

**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): February 16, 2022

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 February 16, 2022, Outset Medical, Inc. (the “Company”) issued a press release and will hold its fourth quarter and full year 2021 earnings conference call announcing the Company’s financial results for the quarter and year ended December 31, 2021. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference. In connection with the earnings conference call, the Company posted an investor presentation on the Investors section of its website at www.outsetmedical.com. A copy of the investor presentation is furnished herewith as Exhibit 99.2 and incorporated herein by reference.

The information contained in this Item 2.02 and Exhibits 99.1 and 99.2 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, (the “Securities Act”) or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

In addition to announcing financial results as discussed above, the Company’s press release issued on February 16, 2022, also announced that its Board of Directors (the “Board”) appointed Leslie Trigg to serve as Chair of the Board, in addition to her ongoing role as the Company’s President and Chief Executive Officer. The Company also announced that former Chair of the Board, D. Keith Grossman, continues to serve on the Board and has been appointed as Lead Independent Director by the independent members of the Board. A copy of the Company’s press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

The information contained in this Item 7.01 and Exhibit 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of 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 or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release entitled “Outset Medical Reports Fourth Quarter and Full Year 2021 Financial Results” dated February 16, 2022
99.2	Investor Presentation dated February 2022
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: February 16, 2022

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

Outset Medical Reports Fourth Quarter and Full Year 2021 Financial Results

Record Annual Revenue of \$102.6 Million; 105% Year-over-Year Growth

San Jose, CA – February 16, 2022 – 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 financial results for the fourth quarter and full year ended December 31, 2021. The Company also announced that Leslie Trigg has been appointed Chair of the Board of Directors in addition to her ongoing role as President and Chief Executive Officer.

Recent Highlights

- Recorded net revenue of \$28.2 million in the fourth quarter of 2021, a 63.2% increase compared to \$17.2 million in the fourth quarter of 2020, and \$102.6 million for the full year of 2021, representing an increase of 105.5% compared to \$49.9 million for 2020
- Achieved gross margin for the fourth quarter of 2021 of 11.8%, compared to 2.4% in the fourth quarter of 2020
- Signed agreements with 7 of the 8 largest national health systems and one-third of the largest 100 regional health systems
- Granted 510(k) clearance from the Food and Drug Administration (FDA) for Tablo® Hemodialysis System cartridge, enabling full production in Mexico
- Received the first-ever approval for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) program from the Centers for Medicare & Medicaid Services (CMS), which deemed Tablo® a substantial clinical improvement over the incumbent home hemodialysis device
- Released its inaugural Environmental, Social, and Governance (ESG) report highlighting the Company’s ESG-related programs, priorities, goals, and performance
- Leslie Trigg appointed Chair in addition to her ongoing role as Chief Executive Officer. Former Chairman D. Keith Grossman continues to serve on the board and has been appointed Lead Independent Director

“Our entire team contributed to an exceptional 2021, driving record revenue growth, meaningful progress toward our long-term gross margin goal and excellent visibility into 2022,” said Leslie Trigg, Chair and Chief Executive Officer. “Our established relationships with 7 of the 8 largest national health systems and one-third of the largest 100 regional health systems puts us in a strong position for growth this year in both the acute and home settings.”

“On behalf of the Outset Board of Directors, I am pleased to announce Leslie’s appointment to the additional role of Board Chair,” said D. Keith Grossman, Lead Independent Director. “We look forward to continuing to support Leslie and the entire team as Outset continues to transform the dialysis industry.”

Fourth Quarter 2021 Financial Results

Revenue for the fourth quarter of 2021 was \$28.2 million, representing an increase of 63.2% compared to \$17.2 million in the fourth quarter of 2020. Product revenue for the fourth quarter of 2021 was \$23.7 million, representing an increase of 79.5% compared to \$13.2 million in the fourth quarter of 2020. Service and other revenue for the fourth quarter of 2021 was \$4.5 million, representing an increase of 10.6% compared to \$4.1 million in the fourth quarter of 2020.

Total gross profit for the fourth quarter of 2021 was \$3.3 million, compared to a gross loss of \$0.4 million for the fourth quarter of 2020. Total gross margin for the fourth quarter of 2021 was 11.8%, compared to 2.4% in the fourth quarter of 2020. On a non-GAAP basis, gross margin for the fourth quarter of 2021 improved to 12% from 2.8% in the fourth quarter of 2020. Product gross profit for the fourth quarter of 2021 was \$2.2 million, compared to (\$1.7) million of product gross loss in the fourth quarter of 2020. Product gross margin for the fourth quarter of 2021 was 9.3%, compared to (13.2)% in the fourth quarter of 2020. Service and other gross profit for the fourth quarter of 2021 was \$1.1 million, compared to \$2.2 million of service and other gross profit in the fourth quarter of 2020. Service and other gross margin for the fourth quarter of 2021 was 25.1%, compared to 53.0% in the fourth quarter of 2020.

