

**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 9, 2023

Outset Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39513

(Commission File Number)

20-0514392
(IRS Employer
Identification No.)

**3052 Orchard Dr.,
San Jose, California**
(Address of Principal Executive Offices)

95134
(Zip Code)

Registrant's Telephone Number, Including Area Code: (669) 231-8200

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange 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))

Securities 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

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

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.

Item 2.02 Result of Operations and Financial Condition.

On January 9, 2023, 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, 2022, as well as guidance for 2023 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, 2022, which will be contained in the Company’s related Annual Report on Form 10-K.

Item 7.01 Regulation FD Disclosure

On January 9, 2023, 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 exhibit 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 preliminary results of operations, including fourth quarter and full year 2022 revenue and 2022 non-GAAP gross margin; statements about possible or assumed future results of operations and financial position, including expectations regarding projected revenues and non-GAAP gross margin; 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 expected drivers of home dialysis adoption, 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release entitled “Outset Medical Reports Expected Fourth Quarter and Full Year 2022 Revenue, Provides 2023 Revenue and non-GAAP Gross Margin Guidance” dated January 9, 2023
99.2	Investor Presentation dated January 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant 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 authorized.

Outset Medical, Inc.

Date: January 9, 2023

By: _____ /s/Nabeel Ahmed
Nabeel Ahmed
Chief Financial Officer

Outset Medical Reports Expected Fourth Quarter and Full Year 2022 Revenue, Provides 2023 Revenue and non-GAAP Gross Margin Guidance

San Jose, CA – January 9, 2023 – Outset Medical, Inc. (Nasdaq: OM) (“Outset” or the “Company”), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis, today reported expected revenue for the fourth quarter and fiscal year ended December 31, 2022.

Fourth Quarter and Year End Highlights

- Revenue in the fourth quarter is expected to be approximately \$31.5 million, a 13% increase compared to \$27.8 million in the third quarter of 2022
- Revenue for 2022 is expected to be approximately \$115 million, a 12% increase compared to \$102.6 million in 2021
- Period-end installed base increased 54% year-over-year to approximately 4,000 Tablo® Hemodialysis Systems, including 3,200 with acute- and sub-acute care providers and a more than doubling of units with home providers to nearly 800
- The Company continues to expect its full-year 2022 non-GAAP gross margin will be in the mid-teens, as previously indicated

“During an important year for Outset, we significantly increased the number of Tablo consoles in hospitals and homes, surpassed 1 million treatments delivered and helped healthcare providers continue to deliver exceptional, lower-cost care in a tight labor market,” said Leslie Trigg, Chair and Chief Executive Officer of Outset. “We also strengthened our foundation by continuing to innovate and extend Tablo’s technological advantage, adding key talent, topping off our balance sheet and exiting the year with momentum, finishing the fourth quarter strong and setting up what we believe will be an even stronger 2023.”

Outset expects 2023 revenue to be between \$140 million to \$150 million, growing approximately 22% to 30% over expected revenue for 2022. Non-GAAP gross margin is expected to expand to approximately 20% for the full year 2023 and exit the year in the mid-20% range for the fourth quarter of 2023.

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 expected results of operations, including fourth quarter and full year 2022 revenue and 2022 non-GAAP gross margin, statements about possible or assumed future results of operations and financial position, including expectations regarding projected revenues and non-GAAP gross margin; 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, 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, 2022, 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.

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.Outset

Outset Medical
Investor Presentation
January 2023

Forward-looking statements

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 2022 revenue and 2022 non-GAAP gross margin, statements about our possible or assumed future results of operations and financial position, including expectations regarding projected revenues, and revenue growth rate, gross margin (including non-GAAP 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 and expected drivers of home dialysis adoption, our expectations with respect to anticipated benefits of the TPNIES approval, 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 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, 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; 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 Report on Form 10-K and Quarterly Reports on Form 10-Q filed with the Securities and Exchange Commission. 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.

