## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K	

## **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 8, 2024

# Outset Medical, Inc. (Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-39513

20-0514392 (IRS Employer Identification No.)

(Commission File Number)

	3052 Orchard Dr., San Jose, California		95134
	(Address of Principal Executive Offices)		(Zip Code)
	Registrant's Te	lephone Number, Including Area Code:	(669) 231-8200
	(Former	Not Applicable Name or Former Address, if Changed Since Last	Report)
Chec	ek the appropriate box below if the Form 8-K filing is intended t	to simultaneously satisfy the filing obligati	ion of the registrant under any of the following provisions:
	Written communications pursuant to Rule 425 under the Sect	urities Act (17 CFR 230.425)	
	Soliciting material pursuant to Rule 14a-12 under the Exchar	nge Act (17 CFR 240.14a-12)	
	Pre-commencement communications pursuant to Rule 14d-2	(b) under the Exchange Act (17 CFR 240.	14d-2(b))
	Pre-commencement communications pursuant to Rule 13e-4	(c) under the Exchange Act (17 CFR 240.	13e-4(c))
Secu	rities registered pursuant to Section 12(b) of the Act:		
	Title of each class	Trading Symbol(s)	Name of each exchange on which registered
	Common Stock, \$0.001 par value per share	OM	The Nasdaq Stock Market LLC
	rate by check mark whether the registrant is an emerging growth ecurities Exchange Act of 1934 (§ 240.12b-2 of this chapter).	n company as defined in Rule 405 of the Se	ecurities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of
Eme	rging growth company		
			20 110 11 24 110 11

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.  $\Box$ 

### Item 2.02 Result of Operations and Financial Condition.

On January 8, 2024, Outset Medical, Inc. (the "Company") issued a press release announcing, among other items, expected revenue for the fourth quarter and fiscal year ended December 31, 2023, as well as guidance for 2024 revenue and non-GAAP gross margin. A copy of the Company's press release is furnished herewith as Exhibit 99.1.

Certain financial information contained in Exhibit 99.1 is preliminary, unaudited and subject to change or adjustment in connection with the completion of the Company's quarter and year-end closing processes and the preparation of its audited financial statements for the fiscal quarter and year ended December 31, 2023, which will be contained in the Company's related Annual Report on Form 10-K.

### Item 7.01 Regulation FD Disclosure

On January 8, 2024, the Company posted a presentation on the investor section of its website at investors.outsetmedical.com to be used by the Company in connection with its participation in the J.P. Morgan Healthcare Conference. A copy of the presentation is furnished herewith as Exhibit 99.2.

The information contained in Items 2.02 and 7.01 (including Exhibits 99.1 and 99.2 attached hereto) shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

### Forward-Looking Statements

This report and the exhibits attached hereto contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's 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. Forward-looking statements include, but are not limited to, statements about the Company's unaudited results of operations, including fourth quarter and full year 2023 revenue, statements about possible or assumed future results of operations and financial position, including expectations regarding projected revenues and non-GAAP gross margin, profitability and outlook; statements regarding the Company's overall business strategy, plans and objectives of management; the Company's expectations regarding the market sizes and growth potential for Tablo and the total addressable market opportunities for Tablo, the Company's planned expansion within the home hemodialysis market, and continued execution of the Company's initiatives designed go expand gross margins; as well as the Company's expectations regarding the impact of macroeconomic factors on the Company, its customers and suppliers. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release can be found in the Risk Factors section of the Company's public filings with the Securities and Exchange Commission, including its latest annual and quarterly reports. Because forward-looking statements are inherently subject to risks and uncertainties, you should not

### Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
	Press Release entitled "Outset Medical Reports Unaudited Fourth Quarter and 2023 Revenue, Provides 2024 Revenue and non-GAAP Gross Margin Guidance"
99.1	dated January 8, 2024
99.2	Investor Presentation dated January 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

## SIGNATURES

rsuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly thorized.		
	Outset Medical, Inc.	
Date: January 8, 2024	By:	/s/Nabeel Ahmed
		Nabeel Ahmed Chief Financial Officer

#### Outset Medical Reports Unaudited Fourth Quarter and 2023 Revenue, Provides 2024 Revenue and non-GAAP Gross Margin Guidance

San Jose, CA January 8, 2024 – Outset Medical, Inc. (Nasdaq: OM) ("Outset"), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis, today reported unaudited revenue for the fourth quarter and fiscal year ended December 31, 2023, and provided 2024 financial guidance.