Operating expenses for the fourth quarter of 2021 were \$44.1 million, including research and development (R&D) expenses of \$11.4 million, sales and marketing (S&M) expenses of \$23.0 million, and general and administrative (G&A) expenses of \$9.7 million. This compared to operating expenses of \$32.0 million, including R&D expenses of \$7.8 million, S&M expenses of \$15.2 million, and G&A expenses of \$9.1 million in the fourth quarter of 2020.

Excluding stock-based compensation expense, non-GAAP operating expenses for the fourth quarter of 2021 were \$39.4 million, including R&D expenses of \$10.2 million, S&M expenses of \$21.1 million, and G&A expenses of \$8.1 million.

Fourth quarter 2021 net loss was (\$41.2) million, or (\$0.87) per share, compared to net loss of (\$32.0) million, or (\$0.75) per share, for the same period in 2020. On a non-GAAP basis, net loss for the fourth quarter of 2021 was (\$36.4) million, or (\$0.77) per share, compared to non-GAAP net loss of (\$25.8) million, or (\$0.60) per share for the same period in 2020.

Full Year 2021 Financial Results

Revenue for the full year of 2021 was \$102.6 million, representing an increase of 105.5% compared to \$49.9 million for 2020. Product revenue for the full year of 2021 was \$84.3 million, representing an increase of 112.8% compared to \$39.6 million for 2020. Service and other revenue for the full year of 2021 was \$18.3 million, representing an increase of 77.2% compared to \$10.3 million for 2020.

Total gross profit for the full year of 2021 was \$7.6 million, compared to a gross loss of (\$13.0) million for 2020. Total gross margin for the full year of 2021 was 7.4%, compared to (26.1)% in 2020. Product gross loss for the full year of 2021 was (\$0.3) million, compared to (\$17.4) million of product gross loss in 2020. Product gross margin for the full year of 2021 was (0.4)%, compared to (44.0)% in 2020. Service and other gross profit for the full year of 2021 was \$7.9 million, compared to \$4.4 million of service and other gross profit in 2020. Service and other gross margin for the full year of 2021 was 43.4%, compared to 42.5% in 2020.

Operating expenses for the full year of 2021 were \$138.1 million, including R&D expenses of \$36.7 million, S&M expenses of \$65.1 million, and G&A expenses of \$36.3 million. This compared to operating expenses of \$104.4 million, including R&D expenses of \$28.9 million, S&M expenses of \$45.1 million, and G&A expenses of \$30.5 million for 2020.

Excluding stock-based compensation expense, non-GAAP operating expenses for the full year of 2021 were \$121.0 million, including R&D expenses of \$32.9 million, S&M expenses of \$59.2 million, and G&A expenses of \$28.8 million.

Full year 2021 net loss attributable to common stockholders was (\$131.9) million, or (\$2.89) per share, compared to a net loss attributable to common stockholders of (\$79.3) million, or (\$4.85) per share, for 2020. On a non-GAAP basis, net loss for the full year of 2021 was (\$114.5) million, or (\$2.51) per share, compared to a non-GAAP net loss of (\$57.9) million, or (\$3.54) per share for 2020.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$372.8 million as of December 31, 2021.

Full Year 2022 Financial Guidance

Outset projects revenue for the full year 2022 to range from \$142 million to \$150 million, which represents approximately 38% to 46% growth over the Company's fiscal year 2021 revenue.

Webcast and Conference Call Details

Outset will host a conference call today, February 16, 2022, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its fourth quarter and full year 2021 financial results. The dial-in numbers are (833) 614-1409 for domestic callers and (914) 987-7130 for international callers. The conference ID is 6892802. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at <https://investors.outsetmedical.com>. The webcast will be archived on the website following the completion of the call.

Use of Non-GAAP Financial Measures

The Company may report non-GAAP results for gross profit/loss, gross margin, operating expenses, operating margins, net income/loss, basic and diluted net income/loss per share, other income/loss, and cash flows. These non-GAAP financial measures are in addition to, and not a substitute for, or superior to, financial measures calculated in accordance with GAAP. The Company's financial measures under GAAP include stock-based compensation expense, as listed in the itemized reconciliations between GAAP and non-GAAP financial measures included in this press release. Management has excluded the effects of this non-cash expense item in non-GAAP measures to assist investors in analyzing and assessing past and future operating performance and period-to-period comparisons. 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 the Company's financial statements, and may not be comparable to non-GAAP financial measures used by other companies. The Company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the Appendix A of this press release.