Certain financial information contained in this presentation is preliminary, unaudited, and subject to change or adjustment in connection with the completion of our quarter and year-end closing processes and the preparation of its audited financial statements for the fiscal quarter and year ended December 31, 2022, which will be contained in our related Annual Report on Form 10-K.

**Transforming
dialysis**
from the hospital
to the home



SUMMARY

Reducing the cost and complexity of dialysis



\$11.4B U.S. total addressable market¹



Established footprint in **\$2.5B U.S. acute care market**

Growing patient base in **\$8.9B U.S. home market**



2022 expected revenue of ~\$115M

175% CAGR (2018–2022)

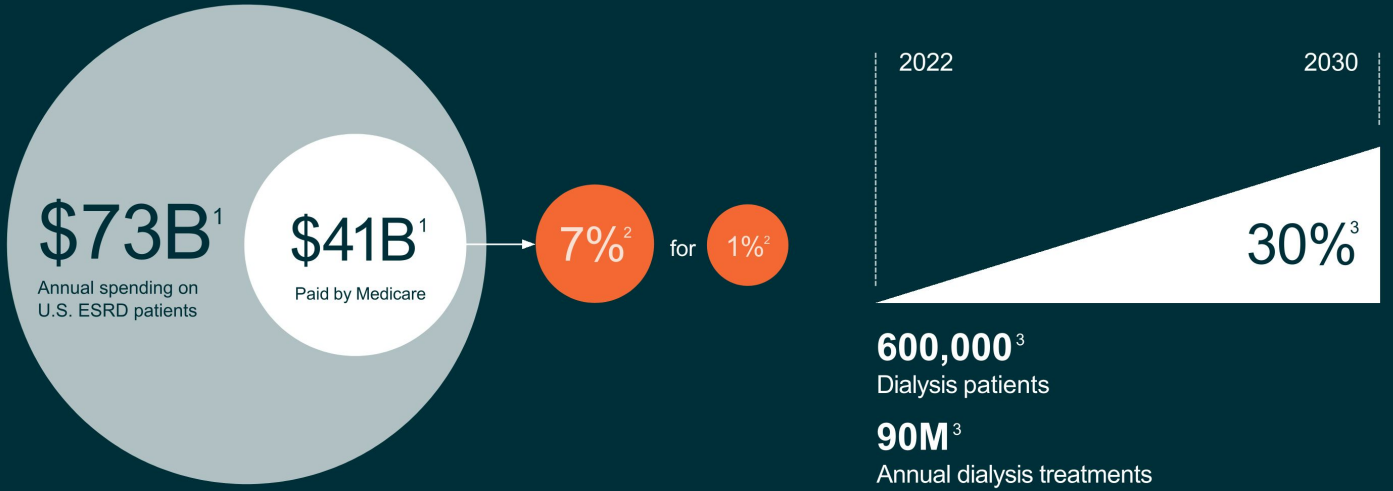


Multiple tailwinds driving Tablo adoption

1. Company estimates based on data contained in U.S. Renal Data System (USRDS) 2021 Annual Data Report

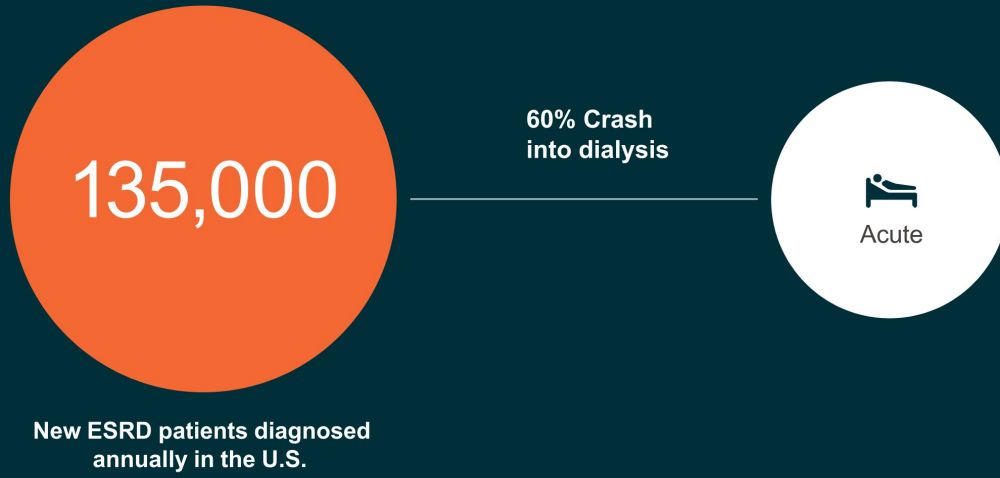
CURRENT STATE

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

