **GAAP** researc

Stock-based co Non-GAAP res

#### GAAP sales an

Stock-based co Non-GAAP sal

#### GAAP general

Stock-based co Non-GAAP gei

#### GAAP total op

Stock-based co Non-GAAP tota

#### **Results of Operations—Non-GAAP (unaudited)**

	 Three Months Ended September 30,			
	2022		2021	
profit	\$ 4,336	\$	2,946	
compensation expense	 210		64	
ross profit	\$ 4,546	\$	3,010	
margin	15.6	%	11.2 %	
compensation expense	 0.8		0.2	
ross margin	16.4	%	11.4 %	
ch and development expense	\$ 13,059	\$	9,729	
compensation expense	(1,919)		(760)	
esearch and development expense	\$ 11,140	\$	8,969	
and marketing expense	\$ 22,276	\$	15,726	
compensation expense	(2,870)		(1,207)	
ales and marketing expense	\$ 19,406	\$	14,519	
al and administrative expense	\$ 10,000	\$	7,629	
compensation expense	(2,431)		(833)	
eneral and administrative expense	\$ 7,569	\$	6,796	
perating expense	\$ 45,335	\$	33,084	
compensation expense	(7,220)		(2,800)	
otal operating expense	\$ 38,115	\$	30,284	