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 possible or assumed future results of operations and financial position, including expectations regarding projected revenues (including sales into the home market and such sales as a percentage of revenues), gross margin, operating expenses, capital expenditures, 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 reduce the cost of producing and shipping Tablo devices and its ability to achieve projected cost reductions at the level or within the timeframe estimated; the Company's expectations with respect to anticipated benefits of the TPNIES approval, as well as the Company's expectations regarding the continuing impact of the COVID-19 pandemic on the Company and its operations as well as the impact on 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 Outset's public filings with the Securities and Exchange Commission, including Outset's 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.

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 Medical, Inc.
Condensed Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product revenue	\$ 23,650	\$ 13,177	\$ 84,312	\$ 39,612
Service and other revenue	4,502	4,070	18,290	10,323
Total revenue	28,152	17,247	102,602	49,935
Cost of revenue:				
Cost of product revenue ⁽²⁾	21,459	14,917	84,639	57,035
Cost of service and other revenue	3,372	1,913	10,355	5,937
Total cost of revenue	24,831	16,830	94,994	62,972
Gross profit ⁽¹⁾	3,321	417	7,608	(13,037)
Gross margin ⁽¹⁾	11.8 %	2.4 %	7.4 %	(26.1) %
Operating expenses:				
Research and development ⁽²⁾	11,410	7,784	36,741	28,850
Sales and marketing ⁽²⁾	22,991	15,198	65,070	45,068
General and administrative ⁽²⁾	9,719	9,050	36,316	30,512
Total operating expenses	44,120	32,032	138,127	104,430
Loss from operations	(40,799)	(31,615)	(130,519)	(117,467)
Other income (expense):				
Interest income and other income, net	123	2	498	526
Interest expense	(431)	(430)	(1,715)	(2,891)
Change in fair value of redeemable convertible preferred stock warrant liability	—	—	—	(93)
Loss on extinguishment of term loan	—	—	—	(1,567)
Loss before provision for income taxes	(41,107)	(32,043)	(131,736)	(121,492)
Provision for income taxes	125	—	199	—
Net loss	<u>\$ (41,232)</u>	<u>\$ (32,043)</u>	<u>\$ (131,935)</u>	<u>\$ (121,492)</u>
Net loss attributable to common stockholders, basic and diluted ⁽³⁾	<u>\$ (41,232)</u>	<u>\$ (32,043)</u>	<u>\$ (131,935)</u>	<u>\$ (79,324)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.87)</u>	<u>\$ (0.75)</u>	<u>\$ (2.89)</u>	<u>\$ (4.85)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>47,169</u>	<u>42,715</u>	<u>45,589</u>	<u>16,358</u>

⁽¹⁾ Gross profit and gross margin by source consisted of the following:

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Gross profit				
Product revenue	\$ 2,191	\$ (1,740)	\$ (327)	\$ (17,423)
Service and other revenue	1,130	2,157	7,935	4,386
Total gross profit	<u>\$ 3,321</u>	<u>\$ 417</u>	<u>\$ 7,608</u>	<u>\$ (13,037)</u>
Gross margin				
Product revenue	9.3 %	(13.2) %	(0.4) %	(44.0) %
Service and other revenue	25.1 %	53.0 %	43.4 %	42.5 %
Total gross margin	11.8 %	2.4 %	7.4 %	(26.1) %

⁽²⁾ Include stock-based compensation expenses as follows:

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Cost of revenue	\$ 68	\$ 74	\$ 269	\$ 255
Research and development	1,241	1,289	3,809	4,615
Sales and marketing	1,896	1,595	5,897	4,423
General and administrative	1,587	3,310	7,470	12,146
Total stock-based compensation expenses	<u>\$ 4,792</u>	<u>\$ 6,268</u>	<u>\$ 17,445</u>	<u>\$ 21,439</u>

⁽³⁾ A reconciliation of the net loss to net loss attributable to common stockholders is as follows:

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Net loss	\$ (41,232)	\$ (32,043)	\$ (131,935)	\$ (121,492)
Adjustment to redemption value on redeemable convertible preferred stock	—	—	—	(362)
Deemed dividend on settlement of accrued dividend*	—	—	—	42,530
Net loss attributable to common stockholders, basic and diluted	<u>\$ (41,232)</u>	<u>\$ (32,043)</u>	<u>\$ (131,935)</u>	<u>\$ (79,324)</u>

* Deemed dividend on settlement of accrued dividend arose as a result of the terms and conditions associated with the Company's redeemable convertible preferred stock outstanding prior to the Company's initial public offering ("IPO"). These terms and conditions were described in the Company's previous SEC filings, including the 424(b) prospectus filed on September 16, 2020 in connection with the IPO.