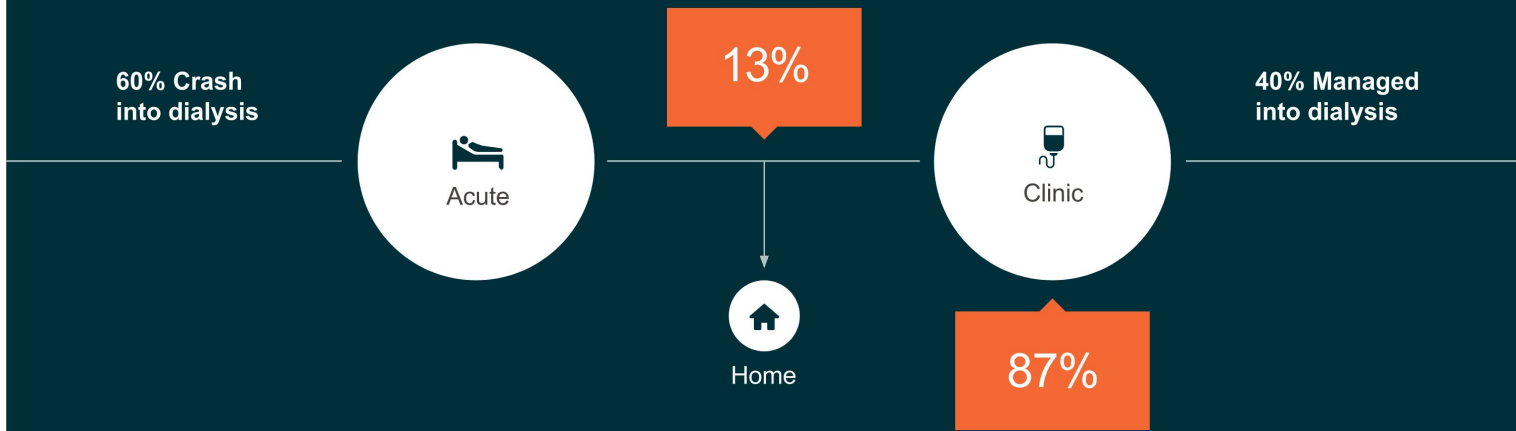


1. Company estimates based on data contained in USRDS 2021 Annual Data Report
2. Percentage of entire Medicare budget spent on dialysis for ESRD patients, who comprise 1% of the Medicare population (2019)
3. Company estimates based on data contained in USRDS 2022 Annual Data Report

Dialysis care pathways



Dialysis care pathways



CURRENT STATE

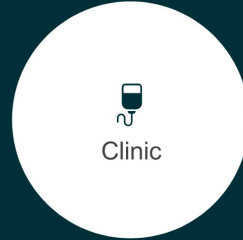
This is an expensive care delivery model...

60% Crash into dialysis



34%¹

30-day hospital readmission rate for hemodialysis patients¹



40% Managed into dialysis

\$5,000–\$25,000

Average loss by hospital for each inpatient stay for renal failure with dialysis¹

2021 Medicare Claims data for MS-DRG 682 and MS-DRG 683

\$30 billion

Annual cost of in-center dialysis treatment in clinics

Company estimates based on data contained in USRDS 2022 Annual Data Report; League et al, JAMA Feb. 2022; Lin et al Health Affairs, Aug. 2022