### Unaudited Fourth Quarter and Year End Results, and Recent Highlights

- Revenue in the fourth quarter totaled \$30.5 million, bringing revenue for 2023 to \$130 million, a 13% increase compared to \$115 million in 2022.
- Period-end installed base increased 34% year-over-year to approximately 5,350 Tablo® Hemodialysis Systems, including approximately 4,050 with acute- and sub-acute care providers and 1,300 with home providers.
- Consumable revenue grew nearly 50% year-over-year driven by strong utilization of Tablo consoles in the acute and home settings, and contributing to recurring revenue of more than 50% of total revenue in 2023.
- On January 2, the Company reported borrowing \$66.5 million under its term loan agreements with SLR Investment Corp., adding to its balance as of December 31, 2023 of \$207 million in cash, cash equivalents, short-term investments and restricted cash. With this additional funding, Outset's cash position is now approximately \$270 million.

"We enter 2024 with a truly differentiated offering, scale in the acute setting, recurring revenue exceeding 50% of total revenue for the year and a strengthened balance sheet to fund our continued growth," said Leslie Trigg, Chair and Chief Executive Officer of Outset. "As the only fully integrated mobile dialysis device, Tablo's value continues to resonate with providers and patients from the ICU to the home."

#### 2024 Guidance

Outset expects 2024 revenue to be between \$145 million to \$153 million, growing 12% to 18% over unaudited revenue for 2023 based on the assumptions previously disclosed. Non-GAAP gross margin is expected to expand to the low-30% range for the full year 2024 and exit the year in the mid-30% range for the fourth quarter of 2024.

### Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's 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. Forward-looking statements include, but are not limited to, statements about the Company's unaudited results of operations, including fourth quarter and full year 2023 revenue, statements about possible or assumed future results of operations and financial position, including expectations regarding projected revenues and non-GAAP gross margin, profitability and outlook; statements regarding the Company's overall business strategy, plans and objectives of management; the Company's expectations regarding the market sizes and growth potential for Tablo and the total addressable market opportunities for Tablo, continued execution of the Company's initiatives designed to expand gross margins; the Company's ability to respond to and resolve any reports, observations or other actions by the Food and Drug Administration or other regulators in a timely and effective manner; as well as the Company's expectations regarding the impact of macroeconomic factors on the Company, its customers and suppliers. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release can be found in the Risk Factors section of the Company's public filings with the Securities and Exchange Commission, including its latest annual and quarterly reports. Because forward-looking statements are inherently subject to risks and uncertainties, 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, except to the extent required by law, the Company undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise.

Certain financial information contained in this press release is preliminary, unaudited, and subject to change or adjustment in connection with the completion of the Company's quarter and year-end closing processes and the preparation of its

audited financial statements for the fiscal quarter and year ended December 31, 2023, which will be contained in the Company's related Annual Report on Form 10-K.

### About Outset Medical, Inc.

Outset is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. The Tablo® Hemodialysis System, FDA cleared for use from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels, with 2-way wireless data transmission and a proprietary data analytics platform powering a new holistic approach to dialysis care. Tablo is a registered trademark of Outset Medical, Inc.