Outset Medical, Inc.
Condensed Balance Sheets
(in thousands, except per share amounts)

	December 31, 2021 <u>(Unaudited)</u>	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 182,348	\$ 294,972
Short-term investments	157,140	19,898
Accounts receivable, net	25,600	6,468
Inventories	39,185	18,384
Prepaid expenses and other current assets	5,529	6,189
Total current assets	409,802	345,911
Restricted cash	33,311	33,311
Property and equipment, net	12,964	14,998
Operating lease right-of-use assets	7,231	8,253
Other assets	156	1,356
Total assets	<u>\$ 463,464</u>	<u>\$ 403,829</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,763	\$ 4,948
Accrued compensation and related benefits	24,948	16,845
Accrued expenses and other current liabilities	13,789	7,903
Accrued warranty liability	3,704	2,913
Deferred revenue, current	6,340	3,201
Operating lease liabilities, current	1,151	882
Total current liabilities	51,695	36,692
Accrued interest, noncurrent	721	240
Deferred revenue, noncurrent	312	570
Operating lease liabilities, noncurrent	6,893	8,044
Term loan, noncurrent	29,762	29,674
Total liabilities	89,383	75,220
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of December 31, 2021 and 2020	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of December 31, 2021 and 2020; 47,241 and 42,722 shares issued and outstanding as of December 31, 2021 and 2020, respectively	47	43
Additional paid-in capital	1,000,212	822,624
Accumulated other comprehensive (loss) income	(184)	1
Accumulated deficit	(625,994)	(494,059)
Total stockholders' equity	374,081	328,609
Total liabilities and stockholders' equity	<u>\$ 463,464</u>	<u>\$ 403,829</u>

Outset Medical, Inc.
Condensed Statements of Cash Flows
(in thousands)
(unaudited)

	Years Ended December 31,	
	2021	2020
Net cash used in operating activities	\$ (130,264)	\$ (99,015)
Net cash provided by (used in) investing activities	(142,507)	3,947
Net cash provided by financing activities	160,147	385,682
Net (decrease) increase in cash, cash equivalents and restricted cash	(112,624)	290,614
Cash, cash equivalents and restricted cash at beginning of the period	328,283	37,669
Cash, cash equivalents and restricted cash at end of the period ⁽¹⁾	\$ 215,659	\$ 328,283

⁽¹⁾ The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the accompanying condensed balance sheets that sum to the total of the amounts shown in the accompanying condensed statements of cash flows (in thousands):

	December 31,	
	2021	2020
Cash and cash equivalents	\$ 182,348	\$ 294,972
Restricted cash	33,311	33,311
Total cash, cash equivalents and restricted cash*	\$ 215,659	\$ 328,283

* The total cash, including restricted cash, cash equivalents and investment securities as of December 31, 2021 was \$372.8 million; compared to \$348.2 million as of December 31, 2020.

Outset Medical, Inc.
Results of Operations – Non-GAAP
(in thousands, except per share amounts)
(unaudited)

Reconciliation between GAAP and non-GAAP net loss per share attributable to common stockholders:

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
GAAP net loss per share to common stockholders, diluted	\$ (0.87)	\$ (0.75)	\$ (2.89)	\$ (4.85)
Stock-based compensation expense	0.10	0.15	0.38	1.31
Non-GAAP net loss per share to common stockholders, diluted	<u>\$ (0.77)</u>	<u>\$ (0.60)</u>	<u>\$ (2.51)</u>	<u>\$ (3.54)</u>

Reconciliation between GAAP and non-GAAP net loss attributable to common stockholders:

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
GAAP net loss attributable to common stockholders, diluted	\$ (41,232)	\$ (32,043)	\$ (131,935)	\$ (79,324)
Stock-based compensation expense	4,792	6,268	17,445	21,439
Non-GAAP net loss per share attributable to common stockholders, diluted	<u>\$ (36,440)</u>	<u>\$ (25,775)</u>	<u>\$ (114,490)</u>	<u>\$ (57,885)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
GAAP gross profit	\$ 3,321	\$ 417	\$ 7,608	\$ (13,037)
Stock-based compensation expense	68	74	269	255
Non-GAAP gross profit	<u>\$ 3,389</u>	<u>\$ 491</u>	<u>\$ 7,877</u>	<u>\$ (12,782)</u>
GAAP gross margin	11.8 %	2.4 %	7.4 %	(26.1) %
Stock-based compensation expense	0.2	0.4	0.3	0.5
Non-GAAP gross margin	<u>12.0 %</u>	<u>2.8 %</u>	<u>7.7 %</u>	<u>(25.6) %</u>
GAAP research and development expense	\$ 11,410	\$ 7,784	\$ 36,741	\$ 28,850
Stock-based compensation expense	(1,241)	(1,289)	(3,809)	(4,615)
Non-GAAP research and development expense	<u>\$ 10,169</u>	<u>\$ 6,495</u>	<u>\$ 32,932</u>	<u>\$ 24,235</u>
GAAP sales and marketing expense	\$ 22,991	\$ 15,198	\$ 65,070	\$ 45,068
Stock-based compensation expense	(1,896)	(1,595)	(5,897)	(4,423)
Non-GAAP sales and marketing expense	<u>\$ 21,095</u>	<u>\$ 13,603</u>	<u>\$ 59,173</u>	<u>\$ 40,645</u>
GAAP general and administrative expense	\$ 9,719	\$ 9,050	\$ 36,316	\$ 30,512
Stock-based compensation expense	(1,587)	(3,310)	(7,470)	(12,146)
Non-GAAP general and administrative expense	<u>\$ 8,132</u>	<u>\$ 5,740</u>	<u>\$ 28,846</u>	<u>\$ 18,366</u>
GAAP total operating expense	\$ 44,120	\$ 32,032	\$ 138,127	\$ 104,430
Stock-based compensation expense	(4,724)	(6,194)	(17,176)	(21,184)
Non-GAAP total operating expense	<u>\$ 39,396</u>	<u>\$ 25,838</u>	<u>\$ 120,951</u>	<u>\$ 83,246</u>



Outset Medical
Investor Presentation
February 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 (including projections regarding sales into the home market and such sales as a percentage of revenues), our expectations with respect to anticipated benefits of the TPNIES approval, as well as our expectations regarding the continuing impact of the COVID-19 pandemic on us and our operations as well as the impact on our customers and 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.

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 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 market¹

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**



Guidance of 38% – 46% revenue growth in 2022 and **~50% gross margin** in 2025

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

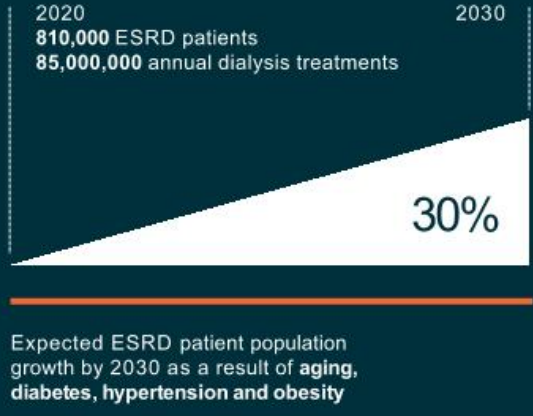
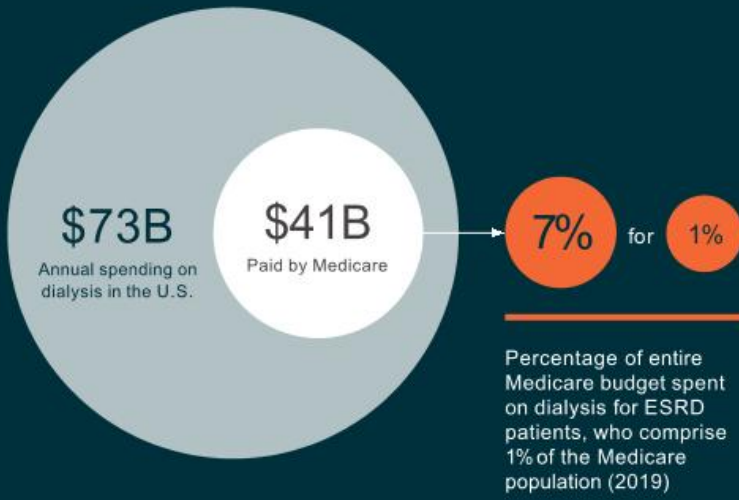