1. Hickson L.J. et al. Nephron. 2018; 139(1): 1–12

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



Complicated technologies made home hemodialysis impractical for most patients



We see
a technology-driven
way forward

Tablo[®] is a first-of-its-kind technology designed to reduce the cost and complexity of dialysis

①

Single device from ICU to home



Connected and intelligent



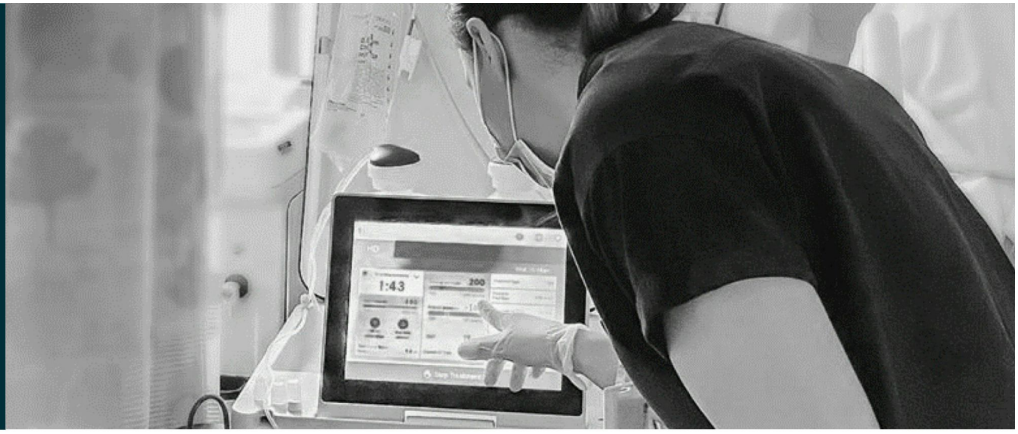
Small and mobile



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

\$2.5B

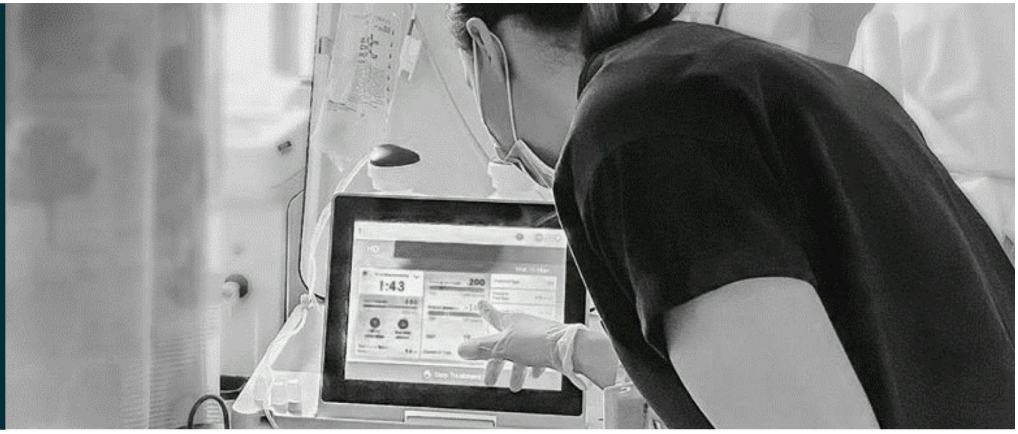
Acute market
Hospital & sub-acute
based dialysis

\$8.9B

Home market
Home hemodialysis
& transitional care

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

One device,
multiple markets



\$11.4B

U.S. TAM

\$2.5B

Acute market
Hospital & sub-acute
based dialysis

\$8.9B

Home market
Home hemodialysis
& transitional care

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

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

1. Company estimates based on data provided by third party health systems

Tablo can deliver significant savings



Hospital	St. Mark's Hospital
Location	Salt Lake City, Utah
Beds	300
ICU beds	24

“(We saw) huge cost savings and high ratings on the training experience, treatment setup and starts, and a 96.2% average success rate.”
—Kasi Moore, Nurse Manager