### Contact

Jim Mazzola Vice President, Investor Relations <u>jmazzola@outsetmedical.com</u>



Outset Medical Investor Presentation January 2024

## 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 the Company's expected results of operations, including fourth quarter and full year 2023 revenue and 2023 non-GAAP gross margin and cash position, statements about the Company's possible or assumed future results of operations and financial position, including expectations regarding projected revenues, recurring revenues, and revenue growth rate, gross margin (including non-GAAP gross margin), operating expenses, capital expenditures, cash burn, profitability and outlook, statements regarding our overall business strategy, expectations regarding future projected installed base, 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 expension within the home hemodialysis market and expected drivers of home dialysis adoption, continued execution of our initiatives designed to expand gross margins, our ability to respond to and resolve any reports, observations or other actions by the Food and Drug Administration (FDA) and other regulators in a timely and effective manner, as well as our expectations regarding the impact of macroeconomic factors on us, our customers and our suppliers.

Forward-looking 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 expand gross margins; our ability to achieve and maintain future profitability; continued execution of our initiatives designed to expand gross margins; 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 orcome manufacturing disruptions; the impact of epidemics, natural or man-made disasters, and similar events, 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 nonvate 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 cur compliance with FDA and other regulations applicable to our products and business operations and our ability to respond to and resolve any reports, observations or other actions by the FDA or other regulators in a timely and effective manner; 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 Report on Form 10-4 and Evator and Evator and Section of our public filings with the SEC, including our most recent Annual Report on Form 10-4 and Evator and Sections of future events. These forward-looking statements as predictions of fu

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.

FROM THE HOSPITAL TO THE HOME

# Transforming dialysis



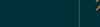
SUMMARY

# Reducing the cost and complexity of dialysis



## SCALE IN ACUTE

Scale in the \$2.5B<sup>1</sup> U.S. Acute Care market



## HIGHLY DIFFERENTIATED

One-of-its-kind product & service ecosystem creates strong customer retention



## RECURRING REVENUE

Business model driving high recurring revenue of ~50%

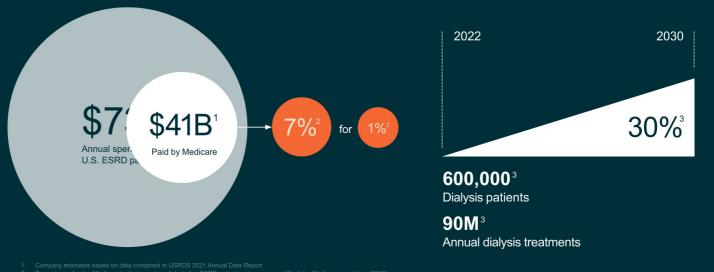


## GROWING HOME FOOTPRINT

Growing footprint in the \$8.9B<sup>1</sup>
U.S. Home market

Company estimates based on data contained in
USBDS 2021 Appual Data Report

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



- Percentage of entire Medicare budget spent on dialysis for ESRD patients, who comprise 1% of the Medicare population (2019)
- 3. Company estimates based on data contained in USRDS 2022 Annual Data Repor

## **Dialysis care pathways**



USRDS 2021 and 2022 Quarterly and Annual Data Reports

Home

87%

USRDS 2022 Annual Data Report

**CURRENT STATE** 

# This is an expensive care delivery model...

60% crash into dialysis

34%

30-day hospital readmission rate for hemodialysis patients

Clinic

\$5,000 – \$25,000

Average loss by hospital for each inpatient stay for renal failure with dialysis'