Recent reimbursement tailwinds expected to drive home dialysis adoption



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

Patients are treated with dialysis across multiple settings of care



ACUTE CARE

Hospital & sub-acute based dialysis

4.5 million
Treatments/year¹

~ 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



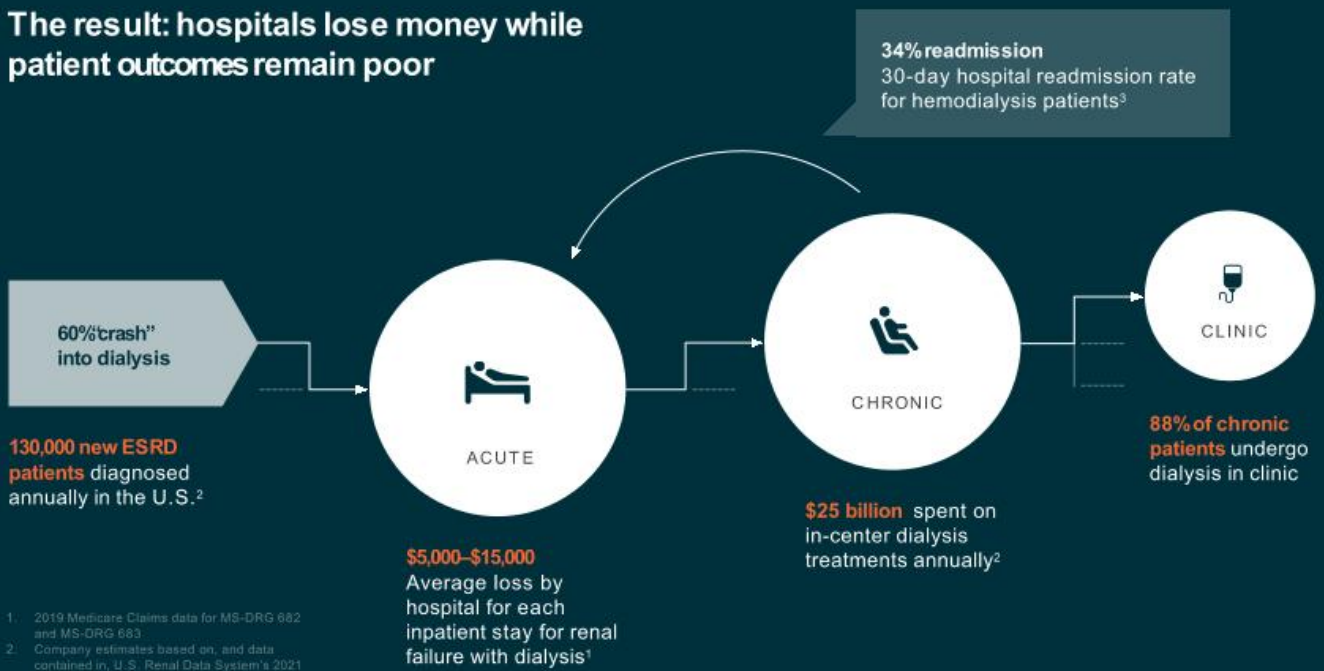
CHRONIC CARE

In-center, transitional care & home hemodialysis

81 million
Treatments/year²

8-10%
Annual growth rate for home dialysis

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



Complicated



Inflexible



Burdensome

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

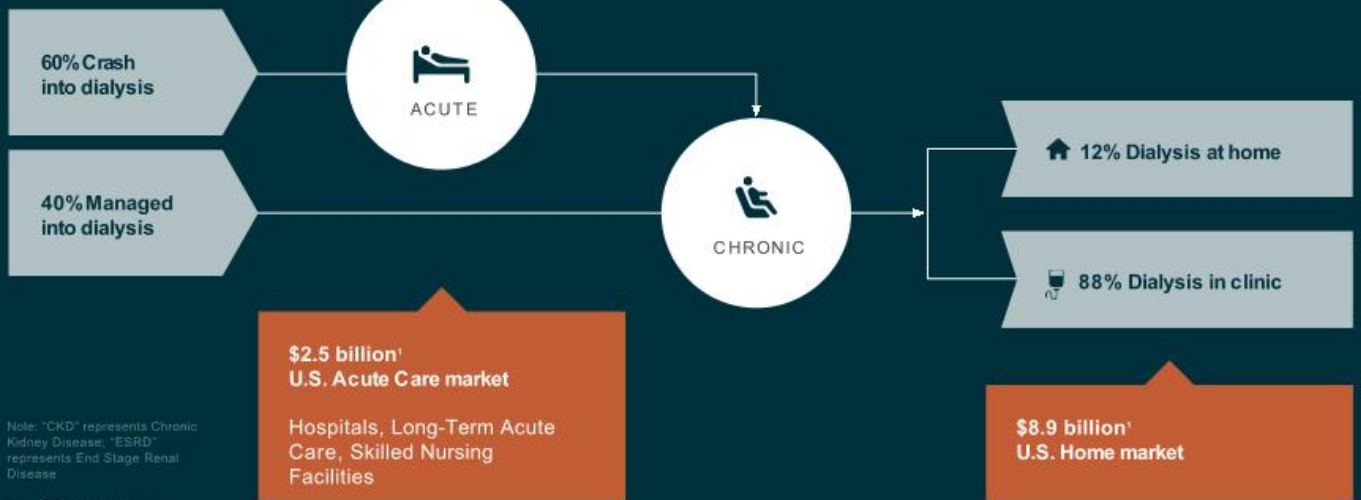
Benefits to Outset

- 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



\$11.4B U.S. addressable market

CKD/ESRD PATIENTS



Note: "CKD" represents Chronic Kidney Disease; "ESRD" represents End Stage Renal Disease