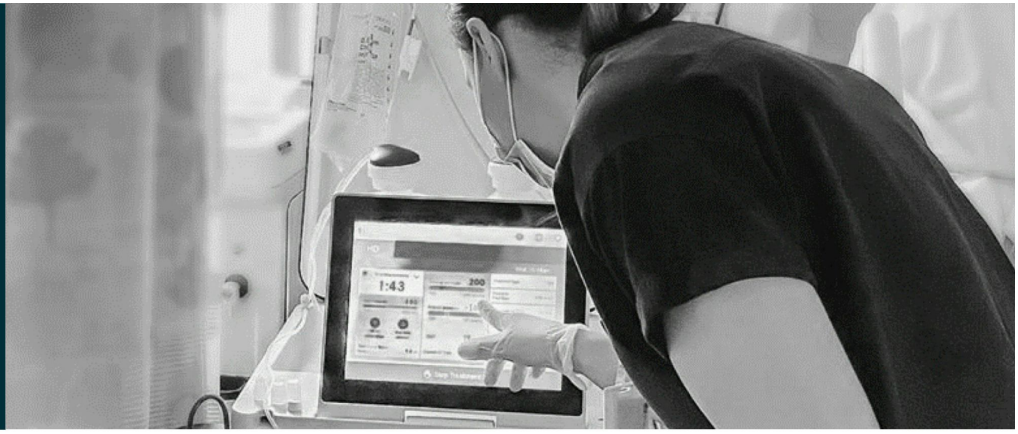
\$450K
Annual estimated savings

\$500
Savings per Tx

~70%
Cost reduction per Tx

50%
Labor cost reduction

One device,
multiple markets



\$11.4B

U.S. TAM

\$2.5B

Acute market
Hospital & sub-acute
based dialysis

\$8.9B

Home market
Home hemodialysis
& transitional care

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

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

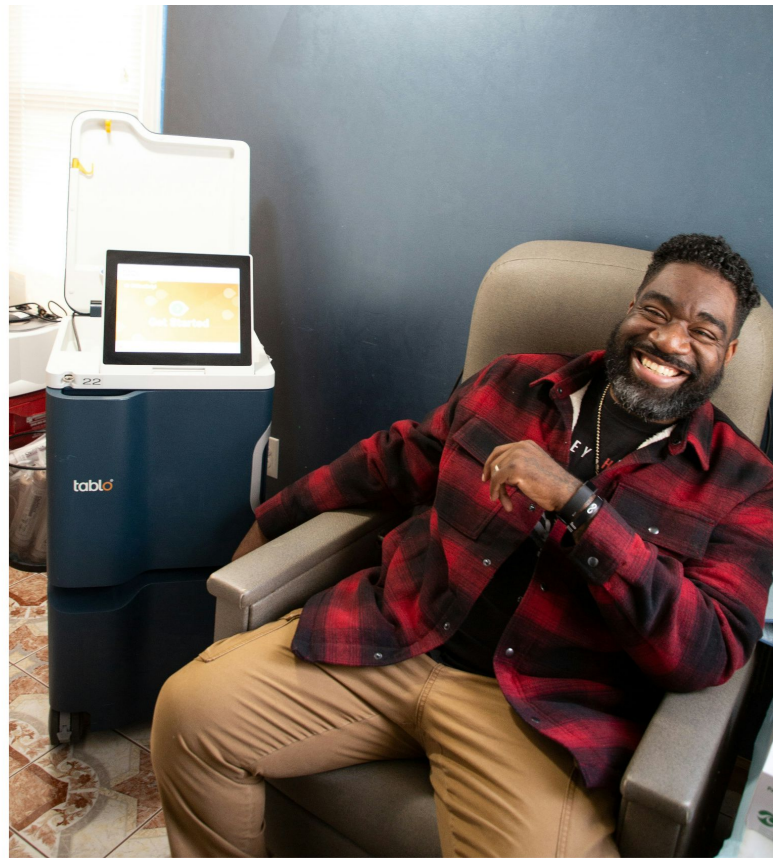
The home market is poised for change. Outset's commercial strategy is designed to capitalize on it