1. Heldenn I.J. et al., Macrona 2018, 189(1): 1–12

2021 Medicare Claume data for MS-DRG 683

CURRENT STATE

# Dialysis is in need of new solutions



Hospitals lose money on every treatment



Staffing challenges constrain optimal patient care and drive up cost



# We see a technology-driven way forward

# Tablo® is a first-of-itskind technology designed to reduce the cost and complexity of dialysis



Single device from ICU to home



Connected and intelligent





# An all-in-one solution that replaces multiple machines and a water treatment room with a single device



# One device, multiple markets



\$11.4B

U.S. TAM

Company estimates based on data contained in USRDS 2021 Annual Data Report

\$2.5B

Acute market Hospital & sub-acute based dialysis \$8.9B

Home market Home hemodialysis & transitional care

# One device, multiple markets



\$11.4B

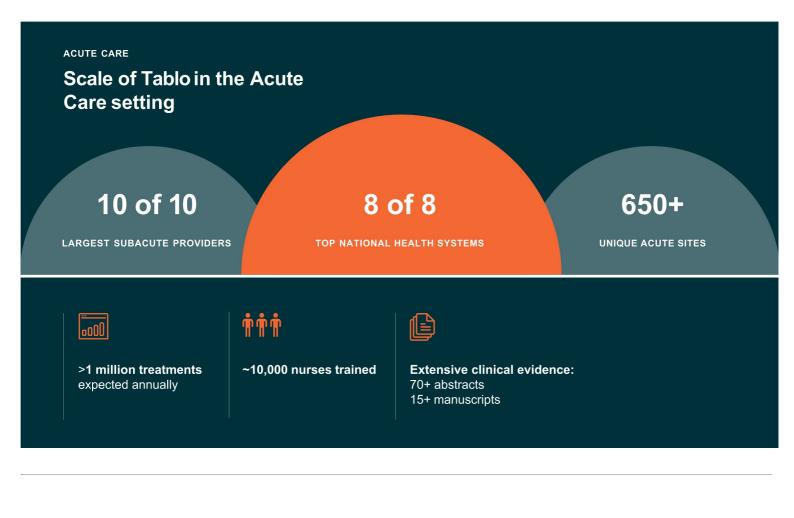
U.S. TAM

Company estimates based on data contained in USRDS 2021 Annual Data Report

\$2.5B

Acute market Hospital & sub-acute based dialysis \$8.9B

Home market
Home hemodialysis
& transitional care



# Tablo reduces the cost and complexity of acute dialysis



	Before Tablo	With Tablo
Supplies cost reduction	Existing ICU machines require numerous dialysate bags for each treatment	Tablo creates the dialysate on demand, eliminating the cost and complexity of bags
\$ Labor cost reduction	Most hospitals incur the additional cost of outsourcing dialysis to a 3rd party provider	Enables hospitals to insource and utilize their existing nursing staff to deliver dialysis

TOTAL POTENTIAL COST SAVINGS 50%-80%1

Potential payback period <1 year

. Company estimates based on data provided by

# Tablo can deliver significant savings in the ICU

	Before Tablo	With Tablo
ICU mean length of stay	13.2	8.4
Total ICU dialysis Tx costs	\$1.33M	\$239K
ICU dialysis cost per Tx hour	\$97.15	\$46.93

Converting from an outsourced program to in-house longduration dialysis, a medium-size ICU reduced costs and increased nurse productivity while demonstrating trends toward improved care quality and patient outcomes

The Tablo® Hemodialysis System is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device. The Tablo Hemodialysis System is also indicated for use in the home. Treatment types available include Intermittent Hemodialysis (IHD). Systained Low Efficiency Dialysis (SLED/SLEDD). Prolonged Intermittent Renal Replacement Therapy (PIRRT), and Isolated Ultrafiltration. This device is not indicated for continuous renal replacement therapy (CRRT) and is cleared for use for up to 24 hours. The dialysate generated by this device is not sterile and should not be used for intravenous (IV) Infusion.



Retrospective, single-center analysis comparing ICU long-duration dialysis treatment (Tx) outcomes before (Nov. 2020-Oct. 2021) and after (Dec. 2021-Nov. 2023) converties to Table

Intensive Care Unit improves Dialysis Care Quality while Reducing Costs: An ICU Quality Improvement Program, Tara Greenleaf Nichols, MSN, RN; David Domain; Sherire Mullen, MSN, RN, Senthil Ramaiyah, MD; Sandy Rowe; Cynthia J. D Alessandri-Silva, MD; Stephan Dunning, MS, MBA, American Society of Nephrology Annual Meeting, November 2023