1. Company estimates based 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 hospital 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

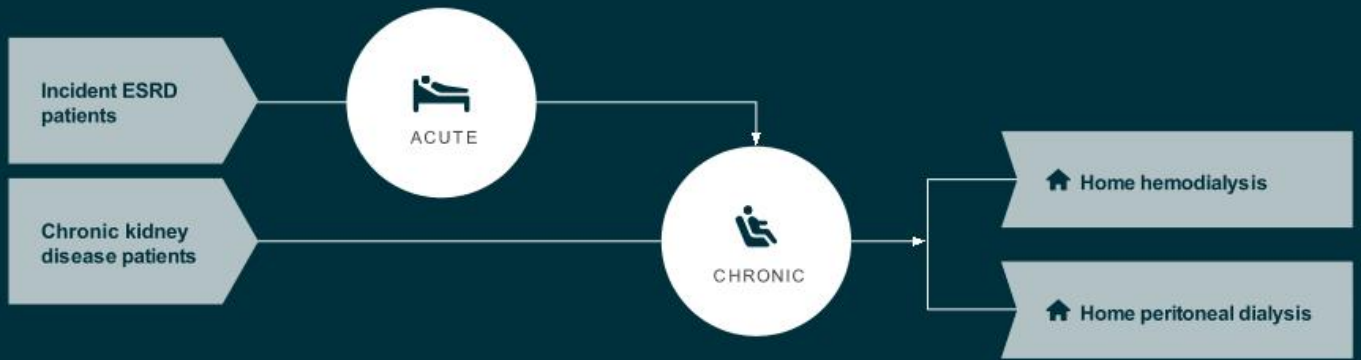
ICU Dialysis Cost Cut by 55% Cleveland Clinic



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
3. 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%¹

02 Over 50% of chronic dialysis patients managed at home²

03 Drive \$15,000–\$17,000 in annual profit per Tablo Home patient³

The Tablo Home program brings economic opportunity

**\$15,000–
\$17,000**

Amount of annual profit each patient has the potential to generate for the provider¹

1. Based on 5-year calculation for Tablo Home program. Key assumptions: \$350 per treatment x 3.5 treatments per week.
2. Key assumption: \$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 ²	~\$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
4%	Ended due to clotting
14 sec	Average alarm resolution time

The First 1,000 Real-World Treatments Study Highlights

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

HOME CARE

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

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

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

Trial participants

26-71	Years of age
43%	Black / Hispanic
27%	Latino
60%	History of diabetes
96%	History of hypertension

Met efficacy endpoints

Achieved weekly $\text{Std Kt/V} \geq 2.1$

In-Center

% weeks that met primary endpoint



2.8 Avg

In-Home

% weeks that met primary endpoint



2.8 Avg

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 home¹

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

Preferred Tablo ■
Preferred prior system ■

PATIENT PREFERENCE RESULTS—TABLO VS PRIOR HOME SYSTEM



Patients report fewer symptoms on Tablo²

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



1. Outset 2019 IDE trial
2. Alvarez L, May Y, Chertow G. Early Patient Experience with the Tablo Hemodialysis System

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

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
- 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

CMS methodology: Price of console/5 yr useful life = \$X/156
treatments per year = 37/Tx x 0.65 = \$2/Tx - \$8.50/Tx to
account for what CMS already pays for equipment/Tx

Outset's highly efficient business model

INITIAL CONSOLE PURCHASE



ONGOING REVENUE

Initial console purchase generates recurring and predictable consumable and service revenue

1

SINGLE PLATFORM

Optimizes commercial outreach and manufacturing



DATA ECOSYSTEM

Streamlines service and support



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

HOME STRATEGY

Target health systems and innovative care providers

Grow patient adoption, retention and cost of care evidence base

SAME CUSTOMERS, PHYSICIANS, TRAINING AND SUPPORT



CLINICAL SALES REPS

Utilization and fleet expansion



CAPITAL SALES TEAM

System-wide console adoption



FIELD SERVICE ENGINEERS

Technical support

Strong financials

as of Dec. 31, 2021

Acute

Strong momentum with both new and existing customers

Home

- Encouraging results on faster training and differentiated retention
- Secured landmark TPNIES approval from CMS

Gross margin

Achieved console insourcing goal and 100% of consoles now manufactured in Mexico facility

Units deployed

Total: ~2,600
Acute Care: 2,000
Sub-Acute: 300
Clinics & Home: 300

Year-end backlog

2020: 551
2021: 1,251

Total cash

\$372.8¹ million

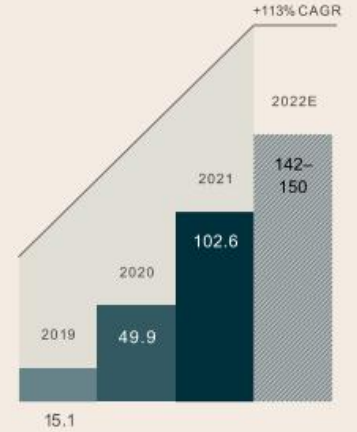
Fourth quarter revenue (\$M)