New 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

0%

Dropout during in-home period

99%

Adherence to prescribed home treatment frequency

~10%

Controllable attrition

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

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

Felt more energized after dialysis

34%

Reported less cramping during treatment

61%

Felt more relaxed during treatment

48%

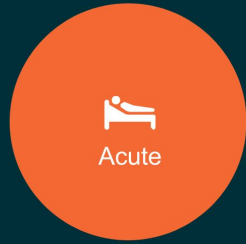
Had fewer headaches after dialysis

47%

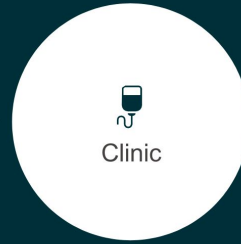
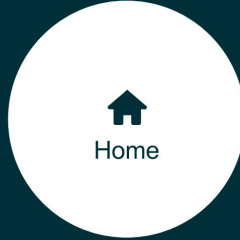
Reported fewer alarms during treatment

78%

Commercial strategy



DRIVERS / BENEFITS
New revenue stream
Attractive contribution margin
Discharge management solution



DRIVERS / BENEFITS
Higher patient adoption of home
Faster training
Longer retention

A highly efficient business model

INITIAL CONSOLE PURCHASE



ONGOING REVENUE

Initial console purchase generates recurring and predictable consumable and service revenue

①

SINGLE PLATFORM

②

RECURRING REVENUE : ACUTE

~\$20K per console per year

③

RECURRING REVENUE : HOME

~\$15K per console per year

Strong financial position exiting 2022

~\$115M

Revenue

175% CAGR
2018–2022e

4,000

Consoles deployed (cumulative installed base at period end)

3,200 with acute/
sub-acute providers,
nearly 800 with home
providers

~800 bps

Expected gross margin expansion

Consistent year-over-
year progress toward
50% gross margin
milestone

\$261M

Cash at Sept. 30, 2022

Secured up to additional
\$300M in debt financing

2023 outlook

Revenue guidance

\$140M–\$150M

~22–30%
year-over-year growth

Non-GAAP gross margin

~20% full year

Mid-20% range
exiting Q4

Commercial execution

Land and expand
in the Acutes

High growth, high retention
focus in the Home

Senior Clinical Sales Specialist at Outset Medical
Reshared from Outset Medical

Very proud of our partnership and accomplishments. #betterbeginsnow




A Pioneer of Change: Dialysis Director January Mendoza - Outset Medical
outsetmedical.com · 4 min read

23 2 comments

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3mo · Edited ·

These happy faces are the dialysis patients who are catching the latest wave of ...see more



288 9 comments · 17 reposts




How 5 People Felt After 50 Hemodialysis Treatments on Tablo - Outset Medical
outsetmedical.com · 2 min read

108 3 comments · 27 reposts

Director, Northeast Market at Outset Medical
Reshared from Rosanne...

Couldn't be more proud of this team and partnership!!!
Valdano De Pina Jason Dent John ...see more



35 6 comments

Sarah Lemorande, ... + Follow
MBA
Global Director of Sales
Reshared from Kimberly...

terbeginsnow #homewithtablo

patients deserve the opportunity ...see more

Outset Medical, Inc.
27,920 followers
9mo ·

There's no better news to share during #DonateLife Month than the story ...see more



Outset Medical, Inc.
27,920 followers
2mo ·

Although paralyzed since the 1970s, Sebastian has not let his disability or kidney ...see more

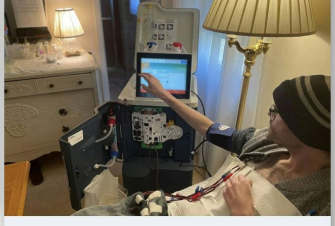


Meet U.S. Army Vet and Wheelchair Athlete Sebastian | Outset Medical
outsetmedical.com · 2 min read

69 1 comment · 10 reposts

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With a determined spirit and support from his family, Conor, a young kidney ...see more



Conor's Story of Independence | Outset Medical





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