# One device, multiple markets



\$11.4B

U.S. TAIV

Company estimates based on data contained in USRDS 2021 Annual Data Report

\$2.5B

Acute market Hospital & sub-acute based dialysis \$8.9B

Home market Home hemodialysis & transitional care HOME CARE

# The Home market is significantly underpenetrated



## **Historical barriers**



REIMBURSEMENT

Medicare reimbursement misaligned with treatment frequency



INCENTIVES

Inadequate provider payment incentives



TECHNOLOGY

Cumbersome technology and training

HOME CARE

# The Home market is poised for change. Outset's commercial strategy is designed to capitalize on it

**CMS** financial incentives

Medicare Advantage eligibility

Clinic staffing shortages

**Patient preferences** 



HOME CARE

Tablo addresses key barriers to home dialysis adoption and retention



## tablo

3

Treatments per week

## <25 hours

Training per patient

## 0 hours

Dialysate prep time



## Historical device

5-6

Treatments per week

100 hours

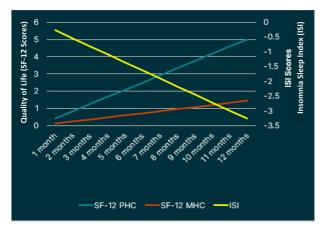
Training per patient

16-24 hours

Dialysate prep time per week

# Tablo changes the Home benefit-burden ratio

Improvement in SF-12 Quality of Life Scores and Sleep Symptoms 12-month trend of patients on Tablo¹



(1) Patient Reported Outcomes (PRO) among Patients Receiving Home Hemodialysis (HHD) with the Tablo® Hemodialysis System. Prospective, multicenter, observational study of patients with ESRD utilizing Tablo Hemodialysis System for Home HD; N=57, reporting at 1, 3,6.9, and 12 months post-home dialysis initiation. Wazny JH1, Holmes CD1, D'Alessandri-Silva C1, Chertow GM2 (2) Data from Outset 2019 IDE trial; Alvarez L, May Y, Chertow G, Early Patient Experience with the Tablo Hemodialysis System; Outset Data Registry, 2022.