2.8% GM%² 12.0%

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

- Guidance of 38%–46% revenue growth in 2022
- Health system-centric enterprise solution sold through ongoing land-and-expand model into national and regional health systems
- Inflection in Tablo home sales

Gross margin improvement

- Guidance of gross margin expansion to the high teens for the full year 2022
- Deliver on ongoing cost reduction roadmap
- Drive Tablo treatment utilization

Home expansion

- Guidance of a more than doubling of home revenue exiting 2022, representing mid-teens percentage of total revenue
- 100 home programs in place with both health systems and specialty providers
- Maintain highly differentiated patient retention rate



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3052 Orchard Drive
San Jose, CA 95134

outsetmedical.com

Appendix

Non-GAAP reconciliations

Results of Operations—Non-GAAP (unaudited) (in thousands, except per share amounts)

Reconciliation between GAAP and non-GAAP net loss per share attributable to common stockholders:	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
GAAP net loss per share to common stockholders, diluted	\$ (0.87)	\$ (0.75)	\$ (2.89)	\$ (4.85)
Stock-based compensation expense	0.10	0.15	0.38	1.31
Non-GAAP net loss per share to common stockholders, diluted	<u>\$ (0.77)</u>	<u>\$ (0.60)</u>	<u>\$ (2.51)</u>	<u>\$ (3.54)</u>

Reconciliation between GAAP and non-GAAP net loss attributable to common stockholders:	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
GAAP net loss attributable to common stockholders, diluted	\$ (41,232)	\$ (32,043)	\$ (131,935)	\$ (79,324)
Stock-based compensation expense	4,792	6,268	17,445	21,439
Non-GAAP net loss per share attributable to common stockholders, diluted	<u>\$ (36,440)</u>	<u>\$ (25,775)</u>	<u>\$ (114,490)</u>	<u>\$ (57,885)</u>

Reconciliation between GAAP and non-GAAP results of operations:	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
GAAP gross profit	\$ 3,321	\$ 417	\$ 7,608	\$ (13,037)
Stock-based compensation expense Non-GAAP gross profit	<u>68</u>	<u>74</u>	<u>269</u>	<u>255</u>
	<u>\$ 3,389</u>	<u>\$ 491</u>	<u>\$ 7,877</u>	<u>\$ (12,782)</u>
GAAP gross margin	11.8 %	2.4 %	7.4 %	(26.1) %
Stock-based compensation expense Non-GAAP gross margin	<u>0.2</u>	<u>0.4</u>	<u>0.3</u>	<u>0.5</u>
	<u>12.0 %</u>	<u>2.8 %</u>	<u>7.7 %</u>	<u>(25.6) %</u>
GAAP research and development expense	\$ 11,410	\$ 7,784	\$ 36,741	\$ 28,850
Stock-based compensation expense Non-GAAP research and development expense	<u>(1,241)</u>	<u>(1,289)</u>	<u>(3,809)</u>	<u>(4,615)</u>
	<u>\$ 10,169</u>	<u>\$ 6,495</u>	<u>\$ 32,932</u>	<u>\$ 24,235</u>
GAAP sales and marketing expense	\$ 22,991	\$ 15,198	\$ 65,070	\$ 45,068
Stock-based compensation expense Non-GAAP sales and marketing expense	<u>(1,896)</u>	<u>(1,595)</u>	<u>(5,897)</u>	<u>(4,423)</u>
	<u>\$ 21,095</u>	<u>\$ 13,603</u>	<u>\$ 59,173</u>	<u>\$ 40,645</u>
GAAP general and administrative expense	\$ 9,719	\$ 9,050	\$ 36,316	\$ 30,512
Stock-based compensation expense Non-GAAP general and administrative expense	<u>(1,587)</u>	<u>(3,310)</u>	<u>(7,470)</u>	<u>(12,146)</u>
	<u>\$ 8,132</u>	<u>\$ 5,740</u>	<u>\$ 28,846</u>	<u>\$ 18,366</u>
GAAP total operating expense	\$ 44,120	\$ 32,032	\$ 138,127	\$ 104,430
Stock-based compensation expense Non-GAAP total operating expense	<u>(4,724)</u>	<u>(6,194)</u>	<u>(17,176)</u>	<u>(21,184)</u>
	<u>\$ 39,396</u>	<u>\$ 25,838</u>	<u>\$ 120,951</u>	<u>\$ 83,246</u>