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

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

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

Felt more energized after dialysis

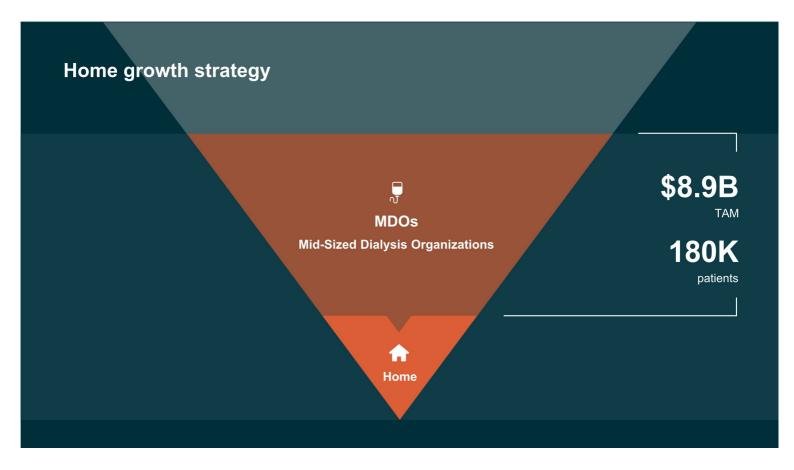
Reported less cramping during treatment

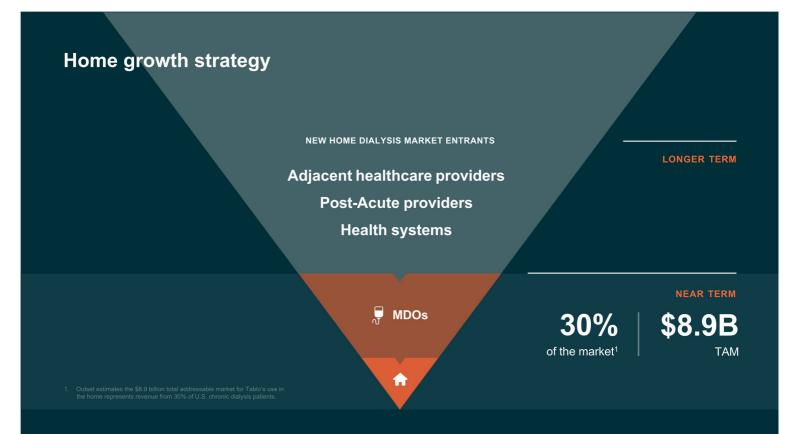
Felt more relaxed during treatment

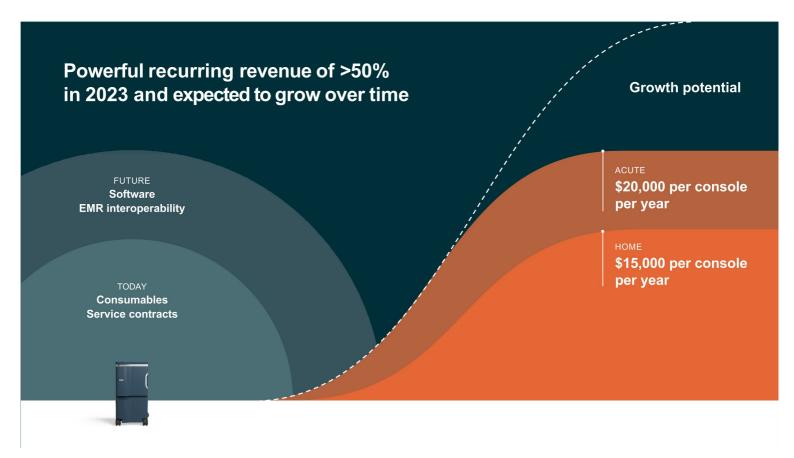
Had fewer headaches after dialysis

Reported fewer alarms during treatment

78%







# Strong financial position exiting 2023

\$130M

Revenue

70% CAGR 2019–2023e 5,350

Consoles deployed (cumulative installed base at period end)

4,050 with acute/ sub-acute providers, 1,300 with home providers >50%

Recurring revenue

Driven by strong utilization in the acute and home settings \$270M\*

Estimated Cash position

\*Cash, cash equivalents, short-term investments and restricted cash totaled \$207 million at Dec. 31, 2023. On Jan. 2, Outset reported receipt of an additional \$66.6M under its term loan agreements with SLR Investment Corp.

## Financial guidance

# 2024 Revenue guidance

\$145M-\$153M

12% to 18% year-over-year growth

# 2024 Non-GAAP gross margin

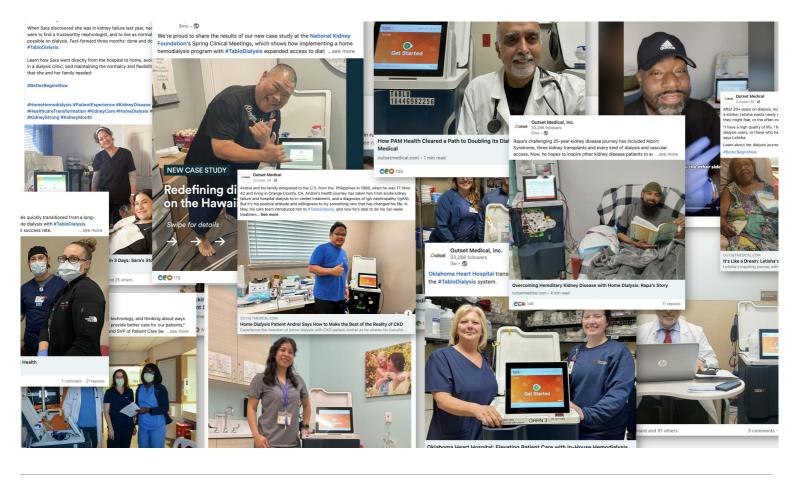
Low-30% range Full year

Mid-30% range Exiting Q4

# Long-term guidance

High-teens annual revenue growth 2025-2027

~50% non-GAAP gross margin as revenues reach ~\$250M, exiting 2027





Outset Medical 3052 Orchard Drive San Jose, CA 95134

outsetmedical.com